The Health Foundation
Inspiring Improvement

MaiKhanda: final evaluation report

The impact of quality improvement at health facilities and community mobilisation by women's groups on birth outcomes: an effectiveness study in three districts of Malawi.

T. Colbourn, B. Nambiar, A. Costello

Evaluation
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Foreword

This evaluation reports on a landmark programme in Malawi funded by the Health Foundation. Working in three districts in central Malawi, the programme was innovative in its ambition to combine two large-scale interventions:

- A community mobilisation intervention, using a participatory action group cycle focused on women's groups that had shown some promising evidence from international studies.
- A quality improvement intervention, working first in nine hospitals that provide comprehensive emergency obstetric care (CEmOC), and later in 29 health centres (facilities) that provide some elements of basic emergency obstetric care.

The programme mobilised a total of 879 communities and worked with nine hospitals and 29 health centres across three districts to identify and implement local strategies for maternal and newborn healthcare improvement. The scale of the programme was considerable – in fact, we believe that the community mobilisation programme is the largest of its kind in Africa.

The Health Foundation commissioned University College London to undertake an independent evaluation of the MaiKhanda programme between 2006 and 2011.

The study incorporated a cluster randomised controlled trial design using four approaches in different locations and evaluating which was most successful. The four approaches were:

- community mobilisation only
- healthcare facility improvements only
- community mobilisation and healthcare facility improvements combined
- no intervention (the control group).

The results of the independent evaluation of the programme are striking.

On the primary outcomes, where the programme undertook community mobilisation only, it achieved a 16% reduction in perinatal mortality.[1] However, where it focused on community mobilisation **and** healthcare facility improvement in the same locations, it achieved a 22% reduction in neonatal mortality.[2] In the second half of the programme the intervention was strengthened, and the evaluation shows that in the last 15 months of the programme it achieved an impressive 28% reduction in neonatal mortality.

On the secondary outcomes, where it undertook healthcare improvement alone, the programme achieved a 33% significant effect on late neonatal mortality.[3]

1 Stillbirths and deaths in the first seven days following birth.
2 Deaths in the first 28 days of life.
3 Deaths occurring after the seventh day but before 28 completed days of life.

Overall, the evaluation estimates[4] that, each year during the 27-month intervention period, the community-based intervention alone averted 933 perinatal deaths,[5] and the combined approach (community mobilisation and healthcare improvements) averted 384 neonatal deaths.[6]

MaiKhanda was not able to achieve a significant reduction in maternal mortality. We think this may be due to the complexity of events surrounding the transport of mothers from their communities and provision of safe care at the healthcare facilities. In addition, the programme never achieved what we might call 'full dosage' of the intervention.

We have learned a great deal about the challenges of improving maternal and newborn health. It is not easy to transpose improvement interventions of proven efficacy, such as quality improvement techniques, from high-income countries to resource-poor settings like rural Malawi. There are many limitations, in terms of resources, supervision systems, staff morale and motivation, that can interfere with and limit impact. Interventions in healthcare facilities need to extend beyond clinical micro-systems and engage in system improvements for long-term sustainability. The leadership support of District Health Management Teams, District Health Officers and local clinicians has been crucial to getting quality improvement work accepted within healthcare facilities.

The evaluation makes an important contribution to the debate about whether the greatest reductions in maternal and newborn mortality in low income countries can be achieved by educating and empowering communities or by improving healthcare systems. The evidence clearly points to an answer that, by simultaneously doing both, and addressing the linkages between them, more can be achieved.

The evaluation has also generated new evidence to strengthen recent claims of a general decline in maternal deaths in Malawi.

Finally, the evaluation, which created a community-based population mortality surveillance system using local village leaders as 'key informants', has demonstrated that such a system can be set up and run at low cost using a combination of government Health Surveillance Assistants, volunteer key informants in villages, and a handful of staff to collate the data collected. This is of enormous significance for governments in sub-Saharan Africa where real-time information about population mortality is a policy aspiration rarely achieved.

Policy makers are starting to think about the need for an integrated approach to developing the full range of evidence-based interventions to reduce maternal and newborn mortality in low-income countries. We hope that the results and learning from MaiKhanda will strengthen the evidence for simultaneously working with healthcare facilities and the communities they serve in the drive to improve maternal and newborn health.

Dr. Dale Webb
Director of Evaluation and Strategy
The Health Foundation

4 Estimates of this kind need to be provided alongside their 'confidence interval'. A 95% confidence interval (95%CI) provides a range within which we can be 95% confident the true value of the statistic lies, in the total population that our sample represents.

5 95%CI: The estimate is 933 per year. There is 95% confidence that the figure lies between 159 and 1,609 perinatal deaths averted.

6 95%CI: The estimate is 384 per year. There is 95% confidence that the figure lies between 14 extra neonatal deaths and 695 neonatal deaths averted.

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Executive Summary

Maternal, perinatal and neonatal mortality remain high in Malawi and throughout sub-Saharan Africa. The Health Foundation funded community and facility interventions aimed at reducing this burden. MaiKhanda was set up as an independent NGO in Malawi to deliver both interventions with technical support from IHI and WCF. The community intervention involved mobilisation of rural communities through women's groups, and later, maternal and neonatal health task forces. 729 women's groups completed a participatory learning and action cycle to identify and prioritise maternal and neonatal health problems, decide upon local solutions/advocate and lobby for alternatives, and, implement and evaluate such strategies. The facility intervention involved coaching of health facility staff in quality improvement methodology, including Plan-Do-Study-Act cycles, change ideas, bundles and packages and death reviews to improve obstetric and newborn care at 29 health centres (randomised) and 9 hospitals (not randomised).

The community and facility interventions were evaluated via a two-by-two factorial cluster randomised controlled trial. All pregnant women in surveillance areas were eligible to take part and consenting women were followed-up to two months after birth via a low-cost community surveillance system using village-based key informants. Primary outcomes were maternal, perinatal and neonatal mortality. A separate non-controlled time-series evaluation of the quality improvement work at the 9 hospitals was under-taken with maternal and neonatal case-fatality rates as primary outcomes. Parallel process evaluations seeking to understand the processes, mechanisms, and intermediate outcomes of the interventions and the context within which they succeeded or failed were also undertaken and are reported in full. A preliminary cost-effectiveness analysis was also undertaken.

Both the interventions underwent changes throughout the evaluation period (2007-2010) and could have had sub-optimal dosages. Implementation could also have been improved. There were also political, management and resource challenges in the three districts (Lilongwe, Salima and Kasungu), and at the health facilities, which may have accounted for the lower impact of the interventions than hoped for. Our 21 main findings are as follows. Each of these is extensively discussed with respect to its implications, precision, potential bias, and relevant literature, in chapter 5.

Impact on death rates in the overall population and within health facilities

1. The randomised controlled trial suggests **neonatal mortality decreased by 22% in areas with both the facility intervention at the health centre and the community intervention in surrounding villages compared with control areas**; and, that **perinatal mortality decreased by 16% in areas with the community intervention relative to those without the community intervention** (see section 4.1).

2. **It is likely that the observed effects on mortality of both interventions occurred in the community** (section 4.2.4). This seems likely given the lack of observed effects on deaths at the health centres and hospitals (section 4.2.2), and data on the place of death collected from verbal autopsies. The latter indicate lower neonatal mortality rates in the community, but not in the facility, in areas with both the facility and community interventions compared to control areas; and, lower perinatal mortality rates in the community, but not in the facility, in community intervention areas compared to areas without the community intervention. For the facility intervention this suggests that neonates were leaving facility intervention health centres less likely to die in the community than neonates leaving control health centres, which fits with any facility intervention effect most likely being on late neonatal deaths (section 4.1.5).

3. Cause of death data and calendar data (section 4.2.3) suggest **the observed effect of the combined facility and community intervention on neonatal mortality may**

have been mediated by reductions in mortality due to asphyxia, prematurity and sepsis, in both the early and late neonatal periods, but that the effect was mainly observed in the last, more intensive, 15 months of the intervention period (see section 3.2), when it was larger (a 28% reduction); and, that **the effect of the community intervention on perinatal mortality may have been mediated through a reduction of stillbirths during the first 12 months of the intervention period and through a reduction in early neonatal mortality due to sepsis, prematurity and asphyxia in the second, more intensive intervention period** (section 4.2.3; also see section 4.1.5).

4. The randomised trial shows **no impact of either of the interventions on maternal mortality** and **given the observed number of births and deaths in each arm of the randomised trial the probability (calculated using the properties of the binomial distribution) that 30% reductions in maternal mortality really occurred as a result of the MaiKhanda interventions in the total population our sample sought to represent (intervention areas vs. control areas) was only around 1% for the facility intervention and 28% for the community intervention (section 4.1.4)**.

5. **Because of low incidence of maternal deaths in health centres it was not possible to determine if maternal case fatality rates were different between intervention and non-intervention health centres.** Maternal death rates were very low compared to those in the hospitals, probably due to most serious cases either being referred to or initially presenting at the hospitals. **Neonatal case fatality rates and fresh stillbirth rates** were also lower at health centres than hospitals and rates in the community, but were high enough to determine differences. **Neonatal case fatality rates were not significantly different between health centres undertaking the quality improvement intervention and those not. Fresh stillbirth rates were lower in facility intervention health centres (7.8 fresh stillbirths per 1000 births) than control health centres (5.5 fresh stillbirths per 1000 births), though given the low rates, the absolute reduction in mortality was small** (section 4.2.2.1)

6. **There is no evidence that the MaiKhanda facility intervention had an impact on case fatality rates at the non-randomised hospitals (CEmOCs).** Maternal case fatality rates in the non-randomised hospitals went down in 2009 but increased in 2010 despite an increase in the intensity of the facilities intervention (section 4.2.2.2.1). Similarly, neonatal case fatality rates in 2008 were lower, before rates increased in 2009 and 2010 when the neonatal interventions of the facilities intervention were rolled-out (section 4.2.2.2.2). The worsening of rates after mid-2010 occurred after a rapid increase in rates of health facility delivery, an increase that started in 2008 (sections 4.2.1.2.1 and 4.2.2.1). **It is possible that a threshold for overcrowding was reached in mid-2010, limiting the ability of these poorly resourced facilities to effectively manage the higher volume of patients. All available data on the timing and dosage of the interventions** (section 4.2.1.1) **and cause of death** (section 4.2.2.2.1) **suggest no link between the interventions and changes to the maternal and neonatal case fatality rates at the hospitals.** In the absence of comparison group data for the CEmOCs we analysed secular trends for Malawi using available national data. Analysis of available data shows that **between 2005 and 2010 the secular trend in Malawi was of falling maternal case fatality in hospitals and falling population based maternal mortality** (section 4.2.2.2.1)**; and, slightly declining neonatal mortality** (section 4.2.2.2.2).

7. Place of death data from the verbal autopsies suggest that the randomised controlled trial population (primarily rural) was distinct from the population served by the non-randomised hospitals (primarily local and urban), with only a 17-22% overlap for stillbirths and neonatal deaths but possibly a 50% overlap for maternal deaths (4.2.4.5).

Although the lack of an apparent effect of the MaiKhanda facilities intervention in the non-randomised hospitals precludes this work from biasing the randomised trial results as a consequence of this overlap, this data, especially that for stillbirths and neonatal deaths, provides additional support for the robustness of the randomised trial results with respect to potential dilution from MaiKhanda work in the CEmOCs.

Facility Intervention

8. **There was no clear evidence for the impact of specific quality improvement activities on clinical practices and intermediate outcomes such as post-partum haemorrhage (PPH) and asphyxia** (section 4.2.1.1).

9. Both the health facility surveillance (section 4.2.2) and the health facility resources survey (section 4.2.5.1.1) show that **the health centres were severely under-resourced in terms of emergency obstetric care signal functions (see Box 2) and human resources.** MaiKhanda was not able impact on the availability of such resources.

10. The initial 2008 staff psychology survey provided evidence suggesting that **motivation and morale among health staff was poor**. (section 4.2.5.1.2). Given that the follow-up survey was still pending were are unable to assess whether this situation has changed or whether MaiKhanda may have contributed to any improvement in motivation/morale.

11. The provider knowledge survey provides evidence **from 2010, towards the end of the evaluation period,** that **the clinical knowledge of emergency obstetric and neonatal care was lacking** (section 4.2.5.1.3). Unfortunately the names of the facilities were mistakenly not recorded, preventing disaggregation by whether or not the facilities were under the MaiKhanda facilities intervention or not, making it difficult to draw inferences regarding MaiKhanda's impact on this indicator. However, since the termination of LSTM training (2008) clinical skills training has not been part of the facilities intervention (see section 3.1).

12. The women friendly care survey showed that **the MaiKhanda facilities intervention may have improved the way both patients and guardians felt they were treated at facilities in Lilongwe, but not in Salima** (section 4.2.5.1.4). The survey was not conducted in Kasungu.

13. Capacity constraints in Ministry of Health (MoH) management structures and competing priorities in the external health system environment mean that **it may be challenging to sustainably embed quality improvement in the health system** (section 4.2.1.5.5). **However, the Malawian government is committed to improving maternal and neonatal health** (section 1.1.4), **and is also committed to supporting quality improvement as detailed in recent strategic documents.**

Community Intervention

14. **Community surveillance data on place of delivery showed that the community intervention did not increase health facility deliveries over and above the rapid increase observed in all areas** (section 4.2.1.2.1), which probably occurred due to a 2008 government ban on deliveries by traditional birth attendants (section 4.2.5.2.4.2).

15. The review of the routine monitoring data from the women's group register revealed that the **number of newly pregnant women who attended women's groups was fairly low at 10% and that the percentage of members who had never had children before was also low at 2%;** we also estimate a **population coverage of**

approximately 1 women's group to 1200 population (section 4.2.1.2.2). Given the results of recently published studies[8,10, page 14] **such coverage is likely to be sub-optimal**.

16. A survey of the strategies chose by women's groups and the success with which the groups implemented those strategies showed **the most popular strategies chosen by the women's groups to be bicycle ambulances, health education, vegetable gardens and bed nets** and **the most successfully implemented strategies to be health education, voluntary testing and counselling for HIV/AIDS, village savings and loans, bed nets and vegetable gardens** (section 4.2.1.2.3).

17. Evidence from a survey of knowledge, attitude and practices related to maternal and neonatal health among women in women's group (community intervention) areas and women in areas without women's groups suggests **the community intervention did not improve key maternal and neonatal health practices, although knowledge among women in community intervention areas was better for some indicators** (section 4.2.1.2.4).

18. Despite being (unpaid) volunteers, our survey showed that **the women's group facilitators were generally satisfied with their working conditions and were facilitating the groups well**. However allowances and material support were an issue (section 4.2.5.2.1).

19. The self-evaluation of the women's groups by their members in Phase-IV of the action cycle (see Figure 4) was generally positive (section 4.2.5.2.2), providing **subjective evidence that the groups were successful and supported by the community.**

20. **Traditional leaders in the community are likely to be very important** and in many areas likely to determine the success or failure of the community intervention. **On the whole, MaiKhanda engaged these leaders well** with an extensive community entry process, regular communication with traditional leaders and open days show-casing the community intervention work in the communities (section 4.2.5.2.4). **In addition the Malawian government is committed to supporting community interventions as detailed in recent strategic documents.**

Cost-Effectiveness Analysis

21. Preliminary results of the cost-effectiveness analysis indicate that **both the effect of the community intervention on perinatal mortality and the effect of the facility and community intervention combined on neonatal mortality are highly cost-effective by WHO criteria** (less than the per capita GDP of Malawi per Disability Adjusted Life Year (DALY) averted, which is **less than US$5,400 per stillbirth or neonatal death averted**; see section 4.3).

This study has added to the literature on the effectiveness of women's groups and constitutes the first randomised trial of a quality improvement intervention for maternal and neonatal health. The study endorses a combined community and facility approach, which is also indicated to be highly cost-effective. Notwithstanding serious issues related to resource and capacity constraints, both interventions could be sustained given Ministry of Health support for both approaches in recent policy documents. Overall, this complex study has generated much fascinating and valuable data about maternal and newborn mortality in Malawi. We hope that both positive and negative results will benefit those engaged in improving policy implementation to reduce the high levels of maternal and newborn deaths in Malawi.

Preface

This report presents the evaluation of the MaiKhanda facility and community interventions between 2007 and 2010, including the randomised controlled trial. The report is divided into five main chapters as follows.

- Chapter 1 begins by explaining what MaiKhanda was and why it was needed in Malawi, and summarises relevant background information.
- Chapter 2 presents the methods of the evaluation in detail, focusing on the three main areas: the impact evaluation, the process evaluation and the economic evaluation.
- Chapter 3 details what happened in the programme, including details of how the interventions evolved throughout the programme and the dosages of the intervention that were actually implemented.
- Chapter 4 presents the results of the studies undertaken to assess the impact of MaiKhanda, which are summarised at the beginning of the chapter and include: the randomised controlled trial; extensive process evaluation studies on intervention activities, processes, and mechanisms, outputs, and internal and external contextual factors; and, results of the cost-effectiveness analysis.
- Chapter 5 provides further interpretation of the results, focusing on what we can learn from the data generated, considering precision and potential biases, and with reference to external literature on health facility quality improvement and community mobilisation interventions in low income countries, for which a review is provided. Here we also consider the further potential of the interventions given their often sub-optimal implementation throughout the evaluation period. We finish with recommendations for policy makers, implementers and researchers, based on the evidence generated by the evaluation.

Please note that the MaiKhanda facility intervention, quality improvement of maternal and neonatal healthcare, is sometimes referred to as FI and sometimes as QI, and the MaiKhanda community intervention, community mobilisation via women's groups (and later, task forces) is sometimes referred to as WG and sometimes as CI. Figures and tables throughout the report have the following colour code to aid the readers interpretation: control: white/uncoloured; FI: red; CI: blue; FI+CI: purple.

Other useful things to note are that Odds Ratios are measures of effect, which for large populations like this study, correspond to percentage reductions (or increases) in the outcome (mortality): an odds ratio of 0.78 equals a 22% reduction (i.e. there is 78%, or *22% less*, mortality in the intervention group compared to 100% in the comparison group), and an odds ratio of 1.10 equals a 10% increase. And 95% confidence intervals (95%CI) are ranges within which we can be 95% confident that the true value of the statistic (e.g. the odds ratio) in the total population that our sample represents, lies between; 95%CI become narrower (i.e. we become more certain of the result) as sample sizes increase i.e. when the samples are more representative of the total population because they contain more of it. Therefore an odds ratio of 0.84 (95%CI: 0.72, 0.97) should be read as: "the observed data from our sample indicate that it is most likely that there was a 16% reduction in the total population, but that the reduction in the total population could have been as much as 28%, or as low as 3%, with 95% certainty". The 95%CI directly relates to the p-value of statistical significance in that a p-value of 0.05 (5%) corresponds to an upper 95%CI for odds ratios of 1.00 – i.e. a reduction of 0%, whilst higher p-values correspond to higher odds ratios meaning that there could have also been an increase in the outcome within our 95% range of confidence, or that we are more than 5% sure that we cannot rule out the possibility that there has not, in fact, been a reduction in mortality in the total population. Readers are referred to statistics textbooks, such as *Essential Medical Statistics* by Kirkwood and Sterne, for further details.

This report underwent peer review by two experts and several rounds of review by implementers (MaiKhanda), technical advisors (IHI, WCF) and funders (THF). We thank all of these reviewers who contributed to improving the report, however, any remaining errors are our own.

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Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
ART	Antiretroviral Therapy (for HIV/AIDS)
BEmOC	Basic Emergency Obstetric Care (Health Centre)
CEmOC	Comprehensive Emergency Obstetric Care (Hospital)
CFR	Case Fatality Rate
CHAM	Christian Health Association of Malawi
CMO	Community Mobilization Officers
CSMF	Cause Specific Mortality Fraction
DfID	Department for International Development (of the UK government)
DHMT	District Health Management Team
DHS	Demographic and Health Survey
DSMB	Data Safety Monitoring Board
EHRP	Essential Human Resources Package (for health)
EmOC	Emergency Obstetric Care
EOR	Emergency Obstetric Referral
GDP	Gross Domestic Product
GFATM	Global Fund for AIDS, Tuberculosis and Malaria
HC	Health Centre
HF	Health Facility (encompasses Health Centres and Hospitals)
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HRPW	High-Risk Pregnant Women
HSA	Health Surveillance Assistant(s)
ICH	Institute of Child Health (UCL)
IHI	Institute for Healthcare Improvement
KCH	Kamuzu Central Hospital
KDH	Kasungu District Hospital
KI	Key Informants (community surveillance data collectors)
LATH	Liverpool Associates in Tropical Health
LSTM	Liverpool School of Tropical Medicine
MCFR	Maternal Case Fatality Rate
MDA	Maternal Death Audit
MGD	Millennium Development Goal
MGDS	Malawi Growth and Development Strategy (2006 to 2011)
MoH	Ministry of Health (of the government of Malawi)
NCFR	Neonatal Case Fatality Rate
NGO	Non-Governmental Organisation
NHSRC	National Health Sciences Research Committee (Malawi)
QI	Quality Improvement
RCT	Randomised Controlled Trial
SDH	Salima District Hospital
SWAp	Sector-Wide Approach (for health)
TBA	Traditional Birth Attendant
TFR	Total Fertility Rate
THF	The Health Foundation
THFC	The Health Foundation Consortium – the precursor to MaiKhanda
UCL	University College London
USAID	United States Agency for International Development
WCF	Women and Children First
WGF	Women's Group Facilitator
95%CI	95% Confidence Interval (the values within which it is 95% likely that the true population value lies between)

1 What was MaiKhanda and why was it needed?

In this chapter we provide an overview of Malawi, the state of Malawian maternal and newborn health, the Malawian health system, and the 'Road Map' for accelerated progress towards better maternal and neonatal health as background and context to the work MaiKhanda undertook between 2006 and 2010, the subject of this evaluation. We then describe the formation of MaiKhanda in Malawi by the Health Foundation, the underlying theory and pre-existing evidence in support of the MaiKhanda facility and community interventions, the design of the interventions, and the implementation of the interventions including their evolution over the evaluation period. Subsequent chapters then present the methods and results of the evaluation and the interpretation of the results.

1.1 Context and Background

1.1.1 Malawi

With a GDP of $290 per capita, Malawi is one of the poorest countries in Sub-Saharan Africa. It is landlocked and mainly dependent on agriculture, especially tobacco, for its income (contributing to 35% of the GDP and 80% of the employment). Malawi has a population of 13 million[1] with an annual population growth rate of 2.8%. Most people (85%) live in rural areas. The crude birth rate is 39.2 per 1000 population per year while the crude death rate is 8.6 per 1,000 population per year. The Total Fertility Rate has been on the decline, with the current TFR being 5.7 overall, and lower in urban areas. With an HIV prevalence of 11%, Malawi is one of the countries severely affected by the AIDS epidemic[2]. In recent years government efforts to provide counselling, testing and Antiretroviral Therapy (ART) services have helped slow down the epidemic although inequities in the provision of ART remain.

1.1.2 Maternal and newborn health in Malawi

Maternal mortality in Malawi, at 984 per 100,000 live births at the time of the last DHS survey (2004), during the planning stages of the programme, was one of the highest in Africa and globally; although recent trends show a decline in mortality (the DHS 2010 puts maternal mortality at 675 per 100,000).[2] The main direct causes of maternal death in Malawi are haemorrhage, sepsis, eclampsia, and ruptured uterus; the main indirect causes are anaemia and HIV, the latter perhaps becoming less important in recent years due to the large-scale rollout of antiretrovirals. Infant mortality, at 66 per 1000 live births[2], and neonatal mortality, 31 per 1000 live births[2] are also high in Malawi. The main causes of neonatal death are prematurity/low birth weight, asphyxia and sepsis. The uptake of antenatal care is very high at 98% for at least 1 ante-natal visit[2], although women undergoing the recommended 4 visits is lower at 46%[2], while institutional deliveries were at 57% at the beginning of the programme[3], but are at 73% as of 2010.[2] The uptake of post-natal care is 43% while the use of modern contraception by women is 33%.[2]

1.1.3 Malawian health system overview

The government expenditure on health is 12.9% of its GDP[4]. The DfID led SWAp (Sector Wide Approach) in Malawi has provided a major support to the health system and other

[1] National Statistical Office. *Malawi Census Report 2008*.

[2] National Statistical Office (NSO) and ICF Macro. 2011. *Malawi Demographic and Health Survey 2010*. Zomba, Malawi and Calverton, Maryland, USA: NSO and ICF Macro.

[3] National Statistical Office (NSO) and ORC Macro. 2006. *Malawi Demographic and Health Survey 2004*. Zomba, Malawi and Calverton, Maryland, USA: NSO and ORC Macro.

[4] *World Health Statistics Report, 2009*

donor support (USAID, GFATM) contributes 30% of the budget support for health, so Malawi health is largely donor dependent.

1.1.4 Malawi's road map for reducing maternal and infant mortality

In early 2005, the Reproductive Health Unit (RHU) at the Ministry of Health, Malawi conducted a thorough field assessment of EOC services, which became the basis of a National "Road Map" for reducing maternal and infant mortality. Two findings of the assessment were particularly striking: Malawi had almost double the recommended minimum number of Comprehensive Emergency Obstetrical Care (CEmOC) facilities with 1.8 facilities per 500,000 population but almost no facilities capable of providing the full scope of basic obstetrical services (0.1 per 500,000 as opposed to the recommended level of 4). Secondly, many facilities (especially at CEmOC level) had the theoretical capacity to provide the full range of CEmOC but did not perform at this level in practice.

The more general recommendations from the Road Map indicated a need to improve the quality of maternal and newborn health care in both the provider system (supply side) and the community (demand side). They included:

- Develop and implement appropriate behaviour change interventions and advocacy strategies to address maternal and newborn health issues.
- Strengthen health facilities at all levels to ensure adequate coverage with functional EmOC facilities.
- Review and implement minimum standards of care for maternal and newborn health services with clear mechanisms for monitoring and supervision.
- Review Health Management Information Systems (HMIS) and orient staff to ensure quality collection and utilization of data for decision making and quality improvement.
- Conduct maternal death reviews and clinical audit.
- Reinforce ethical and professional issues in collaboration with the regulatory bodies.

Much of the emphasis of the "Road Map" was towards systems strengthening (including improved data quality and information systems) and capacity building. The 2011 updated version of the Road Map is discussed in relation to the MaiKhanda community and facility interventions in section 5.1 (under findings 13 and 20).

1.2 MaiKhanda Interventions

1.2.1 The Health Foundation in Malawi

The Health Foundation has a strategic focus to support health improvement in the developing world that is closely aligned to their work in the UK. They carried out an initial scoping exercise in Malawi with the Ministry of Health in 2005. Based on their scoping exercise and the recommendations in the 'Roadmap', The Health Foundation was keen on supporting a programme in Malawi that could impact on maternal and neonatal survival through a supply side intervention using quality improvement approaches and a demand side intervention using women's groups for community mobilization.

They brought together a consortium of partners involving Liverpool School of Tropical Medicine, Liverpool Associates in Tropical Health, Institute for Healthcare Improvement, Women and Children First (UK) and University College London (Institute of Child Health), to design and deliver the interventions. The UCL Institute of Child Health was responsible for conducting an independent evaluation of this innovative and ambitious programme, reported here.

The programme has been operational in three central region districts of Malawi, Kasungu, Lilongwe and Salima, since 2006. It has established 729 women's groups, running the women's group action cycle in rural village communities and the model for improvement implemented across 9 CEmOCs and 29 health centres across the 3 districts (see section 2.1.1).

The total cost of the programme was £6.3 million, with £2.9 million in Phase I (2006-2008) and £3.5 million for Phase II (2009-2011).

1.2.2 Intervention Theory

The theory underpinning the interventions was based on three delays model (Figure 1) suggested by Thaddeus and Maine in 1994.[5] Delay 1 is defined as the delay in seeking medical care. Delay 2 is defined as delay in reaching the medical facility and delay 3 is defined as a delay in receiving appropriate treatment at the facility. The MaiKhanda ***demand side interventions*** (community-based) were focused on reducing delays 1 and 2. The ***supply side intervention*** (facility based) were focused on reducing delay 3 (and delay 2 via improvement of the referral system from health centres to hospitals). It should be noted that community mobilisation does not reduce mortality only through ensuring referral to health facilities. Studies led by UCL in Nepal[7] and India[8] have shown sizeable reductions in neonatal and perinatal mortality through direct improvements in home care, independent of any health services effect.

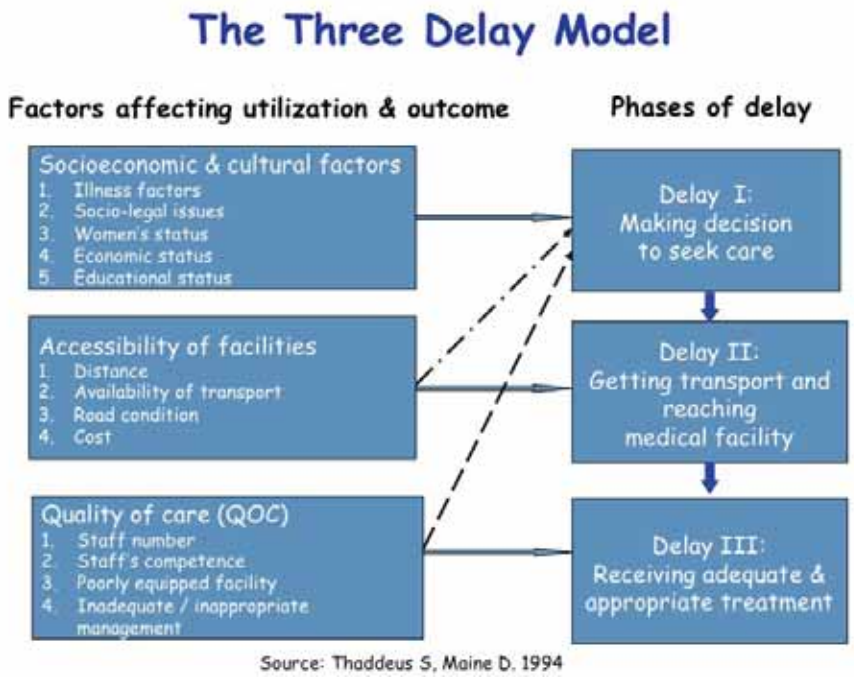

Figure 1: Three Delays Model

1.2.3 Pre-existing evidence, proof of concept and Innovation

Community mobilization has been defined as a "capacity building process through which community members, groups or organizations plan, carry out and evaluate activities in a participatory, sustained way to improve their health and other conditions, either through their own initiative or stimulated by other"[6]. Community mobilization through women's groups has proven to be an effective way of reducing neonatal mortality in Nepal[7] and India[8] and a

[5] *Thaddeus S., Maine D. (1994). Too far to walk: Maternal Mortality in context.* Social Science in Medicine *38 (8), 1091-1110.*

[6] *Grabman H et al (2007) Demystifying community mobilization: An effective strategy to improve maternal and newborn health.*

[7] *Manandhar D., Osrin D., Shrestha B. et al (2003). Effect of a participatory intervention with women's groups on birth outcomes in Nepal: cluster-randomised controlled trial.* Lancet *364, 970-979.*

[8] *Tripathy P.; Nair N.; Barnett S. et al (2010), Effect of a participatory intervention with women's groups on birth outcomes and maternal depression in Jharkhand and Orissa, India: a cluster-randomised controlled trial.* Lancet *375, 1182-1192.*

similar study is also being conducted in Mchinji district in Malawi by MaiMwana project.[9] In Bangladesh[10] women's groups were not found to be effective in reducing neonatal mortality – it was thought that this may have been due to an inadequate population coverage of the women's groups, something which is discussed further later. Evidence in support of women's groups reducing maternal mortality is less clear given inadequate power of previous studies.[6,8,10]

In many communities, where women have fewer opportunities, working with women's groups can contribute to wider empowerment, which becomes a critical factor for maternal and neonatal survival.

The model for improvement proposed by IHI was based on their experience of conducting quality improvement work in the US and UK as well as their work in South Africa, for which there have been no rigorous controlled evaluations measuring effects on mortality published in the academic literature to date. Franco and Marquez detail non-controlled time-series evidence in support of quality improvement breakthrough series collaboratives leading to improvement in adherence to essential standards of care and some health outcomes in 12 low and middle income countries.[11]

The greatest challenge to healthcare systems is to deliver already proven existing interventions reliably under resource-constrained settings.

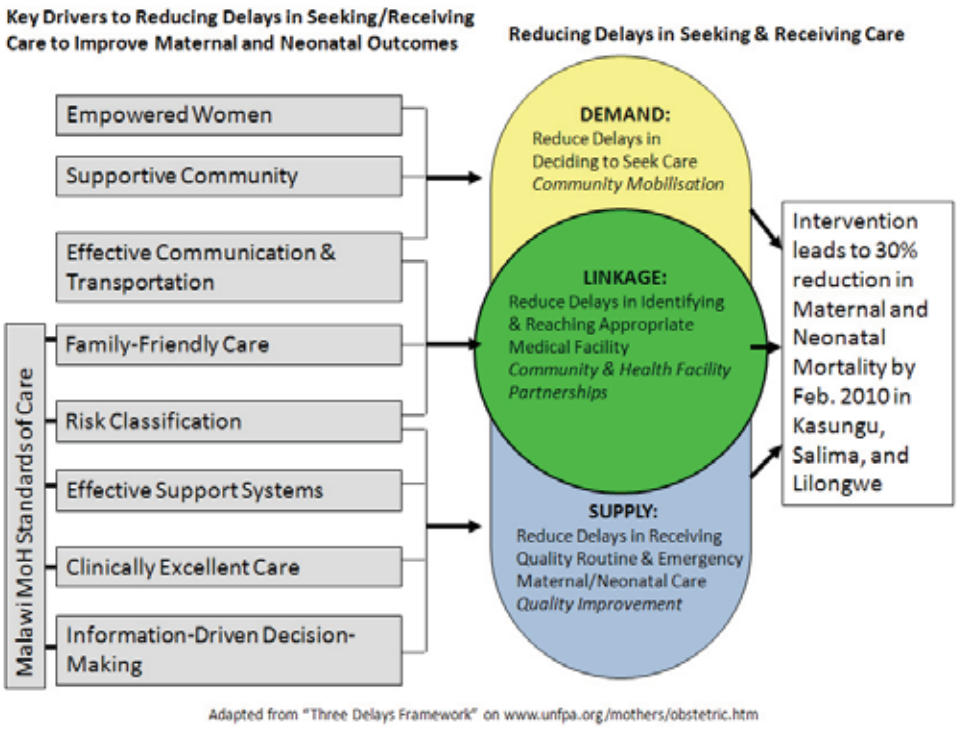

Figure 2: MaiKhanda Conceptual Model

The innovation brought into the MaiKhanda programme was the combination of a supply and demand side intervention within a single programme of work, with the aim of reducing maternal and neonatal mortality in the selected 3 districts over a six year period.

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[9] *Lewycka S., Mwansambo C., Kazembe P., et al (2010). A cluster randomised controlled trial of the community effectiveness of two interventions in rural Malawi to improve health care and to reduce maternal, newborn and infant mortality.* Trials *11:88.*

[10] *Azad K, Barnett S, Banerjee B, et al. Effect of scaling up women's groups on birth outcomes in three rural districts in Bangladesh: a cluster-randomised controlled trial. Lancet 2010: 1193-1202*

[11] Franco LM, Marquez, L. Effectiveness of collaborative improvement: evidence from 27 applications in 12 less-developed and middle-income countries. BMJ Qual Saf 2011; 20: 658-665

Figure 2, represents the conceptual model adopted by MaiKhanda. It shows how the key drivers in the left column affect seeking and receiving maternal and neonatal care.

1.2.4 Intervention Design

1.2.4.1 Demand-side Community intervention

The ***demand side interventions*** (community interventions) are focused on delays 1 and 2. The intervention consisted of the women's group action cycle where women from the community are brought together regularly (usually monthly) to discuss issues around pregnancy and birthing and to find solutions to their problems. They go through an action cycle which has four phases. Phases I & II consist of a series of 8 meetings to identify and prioritize issues; these are followed by strategy development (Phase III) and implementation (Phase IV; Figure 4). A facilitator who is usually a community member facilitates these action cycles. Several models for the facilitators have been tried previously - In the MIRA (Nepal) trial[7] and an on-going trial in Mchinji district, Malawi[9] the women's group facilitators are paid employees of the project, while a similar women's group intervention in Ntcheu district in Malawi has used health surveillance assistants (HSAs) from the existing health system to facilitate the women's group interventions. MaiKhanda has women volunteering from the community acting as women's group facilitators.

1.2.4.2 Supply-side Facility intervention

The supply side intervention consisted of a model which integrated the Criterion-Based Audit (or standard-based audit) cycle and the Rapid Cycle process improvement (Plan-Do-Study-Act, PDSA). These approaches, along with Maternal (and Neonatal) Death Reviews and Data Improvement formed the components of the 'quality improvement' intervention in the facilities (Figure 3).

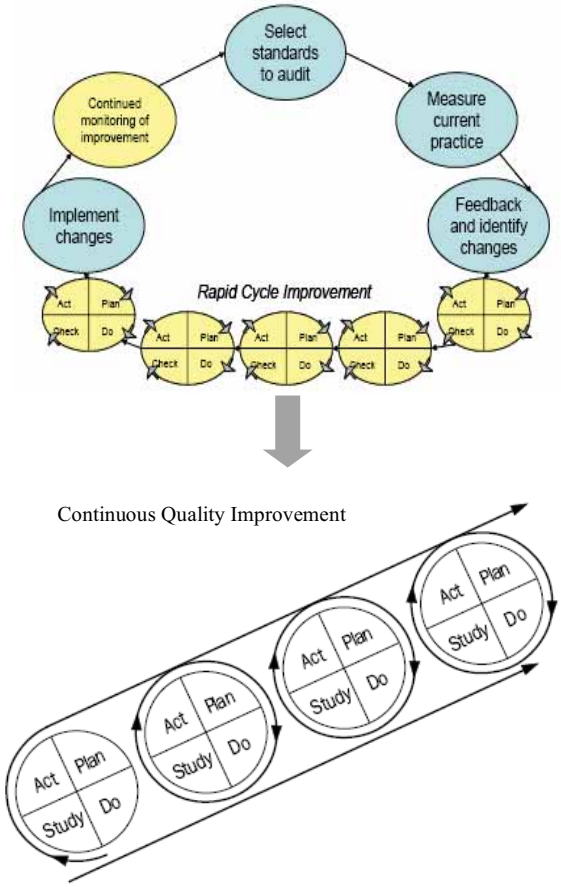


Figure 3: Integrated Improvement Model

The Criterion Based approach involved a series of five steps: agree on standards of care, measure current practice, identify problems encountered, introduce change, and repeat measurement of practice. It involved a process of reviewing existing guidelines, and it links with the standards of practice. Standards of practice were developed by the MoH to act as a guide for providers regarding the best standards of care in specific areas of healthcare. An example of a Criterion-Based Audit was ensuring adherence to a seven-point protocol for prevention of post-partum haemorrhage (PPH).

The Rapid Cycle (PDSA) approach also built on the providers' knowledge base and was to be done through a structured series of small interventions, designed by the providers themselves, and focuses on a more efficient use of existing resources. The integration of the two approaches would occur with the process beginning

with an audit cycle and then moving into rapid cycle change when the problems have been identified. This model used a 'bottom-up', participatory approach and was in line with MoH recommendations.

MoH recommendations also included the implementation of the Maternal and Neonatal Death Review (Audit) programme. MaiKhanda would facilitate the local staff to conduct audits in a blame-free and participatory manner. The information generated by the review would then be used to determine the focus of the criterion-based and rapid-cycle improvement activities.

Other factors that have been critical in the design of facility interventions were the CEmOC facilities, and the complexities of Lilongwe district and Bwaila and KCH referral hsopitals, as detailed below.

CEmOC facilities

While the intervention(s) were designed within the framework of an RCT, the original 9 referral CEmOC facilities were not intended to be part of the randomization process.[12] The CEmOC facilities cater to the entire district population and it was therefore difficult to include them in the randomization process. This includes the district hospital and CHAM hospitals as well as the tertiary hospitals within Lilongwe i.e. Bwaila Hospital and Kamuzu Central Hospital (KCH). Instead, only the health centres (intended as BEmOC facilities) were randomised to either receive or not receive the facility quality improvement intervention.

Despite their exclusion from the RCT, a lot of the improvement activities were concentrated in the CEmOC facilities, as these get the most referrals as well as complicated cases and therefore also the most maternal and neonatal deaths. The latter point also became an important consideration in the interpretation of the RCT results.

Lilongwe district

The decision regarding choice of districts for programme implementation was made by the Ministry of Health, with the Consortium partners having no say in it. In terms of population, Lilongwe is twice the size of Kasungu and Salima put together (1.9 million, vs 0.6 million and 0.3 million respectively). Lilongwe is divided into 5 health areas each of which, in terms of population, is a sub-district in itself. The limited programme resources had to be stretched to accommodate Lilongwe. This had implications for the implementation of interventions.

Bwaila/KCH

Bwaila/KCH being a high volume referral centre with many other demands on staff time, was to be provided with intensive consulting and coaching, which proved to be difficult. The referrals for Bwaila/KCH came from all district hospitals (in the central region of Malawi) as well as nearby health centres.

1.2.5 Implementation

1.2.5.1 Women's Group Intervention

The women's groups were developed and supported through community mobilization officers (their position was initially titled as women's group supervisors). These CMOs were trained in the conduct of the women's group action cycle (Figure 4) through field visits to Maimwana programme in Mchinji district. After the initial district orientation meetings, Women's Group Facilitators (WGFs) were identified and recruited from the local communities. Community members and the local chiefs assisted in identifying potential candidates using criteria including: maturity and motherhood, opinion leadership, previous experience and having received at least some secondary education.

The WGFs received initial and on-going training and support from CMOs to facilitate the women's group action cycle. In addition they were provided with a manual that outlines

[12] A 10th, newly established CEmOC facility, Daeyung Luke in Lilongwe was added later; and including KCH as a distinct entity from it's maternity-service part, Bwaila, brings the total number of CEmOCs to 11.

the meetings and phases of the cycle and presents Participatory Rural Appraisal (PRA) tools that can be used to facilitate discussion. To assist the discussions they were also provided with a pack of picture cards illustrating some of the main maternal and neonatal health problems, contributing factors and preventative and management activities.

Each of the WGFs was responsible for formation and development of 9 women's groups. Each CMO in turn was responsible for training and supervising 9 WGFs. Thus in total the programme had 9 CMOs, 81 WGFs and 729 women's groups across the three districts in the central region. There are about 20-30 members per group, which usually comprise women aged 25 and above who usually have experience of child birth. The last criterion was not intentional and seemed to stem from Malawian culture whereby it is thought inappropriate for girls/women yet to have got pregnant/given birth to discuss reproductive health issues. Given first time mothers are often more at risk of morbidity and mortality MaiKhanda advocated for non-mothers and first-time mothers to be allowed to join the groups once it was apparent that only 2% of women's group members were childless (see section 4.2.1.2.2). Despite the fact many first-time mothers were not/are still not members is ameliorated to some extent by messages from group meetings spreading to such women via family and friendship networks. Similarly, successful strategy implementation affects such non/first time mothers as well as other non-members in the community (see section 4.2.1.2.3).

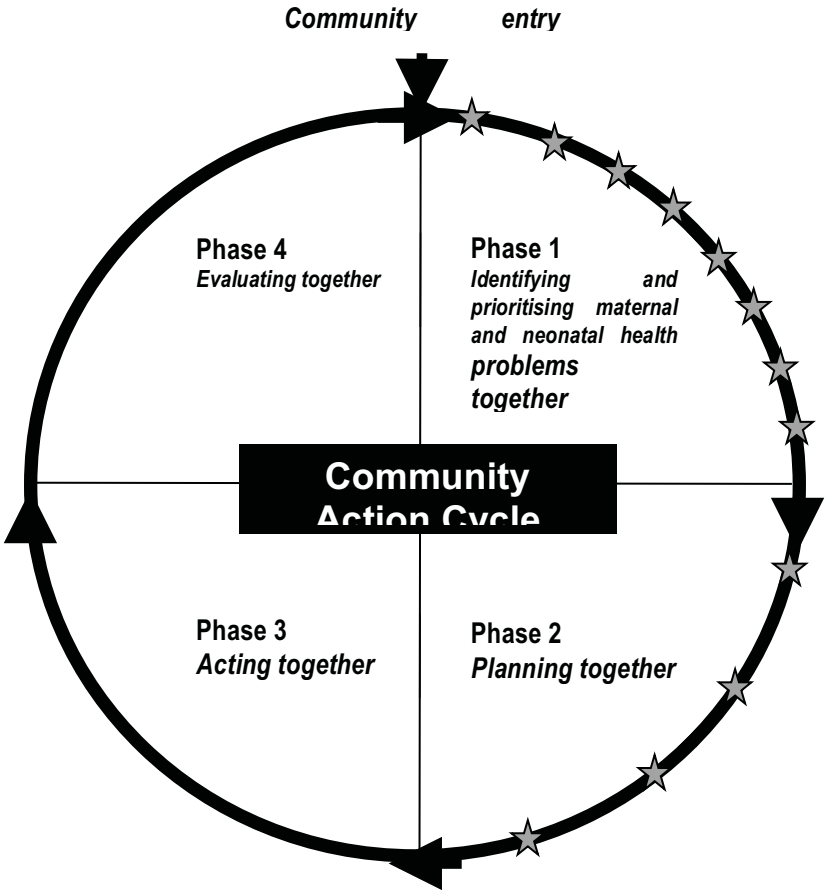


Figure 4: Women's Group Action Cycle

The Women's Group Facilitators facilitated the community mobilisation cycle (women's group action cycle) with communities in their areas according to the following guidelines:

Community entry process

The Women's Group Facilitators will carry out community entry meetings in their areas. All members of communities and representatives from organisations working in those communities will be invited. At these meetings the programme and the women's group intervention will be presented, questions will be answered and women of childbearing age (15 – 49) will be invited to join the women's group.

Phase 1 – Identifying and prioritising maternal and neonatal problems together

The Women's Group Facilitator will guide the women in her area through five meetings:

Meeting 1 – Group Formation – The Women's Group Facilitator will form between 10 and 12 groups in her area with the women invited during the community entry process. Groups may have membership from one village or from several villages depending on the size of communities, distance between villages and choice of community members. In this meeting they will discuss the women's group intervention in more detail and outline the constitution for their group.

Meeting 2 – Identification of maternal and neonatal health problems – The group will discuss and identify all the maternal health problems faced by members of their community, their symptoms and local names.

Meeting 3 – Feedback on problems identified by other community members – Before this meeting members will consult other members of their community about the maternal and neonatal health problems they face in their community. At this meeting they will feedback these problems to the group.

Meeting 4 – Prioritisation of problems – The group will decide criteria on which to prioritise between 3 – 5 problems they want to address in this cycle and then identify these priority problems.

Meeting 5 – Sharing with men – The group will present what they have been discussing including the problems identified and prioritised, the contributing factors and the preventative and management activities to men in their communities to find out their opinions and ideas.

Phase 2 – Planning strategies together

The Women's Group Facilitator will guide the women in her area through three meetings:

Meeting 6 – Identification of strategies – The group will discuss and identify strategies the community can employ to address the problems they are facing.

Meeting 7 – Identification of opportunities and barriers – The group will discuss what opportunities and barriers exist in their community that may help or hinder implementation of the strategies and use this information to develop more feasible strategies.

Meeting 8 – The community planning meeting – The group will present everything they have done including the problems identified and prioritised, the contributing factors, the preventative and management activities and the strategies to other members of their community and representatives from organisations working in their area. They will gather the opinions and ideas of these participants and plan how to implement their strategies with the support of these participants.

Phase 3 – Implementing strategies together

The Women's Group Facilitator will guide the women and communities in her area through a process of refining, further planning and implementing the strategies that have been identified.

Phase 4 – Evaluating together

The WGFs guide the women and communities in her area through a process of evaluating the strategies they have implemented and planning for the future in terms of improving the strategies and identifying new problems and how to address them.

The community intervention evolved during implementation as detailed in chapter 3.

1.2.5.2 Facilities Intervention

The objective of the facilities intervention was to reduce maternal and neonatal case fatality through four key drivers of change specified in the initial organisation of the change package:

- Family/Women friendly care
- Clinically excellent care for women/newborns
- Information driven decision making
- Effective support systems

The facilities intervention engaged 29 randomised health centres and 11 CEmOC hospitals[12, page 17] in the implementation of maternal and neonatal change packages using rapid PDSA cycles. This was done through QI teams that were set up in the facilities; the members of which were trained and coached by MaiKhanda staff, both at their facilities and in separate learning sessions, to do the interventions themselves.

Based on the IHI model for improvement, implementation of QI work in health facilities involved the following major components:

- QI teams
- Collaborative learning sessions
- Action periods
- Data improvement

QI teams

The development of Quality Improvement (QI) teams within the facilities was an integral part of the QI implementation programme. In general, a team comprised representatives from the various provider roles within the facilities, for example, QI team members typically included a Matron, Nurse-Midwife, Clinical Officer, Lab Technician, and Data Clerk. Each QI team would have a day-to-day leader who would regularly liaise with MaiKhanda QI Officers to inform them of their QI work, to submit data, prepare for workshops and to arrange meetings. The leader's role would also be to encourage and support the other team members.

Collaborative learning sessions

This involved learning sessions for both the CEmOC facilities and the health centres.

The *CEmOC collaborative* focussed on the most frequent causes of maternal death in the hospitals such as haemorrhage and puerperal sepsis. Neonatal topics addressed included neonatal sepsis and birth asphyxia.

District-based *health centre collaboratives* focussed on building linkages with communities, risk classification, and the referral system. Learning sessions would provide an opportunity for health centres to learn from other health centres in their own district to enable the spread of successful ideas and strengthen linkages at all levels of the health system. QI teams from CEmOC hospitals were expected to assume a leadership role and mentor health centres in QI methods. The health centres included

- Eight health centres from Kasungu and six from Salima linked to their respective district hospitals.
- A Lilongwe collaborative with fifteen referring health centres and Bwaila/KCH, six CEmOC and two community hospitals.

Learning sessions provide an opportunity for health centres to learn from other clusters in their own district to enable the spread of successful ideas and strengthen linkages at all levels of the health system.

Action periods

Following on the learning sessions, MaiKhanda's QI officers would conduct field visits to CEmOCs and health centres to ensure the implementation of the change packages and the testing of new ideas using PDSA cycles. In addition, they would also facilitate maternal death reviews in the CEmOCs. A typical action cycle lasted on average 90 days between two consecutive learning sessions.

- *Change package*

The Change Package provides a list of primary and secondary drivers of change that facilities need to implement to improve changes in current practice in their facility. The change package has been developed from the three delays framework and is closely linked with the standards. The standards of care are broken down by the package into actions that the providers can do. Thus there are maternal and neonatal change packages. Initially, facilities chose elements from the change package on the basis of 'gut feeling'. However, through the course of the QI programme, decisions on which ideas to test became more 'data driven'.

- *PDSA Cycle*

PDSA Cycle stands for Plan-Do-Study-Act. This includes 'Plan' to answer a question and 'Plan' for collection of data to answer the question. 'Do' refers to the carrying out of the change or test. 'Study' involves complete analysis of data. And 'Act' refers to reflecting on what changes are to be made and then plan for the next cycle. The PDSA is run to test different ideas for implementing part of the change package. Once the PDSA has been run, the facilities have to make sure that there is a certain level of reliability before that idea is adopted as an improvement.

- *Maternal Death Reviews*

The process of MDR typically involves analysing a maternal death followed by discussion focusing mainly on the 'action points' or activities that are brought up by the review. The QI teams then target specific ideas that the facilities can take to prevent such a death from reoccurring. Although challenging, an important part of MaiKhanda-facilitated death reviews were to introduce the concept of no name, no blame in MDRs.

Data improvement

All the processes of QI rely on the collection of reliable and accurate data from the facilities. This data capture allows the facilities to recognise areas for improvement, and to measure their progress. Data improvement measures were implemented in all the hospitals and health centres MaiKhanda worked in with data clerks being trained in collection of good quality data. The data improvement work in described in section 3.3.

The facility intervention evolved during implementation as detailed in chapter 3.

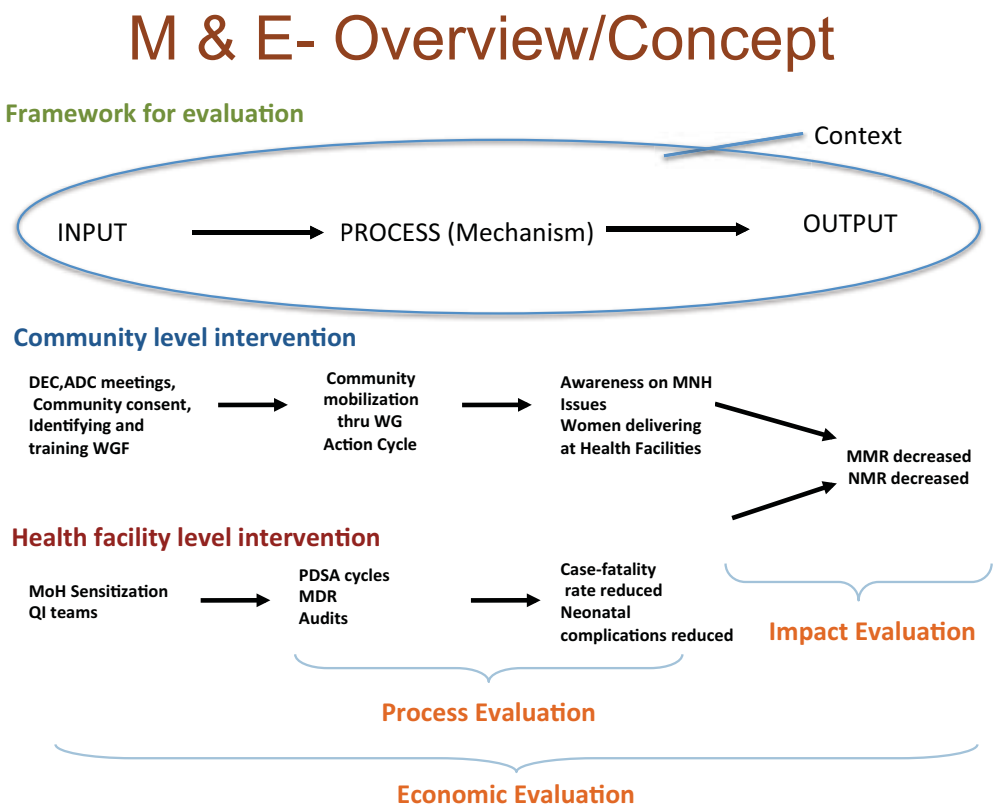
2 How did we evaluate the programme and why was it important?

The Institute of Child Health, UCL was contracted to conduct an independent evaluation of the MaiKhanda programme. The hypothesis was that if we were able to implement the supply and demand side interventions (as described in section 1.2 above, and chapter 3 below), then we would be able to have an impact on maternal and neonatal mortality at population level.
The main objectives of the evaluation were:

- To **measure the impact** of health facility level and community level interventions on maternal and neonatal mortality.
- To **understand the processes and context** at the health facility and community level which affect maternal and neonatal mortality and the **mechanisms** by which the interventions may have affected the processes and context to impact on maternal and neonatal mortality.
- To **estimate the cost-effectiveness** of the interventions.

Figure 5 provides a conceptual overview of the evaluation.

Figure 5: Evaluation overview



2.1 Impact evaluation

To measure the effect of the two interventions individually and combined, the impact evaluation included the following primary outcome measures:

Primary outcome measures

- Maternal mortality ratio

- Neonatal mortality rate (overall, early and late)
- Perinatal mortality rate (stillbirths plus first week deaths).[13]

See Box 1 for the ICD10 definitions of stillbirth, neonatal death and maternal death, which were used in this study. Secondary outcome measures were assessed as part of the process evaluation (section 2.2), which was undertaken in order to explain any impacts that may have been observed.

Box 1 Definitions for perinatal outcomes (ICD 10)[14]

> **Stillbirth** – "A stillbirth or foetal death is a death prior to the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation the foetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles." We use the ICD-10 criteria for stillbirth modified to include births after 28 completed weeks rather than 22 weeks.
>
> **Neonatal death:** death within the first 28 days of an infant after "the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached."
>
> **Maternal death:** "the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes."

Secondary outcome measures

At the facility level:

- Percentage of skilled attendants at birth
- Percentage met need for emergency obstetric care
- No. of deliveries at facility
- Percentage of maternal deaths subjected to maternal death audit.
- Case fatality rate
- Caesarean section rate
- Practice of signal obstetric care functions

At the community level

- No. of women's groups mobilized annually
- Percentage of women of reproductive age attending women's groups

See Box 2 for the definition of secondary outcomes used in this study, and the chapter 4 sections that they are reported in.

[13] Although perinatal mortality was stated as a primary outcome of the study in some parts of the initial 2005 proposal and in the 2007 evaluation study design submitted to and approved by the ethics board in Malawi, it was not monitored with maternal and neonatal mortality from the beginning of the programme and was often overlooked. However, we believe that it would be difficult for most of the maternal and neonatal interventions, especially those around the time of childbirth, to be effective without also being effective on perinatal mortality. We are therefore reporting perinatal mortality as a primary outcome of the study.

[14] International Classification of Diseases, Tenth Revision (ICD-10), World Health Organisation, Geneva, 2007

Box 2 Definitions for Secondary outcomes and details of where they are reported

Percentage of deliveries with Skilled Attendance – The percentage of deliveries at a Health Facility – it is assumed that all deliveries at a health facility are done by skilled clinical personnel such as a nurse or a clinical officer (see sections 2.2.1.2.1 and 4.2.1.2.1)

Percentage met need for emergency obstetric care – The percentage of complicated births cared for in either a basic, or comprehensive emergency obstetric care facility. Due to the simple nature of our community surveillance system (see section 2.1.4) we were not able to collect information on all complicated births occurring in the community and therefore were not able to report on this indicator.

Percentage of maternal deaths subjected to maternal death audit – The percentage of maternal deaths occurring at a health centre or hospital that are subjected to audit by the clinical team (see end of section 2.2.2 and section 4.2.2.3)

Case Fatality Rate – The number of deaths divided by the number of cases at the facility. We evaluate both maternal and neonatal case fatality rates (see sections 2.2.2 and 4.2.2).

Caesarean Section Rate – The number of deliveries by Caesarean section divided by the total number of deliveries. Caesarean sections were not a focus of the MaiKhanda facilities intervention (see section 4.2.1.1) and numbers of C-sections were not recorded, (see end of section 2.2.2) precluding the reporting or analysis of trends in C-section rates.

Practice of signal obstetric care functions – The availability and practice of signal functions gives an indication of the status of the facility. Health Centres are intended to be Basic Emergency Obstetric Care (BEmOC) facilities and qualify as such if they are able to provide all 6 BEmOC signal functions: Manual removal of placenta; Manual vacuum aspiration; vacuum extraction and breech deliveries; parenteral antibiotics; magnesium sulphate; oxytocic drugs (ergometrine or oxytocin). Hospitals are intended to be Comprehensive Emergency Obstetric Care (CEmOC) facilities and qualify as such if they are able to provide all 6 BEmOC signal functions *and* the 2 CEmOC signal functions: Caesarean Section and Blood Transfusion (see sections 2.2.2, 4.2.2, 2.2.5.1.1 and 4.2.5.1.1). The MaiKhanda facilities intervention did not specifically work on improving the availability of signal functions (see discussion of finding 9 in section 5.1)

Number of Women's Groups mobilized annually – This gives an indication of the implementation of the women's groups. 729 women's groups were formed in 2007 (see sections 1.2.5.1 and 3.1). And additional 90 women's groups were formed in late 2010 and early 2011 but were not considered in the RCT evaluation of the community intervention, which ended in Dec-10 (section 2.1.11).

Percentage of women of reproductive age attending women's groups – This gives an indication of the population coverage of the women's groups and is reported in section 4.2.1.2.2 (see section 2.2.1.2.2 for methods) and is discussed under finding 15 in section 5.1.

In order to rigorously evaluate the effects (primary outcomes) of the facility quality improvement and community women's group interventions, a cluster randomised controlled trial (RCT) design was adopted. The RCT design, which includes measurement of a control group where neither of the interventions was carried out, enables the influence of secular trends (i.e. changes happening in the population anyway as a result of other factors) to be controlled for – effects on mortality are measured net of such secular trends. Allocation of interventions to specific areas by randomisation also helps to control for both known and unknown potential confounding variables (variables that also influence the outcome independently of the intervention). The RCT was carried out as detailed in the following sub-sections. First we present the design of the RCT, then the randomisation procedures, hypotheses of intervention effect and study power to detect any effects that may have occurred. Following this we provide a description of the community surveillance system and key informants used to collect the data on births and deaths used to assess the primary outcomes. Then we give details of ethical approval, assessment of data quality and verification of deaths by verbal autopsy, before finishing the RCT methods with a detailed description of the pre-planned analyses of the RCT data.

2.1.1 RCT design

The impact evaluation of the facility and community interventions was originally designed as a two-by-two factorial cluster Randomized Controlled Trial (RCT) with health centres (clusters) randomised[15] to either receive or not receive the Quality Improvement (QI) intervention and the communities surrounding each group of health centres then randomised to either receive or not receive the Women's Group (WG) intervention (Figure 6, Figure 7).[16] Following consideration of the CONSORT guidelines, deviations from protocol and review by an External Data Monitoring Committee on 8th April 2011, changes were made to the number of clusters that were included in the final analysis. The main changes were that none of the 9 clusters with dispensaries (health centres that don't do deliveries) had women's groups formed in them (this left 15 WG only clusters), the dispensary control clusters and Kasungu and Salima district hospital catchment areas were also excluded as they were not part of the randomisation (leaving 17 control clusters and 15 QI only clusters), and, no surveillance was done in the WG+QI allocated St. Andrew cluster in Kasungu due to no Health Surveillance Assistants being based at St. Andrews (leaving 14 WG+QI clusters; further details are provided in Table 1 and footnotes).

2.1.2 Randomisation and concealment of intervention allocation

Randomisation was done using Stata's random number generator traceable by setting the seed number from which future random numbers were generated (e.g. for Kasungu where there were 17 clusters to randomise ("/" denotes a new line of Stata syntax): set seed 36576 / set obs 17 / gen id=_n / gen rand=uniform() / sort rand / gen order=_n / gen str4 alloc="WG" / replace alloc="QI" if order>4 / replace alloc="WG+QI" if order>8 / replace alloc="Nothing" if order>12 / replace alloc="Extra" if order>16 /sort id). Randomisation was stratified by the two interventions and by district, so that the numbers of intervention and control clusters in each district balanced.

[15] Randomisation was done using Stata's random number generator traceable by setting the seed number from which future random numbers were generated (e.g. for Kasungu where there were 17 clusters to randomise (/ denotes a new line of Stata syntax): set seed 36576 / set obs 17 / gen id=_n / gen rand=uniform() / sort rand / gen order=_n / gen str4 alloc="WG" / replace alloc="QI" if order>4 / replace alloc="WG+QI" if order>8 / replace alloc="Nothing" if order>12 / replace alloc="Extra" if order>16 /sort id)

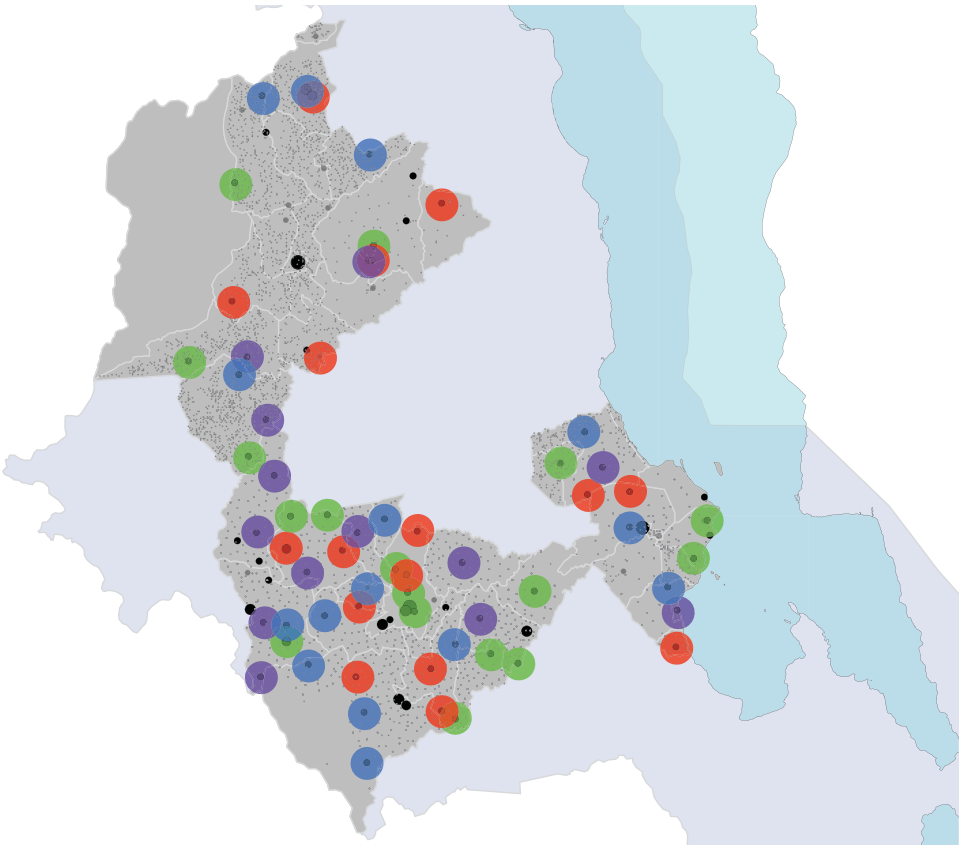
[16] Costello, A, Mwansambo, C., Rosato, M., Lewycka, S., and Nambiar, B. The effect of demand and supply side interventions on maternal and neonatal mortality in three districts in Malawi: a cluster randomized controlled programme. Proposal for carrying out Evaluation. 2005.

As the Stata syntax quoted above shows, ID numbers were assigned for each cluster and a random number generated for each. These were then sorted in ascending order, and a new 'order' variable generated. This was used to allocate to each of the four intervention groups in each district. The sequence was concealed until interventions were assigned.

2.1.3 Hypothesis and power

The hypotheses being tested by the RCT were that each intervention would reduce population-level maternal mortality[17] and neonatal mortality[18] by 30%. Following the collection of prospective baseline data it became apparent that the MMR was less than that assumed in the original sample size calculations (415 instead of 984 deaths per 100,000 live births, see section 4.1.2.1) meaning that the power of the RCT to detect a 30% reduction in MMR was reduced to only around 36% (rather than the recommended 80% as originally designed). This is explained further in Appendix 1, which also includes details of the observed intracluster correlation coefficients which were used (0.00118 for maternal and 0.00213 for neonatal). The power of the RCT to detect a 30% reduction in NMR remains very good at 98% due to the fact neonatal mortality is a more common occurrence and baseline NMR was slightly higher than assumed, at 30.7/1000. In fact the RCT had an 80% power to detect a reduction in NMR as small as 22% if such a reduction occurred.[19]

Figure 6: Map of districts, health facilities, villages and randomised intervention areas

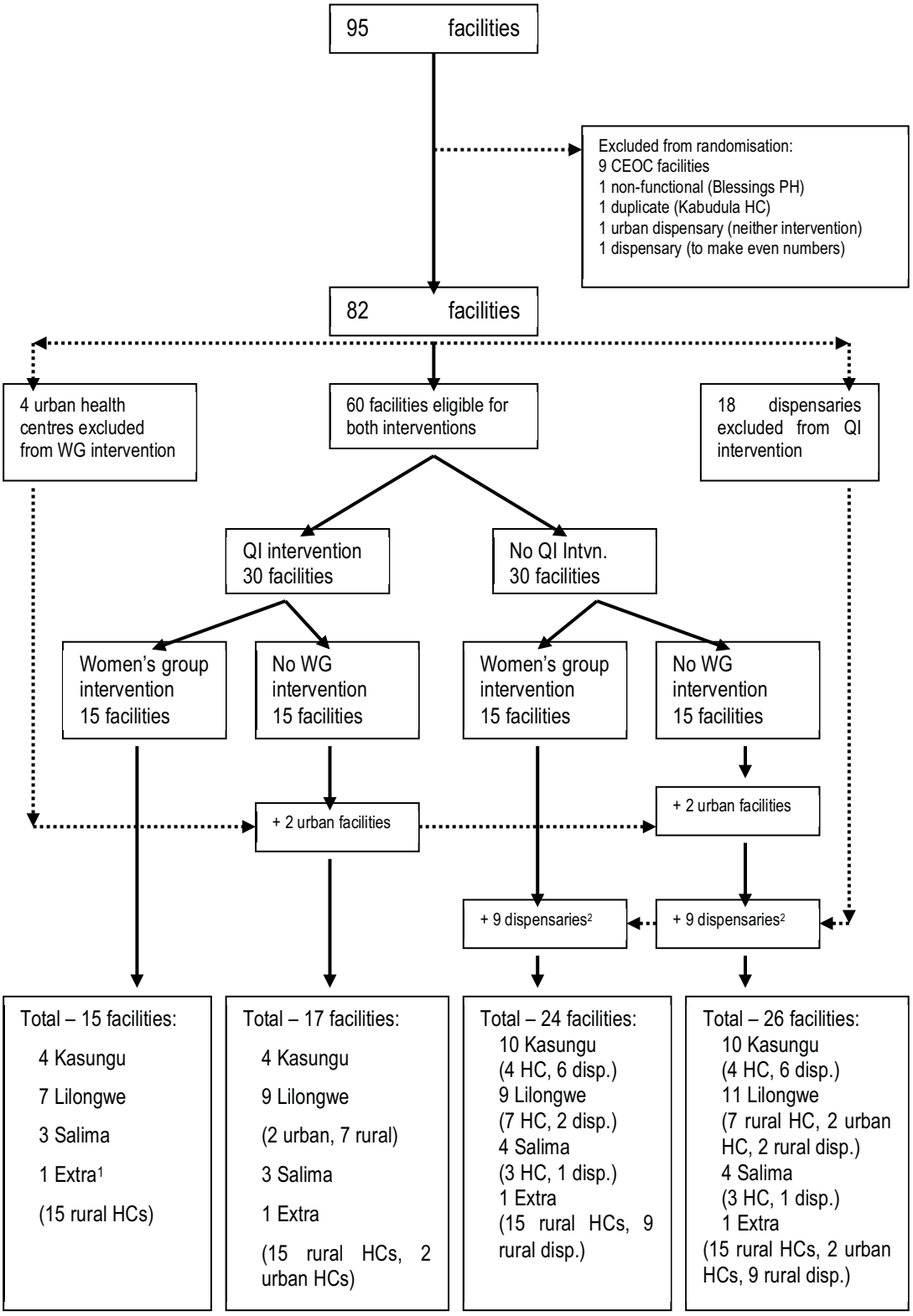


[17] As measured by the Maternal Mortality Ratio (MMR) which is maternal deaths per 100,000 livebirths. The Malawi DHS 2004 baseline MMR of 984/100,000 was used in the sample size calculations and the 30% reduction was therefore an original target of achieving an MMR of 688 /100,000.

[18] As measured by the Neonatal Mortality Rate (NMR) of neonatal deaths per 1,000 livebirths. The Malawi DHS 2004 baseline MMR of 27/1000 was used in the sample size calculations and the 30% reduction was therefore an original target of achieving an NMR of 19 /1000.

[19] Power percentages given are for the final 61 clusters that were included in the analysis for both the WG and QI trials (see Table 1: CONSORT flowchart for explanation of excluded clusters).

Figure 7: Randomised Controlled Trial design



[1] The 'extra' facilities are three from Lilongwe and one from Kasungu that were left over after randomly allocating the others to each of the four intervention groups. To ensure the balance across interventions was maintained, these were allocated to each of the four intervention groups

[2] Some of the rural clusters with dispensaries (health centres that does not do deliveries) that were supposed to have Women's Groups in, in the original design mistakenly never had Women's Groups formed in them so there are actually 31 control clusters out of the 82 originally randomised to receive QI and WG.

Table 1. Flow of the progress of clusters and individuals through the phases of an RCT as recommended in the CONSORT guidelines

		WG+QI	QI only	WG only	control	Total
Allocation to Intervention	Clusters	15	17	24	26	82
	Ave. cluster size (total population)	40,000	40,000	40,000	40,000	40,000
	Total population	600,000	680,000	960,000	1,040,000	3,280,000
Received Allocated Intervention	Clusters	15	15	15	17	62
	Ave. cluster size (Births)[2]	359	382	339	289	338
	min. cluster size (Births	188	160	148	75	75
	max. cluster size (Births)	577	524	690	610	690
	different districts than plan?	No	Lilongwe: 7 instead of 9 - see below	Not for remaining clusters (HC only)	Not for remaining clusters (HC only)	
	Ave. cluster size (total population)	40,000	40,000	40,000	40,000	40,000
	min. cluster size (total population)	10,000	10,000	10,000	10,000	10,000
	max. cluster size (total population)	160,000	160,000	160,000	160,000	160,000
	Total population	600,000	600,000	600,000	680,000	2,480,000
Did not receive Allocated Intervention	Clusters	0	2	9	9	20
	Ave. cluster size	NA	No data collected but assume sample taken from total cluster populations would have been similar	No data collected but assume sample taken from total cluster populations would have been similar	NA	
	min. cluster size	NA			NA	
	max. cluster size	NA			NA	
	Reasons		Kamuzu Barracks (Lilongwe, urban) not included as military didn't give permission; Kabudula (Lilongwe) not included as it became one of the 9 CEmOCs outside of the trial.	see note 3 below	see note 3 below	
Follow-up						
Sample Population under surveillance (during 27 month intervention period - used for analysis - 01oct2008 to 31dec2012)	Clusters	14	17	15	31	77
	Difference from Received Allocated Intervention	-1	2	0	14	15
	Reasons	St. Andrew's has no Health Surveillance Assistants so surveillance was not done. Also, as it is next to Mtumthama (QI only) it shares Mtuthama's catchment area, meaning separate surveillance was not possible. Cluster sizes for Received Allocated Intervention above are for the 14/15 clusters with surveillance data.	Kasungu District Hospital and Salima District Hospital were also included in surveillance, although they were outside of the RCT so were not included in analysis.		see note 3 below	

continued on next page

Table 1 continued

		WG+QI	QI only	WG only	control	Total
Surveillance population analysed (61 clusters intervention period 01oct2008 to 31dec2010 - light blue shading)	Total Population	59713	61412	60268	69504	250897
	Total Pregnancies[4]	6964	7544	7590	7333	29431
	Total Births	5455	6035	5331	5665	22486
	Ave. Population per cluster	3981	4387	4018	4088	4113
	min. Population per cluster	2705	2294	1905	2121	1905
	max. Population per cluster	5321	7598	6042	6021	7598
	Ave. Pregnancies per cluster	464	539	506	431	482
	min. Pregnancies per cluster	261	205	182	156	156
	max. Pregnancies per cluster	713	842	832	955	955
	Ave. Births per cluster	358	372	348	293	340
	min. Births per cluster	192	166	154	77	77
	max. Births per cluster	589	537	702	634	702
Loss to follow-up	Clusters	1	0	0	0	0
	Reasons	As above				
Pregnancies missed if Crude Birth Rate of 40 per 1000 population[5]	Expected pregnancies (births)	5535	5693	5587	6443	23258
	Total missed Pregnancies	-1429	-1851	-2003	-890	-6173
	Total % of pregnancies missed	-25.8%	-32.5%	-35.9%	-13.8%	-26.5%
	Ave. Pregnancies missed per cluster	-106	-144	-144	-63	-112
	min. Pregnancies missed per cluster	-317	-315	-473	-475	-475
	max. Pregnancies missed per cluster	181	53	96	181	181
	Ave. % of Pregnancies missed per cluster	-33.1%	-41.6%	-44.0%	-18.7%	-33.7%
	min. % of Pregnancies missed per cluster	-8.0%	-129.8%	-156.4%	-107.1%	-156.4%
	max. % of Pregnancies missed per cluster	41.0%	13.6%	27.5%	46.3%	46.3%
	Reasons	Lack of diligence by data collectors	Lack of diligence by data collectors	Lack of diligence by data collectors	Lack of diligence by data collectors	
Pregnancies lost-to-follow-up after initial recording	Total Pregnancies not followed-up (nofu)	1509	1509	2259	1668	6945
	Total % of pregnancies nofu	21.7%	20.0%	29.8%	22.7%	23.6%
	Ave. Pregnancies nofu per cluster	114	157	167	142	145
	min. Pregnancies nofu per cluster	35	45	34	60	34
	max. Pregnancies nofu per cluster	187	384	369	345	384
	Ave. % of Pregnancies nofu per cluster	24.3%	28.3%	32.1%	35.1%	30.2%
	min. % of Pregnancies nofu per cluster	11.5%	18.7%	16.9%	20.6%	11.5%
	max. % of Pregnancies nofu per cluster	34.6%	45.6%	48.4%	63.7%	63.7%
	Reasons	Migration; Lack of diligence by data collectors?	Migration; Lack of diligence by data collectors?	Migration; Lack of diligence by data collectors?	Migration; Lack of diligence by data collectors?	
Expected - Observed births (missed pregnancies and not followed up combined)	Total Expected - Observed births	80	-342	256	778	772
	Total % of births not as expected	1.5%	-6.0%	4.6%	12.1%	3.3%
	Ave. Expected-Observed births per cluster	8	13	23	79	32
	min. Expected-Observed births per cluster	-181	-158	-154	-156	-181
	max. Expected-Observed births per cluster	245	163	213	411	245
	Ave. % Expected-Observed births per cluster	-0.8%	-2.3%	4.8%	20.7%	6.2%
	min. % Expected-Observed births per cluster	-45.7%	-74.0%	-40.5%	-64.5%	-74.0%
	max. % Expected-Observed births per cluster	56.6%	41.9%	50.0%	75.8%	75.8%
Discontinued Intervention	Clusters	0	0	0	0	0

continued on next page

Table 1 continued

Analysis		WG+QI	QI only	WG only	control	Total
Analysed	Clusters	14	15	15	17	61
	Ave. cluster size (Births)	359	382	339	289	338
	min. cluster size (Births	188	160	148	75	75
	max. cluster size (Births)	577	524	690	610	690
Excluded from Analysis	Clusters	0	2	0	14	16
	Ave. cluster size (Births)	NA		NA		
	min. cluster size (Births	NA		NA		
	max. cluster size (Births)	NA		NA		
	Reasons	NA	As above. KDH and SDH were not part of the RCT	NA	see note 3 below. The 14 clusters were not part of the RCT	
Exploratory Analyses						
Differences in Cluster numbers	Per Protocol	15	14	15	17	61
	Differences from Intention to Treat	Mtumthama considered as QI+WG instead of QI because it has the same catchment area as St. Andrew's (no data - see above) which received QI+WG (as allocated)				
	Exclusion of stratified as Urban clusters[6]	14	14	15	16	59
	Exclusion of all Urban Clusters[6]	14	12	15	14	55
	Differences from stratified as urban		As well as Area 18 and originally not included Kamuzu Barracks, Chitedze and Lumbadzi are also urban and excluded (although weren't included in stratification because they are outside Lilongwe City limits		As well as Area 25 and Kawale (stratified urban) Dzenza is also urban and excluded (although it wasn't included in stratification because it is outside Lilongwe City limits)	
Same cluster numbers - different variables	Evolution of Interventions: split by first 12 months (01oct2008 to 30sep2009) and subsequent stepped-up 15 month period (01oct2009 to 31dec2010)					
	Number of Women's Groups and number of Task Forces per cluster					

[1] The 'extra' facilities are three from Lilongwe and one from Kasungu that will be left over after randomly allocating to each of the four intervention groups. To make sure the balance across interventions is maintained, these were randomly allocated so that one goes to each of the four intervention groups

[2] Births recorded from the sample population under surveillance (see below) are used to calculate the denominator of the primary mortality outcomes. This is also why Pregnancies not followed-up to birth is the measure of loss-to-follow-up (see below)

[3] All 9 of the rural clusters with dispensaries (health centres that does not do deliveries) that were supposed to have Women's Groups in, in the original design were not randomised and never had Women's Groups formed in them, therefore 15 clusters instead of 24 had WG only and, given that data collection still occured in 3 of these dispensary clusters (as well as the 9 originally designated control dispensaries) there were 29 control clusters instead of 26. Data were also collected in 2 extra areas (Kangoma in Lilongwe and Lifuwu in Salima) bringing the total 'control' clusters to 31. However, given that none of the 12 dispensaries or 2 extra surveillance clusters were originally randomised, all 14 of them should be excluded from the analysis. Given these 14 were not included in the randomisation it could also be argued that they they did not receive the allocated intervention either (although given the 'intervention' in the case of the control arm is nothing it can be argued that they did receive nothing).

[4] Pregnancies that were not finished by 31/12/2010 (the end of the follow-up period) are not included here. All pregnancies that should have finished by Dec-2010, including those with missing data that could have finished at 7 months or more (cut offf for stillbirths - part of the primary outcome of Perinatal Mortality) are inlcuded here, whether the outcome (birth) was follow-up or not.

[5] The Crude Birth Rate (CBR) was estimated at 42.4 per 1000 or the period 1999 to 2004 in the Malawi 2004 DHS 2004 (ref); 44 per 1000 for the period 2001 to 2006 in the Malawi MICS 2006; and 39.2 for the period 2005 to 2010 in the preliminary Malawi 2010 DHS report. It should also be borne in mind that the original total population estimates of the HSA areas under surveillance may not be that accurate. Assuming a CBR of 40 per 1000 population per year for the 27 month intervention follow-up period is (40/12)*27 = 90 births per 1000 population.

[6] A difference of effect is hypothesised for urban and rural clusters. However, please note that a variable denoting clusters as either rural, per-urban or urban was examined for it's association with the three primary outcomes in the model building for the adjusted analysis. It was only found to be associated with MMR and was accordingly added to the adjusted model.

2.1.4 Community surveillance

Maternal and neonatal mortality were measured at the population level by a community surveillance system set up as follows. For each of the 78 Health Centre / dispensary catchment areas included in the RCT design (Figure 7) a population of approximately 4,000 was randomly chosen. This was done by first enumerating the size of the catchment populations of all Health Surveillance Assistants (HSA; government community health workers; initial average catchment area size was a population of 2000) working in all the 78 catchment areas and then randomly choosing an HSA from each until a population of roughly 4,000 was gained. Random selection was done using the Complex Samples procedure in SPSS. It should be noted here that some of the cluster populations were significantly less or more than the desired 4000 population due to the large size of some HSA areas, which could not be subdivided given that the HSA were the individuals we were to work with for community data collection. HSA catchment area sizes and the selected HSA are detailed in Appendix 2. Within 6-12 months of initiation of data collection (late 2007, mid-2008) a government drive, sponsored by the Global Fund to fight AIDS, TB and Malaria to reduce HSA catchment areas to 1000 population had successfully increased the number of HSA two to three fold. We maintained the same surveillance population by working with the new HSA who were each assigned to parts of the existing HSA catchment areas.

2.1.5 Key informants

Volunteers called Key Informants (KI) who were based in the villages they collected data for (usually one village per KI) and supervised by the HSA collected the data in the villages. Data on pregnancies, miscarriages, abortions, stillbirths, livebirths, neonatal deaths, maternal deaths and place of delivery were recorded on a monthly basis using a standard form (see Appendix 3). The form was translated into Chichewa, the main local language, for ease of use by the KI.

Key Informants were selected by the local chiefs in consultation with THFC (MaiKhanda) Monitoring and Evaluation Officers (MEO) to collect the data. They collected the data by going from house to house and enquiring as to the status of any pregnant women / new mothers every month. Each Key Informant covered a population of around 250 (usually one village), so typically followed around 5 women each month.

Key Informants were supervised by government Health Surveillance Assistants (HSA) who collected the forms from the KI each month and passed them on to the MEO. Each HSA supervised around 5 – 10 KI, who worked in the villages in their catchment area. Each MEO supervised around 20-25 HSA. Supervision consists of ensuring that information is collected accurately and in a timely manner.

The community surveillance system consisted of around 1800 KI, who worked in a total of 1900 villages throughout the three districts, and were supervised by 250 HSA, and the 11 MEO. The surveillance system covered approximately 8% of the rural population of Lilongwe district (around 150,000 people out of a total of approximately 1,900,000), 15% of the population of Kasungu district (90,000, out of a total of around 600,000) and 21% of the population of Salima district (70,000 out of a total of around 330,000).

The data used for the RCT was prospectively collected from June 2007 to December 2010.

2.1.6 Ethics

An evaluation proposal was submitted to the Ethic Board in Malawi-the National Health Sciences Research Committee (NHSRC) for approval. The study was approved in Malawi in 2007 (Protocol #420).

A *Data Safety Monitoring Board* (DSMB) was constituted at the initiation of the programme. The DSMB met thrice during the life of the programme first at the beginning of the

programme in 2006, then mid-term in May 2008 and finally in April 2011. The primary purpose of the DSMB was:

- To ensure that the study protocol had been adequately followed, and that the major specific aims of the trial had been met.
- To ensure that randomisation resulted in creating two comparable groups, so that in the absence of intervention it would be reasonable to expect similar health outcomes over time in both groups

Summaries of the DSMB meetings are available from the authors on request.

2.1.7 Data quality

To ensure good quality data was collected, the following steps were taken:

1. Training: HSA were trained on the community surveillance form at the beginning of the project, with refresher training at meetings every month. KI were trained by HSA, with refresher training by MEO at quarterly meetings.
2. Supervision: KI data collectors were supervised by HSA who were in turn supervised by MEO who were in turn supervised by the authors.
3. Call-backs: where data was unclear call-backs to the community were made.[20]
4. Data entry: data was entered into a Microsoft Access database with validation rules by two trained data clerks.
5. Data cleaning: duplicate records of women and babies were identified and removed from the database, and the assignment of all women and all deaths in the database to the correct cluster and district was checked and amended as necessary.
6. Data verification: Deaths were verified by verbal autopsy interview with relatives of the mother or baby who died. A simple algorithm (Appendix 4) based on movement, breathing and crying of the baby was used to differentiate between stillbirths and neonatal deaths.

2.1.8 Verbal autopsies

Verbal Autopsies were used to verify all deaths to ensure the quality of the data used in the Randomised Controlled Trial analysis; and were also used in attempts to triangulate the RCT findings with data on the intervention processes and mechanisms (see section 2.1.14). Maternal deaths were followed up with a Maternal Verbal Autopsy and Neonatal deaths and Stillbirths were followed up with a Perinatal Verbal Autopsy; English versions of both the MVA and the PVA tool are provided in Appendices 5 and 6, however, Chichewa versions were used in practice to ensure understanding by respondents and data collectors alike. Verbal Autopsies involve the Monitoring and Evaluation Officer interviewing a member of the family of the dead baby (usually the baby's mother) / the dead mother (usually the husband or female relative) after obtaining informed consent. The MEO would usually be accompanied by the KI and/or HSA covering the village.

The MVA form collects detailed information on the pregnancy history, antenatal period, delivery (if applicable) and post-natal period (if applicable). Cause(s) of death are ascertained by asking questions pertaining to symptoms of most conditions in lay language e.g. headaches and blurred vision (Eclampsia), bleeding (haemorrhage), vaginal discharges (Sepsis) etc. An open history is also taken to enable as much information on the events surrounding the death as possible to be collected. (Appendix 5)

The PVA form collects detailed information on the delivery and status of the baby with respect to movement, breathing, crying etc. (to ascertain whether the baby lived at all after

[20] Given the volume of data call-backs could not be made in all cases of unclear data. Data pertaining to deaths (especially Maternal deaths) were prioritised for verification and all deaths were verified by Verbal Autopsy.

birth i.e. whether the death was a neonatal death rather than a stillbirth). Cause(s) of death are again ascertained by lay language questions pertaining to medical algorithms seeking to determine common conditions/causes, as well as the Open History section of the form (Appendix 6).

It was intended that all Verbal Autopsies be analysed independently by two doctors to ascertain cause of death and a third if the initial assessments by the two original doctors are not in agreement. However, due to the severe shortage of suitably trained doctors in Malawi only around half of the MVA (51/102; 50%) and none of the PVA have so far been analysed in this way.

Using a simple algorithm based on movement, breathing and crying of the baby (see Appendix 4), it was possible to analyse the PVA automatically within Microsoft Access to determine which deaths were stillbirths and which were Neonatal Deaths (NND). Using a more advanced Bayesian algorithm, the InterVA method[21], it was possible to obtain causes of death for all 1817 PVA entered into the database (see section 4.3.2)

In order to complete the remaining 1482 PVA quickly a short form questionnaire (4 pages instead of the original 11, see Appendix 7) was created, which includes only the information used by InterVA. The remaining PVAs were completed in May 2011.

2.1.9 Contamination

Although buffer zones were not used to separate the four types of clusters in the RCT the fact that each population cluster was based on a health centre catchment area (i.e. that the people of each cluster generally go to the same health centre and not that of a neighbouring cluster, which is further away) goes some way towards ensuring against contamination of the facilities intervention. We also analysed the place of stillbirth or neonatal death recorded on the perinatal verbal autopsy (see above) with respect to the place where the woman was registered by the community surveillance (see section 2.1.4) to estimate how much contamination may have occurred by migration of women between the RCT arms, and found **net contamination to only be around 1% to 4% for each arm** (see section 4.2.4.4)

There is a lack of data measuring contamination of control areas with facilities intervention activities. However, given a lack of spread of the facilities intervention to all areas post-RCT in 2011 we think the scale of such spread during the intervention period of the RCT was limited.

Plotting the locations of the individual women's groups with reference to the edges of each cluster area would give an indication of how much any effects of the women's groups may have spread into neighbouring control clusters. However, we were unable to undertake such a study due to a lack of time and resources.

2.1.10 Loss to follow-up

As detailed more fully in the RCT results section, 25% of the pregnancies recorded initially were not followed-up to outcome. Given the fact the observed births (outcomes) match very closely with the expected crude birth rate it is thought that many of the pregnancies initially indicated as lost-to follow-up may in-fact not have been real pregnancies and as such the actual loss-to-follow-up may be much lower.

[21] Vergnano S, Fottrell E, Osrin D, Kazembe PN, Mwansambo C, Manandhar DS, Munjanja SP, Byass P, Lewycka S, Costello A. *Adaptation of a probabilistic method (InterVA) of verbal autopsy to improve the interpretation of cause of stillbirth and neonatal death in Malawi, Nepal, and Zimbabwe*. Population Health Metrics 2011, 9:48. Also see www.interva.net

2.1.11 Analysis of the RCT

The following time periods are relevant to the RCT analysis:

WG Intervention:	Baseline:	June 2007 – September 2008[22]
	Intervention:	October 2008 – December 2010
QI intervention:	Baseline:	June 2007 – September 2008[23]
	Intervention:	October 2008 – December 2010

The analysis was a post-intervention comparison i.e. we compared mortality rates in intervention areas with mortality rates in control areas during the intervention period only. We only used the baseline data to assess differences between intervention and control groups (the success of the randomisation in achieving balance in the levels of potentially confounding variables), and as part of additional analyses adjusting for such differences, but only if they were also found to be associated with the mortality outcome being tested. This resulted in a 'Difference-in-difference' (i.e. accounting for baseline mortality rates) analysis only being under-taken when baseline cluster-level rates were significantly associated with intervention rates. This was only the case for perinatal mortality. We decided not to undertake analyses that subtract the baseline rate from the intervention rate because of the problem of regression to the mean.[24] The analysis of the RCT was conducted by Tim Colbourn in Stata 11.2 for Mac and was planned in advance as follows. We follow the convention of undertaking progressively more complex analyses: descriptive, then cluster level, then individual level.

As stated in the original Evaluation proposal approved by the Malawian NHSRC in May 2007, the outcome measures of the trial are as provided in section 2.1, page 22.

The statistical analyses detailed in 3 - 5., which take account of between cluster variation, will be conducted with reference to Chapters 10 – 12 of the book *Cluster Randomised Trials* by Richard Hayes and Lawrence Moulton (2009).

1. Following data cleaning (see section 2.1.7), data quality will be assessed by looking at cluster summaries of the following indicators:
    a. % of pregnant women with no outcome data (loss to follow-up)
    b. % of Maternal Deaths with no MVA (no verification)
    c. % of SB/NND with no PVA (no verification including of designation as either SB or NND).

    If substantial loss to follow-up/lack of verification is found or large differences in loss to follow-up/verification are observed between clusters or between trial arms, further follow-up and verification is recommended prior to final analysis. Initial analyses based on an unclean dataset may be conducted given that they have no bearing on the statistical precision of the final analysis. This is because the time period of the events in question is the same i.e. the initial analysis cannot be considered to be an interim analysis.

[22] Women's Groups were formed in June and July 2007. Effects on Neonatal and Maternal mortality are only likely to be seen after the initial 8 meetings (Figure 2) are completed (average for all groups was September 2008) and newly pregnant women have started and completed their 9 month pregnancy during activity of the WG intervention.

[23] Although the initial QI intervention at the Health Centres started in July 2007 with workshops held by LSTM, the Health Centre QI intervention was re-launched in July 2008 led by IHI. Given that it is thought by IHI that 90-days are needed for initial improvement (the end of the first 90-day cycle) the baseline period runs to the end of September 2008. It should be noted that the QI intervention has evolved considerably since September 2008 however, and what can be considered the 'full-power' intervention and the date since this has been running (and hence the appropriate Intervention period to evaluate) is open to debate.

[24] i.e mortality rates in individual cluster, which have small sample sizes, are likely to vary a lot from year to year but stick to a long-term average (based on their characteristics). Therefore it is likely that an individual cluster that has a very low mortality rate in the baseline period will have a higher rate in the intervention period (show an increase in morality) as the annual rates converge to the long-term average somewhere in between the two. Such differences will distort the analysis with respect to intervention effects.

2. Descriptive analyses showing time trends annotated by baseline period (Jun-07 to Sep-08) and intervention period (Oct-08 to Dec-10; see above) for each of the primary outcome measures by RCT arm and by district will first be undertaken. Overall baseline and intervention period rates will also be tabulated. These results will provide the reader with a sense of any intervention effects as well as a sense of initial balancing of the RCT arms with respect to baseline mortality rates.

3. Cluster-level analyses of intervention effects on maternal mortality, neonatal mortality and perinatal mortality (the three primary outcomes) by weighted T-Test of cluster mortality rate summaries taking stratification by district into account:
    a. FI vs. no FI clusters
    b. CI vs. no CI clusters
    c. FI vs. FI+CI vs. CI vs. control clusters (2x2 factorial design). Any synergy between the two interventions, which may be expected given their complementary nature addressing supply and demand (see section 1.2), will be assessed by examining the intervention effects of FI+CI compared to FI and CI respectively in subgroup analyses. It should be noted that this analysis will be underpowered (see Appendix 1) and that assessing synergy (interaction effects) will be even more underpowered, therefore conclusions will be of a qualitative rather than quantitative nature.
    d. a. to c. repeated adjusting for baseline mortality rates in each cluster, by including baseline mortality as a covariate.
    e. It is hypothesized that the following covariates may also effect mortality rates: maternal, neonatal and perinatal mortality rates at baseline, percentage Health Facility delivery at baseline; nurse/delivery ratio at HC; signal function availability at HC; baseline staff psychology score at HC; urban/peri-urban/rural setting; access to HC by tar road; HC being either Government run or run by CHAM; Tobacco estate (lots of migration) vs. not Tobacco estate (see Box 3 for further details). The effect of each of these on mortality rates (the three primary outcomes) will first be assessed by descriptive univariate analyses followed by a stepwise logistic regression analysis of all variables (as detailed in Hosmer and Lemeshow, Applied Logistic Regression, Second Edition, 2000). All remaining variables with $p<0.1$ significant effects will then be used to adjust the intervention effects in a two stage process whereby the residual mortality rates from the covariate adjusted logistic regression analysis will be used as the dependent variables in all of the weighted cluster level T-tests of intervention effect detailed in d.

    Each subsequent analysis (a. + b. then c. then d. then e.) will be considered to provide a more accurate picture of the true net effects of the FI and CI interventions and should be given more weight when considering overall interpretations and conclusions along with the other data available from the Data Deep Dive exercise (see section 2.1.14 below), especially that regarding % of deaths occurring in the CEmOCs which all received FI but were not randomised (see below). The preceding analyses will provide useful information for interpretation.

    Given we are testing for effects on three primary outcomes (maternal, neonatal and perinatal mortality) the p-value cut-off for statistical significance will be adjusted sequentially from 5% for each significant effect observed within each of the analyses a. to e. (Holm correction).

    If no significant differences are observed the power of the RCT to detect such differences (see Appendix 1) and the uncertainty surrounding the observed non-significant difference will also be considered in the interpretation of the results.

4. Individual-level analyses of intervention effects on neonatal mortality and maternal mortality (the two primary outcomes) by logistic regression with stratum included as

a covariate – repeat of a. to e. above. However, given no data on individual level covariates has been collected we can only adjust for cluster-level covariates meaning that the results of the individual level analysis will be the same as those of the cluster-size weighted cluster-level analyses detailed above. According to Hayes and Moulton stratified analysis of individual data may not be robust with <20 clusters per arm (as is the case here for the four arm comparison; although number of strata is not mentioned). Given this problem and the fact that the T-test weighted by cluster size should produce the same results, the cluster-level analyses detailed above could be prioritised over the individual-level analyses. However, only the individual-level analyses take account of the presence of the other intervention (the factorial nature of the trial) and account for clustering assuming random effects by cluster so are perhaps more accurate.

5. Secondary and exploratory analyses (with less power due to repeated significance testing):
    a. Analysis of the secondary outcome measures detailed above, using available data from community surveillance, health facility surveillance and other process evaluation studies.
    b. Annual trends in intervention effects (given increase of FI intervention dosage, and time-delay for full effects of Women's Groups). The last stepped-up 15 months of the intervention period (Oct-09-Dec 2010) will be compared with the first 12 months of the intervention period (Oct-08 to Sep-09; see section 3.2 for further details of the rationale for doing this).
    c. Effect of shortening the baseline period given possible early intervention effects, and leaving a buffer period between baseline and intervention effects to test for possible dilution of the intervention period with baseline as well as vice versa.[25]
    d. Sub-group analyses:
        i. Density and population coverage of WG within CI clusters
        ii. % of first time mothers and <20 yr old women in WG in CI clusters. Unfortunately given that women's group members are not identified in the community surveillance database (an important limitation of our study) it is not be possible to explore differential dose-response effects depending on whether a women actually attended a group or not.
        iii. Frequency of QI visits within FI clusters (if adequate data is available)
        iv. % of deaths occurring at the CEmOC in all clusters (this could be added as a covariate in analysis 2. e., however, given that referral patterns may have been affected by the FI intervention both due to QI work at the HC (FI clusters) and due to QI work at the CEmOC (all clusters), it may be impossible to distinguish the effects of the HC-level FI in the RCT from that of the CEmOC level FI which will effect all clusters).

It should be noted that any significant results of the secondary and especially the exploratory analyses detailed above must be interpreted with caution due to repeated significance testing and the fact that spurious significant results sometimes arise in some subgroups e.g. if they have a larger number of observations than the other subgroups.

[25] Although the likely timing of the effects of the interventions have been carefully considered when setting the baseline (Jun-07 to Sep-08) and intervention periods (Oct-08 to Dec-10) for analysis, it is of course possible that timings were different in reality.

Box 3 Potential confounding variables used in the adjusted RCT analyses

As explained in the text each of these factors could affect maternal, perinatal or neonatal mortality rates (the primary outcomes of the RCT) and as such could affect the RCT results if the randomisation did not result in RCT comparison arms balanced with respect to each of them (see Table 5, section 4.1.2.4). They were therefore tested for their association with the mortality rates (see Appendix 20) and added as covariates in the adjusted analyses if associated with the mortality outcome in the final restricted multivariate regression model (see 3. e in the text to section 2.1.11 above)

Maternal, neonatal and perinatal mortality rates at baseline – Each of the primary outcome mortality rates during the intervention period could of course have been influenced by it's value at baseline, although the possibility of regression to a longer-term mean discouraged us from automatically adjusting all intervention period mortality rates for differences in their baseline value (see introduction to section 2.1.11 including footnote 27). Maternal, neonatal and perinatal mortality are also all inter-related. For this reason we also tested associations between each of their baseline values and each of their intervention values.

Percentage Health Facility delivery at baseline – The percentage of deliveries at a health facility (reported in sections 4.1.2.4 and 4.2.1.2.1) could be an intermediate outcome on the pathway towards reduced mortality (see Three Delays, section 1.2.2). Given that the MaiKhanda interventions both have potential to increase health facility delivery we only tested for associations between baseline health facility delivery rates and mortality outcomes.

Nurse/delivery ratio at health centres – Overcrowding at health centres could affect outcomes mortality outcomes. The nurse to delivery ratio, which was not altered by MaiKhanda was used as an indicator of overcrowding and tested as a potential confounding variable. The number of nurses was obtained from the health facility resources survey (see sections 2.2.5.1.1 and 4.2.5.1.1) and the number of deliveries at health centres from the health facility surveillance data (section 2.2.2).

Signal function availability at health centres – The availability of signal obstetric care functions (see Box 2) were also not influenced by MaiKhanda but could have influenced mortality rates, and the results of the RCT if unbalanced between arms.

Baseline staff psychology score at health centres – Motivation and morale of staff at health centres could also have influenced mortality outcomes. Given that the MaiKhanda facility intervention had the potential to improve the psychology of staff we only tested for associations between baseline staff psychology scores and mortality outcomes. Staff psychology scores were obtained by taking an average of all the 1-5 scale scores from each of the 19 questions included on the questionnaire (Appendix 12; see sections 2.2.5.1.2 and 4.2.5.1.2 for details of the staff psychology survey methods and results).

Urban/peri-urban/rural setting – Urban-rural disparities exist in maternal, neonatal and perinatal mortality rates (DHS 2010 [3, page 12] MICS 2006 [48, page 68]), therefore whether clusters are urban, peri-urban or rural could effect mortality rates in our study and needs controlling for if found to do so. A variable identifying the urban clusters included in the final RCT analysis (see Table 1) was always included in the logistic regression models (see section 4.1.4) to account for the original stratification of the randomisation accounting for the urban clusters (as well as the different districts, see Figure 7).

Access to health centre by tar road – Access to health centres by tar roads enables quicker access and therefore could reduce mortality in emergencies.

Health centre being either government run or run by CHAM – It is possible that different management, via differences in policy, could affect mortality rates.

Tobacco estate vs. not tobacco estate – High rates of in-migration from outside areas are common in tobacco estate areas. It is possible that such transient populations suffer from higher mortality rates.

2.2 Process evaluation

Evaluations focusing exclusively on outcomes face a number of limitations[26] and are thus unable to answer a number of important questions related to: contextual factors[27], extent and quality of delivery of an intervention; the mechanism; and, the differential effects of the intervention on different populations. Impact evaluation therefore needs to be complemented with a process evaluation that includes quantitative and qualitative studies to understand the context and mechanism of quality improvement in health service delivery[28] and community mobilisation.[29]

Process evaluation was therefore an integral part of the evaluation of MaiKhanda and was conducted at health facility as well as at community level. As part of the process evaluation we looked at the specific activities of each intervention -their processes/mechanisms- (section 2.2.1) and the likely impact of these processes/mechanisms on key drivers of total population maternal, neonatal and perinatal mortality. Key drivers of population mortality are assessed in studies looking at: intermediate outcomes (e.g. improving emergency obstetric referral or improving birth preparedness practices in the community; section 2.2.1), case-fatality rates at facilities (section 2.2.2) and changes in specific causes of total mortality (section 2.2.3) and place of death (section 2.2.4). We also studied the context within which the interventions worked and possible influences of the interventions on these contextual factors (section 2.2.5). We then attempted to triangulate the RCT results with the results of all of the process evaluation studies to explain the observed impact of the interventions. An exercise by the implementers and evaluators to explore all of the available data on intervention inputs, processes and outcomes in order to come to conclusions regarding the impact of the MaiKhanda interventions independent of the RCT, the *Data Deep Dive* (section 2.2.6), aided this process. Figure 8 and Figure 9 respectively provide overviews of the process evaluations for the facility and community interventions. The sub-sections of this chapter describing the methods we used to investigate each aspect of the process evaluation are shown in brackets.

2.2.1 Intervention activities, processes and mechanisms

In this section we describe the methods we used to assess the activities, processes and mechanisms of the interventions as they actually happened. It should be noted that the interventions evolved from how they were originally designed (see section 3.1), and also that the dosage of the interventions was not necessarily adequate or compatible with high-fidelity implementation of the interventions as designed (section 3.2).

2.2.1.1 Facilities Intervention

As part of the *Data Deep Dive* (section 2.2.6) we analysed all available data on specific quality improvement efforts at the randomised health centres and the non-randomised hospitals. For the health centres some data was available on identification of high-risk pregnant women (HRPW) and blood donors, and emergency obstetric referrals. For the hospitals (CEmOCs) some data was available on prevention of post-partum haemorrhage (PPH), treatment of neonatal asphyxia, and kangaroo mother care. Data was limited to only a subset of all facilities and intervention period months, due to a lack of due diligence in data collection by the implementing QI teams and MaiKhanda staff.

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[26] *Wight, D., & Obasi, A. (2003). Unpacking the 'black box': the importance of process data to explain outcomes. In J. Stephenson, J. Imrie, & C. Bonell (Eds.), Effective Sexual Health Interventions: issues in experimental evaluation Oxford: Oxford University Press.*

[27] *Pawson, R. and Tilley, N. (1997). Realsitic Evaluation. Sage: London.*

[28] *R Grol, R Baker, F Moss. Quality improvement research: understanding the science of change in health care. Qual.Saf. Health Care 2002;11;110-111*

[29] *Rath S, Nair N, Tripathy P, Barnett S, Rath S, Mahapatra R, Gope R, Bajpai A, Sinha S, Costello A, Prost A.* Explaining the impact of a women's group led community mobilization intervention on maternal and newborn health outcomes: the Ekjut trial process evaluation. *BMC International Health and Human Rights* 2010, **10**:25

Figure 8: Overview of Process Evaluation at Facility Level

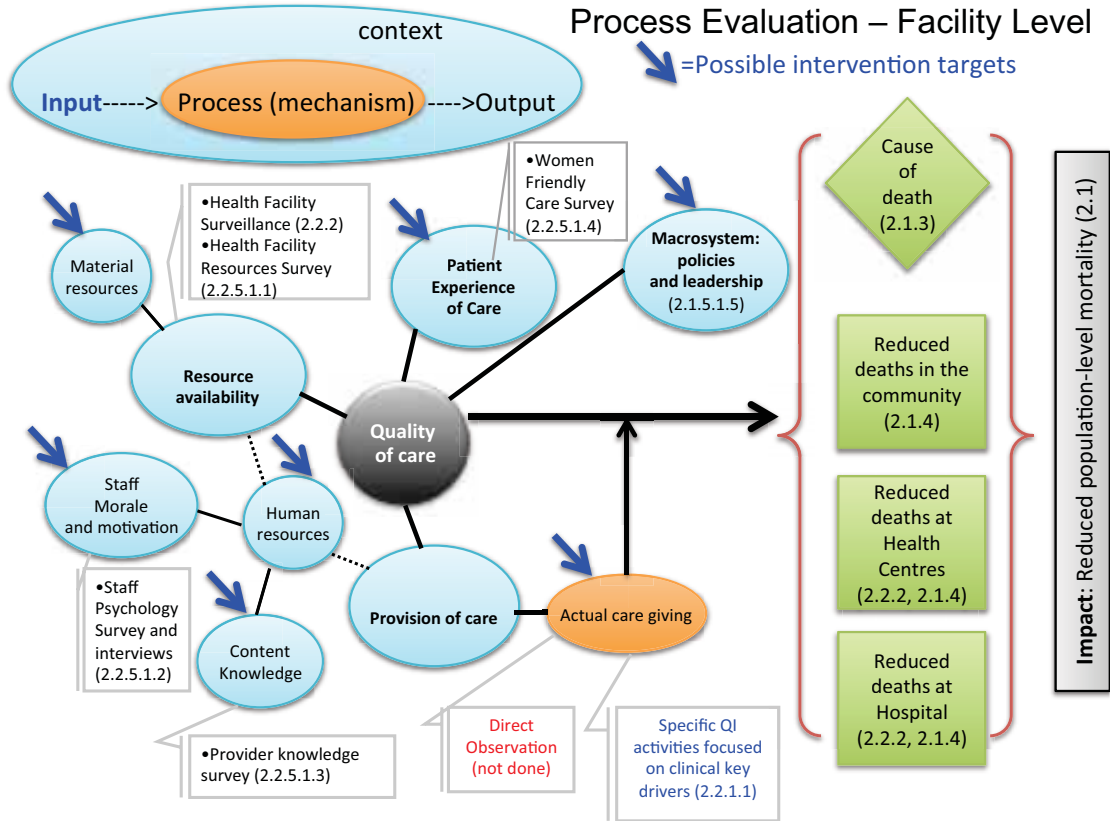
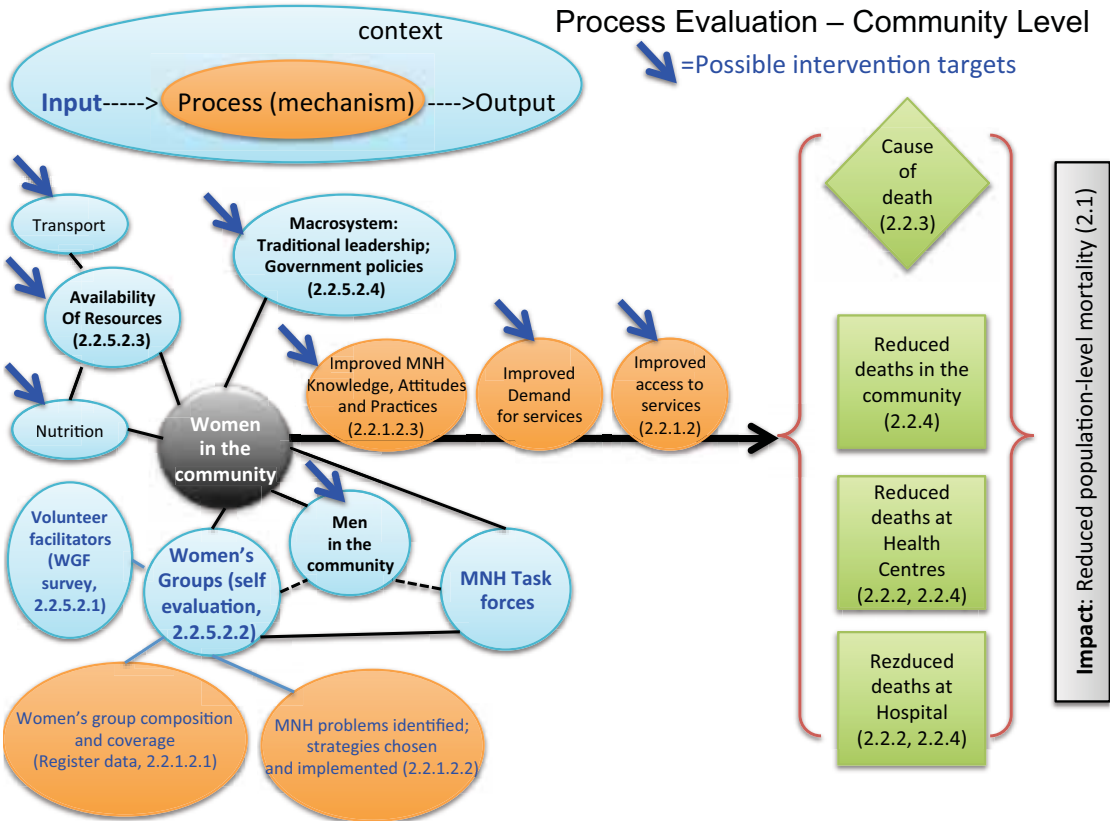


Figure 9: Overview of the Process Evaluation at Community level



2.2.1.2 Community Intervention

First we examined whether the community intervention had any effect on the percentage of women delivering at a health facility, or on the promptness of health seeking behaviour (section 2.2.1.2.1).

We also analysed available data on the composition and population coverage of the women's groups (section 2.2.1.2.2), the maternal and neonatal health problems identified by the women's groups and the strategies the women chose and implemented to overcome these problems (section 2.2.1.2.3).

We did not evaluate any of the specific activities of the MNH task forces, which were added to the community intervention in mid-to-late 2009 (see section 3.1). However, we did a survey to assess MNH knowledge, attitudes and practice, among women in community intervention areas and women in areas without the community intervention (section 2.2.1.2.4).

2.2.1.2.1 Health facility delivery and health-seeking behaviour

Given that a key focus of the MaiKhanda women's group intervention was to encourage women to deliver at health facilities, we begin our assessment of community intervention activities, processes and mechanism by looking at the community surveillance data on place of delivery to determine if the community intervention had increased the percentage of women delivering at health facilities. We compare all four RCT arms (CI only, CI+FI, FI only, and control) in terms of the percentage of women delivering at a health facility, bearing in mind that any improvements in quality of care brought about by the facilities intervention could also drive more women to deliver at health facilities in facilities intervention areas, and that external influences such as the ban on deliveries by Traditional Birth Attendants (TBA) could drive health facility deliveries in all areas.

As part of the *Data Deep* Dive (see section 2.2.6) we also attempted to assess changes in health seeking behaviour that may have resulted from the community intervention by looking at health centre partograph and delivery book records to see if we could discern differences in time of arrival indicating reductions in Delay 1 (the decision to seek care) and Delay 2 (getting to the appropriate facility; see section 1.2.2).

2.2.1.2.2 Women's group register study

For each of the 8 meetings in Phase I and II of the MaiKhanda Women's Group action cycle, the Women's Group Facilitator (WGF) kept a register of all women attending. This register recorded the: names; ages; number of children of women's group members; the place of their last delivery; whether they attended a specific meeting and their pregnancy status at that meeting (see Appendix 8). This register data was entered into a Microsoft Access database by hired temporary data clerks and analysed in Microsoft Excel. Analyses of the main variables covered in the register are then presented including an assessment of the population coverage of the Women's Group intervention.

2.2.1.2.3 MNH problems and strategies identified by women's groups

Part of the women's group self-evaluation (see section 2.2.5.2.2) involved review of the maternal and neonatal health problems identified by the groups and the strategies chosen and implemented by the group to address these problems. We aggregated this data by district and for the whole of the community intervention across the three districts to assess the main focuses of the intervention.

2.2.1.2.4 MNH knowledge, attitudes and practice

The MNH KAP study was conducted in in rural communities of Lilongwe district in March and April 2011 (please not timing is post RCT intervention period, which ended in Dec-2010). The objective of the survey was to establish knowledge, attitude and practices of

recently delivered women towards Maternal and Newborn Health (MNH). Specifically the survey aimed to assess the knowledge of women about danger signs that could appear during the antenatal, delivery and postnatal period; gather information about the practices of receiving antenatal and postnatal services from existing health facilities or health personnel; and collect information about the women's attitudes and practice towards health facility delivery, birth preparedness and management of newborns. The survey questionnaire was adapted from the questionnaire developed by Valley Research Group of India to conduct their CB-MNH baseline survey report of 2006. A team of eight experienced data collectors were recruited on a temporary basis and given one day training in data collection. The survey was administered by the data collectors to randomly selected Recently Delivered Women from 5 CI areas (Chiunjiza, Chadza, Ngoni, Malembo and Nthondo) and 4 No CI areas (Katchale, Chikowa, Nambuma and Diamphwe) in Lilongwe district only, with the reference period being the 12 months prior to the survey. A three-stage sampling design was followed. The first stage was the random selection of clusters i.e. Health Centres (done for the RCT, see section 2.1.1), the second stage was the random selection of enumeration areas (HSA catchment areas), and the third stage was the random selection of respondents (recently delivered women) and the recruitment of respondents was done through a systematic random walk. During the data collection and entry periods, the part time officers were being supervised by MaiKhanda M&E Officers who were responsible for ensuring data quality. Final validation and cleaning of data was done by MaiKhanda M&E staff. The survey was conducted in 9 randomly selected clusters in Lilongwe of which 5 were randomised to receive the community intervention (CI) and 4 to not received the community intervention (No CI). A total of 596 recently delivered women were surveyed; 345 in CI areas and 251 in No CI areas, with a 100% response rate.

2.2.2 Health centre and hospital complications and case-fatality rates

In order to track changes in health centre and hospital mortality to compliment the population level mortality data collected as part of the RCT (see section 2.1), we also undertook monthly Health Facility Surveillance. Data on the number and type of deliveries, maternal and neonatal complications, availability and use of EmOC signal functions (see Box 2) and maternal and neonatal deaths and case-fatality rates were collected on a monthly basis directly from the Health Centres by the MEOs and from the Hospitals (CEmOC) by Facilities Intervention Officers (FIO), using a standard Health Facility Surveillance form. To begin with a form designed by LSTM was used, later (from around October 2007 onwards) a form designed by IHI was used. The latter form has undergone several revisions to capture additional indicators, the final version in use today is provided in Appendix 10.

The forms were usually filled in by a member of staff at the Health Facility with supervision and assistance from the MEO/FIO. Sometimes, when staff were busy, the form was left at the Health Facility to be collected, once completed, at a later date; on these occasions the staff member completing the form was not supervised. Guidance on how to fill the form correctly and on the meanings of medical terms on the form was provided to the MEO/FIO by technical advisors from IHI, LSTM and ICH both informally during field visits and discussions in the office and formally during M&E quarterly review meetings and data improvement workshops.

Once the forms were collected, the data was entered into a specially designed Microsoft Excel database that produces automated summaries and graphs of key data. This database was customized for each district and is available at the district level. Data were checked with reference to the paper forms and corrected where necessary. Further analyses and aggregations of the data in addition to those produced automatically by the database were conducted for this report.

Trend in facility case-fatality rates were assessed by several methods of time series analysis, including calculation of annual medians and means, quality improvement control

chart statistics with significant changes based on 6 or 8 consecutive points below or above running median (or mean), and Lowess Regression.

Although the MaiKhanda facilities intervention did not specifically track the percentage of maternal deaths that were audited as an indicator the health facility surveillance form did have space to record the number of maternal death audits (see Appendix 10). We report on the percentage of maternal deaths that were audited using the available data (section 4.2.2.3). Throughout the evaluation period neonatal death audits were not a focus and we have no data supporting their occurrence at any of the facilities.

Caesarean sections were also not a focus of the MaiKhanda facilities intervention and although the availability of C-section is one of the signal obstetric care functions (see Box 2) and was recorded as such on the health facility surveillance form (Appendix 10), numbers of C-sections were not recorded, precluding the reporting or analysis of trends in C-section rates.

2.2.3 Investigation of differences in causes of mortality

We used data from the Perinatal Verbal Autopsies analysed by InterVA[21, page 33], to investigate differences in type of stillbirth (macerated and fresh) and specific causes of neonatal mortality between intervention and non-intervention areas in baseline and intervention periods. We focused our analyses on comparisons relevant to the effects of the interventions observed by the RCT. Due to there being a relatively small number of maternal deaths, a lack of Maternal Verbal Autopsy data and no observed impact of either of the interventions on maternal mortality, we did not investigate differences in maternal mortality.

2.2.4 Investigation of differences in place of death

Using data from the Perinatal Verbal Autopsies (section 2.1.8) on place of death and cause of death, we investigated differences in place of death between intervention and non-intervention areas in baseline and intervention periods for different causes of mortality. In addition we also used community surveillance data (section 2.1.4) on place of delivery to analyse differences in place of death with respect to place of birth. To simplify the analysis we dichotomised places of birth and death to either community (a combination of "Home", "TBA" "on the road" and "traditional doctor [place of death category only]" categories) or facility. Again, we focused our analyses on comparisons relevant to the effects of the interventions observed by the RCT.

2.2.5 Context: description and assessment of intervention effects

2.2.5.1 Facility level

The quality of service provision at health facilities is obviously dependent on the context within which the services are provided. We identified four contextual factors determining the quality of service provision to be: availability of human and material resources, provision of care, patient experience of care, and the macro-system of policies and leadership within the local and national health system (Figure 8).

The availability of resources includes the availability of physical infrastructure, human resources, and the availability of drugs and supplies. The availability of drugs, supplies and BEmOC and CEmOC signal functions (see Box 2) was assessed on a monthly basis using the Health Facility surveillance tool described in section 2.2.2 above. The availability of human and material resources was determined by the Health Facility Resources Survey, presented in section 2.2.5.1.1 below. Measures such as the nurse to population ratio; provision of water, electricity and referral services, were looked at.

In addition to the availability of human and material resources, the provision of care is dependent on the level of clinical knowledge of health facility staff and their motivation to

work under adverse conditions. Provision of care also includes appropriate management of emergencies and the referral system, and collection and utilization of good data for decision-making. We assessed two up-stream aspects of the provision of care. Firstly, the motivation and morale of staff by the Staff Psychology survey presented in section 2.2.5.1.2 below. Secondly, the clinical knowledge of staff by the provider knowledge survey, presented in section 2.2.1.3 below. The actual physical provision of care to patients, which would require direct observation by clinically skilled personnel, was not assessed. However, specific efforts to improve aspects of clinical care such as prevention of post-partum haemorrhage (PPH) and neonatal asphyxia were assessed to some extent (see sections 2.1 and 4.2.1).

Patient's experience of care includes respect, dignity and emotional support provided to the mothers/patients at the point of care as well as addressing equity concerns in service delivery. We assessed patient's experience of care via the Women Friendly Care survey, presented in section 2.2.5.1.4 below.

The influence of the macro-system/external policy environment on the quality of care was assessed as part of the *Data Deep Dive* exercise, see section 2.2.5.1.5 below.

2.2.5.1.1 Health centre resources survey

This study aimed to determine the context within which the MaiKhanda QI intervention has to succeed. Using a form designed by the authors with input from the MaiKhanda MEO (see Appendix 11) information was collected on staff availability, training in the last three months, physical infrastructure, material inventories, transport and communication, and the labour ward.

The study was conducted in all 37 Health Centres (HC) under community and facility surveillance in Lilongwe; 18 out of the 24 facilities in Kasungu; and all 14 Health Centres in Salima in the first half of 2010. The respondents were clinical staff (Medical Assistants, Clinical Officers or Nursing Officers) except for in HC with no clinical staff, where Senior HSA (SHSA) were interviewed. All interviews were done by MaiKhanda MEO. On occasions where staff were busy the form was left for them to fill and collected by the MEO at a later date.

Data entry and analysis was done using Microsoft Excel and SPSS. The analysis includes a comparison of MaiKhanda intervention areas and control areas.

2.2.5.1.2 Staff psychology survey

One aspect of the QI work is to motivate and encourage staff to work better in the face of the adversities they face on a daily basis (lack of supplies, being overloaded by too many patients). In order to understand the attitude and outlook of Health Centre staff we conducted a general-level survey of members of staff at all 78 health facilities in the three districts (see Appendix 12) and 15 in-depth interviews (see Appendix 13) to obtain more detailed information between January and May 2008. The questionnaire part of the survey was to be repeated in 2011 to determine if the QI intervention had brought about any changes in the attitude and outlook of the staff in the HC where the QI work had been concentrated. However, the follow-up survey was not completed before this report was finalised.

The self-administered questionnaire contains standard questions on the location, age, education, training, type of health facility, designation and amount of work experience of the staff so that responses could be broken down by these background characteristics in order to provide more detail as to the how the psychology of members of staff may differ according to these characteristics. The nineteen questions related to staff psychology that were included in the final version of the questionnaire were chosen as they reflect key areas of psychology that were considered to be relevant to the improvement of the quality of the functioning of staff in their day to day activities at the health facility as aimed at by the MaiKhanda QI intervention. A discussion of the theory and practice of the QI intervention and how each of the nineteen survey questions is related to this theory and practice can be found in the August 2008 report of the baseline staff psychology survey (available from the authors on request).

All the completed questionnaires that were received were entered into SPSS (v14.0). Each of the 19 survey questions, all of which have multiple choice tick-box answers that are arranged in an ordinal scale (see Appendix 12), were numerically coded in SPSS e.g. 'Totally' = 1, 'Mostly' = 2, 'Sometimes' = 3, 'Rarely' = 4, 'No (not at all)' = 5. This form of coding enabled an average score to be obtained for each question e.g. an average score of 1.5 across all respondents to the question 'How happy do you feel about your work' corresponds to an average of 'Totally'/'Mostly'. The data entry for every questionnaire was checked manually and all analyses were performed using SPSS. Hypotheses pertaining to the effect of one variable on another were made with respect to what would be expected to be observed given the way the questions are grouped together with respect to QI theory and practice, and tested via means of cross-tabulation and one-way Analyses of Variance (ANOVA). In addition hypothesis of how the QI work in the randomised health centres could change the attitudes and practices of staff were formulated.

At baseline a total of 132 questionnaires were collected. Of the 122 surveys with the date of completion known 30 (25%) were completed in January 2008; 2 (2%) were completed in February 2008, 5 (4%) in March 2008, 55 (45%) in April 2008 and 30 (25%) were completed in May 2008. 124(94%) of the questionnaires were from the randomised health centres.

The interview questions were formulated in such a way so as to provide contextual evidence to back up the findings from the survey questionnaire. As such they are similar to the questions in the survey questionnaire, but are more probing i.e. they are not designed to be answered by one word answers, or on a scale of 1 to 5.

The guidelines for carrying out the interviews (Appendix 13) stressed the importance of probing for further information so that all relevant information could be obtained.

The 15 interviews were carried out by MEO between January and May 2008. They were either conducted in English or Chichewa depending on the preference of the interviewee. All interviews were digitally recorded and the recordings were transferred to a computer and the interview transcribed by one of the MaiKhanda data coordinators. The Chichewa interviews were also translated into English during transcription.

The transcripts were analysed using standard qualitative analysis techniques whereby each transcript is analysed with respect to a set of themes and areas and the relevant sections of the transcript are manually cut-out and associated with the theme / area. The themes that the transcripts were analysed with respect to, relate to the interview questions and prompts (see Appendix 13) and to areas that the researchers felt warranted further elaboration following the analysis of the self-completed survey questionnaires. How the different themes relate to each other are determined via drawing linkages between the cut-out statements from the interviews that appear to be discussing related issues. This method of analysis allowed an overall picture of how the respondents feel about a particular issue to be built up. Such a picture was then combined with results of the survey questionnaire to enable a deeper understanding of the issue in question.

2.2.5.1.3 Provider knowledge survey

It has long been recognized that skilled attendance at delivery can prevent maternal and neonatal deaths.[30] However simply increasing health facility deliveries may not have the desired impact if the quality of care provided is poor.[31] Assessing quality of care is, however, a complex process, which requires analysis of many elements of care, including both the provision of care and the patients' experience of care. Frameworks for assessing quality of care have been developed both for obstetrics[32] and for Paediatrics.[33] The MaiKhanda Process Evaluation follows a similar framework, and includes assessment of availability of material

[30] Graham WJ, Bell J, Bullough CHW. Can skilled attendance at delivery reduce maternal mortality in developing countries. *Studies Health Serv Organ Policy* 2001; **17:** 97–130.

[31] Quality of care in Institutionalised deliveries. The paradox of the Dominican Republic. Miller S et al. Int J G O 82 (2003) 89-103

[32] A framework for the evaluation of quality of care in maternity services Hulton L, Matthews Z, Stones R. University of Southampton 2000

[33] Quality of hospital care for seriously ill children in less-developed countries. Nolan T et al. The Lancet 2001 357, 106-110

and human resources, staff psychology and patients' experience of care. The Provider Knowledge Questionnaire was designed to sit alongside this data in providing a holistic picture of quality.

The provider knowledge questionnaire (Appendix 14) was designed to assess providers' knowledge of best practice, as well as to explore providers' perceptions of the care they provide, their confidence with key subject areas and the effect of training on their knowledge of these areas. The questionnaire was designed to identify the degree to which providers' knowledge, confidence and training explain observed case fatality rates. This information may also be used to identify training needs and to help predict the likely impact of, for instance, greater availability of material resources.

The questionnaire was designed by Dr Olivia Bayley in collaboration with practicing in-country experts Dr Tarek Meguid (Bwaila Hospital) and Dr Charles Mwansambo (Kamuzu Central Hospital). The areas assessed were as follows. :

1. Clinical care:
   1A. Emergency obstetric care[34]
   1B. Monitoring and routine labour[35]
   1C. Emergency neonatal care[36] [37]
2. Attitudes and perceptions of care (designed to mirror the Patient experience of care questions)
3. Confidence and training

52 Clinical staff across Kasungu, Lilongwe and Salima Health Centres (BEmOC) and Hospitals (CEmOCs) were surveyed between December 2009 and March 2010. Staff were given as much time as they needed to compete the questionnaire, supervised by a MaiKhanda officer. Data analysis was done in SPSS and Microsoft Excel and results of all questions are presented disaggregated by staff category, district and BEmOC/CEmOC.

2.2.5.1.4 Women friendly care survey

One of the areas the QI intervention was initially focused on was Women-Friendly Care, the rationale being that if women were treated better[38] at the Health Facilities they would be more likely to go to the Health Facilities to deliver. The Survey Questionnaire (see Appendix 13) included 10 questions concerned with how the women were treated at the Health Facility. Each question was to be answered on a 4-point Likert scale ('very unhappy', 'unhappy', 'happy', 'very happy').

HSA were identified as the right people to carry out the survey because they are already in the system and also live within the vicinity of the facility. All facilities with HSA staying far away from the facility were excluded from the study. The survey was administered to 10 mothers who had just delivered and 5 guardians of recently delivered mothers per month per facility in the last quarter of 2009. Twenty-six HC in Lilongwe and 10 in Salima were covered.

The HSA were provided lists of recently delivered women by the Nurses/Midwives at the facility. All interviews were done outside the facility and away from the clinical staff so that the respondents were clearly able to express their views in confidence.

All data were entered into an Excel database and analysis was done (in Stata) by comparison of QI and control HF with respect to average scores for each of the questions and all combined for each of women respondents and guardian respondents.

[34] Fortney J. Emergency obstetric care: the keystone in the arch of safe motherhood. Int J G O 2001;74:95-97

[35] Effective procedures in maternity care suitable for audit. Benbow A, Semple D and Maresh M. Clinical Audit Unit, Royal College of Obstetricians and Gynaecologists, London, 1997

[36] Evidence-based, cost-effective interventions: how many newborn babies can we save? Darmstadt G *et al.* Lancet 2005

[37] Challenges in saving babies – avoidable factors, missed opportunities and substandard care in perinatal deaths in South Africa. Pattinson RC for the PPIP sentinel sites. S Afr Med J 2003; 93:450-455

[38] There was much anecdotal evidence that women were being treated with contempt at Health Facilities as a result of the midwives and nurses not being able to cope due to the fact the HF are severely under-resourced.

2.2.5.1.5 The macrosystem, health policies and leadership

As part of the *Data Deep Dive* (see section 2.2.6) we assessed the policy environment within which the facilities intervention operated as well as local and district-level leadership, crucial for success of the intervention.

2.2.5.2 Community level

The MaiKhanda community intervention sought to improve the maternal and neonatal health of rural communities of Malawi via improving communities' MNH knowledge, attitude and practices, stimulating demand for health and increasing access to health facility care, via community mobilisation through women's groups and, later, MNH task forces (Figure 9). As also depicted in Figure 9, we identified a number of contextual factors affecting community women and the success of the community intervention including: the composition of women's groups and their population coverage (section 2.2.5.2.1); the ability of volunteer women's group facilitators to run women's groups effectively (section 2.2.5.2.2); the availability of resources (specifically those leading to improved transport to health facilities and improved nutrition of pregnant women, section 2.2.5.2.3); the macrosystem of traditional leadership in the community and government policies (section 2.2.5.2.4); and, the influence of men on women (not studied).

2.2.5.2.1 Women's Group Facilitator survey

The WG intervention differs from that of MaiMwana in Mchinji district[9, page 15] in that the facilitators who run the WG in MaiKhanda are volunteers rather than salaried workers. A survey of Women's Group Facilitators (WGF) was therefore undertaken in order to understand the experience of WGF as volunteers with the purpose of determining the scope and sustainability of community volunteers as WGF when scaling up the WG intervention.

Like the Staff Psychology survey (see section 2.2.1.2) information on WGF was collected both at the general level where primarily quantitative data was using a self completed survey questionnaire (see Appendix 16), and at the case study level where primarily qualitative data was collected from selected WGF in the three districts through in-depth interviews using a list of questions to cover in the interview (see Appendix 17). The questions were designed by authors and reviewed by the Community Intervention technical lead and translated to Chichewa by two Community Mobilisation Officers (CMO).

The survey was intended to be completed twice. The baseline was done near the beginning of the project in June-July 2008 (towards the end of phase I &II of the Women's Group Action Cycle) and it is intended that an endline be done before February 2012.

At baseline the questionnaire was completed by 75 of all 81 MaiKhanda WGF and a purposive sample of nine WGF from the three districts was obtained for interview. The interviewees were selected based on their age, education, marital status, period of engagement with the project and their experiences of volunteerism. Further details of the selection of interviewees and the data collection process are given in the 'WGF Survey report, 03/09/2008 – (available from the authors on request)

The questionnaire data were entered into and analysed by SPSS (v14.0). Descriptive analyses were also done in Microsoft Excel. Further analyses on associations between variables including Analysis of Variance (ANOVA) were done in SPSS.

The interview transcripts were analysed by a team comprising of the Community Intervention Programme Officer, the person who carried out the interviews, one of the people who translated the questions into Chichewa and the M&E technical advisors, using methods based on the grounded theory of qualitative analysis.[39] This involves breaking down each

[39] Cresswell, J. W. (1998). Qualitative inquiry and research design: choosing among five traditions. London: Sage Publications.

transcript into segments which correspond to each of a number of categories / areas of interest. A picture of how the respondents feel about each issue is then constructed based on these segments.

2.2.5.2.2 Women's Group self evaluation survey

Forms summarizing the indicators reported here were collected for each Women's Group at meeting 2 (Scoring the WG), meeting 3 (Problems and Strategies) and meeting 4 (future action) of Phase IV of the MaiKhanda Women's Group action cycle (see section 1.2.5.1), by the Women's Group Facilitator (WGF). These forms are provided and the scoring tool explained in Appendix 18. The data from these forms was then entered into a Microsoft Access database by the Community Mobilisation Officers (CMO) and analysed in Microsoft Excel.

The results section for this study (section 4.2.5.2.2) begins with an assessment of the completeness of the data entered into the database so that the reader is aware of the quality of the data and the proportion of the data coming from each district. The scoring of key attributes of the group are then presented. Additional analyses on: problems identified and frequency of their occurrence; strategies chosen to address identified problems and success of implementation; how effective are Women's Groups?; linking strategies to Problems; and, future action; are provided in the report 'Women's Group Self Evaluation (Phase IV)' available from the authors on request.

2.2.5.2.3 Women's Groups and the availability of resources for MNH

As part of the *Data Deep Dive* (see section 2.2.6 below) we attempted to quantify the implementation of women's group strategies impacting on the availability of key resources for MNH including the procurement of bicycle ambulances for transport to health facilities and community *'dimba'* gardens for improved nutrition.

2.2.5.2.4 Traditional leadership and government policies

Also as part of the *Data Deep Dive* (see section 2.2.6 below) we assessed the role of traditional leaders within the community in influencing MNH outcomes with reference to how the MaiKhanda community intervention has engaged traditional leaders; and also assessed the likely impact of government policies, in particular the ban on deliveries by Traditional Birth Attendants, on health facility delivery and MNH outcomes.

2.2.6 Data Deep Dive

The evaluators and implementers of MaiKhanda sought to gain a deeper understanding of how all available sources of data could be used to assess the impact of the MaiKhanda interventions through a 'Data Deep Dive' process. The Data Deep Dive refers to a joint exercise by two representatives of all partner organisations of MaiKhanda to explore all of the available data on intervention inputs, processes and outcomes in order to come to conclusions regarding the impact of the QI and WG interventions independent of the RCT. The initial terms of reference of the Data Deep Dive in advance of the first meeting held in July 2010 are as follows:

Aim: To develop a consensus statement on the impact that MaiKhanda has had to date
Purpose: To help the advocacy work; to help inform decisions about the strategic direction of MaiKhanda.
Tasks: 1. To identify the key questions that need to be asked to determine what effects have occurred through MaiKhanda.

2. To identify the data sources that are needed to answer the questions
3. To work through each question, using the agreed data sources, to identify the presence and strength of any effect, whether it is triangulated and the certainty of the evidence.
4. Where differences of view remain unresolved, to agree a process and timescale for resolving them.
5. To write a document that summarises the impact achieved so far.

The key questions from Task 1 that the Deep Dive focused on in the first meeting and the two subsequent meetings in October 2010 and February 2011 were as follows:

Q1. How well has MK built capability in the CEmOCs and HCs in the application of QI methods?
Q2. How well has MaiKhanda built capability and capacity in facilities to use data to improve quality?
Q3. How effective are the maternal and neonatal health interventions in facilities and communities?
Q4. How effectively has MK engaged community structures and its leaders?
Q5. What are the optimal linkages between community and facility interventions?
Q6. What effect have we had on reducing the three delays?
Q7. What effect have we had on deliveries, NMR, MMR, NCFR and MCFR?
Q8 So, do we have the right intervention at the right dose?

a. *What has been proven and may be spread?*
b. *What spread approaches do we believe would be effective and why?*
c. *What is ineffective and should be stopped?*
d. *What has promise but requires modification and further testing?*
e. *What gaps are there in the programme (e.g. HIV) that we should test?*
f. *Should some of our successful changes be bundled? If so, which?*

Many of the questions could not be adequately answered due to a lack of availability of relevant or accurate data. Nevertheless some consensus was built among the partners on what MaiKhanda had achieved to date. This information is included throughout chapters 4 and 5.

2.3 Economic evaluation

The primary focus of the economic evaluation was to determine the cost-effectiveness of the interventions. Sensitivity analyses surrounding the costs were undertaken in order to provide estimates of the likely costs of a future scale-up of the interventions.

Additional benefits and costs of the intervention, expanding outward from the narrow focus on mortality reduction were explored as part of Tim Colbourn's PhD , which was completed in October 2012 and is available to freely download at: http://discovery.ucl.ac.uk/1366631/

3 What happened in the programme?

This chapter begins by examining how the interventions evolved throughout the course of the evaluation period before quantifying the dosage of the interventions actually received by the facilities and communities. The evolution and dosage of the interventions can be thought of in terms of the fidelity to which the interventions as designed were implemented in practice.[40] As such this chapter raises the possibility of 'type III' implementation errors, which need to be considered in the interpretation of the results of the impact evaluation (chapters 4 and 5). We finish this chapter with a discussion of the data improvement work undertaken by MaiKhanda.

3.1 Evolution of the interventions

There were some changes to the original women's group intervention model where the original 12 meeting cycle for Phases I and II, as tested in MaiMwana[9, page 15] was changed to an eight meeting action cycle as it was felt by both women's group members and MaiKhanda staff that 12 meetings prolonged the intervention for too long a period.

Based on learning from similar community mobilisation programmes (see section 1.2.3) MaiKhanda sought to engage communities, and women in particular, through a community action cycle to facilitate greater uptake of skilled attendance at delivery. The nature of community engagement takes time and it was considered beneficial to add to this process with the addition of MNHTF (Maternal an Neonatal Health Task Forces) to 365/729 (50%) of the women's groups halfway through the intervention period of the RCT (see section 2.1.11) in mid-to-late 2009. The MNHTF are primarily tasked with identifying high-risk pregnant women and following them up to delivery at a health facility as recommended; ensuring pregnant women and their babies get antenatal and post-natal care; and disseminating health education on MNH and related areas to all women and the wider community.

The facilities intervention was to be implemented, at the beginning of the programme, by consortium partners IHI and the Liverpool School of Tropical Medicine (LSTM) together. They developed an integrated intervention model combining criterion-based audits, death audits and the IHI model for improvement involving rapid PDSA cycles. Later LSTM ceased to be a consortium partner and the programme adopted the IHI model for improvement (Figure 10). The focus of the interventions was on 'breakthrough' collaborative/learning sessions followed by action periods repeated at regular intervals to implement the change package(s), without limiting itself to just meet the standards of care.

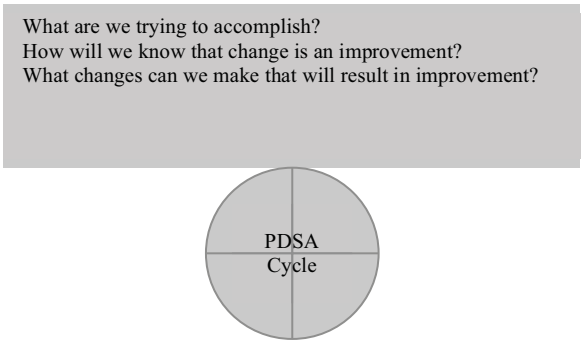


Figure 10: IHI Model for Improvement

[40] Brown C, Hofer T, Johal A, Thomson R, Nicholl J, Franklin BD, Lilford RJ. An epistemology of patient safety research: a framework for study design and interpretation. Part 3. End points and measurement. *Quality and Safety in Health Care*. 2008. **17**:170–177

In summary, the major changes to the original proposed interventions were as follows:

For the facilities intervention:

- Discontinuation of the combined model and the departure of LATH/LSTM and adaptation of the IHI model for improvement, which was rolled out to the health randomised centres from mid-2008.
- Appointment of additional QI staff, especially data coordinator and district level QI officers from mid to late September (see section 3.2 on dosage below).

For community intervention:

- Shortening of the meeting cycle from 12 to 8 meetings
- Formation of task forces to accelerate the movement of women delivering at the health facilities and to improve MNH knowledge in the community, during the middle of the intervention period in mid-to-late 2009.

A timeline containing these changes and all other events of significance for MaiKhanda is provided below:

Timeline	**Event**
January 2006	Proposal approved by THF for implementation
	Quality Improvement pilot in Bwaila hospital
July, 2006	Quality Improvement initiated in CEmOC facilities
	Maternal Death Reviews initiated
January, 2007	First QI breakthrough collaborative
	Introduction of Criterion-Based Audits
June – September 2007	Formation of 729 Women's Groups
July 2007	Surveillance system established
July 2007	Health Centre work initiated by LSTM
March 2008	LSTM & LATH leave Consortium
	THF grants an additional year to the project for Phase II
	Project gets registered as an NGO in Malawi-MaiKhanda
2008	Super-Improver training
May 2008	Second round of proposals with a clear design in place
July, 2008	Health centre work re-initiated by IHI
2009	Implementation of neonatal change ideas
September 2009	FI Officers based in Salima and Kasungu districts and extra officers in Lilongwe district
July 2009	Half of women's groups started Task Forces
July, 2009	Health Centre work being fully implemented
2010	Bi-weekly visits to health centres; regular visits to CEmOCs

3.2 Dosage of the Interventions

3.2.1 Community Intervention

All of the women's groups (WG) started between June and September 2007 and most had completed Phases I and II of the community action cycle, comprised of eight monthly meetings (Figure 4, section 1.2.5.1) by September to October 2008, with implementation of strategies (Phase III) lasting until late 2009 and self-evaluation (Phase IV) taking place in late 2009/ early 2010. Overall 651 (89%) of the original groups were still running as of mid-2010. A new WG manual with increased health education aspects (health talks) included was formulated in mid-2010 to increase the MNH knowledge of group members. This revised manual is currently being used with newly formed WG, set-up in the latter half of 2010/ early 2011. The newly formed WG are being run by the Women's Group Facilitators (WGF) whilst existing WG, with strong leading members are being managed by these members (who are

called 'promoters'). It should be noted that new groups were formed in response to clear evidence from other trials (Nepal, Bangladesh, Jharkhand) that the ratio of groups to population was sub-optimal i.e. trial findings in other sites that suggested a WG to population ratio of 1:500[8,page 11] was preferable to that of 1:1400[10, page 15] – the original ratio of the MaiKhanda WG was 729:1,000,0000 or approximately 1:1400.

In mid-2009, following consideration of the need for increased MNH knowledge and a greater focus on facility delivery, a visit to the MaiMwana project in Mchinji and engagement of Traditional Authorities (see section 4.2.5.2.4.1), Maternal and Neonatal Health Task Forces (MNHTF) were set up as complementary structures residing sometimes within / sometimes alongside the existing WG. In total 365 MNHTF were formed representing half of all the WG. However, as they were formed randomly in each RCT CI cluster (HC catchment area) it has not been possible to disaggregate their effects from the effects of the WG following their introduction (July 2009). The spread of planned TF will be evaluated in future.

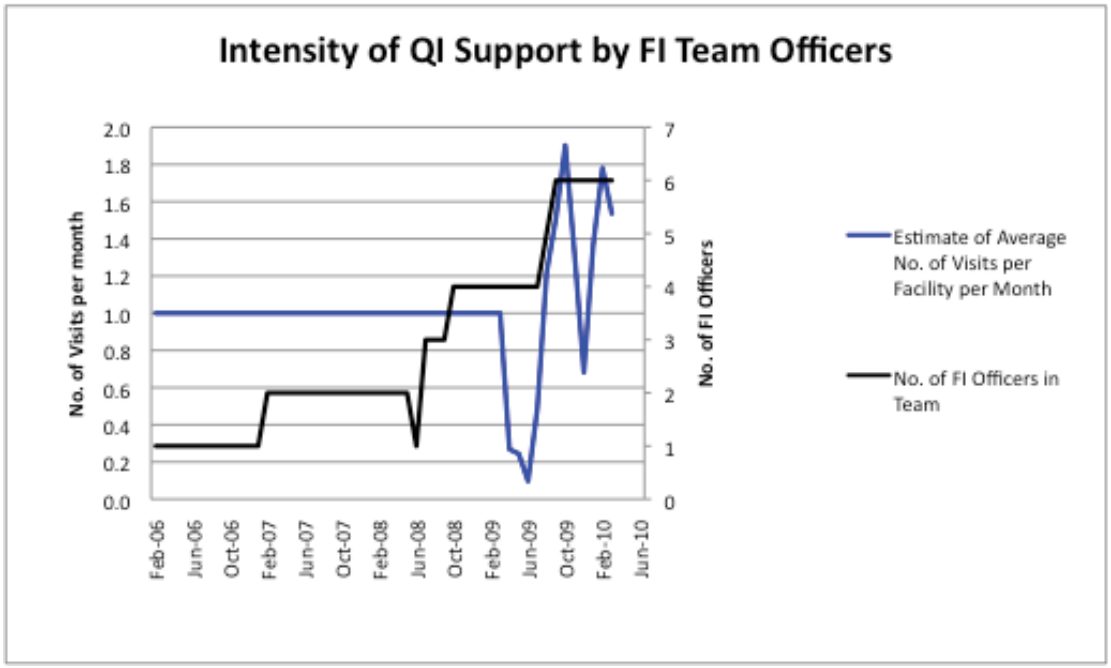
The dosage (in terms of input from MaiKhanda) of the Community Intervention remained steady throughout the intervention period. Therefore, except for the introduction of the Task Forces, the whole period from when the WG are thought to have started to have an effect (after Phase II of the action cycle i.e. October 2008– see section 2.1.11) to the end of follow-up in December 2010, can be considered as 'full dosage' for the purposes of evaluation i.e. as originally envisaged in the study design. However, as the introduction of the MNHTF can be considered as an evolution of the CI, separate exploratory analyses of the period following the introduction of the MNHTF were also considered (see section 2.1.11). To allow for a few months lead time for any effects of the task forces, and for the purposes of convenience of analysis considering major changes to the dosage of the facilities intervention (see below), this 'second intervention period' was deemed to be 1st October 2009 (Oct-09) to 31st December 2010 (Dec-10); with the corresponding first part of the intervention period being 1st October 2008 (Oct-08) to 30th September 2009 (Sep-09) i.e. both periods being the same as for the facilities intervention.

3.2.2 Facility Intervention

The original FI inputs are now considered to have been inadequate to achieve the level of change desired in the health facilities. The initial low dose of FI from MaiKhanda (then The Health Foundation Consortium) assumed capacity within the clinical teams whereby these could be managed remotely by a MaiKhanda team member with timed visits e.g. monthly, However, due to a number of reasons (culture of standards and some lack of initiative), lack of resources, lack of motivation as evidenced in our staff psychology survey conducted in 2008 – see sections 2.2.5.1.2 and 4.2.5.1.2), intensive, regular visits to facilities to coach and encourage QI teams were needed.[41] Consequently, the number of MaiKhanda FI staff was increased significantly in 2008/9; these staff subsequently had QI training. Figure 11 shows that from a base of one FI staff member in 2006, the number grew to six by Sep-09. FI staff were in place in Salima and Kasungu from September 2009 onwards. Figure 11 also gives an estimation of the average number of visits per month per facility. Records of individual visits were generally not kept so this data is unreliable, but taken on face value this data shows an average of one visit per month per facility rising roughly in line with staff increase (with a drop in Dec-09 due to holidays). In 2010 there were scheduled bi-weekly visits to health centres and weekly visits to CEmOCs, of which 80-90% were completed in 2010 (personal communication Charles Makwenda, FI programme manager, MaiKhanda). The above data indicate that from Oct-09 onwards the dosage of the facilities intervention was greatly increased. It is for this reason that when exploring possible differences in intervention effect over time (see section 2.1.11) we have chosen to split the facilities intervention period (Oct-08 to Dec-10) into two as follows: first intervention period (less intensive): 1st October 2008 (Oct-08) to 30th September 2009 (Sep-09); second intervention period (more intensive): 1st October 2009 (Oct-09) to 31st December 2010 (Dec-10).

[41] In the follow-up meeting to the third Deep Dive on learning, the fact that MaiKhanda could have learned this from IHI's experience in South Africa during 2005-6 was brought up.

Figure 11: Number of FI staff and intensity of Facility visits



The number of hours spent on visits to the Health Centres and CEmOCs by the FI team was also estimated for the months of April to August 2010, when it was estimated that approximately 60 total person hours per month were spent on health centre QI and 150-200hrs per month were spent on CEmOC QI (there were 29 HC and 9 CEmOC involved in QI at this time; data not shown). This suggests that the dose of CEmOC FI has been roughly 3 times that of the health centre FI. Information on the quality of the visits conducted is also lacking (it is intended that this information will be collected going forwards in 2011/12). Using all available data we determined the activities of the facilities intervention that were implemented at CEmOC level and at health centre level to be as follows.

3.2.2.1 CEmOC level

The roll-out of change ideas to reduce maternal deaths at CEmOCs started in 2006, but how long each of these ideas was continued for was not documented. There was only really a focus on 2 maternal change ideas at CEmOCs (*prevention of PPH* and *Partograph use*; sepsis was worked on in 2007/8 only but is being resurrected throughout 2011; Figure 12).

Change ideas to reduce neonatal deaths at CEmOCs were only rolled-out across the CEmOCs in 2009 and more systematically in 2010 (Figure 13). Four key neonatal change ideas have been worked on during this time (*KMC, Sepsis, Asphyxia, Partograph use*), representing the main causes of neonatal deaths and a plausible ability to reduce overall NCFR, dependent on high coverage and reliable implementation of the interventions.

A CEmOC evaluation was carried out in 2008 to assess the QI activities being carried out in these CEmOCs and to gauge the understanding and general impression regarding QI among the team members. 130 members have once been members of QI teams at CEmOCs from mid-2006 to mid-2008 (when this survey was conducted), with 87.7% retaining their association/involvement in the QI team. As part of the *Data Deep Dive* (see section 2.6), QI team members were followed up in October 2010, and it was found that 5/23 (22%) with data on their whereabouts had left to become (masters) students elsewhere. Anecdotal evidence suggested that these five were among the brightest and most capable members of their QI teams.

A total of 92 QI activities were reported to have been conducted amongst the different CEmOC facilities. Of these, change packages related to neonatal care and data improvement generated the most ideas among the QI teams. Other change packages that generated ideas included management of haemorrhage and women friendly care.

Figure 12: Maternal Change ideas tested at CEmOC by year

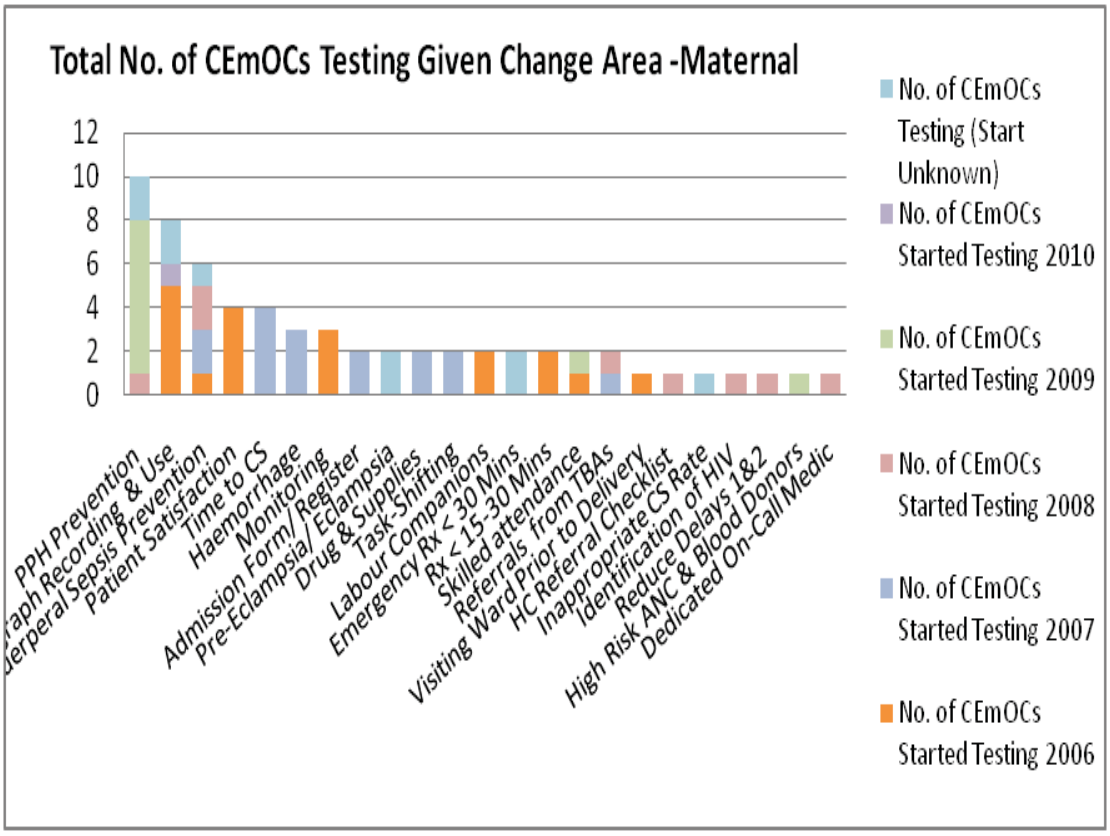
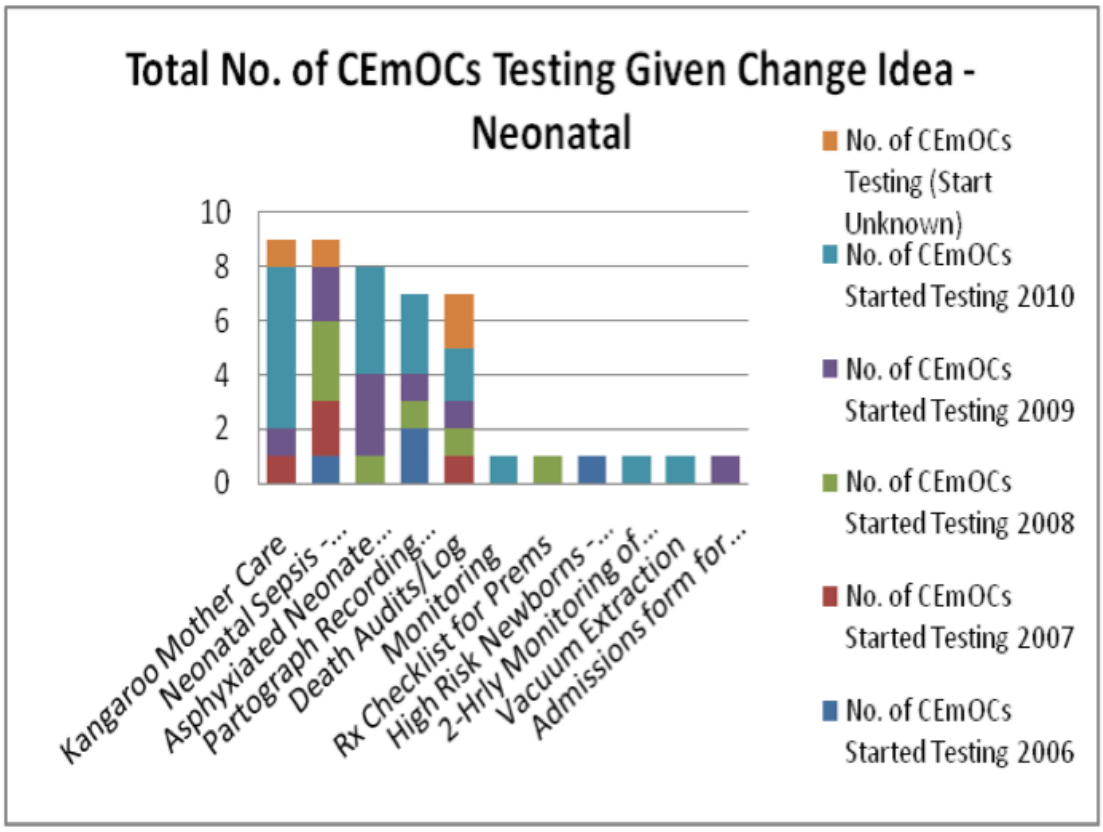


Figure 13: Neonatal Change ideas tested at CEmOCs by year



Of the 92 ideas that were generated through the change packages, 26 ideas did not have any PDSAs run on them. For the 66 ideas that were tested, there were about 180 PDSAs run, giving an average of 2-3 PDSAs for each idea to test. All the respondents unanimously responded that they were aware of data improvement activities happening at their health facility and that they were all involved in it. Almost all the respondents (24) were confident that appropriate records of births and deaths were being maintained at their respective health facilities. However, only 88% (n=22) of the respondents felt that the data was used for decision making.

All the respondents valued the visits by THFC (MaiKhanda) staff with 52% of the respondents suggesting that THFC staff should visit their facilities twice a month; 44% suggested that a once a month visit by THFC staff would be adequate for their facilities. A majority (11 respondents [44%]) felt that QI was a little bit demanding, but worth the effort.

Shortage of staff was one of the most important challenges facing the QI teams. It led to an increased workload, which did not give the QI team members enough time to meet regularly and discuss QI activities.

Stability of QI teams seemed to have an effect on QI work being carried out in the hospitals, with less PDSA being completed in teams who had a higher turnover of staff (data not shown).

Finally, our survey of the MaiKhanda CEmOCs in 2008 highlights the fact that the MaiKhanda facilities intervention was not done in isolation and that other projects were also in operation at the CEmOCs. Figure 14 shows that an average of two other projects were also concurrently in operation in each of the CEmOCs in 2008. With additional consideration of the main focus of day-to-day work in the facilities, Figure 14 is illustrative of both the competing demands on health care workers time and of competing influences on the health outcomes and the resulting problem of attribution to specific interventions such as those run by MaiKhanda. When finalising this report we also became aware of another quality improvement intervention that was scaled-up to run in all district hospitals throughout Malawi following an evaluation in 2009.[42] This intervention used a methodology based more on adherence to standards and criterion based audits like that brought to MaiKhanda by LSTM who left MaiKhanda in 2008 (see section 3.1). It is likely, given the relatively small number of clinicians in Malawi, that it may have shared QI team members with MaiKhanda, which is obviously an important consideration when considering coherence of implementation of either intervention and their likely effects.

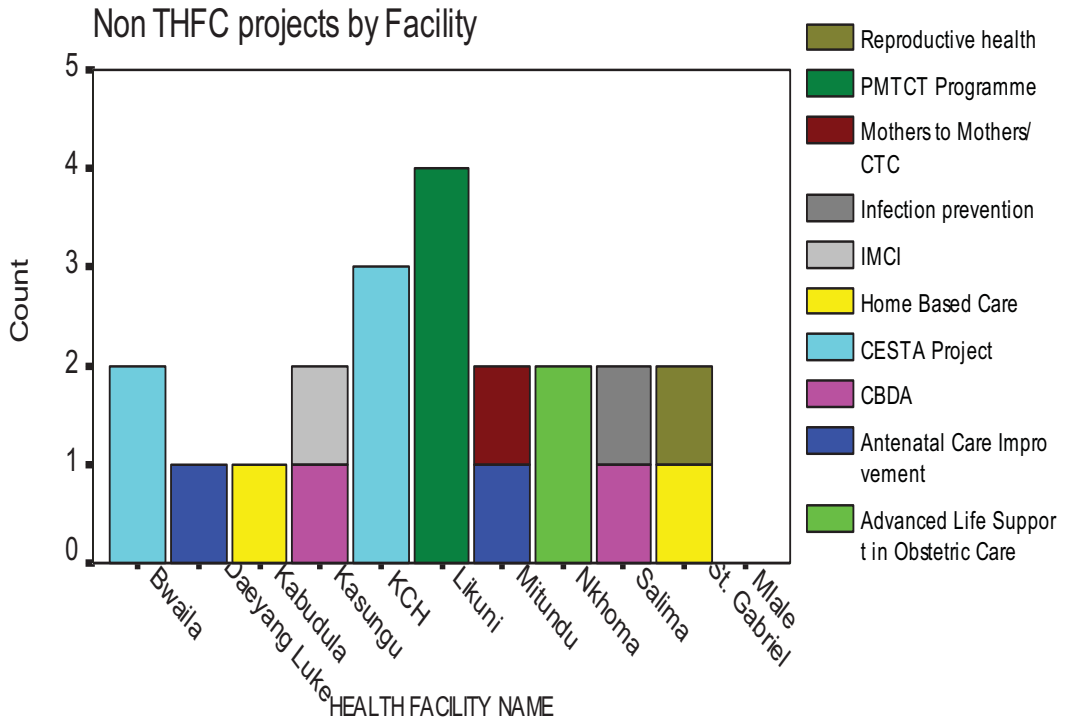
The evaluation sought to avoid the problem of attribution bias via adoption of a randomised controlled trial methodology (with the assumption that different activities in different comparison arms of the trial should roughly balance out given the number of clusters and the random nature of allocation; see section 2.1). However, the CEmOCs were not randomised and not compared to any comparison group and as such the problem of attribution remains (section 4.2.2.2).

3.2.2.2 Health Centre level

The Health Centre (HC) FI work started under LSTM in July 2007 then stopped, then restarted again in July 2008 under IHI, with most HC work only actually started fully in 2009 (see section 3.1). The main change ideas worked on at HC have been: *identification of High-Risk Pregnant Women (HRPW), encouraging Antenatal Care (ANC) attendance*, *CEmOC delivery with follow-ups* (started at most HC in 2009); *Blood donor identification* (started at most HC in 2010); and, work on *Emergency Obstetric Referrals* (checklist to ensure adequate clinical management before referral and timely referral; started at most HC in 2009). These change ideas all reflect the nature of HC care with most serious cases being referred to the CEmOC.

[42] Rawlins BJ, Kim Y-M, Rozario AM, Bazant E, Rashidi T, Bandazi SN, Kachale F, Sanghvi H, Noh JW. Reproductive health services in Malawi: An evaluation of a quality improvement intervention. In press: Midwifery (2011), doi:10.1016/j.midw.2011.10.005

Figure 14: Non-MaiKhanda (THFC) projects being carried out in the CEmOCs



Whilst the change ideas are known to the extent detailed above, neither the intensity with which they were pursued, how well they were pursued (the quality of the work), or how thoroughly they were pursued (how thoroughly the ideas were tested) is known. This information is lacking at both the individual facility level and at aggregate level for both the HC interventions and the CEmOC interventions, a situation which has impeded our ability to connect the dots from intervention to impact. Limited process data on specific interventions (not at this level of detail) is available however, as detailed in the following chapter.

3.3 Data improvement

Before we move on to look at the results it is worth briefly presenting the work on data that MaiKhanda undertook. This was an integral part of the FI work and is useful both for ensuring the quality of the data we make inferences from and for the quality improvement work itself which has 'data driven decision making' as one of it's key components (see section 1.2.5.2). A detailed report summarising all of the work on data was prepared by IHI; here we present a summary of the competency in data use across the CEmOCs (Figure 15) and Health Centres (Figure 16) as of mid-2010 (i.e. towards the end of the evaluation period). From the figures it is apparent that 4/11 CEmOCs reached the maximum score of data competency (5/5) where they 'collect, review, share, use data for decision making and display), 2/11 reached 4/5 (everything but displaying data), 4/11 reached 3/5 'collecting, reviewing and sharing' only, and, 1/11 (KCH) has only reached level 2 where they just collect and review the data. At the Health Centres, most (18/30) reached stage 3, where they 'collect, review and share', but don't use data for decision-making. In summary, the data work helped ensure the data used in the analyses presented in this report are of reasonable quality, and that the FI work was grounded to some extent in data-driven decision making; although, as the assessment shows, many of the facilities still fell short of full data competency.

Figure 15: Data competency scores at CEmOCs

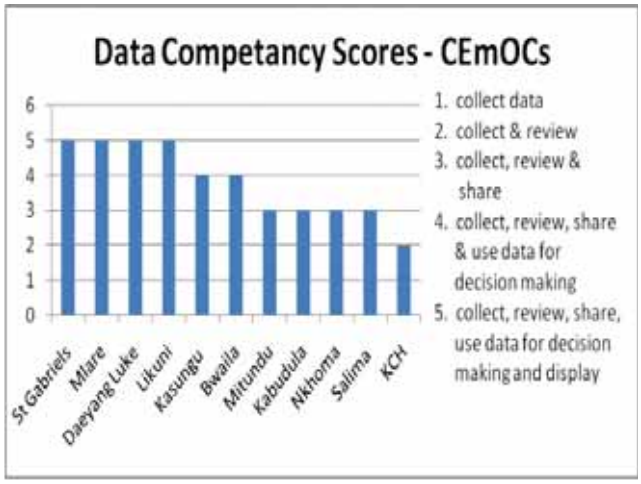
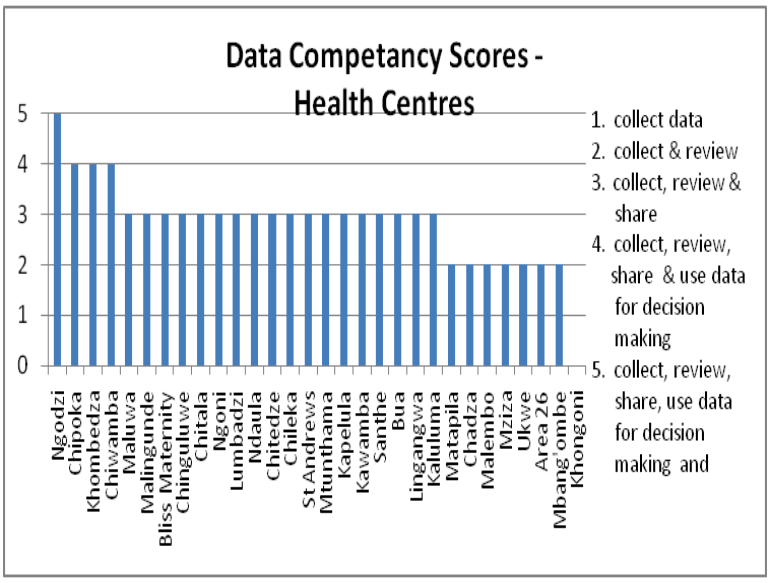


Figure 16: Data competency scores at HC



4 What has been the impact of MaiKhanda?

This chapter presents the results of all of the studies detailed in chapter 2. For ease of reading the studies are presented in the same order as they are introduced in chapter 2, with the randomised controlled trial results presented first, followed by the process evaluation studies and the economic evaluation. The results will be presented with reference to the big picture of MaiKhanda's impact and reasons for the observed impact i.e. how they can be used in triangulation with each other (Figure 17, Figure 18 and following paragraphs). Chapter 5 will then discuss the overall interpretation of all the findings further, with reference to precision, potential biases, the potential of the interventions given that they were often implemented sub-optimally, and the external literature on similar interventions and associated evaluation methodologies.

Following the Three-Delays-based conceptual model of MaiKhanda (Figure 2) the Input-Process/Mechanism-Output, Context framework of the evaluation (Figure 5) and the overviews of the process evaluation at facility level (Figure 8) and community level (Figure 9), which also show potential intervention targets, Figure 17 and Figure 18 provide a detailed overview of the evaluation studies undertaken and how they link together (section numbers of the report where the results of each study are presented are provided in brackets, please note these correspond to those used in Chapter 2 to describe the methods); and also show what was actually targeted by each intervention. To guide the reader each study has been colour-coded to roughly reflect the level of evidence it provides in support of the MaiKhanda interventions impacting on the relevant inputs, process/mechanisms, outputs and contextual factors effecting population-level maternal, neonatal and perinatal mortality (see key at top of Figure 17 and Figure 18). An overview of the impact of MaiKhanda, including a justification for the choice of colours on the figures, and a summary of all key finding is as follows.

Impact on death rates in the overall population and within health facilities

1. The randomised controlled trial suggests **neonatal mortality decreased by 22% in areas with both the facility intervention at the health centre and the community intervention in surrounding villages compared with control areas**; and, that **perinatal mortality decreased by 16% in areas with the community intervention relative to those without the community intervention** (see section 4.1 below).

2. **It is likely that the observed effects on mortality of both interventions occurred in the community** (section 4.2.4). This seems likely given the lack of observed effects on deaths at the health centres and hospitals (section 4.2.2), and data on the place of death collected from verbal autopsies. The latter indicate lower neonatal mortality rates in the community, but not in the facility, in areas with both the facility and community interventions compared to control areas; and, lower perinatal mortality rates in the community, but not in the facility, in community intervention areas compared to areas without the community intervention. For the facility intervention this suggests that neonates were leaving facility intervention health centres less likely to die in the community than neonates leaving control health centres, which fits with any facility intervention effect most likely being on late neonatal deaths (section 4.1.5).

3. Cause of death data and calendar data (section 4.2.3) suggest **the observed effect of the combined facility and community intervention on neonatal mortality may have been mediated by reductions in mortality due to asphyxia, prematurity and sepsis, in both the early and late neonatal periods, but that the effect was mainly observed in the last, more intensive, 15 months of the intervention period (see section 3.2), when it was larger (a 28% reduction)**; and, that **the effect of the**

community intervention on perinatal mortality may have been mediated through a reduction of stillbirths during the first 12 months of the intervention period and through a reduction in early neonatal mortality due to sepsis, prematurity and asphyxia in the second, more intensive intervention period (section 4.2.3; also see section 4.1.5).

4. The randomised trial shows **no impact of either of the interventions on maternal mortality** and **given the observed number of births and deaths in each arm of the randomised trial the probability (calculated using the properties of the binomial distribution) that 30% reductions in maternal mortality really occurred as a result of the MaiKhanda interventions in the total population our sample sought to represent (intervention areas vs. control areas) was: only around 1% for the facility intervention and 28% for the community intervention (section 4.1.4)**.

5. **Because of low incidence of maternal deaths in health centres it was not possible to determine if maternal case fatality rates were different between intervention and non-intervention health centres.** Maternal death rates were very low compared to those in the hospitals, probably due to most serious cases either being referred to or initially presenting at the hospitals. **Neonatal case fatality rates and fresh stillbirth rates** were also lower at health centres than hospitals and rates in the community, but were high enough to determine differences. **Neonatal case fatality rates were not significantly different between health centres undertaking the quality improvement intervention and those not. Fresh stillbirth rates were lower in facility intervention health centres (7.8 fresh stillbirths per 1000 births) than control health centres (5.5 fresh stillbirths per 1000 births), though given the low rates, the absolute reduction in mortality was small** (section 4.2.2.1)

6. **There is no evidence that the MaiKhanda facility intervention had an impact on case fatality rates at the non-randomised hospitals (CEmOCs).** Maternal case fatality rates in the non-randomised hospitals went down in 2009 but increased in 2010 despite an increase in the intensity of the facilities intervention (section 4.2.2.2.1). Similarly, neonatal case fatality rates in 2008 were lower, before rates increased in 2009 and 2010 when the neonatal interventions of the facilities intervention were rolled-out (section 4.2.2.2.2). **Although, according to control chart rules, the increases in maternal and neonatal case-fatality rates at the hospitals in 2009 and 2010 are not statistically significant and the preceding decreases in late-2008 were, all available data on the timing and dosage of the interventions** (section 4.2.1.1) **and cause of death** (section 4.2.2.2.1) **suggest no link between the interventions and changes to the maternal and neonatal case fatality rates at the hospitals.** In the absence of comparison group data for the CEmOCs we analysed secular trends for Malawi using available national data. Analysis of available data shows that **between 2005 and 2010 the secular trend in Malawi was of falling maternal case fatality in hospitals and falling population based maternal mortality** (section 4.2.2.2.1)**; and, slightly declining neonatal mortality** (section 4.2.2.2.2).

7. Place of death data from the verbal autopsies suggest that the randomised controlled trial population (primarily rural) was distinct from the population served by the non-randomised hospitals (primarily local and urban), with only a 17-22% overlap for stillbirths and neonatal deaths but possibly a 50% overlap for maternal deaths (4.2.4.5). Although the lack of an apparent effect of the MaiKhanda facilities intervention in the non-randomised hospitals precludes this work from biasing the randomised trial results as a consequence of this overlap, this data, especially that for stillbirths and neonatal deaths, provides additional support for the robustness of the

Figure 17: Overview of the Impact of the MaiKhanda Facilities Intervention

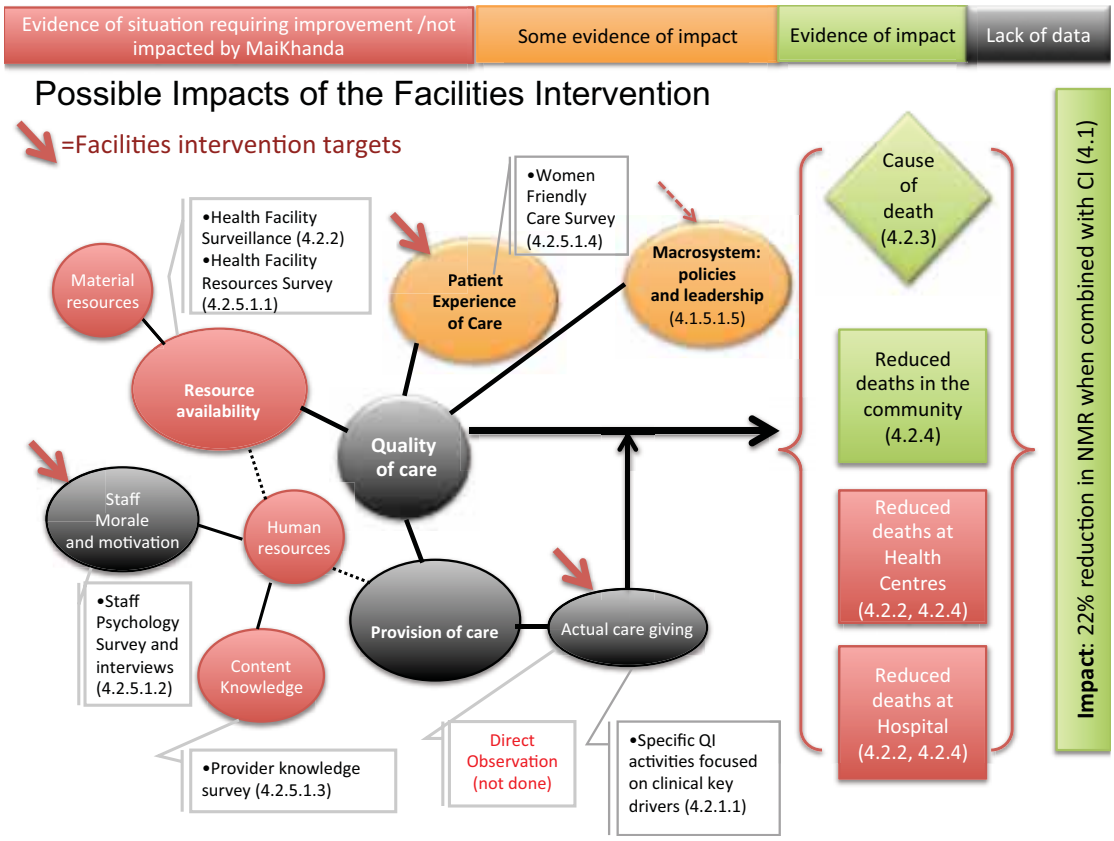
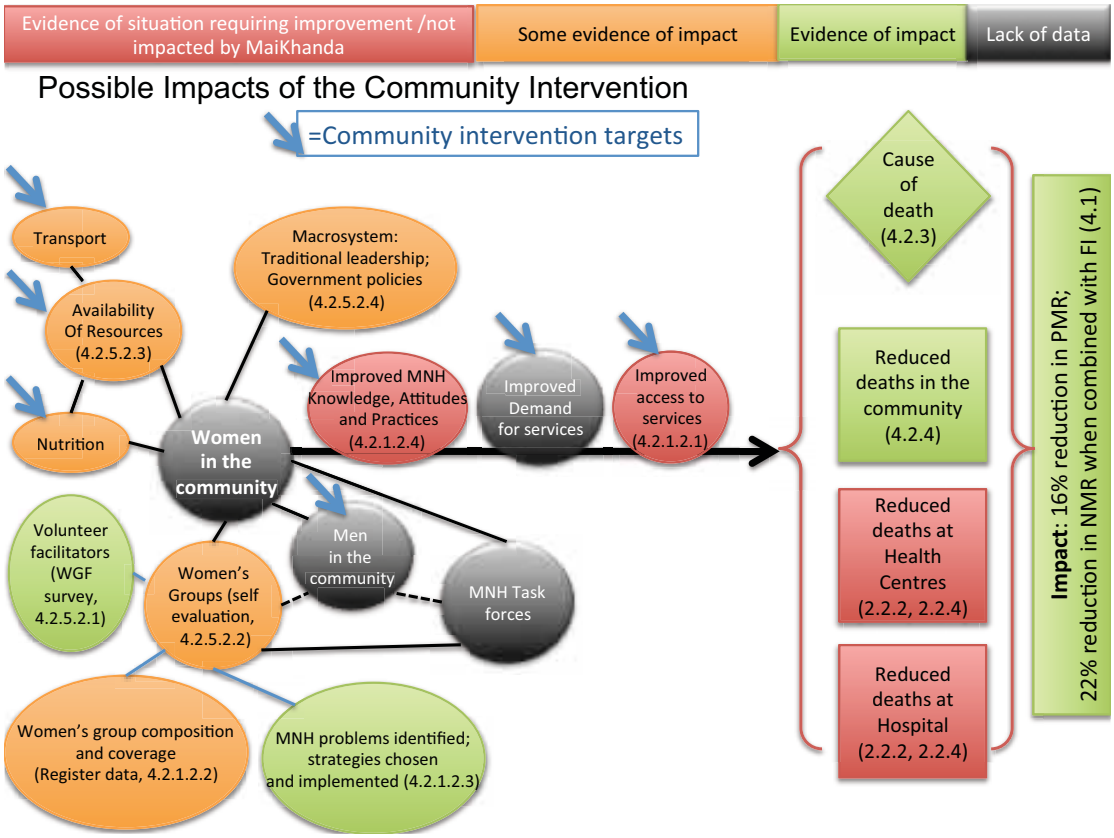


Figure 18: Overview of the Impact of the MaiKhanda Community Intervention



randomised trial results with respect to potential dilution from MaiKhanda work in the CEmOCs.

Facility Intervention

8. **There was no clear evidence for the impact of specific quality improvement activities on clinical practices and intermediate outcomes such as post-partum haemorrhage (PPH) and asphyxia** (section 4.2.1.1).

9. Both the health facility surveillance (section 4.2.2) and the health facility resources survey (section 4.2.5.1.1) show that **the health centres were severely under-resourced in terms of emergency obstetric care signal functions (see Box 2) and human resources.** MaiKhanda was not able impact on the availability of such resources.

10. The initial 2008 staff psychology survey provided evidence suggesting that **motivation and morale among health staff was poor**. (section 4.2.5.1.2). Given that the follow-up survey was still pending were are unable to assess whether this situation has changed or whether MaiKhanda may have contributed to any improvement in motivation/morale (hence the black shading on Figure 17).

11. The provider knowledge survey provides evidence **from 2010, towards the end of the evaluation period,** that **the clinical knowledge of emergency obstetric and neonatal care was lacking** (section 4.2.5.1.3). Unfortunately the names of the facilities were mistakenly not recorded, preventing disaggregation by whether or not the facilities were under the MaiKhanda facilities intervention or not, making it difficult to draw inferences regarding MaiKhanda's impact on this indicator. However, since the termination of LSTM training (2008) clinical skills training has not been part of the facilities intervention (see section 3.1).

12. The women friendly care survey showed that **the MaiKhanda facilities intervention may have improved the way both patients and guardians felt they were treated at facilities in Lilongwe, but not in Salima** (section 4.2.5.1.4). The survey was not conducted in Kasungu.

13. Capacity constraints in Ministry of Health (MoH) management structures and competing priorities in the external health system environment mean that **it may be challenging to sustainably embed quality improvement in the health system** (section 4.2.1.5.5). **However, the Malawian government is committed to improving maternal and neonatal health** (section 1.1.4), **and is also committed to supporting quality improvement as detailed in recent strategic documents.**

Community Intervention

14. **Community surveillance data on place of delivery showed that the community intervention did not increase health facility deliveries over and above the rapid increase observed in all areas** (section 4.2.1.2.1), which probably occurred due to a 2008 government ban on deliveries by traditional birth attendants (section 4.2.5.2.4.2).

15. The review of the routine monitoring data from the women's group register revealed that the **number of newly pregnant women who attended women's groups was fairly low at 10% and that the percentage of members who had never had children before was also low at 2%;** we also estimate a **population coverage of approximately 1 women's group to 1200 population** (section 4.2.1.2.2). Given the

results of recently published studies[8,10 page 14] **such coverage is likely to be sub-optimal** (hence the red shading on Figure 18).

16. A survey of the strategies chose by women's groups and the success with which the groups implemented those strategies showed **the most popular strategies chosen by the women's groups to be bicycle ambulances, health education, vegetable gardens and bed nets** and **the most successfully implemented strategies to be health education, voluntary testing and counselling for HIV/AIDS, village savings and loans, bed nets and vegetable gardens** (section 4.2.1.2.3).

17. Evidence from a survey of knowledge, attitude and practices related to maternal and neonatal health among women in women's group (community intervention) areas and women in areas without women's groups suggests **the community intervention did not improve key maternal and neonatal health practices, although knowledge among women in community intervention areas was better for some indicators** (section 4.2.1.2.4).

18. Despite being (unpaid) volunteers, our survey showed that **the women's group facilitators were generally satisfied with their working conditions and were facilitating the groups well**. However allowances and material support were an issue (section 4.2.5.2.1).

19. The self-evaluation of the women's groups by their members in Phase-IV of the action cycle (see Figure 4) was generally positive (section 4.2.5.2.2), providing **subjective evidence that the groups were successful and supported by the community.**

20. **Traditional leaders in the community are likely to be very important** and in many areas likely to determine the success or failure of the community intervention. **On the whole, MaiKhanda engaged these leaders well** with an extensive community entry process, regular communication with traditional leaders and open days show-casing the community intervention work in the communities (section 4.2.5.2.4). **In addition the Malawian government is committed to supporting community interventions as detailed in recent strategic documents.**

Cost-Effectiveness Analysis

21. Preliminary results of the cost-effectiveness analysis indicate that **both the effect of the community intervention on perinatal mortality and the effect of the facility and community intervention combined on neonatal mortality are highly cost-effective by WHO criteria** (less than the per capita GDP of Malawi per Disability Adjusted Life Year (DALY) averted, which is **less than US$5,400 per stillbirth or neonatal death averted**; see section 4.3).

We now begin this chapter with a detailed exportation of the results of the randomised controlled trial (the reader is referred to section 2.1 for a detailed account of the RCT methods).

4.1 Impact Evaluation: Randomized Controlled Trial Results

The headline results are that there appears to be an effect of both the Facility and Community interventions combined reducing Neonatal Mortality by 22% (Odds Ratio=0.78 (95%CI: 0.60, 1.01; p=0.057), there is strong evidence suggesting the Community Intervention has reduced Perinatal Mortality by 16% (Odd Ratio: 0.84 (95%CI: 0.72, 0.97; p=0.020), and that there is no evidence supporting the interventions having an impact on Maternal Mortality (FI on MMR: Odds Ratio=1.18 (95%CI: 0.66, 2.11; p=0.570; probability of 30% reduction in

MMR given observed data=1%; CI on MMR: Odds Ratio=0.91 (95%CI: 0.51, 1.63; p=0.754; probability of 30% reduction in MMR given observed data=28%).

Following the analysis plan detailed in section 2.1.11, this section begins with an assessment of the quality of the data used in the analysis, before continuing with descriptive statistics and graphs of the outcomes by intervention, and finishing with a presentation of cluster-level and individual-level analyses of the effects of the facility and community interventions on the primary outcomes of maternal, neonatal and perinatal mortality (we follow the convention of presenting results of progressively more complex analyses: descriptive, then cluster level, then individual level). We then add a final section detailing the internal consistency of the observed results with respect to the separate effects of each intervention on their own, their combined effects when together and the overall effects of each intervention in the two arm vs. two arm comparisons.

4.1.1 Data quality

For a detailed account of enrolment, allocation, follow-up and analysis by trial arm as mandated by the CONSORT guidelines[43], see Table 1 (page 24).

4.1.1.1 Percentage of pregnant women with no outcome data (loss to follow-up)

For the whole baseline (1st June 2007 to 30th September 2008) and intervention (1st October 2008 to 31st December 2010) periods combined, an average of 25.3% of pregnancies recorded in the database have no outcome (miscarriage, abortion, stillbirth, livebirth) data. This is excluding women who were still pregnant in Dec 2010 or whose last data collected indicated that they could not have reached 7 months pregnancy (stillbirth possible) by the end of Dec-10; and, excluding duplicate records that were removed as far as possible. From looking at many of the records that are 'not followed-up' it appears that many were indicated to be 'not expecting anymore', although no details of the pregnancy outcome or birth were given (i.e. the follow-up was not good enough and although it was attempted it can still be considered as 'lost to follow-up'). It is likely that some of the 25% lost to follow-up were actually made up by the Key Informants (see discrepancies between expected pregnancies and recorded pregnancies in Table 1 flowchart, page 28-30), in which case the true % of loss-to-follow-up will be less. However, if this were true the credibility of those that are indicated as births (used in the analysis) is also then under question. However, births are clear outcomes which are harder for the Key Informants to fake than pregnancies, and the trend of an overall month on month steady increase in health facility deliveries (section 4.2.1.2.1) would have been hard to fake as it would've required coordination between KI).

No significant differences in the percentage 'lost to follow-up' were observed between treatment arms as shown in Figure 19. Only records with outcomes were used in the analyses of mortality rates.

During the baseline period, the loss-to-follow-up is 19% and during the intervention period the loss-to-follow-up is 29%. Figure 20 shows the loss-to-follow-up by month. Clearly there is a trend towards less-follow-up over time, perhaps due to lack of supervision or a clear way forward for the KI toward the end, although loss-to-follow-up is generally around 20% for most months until March 2010. Ideally, the 'lost to follow-up' records should be analysed to determine whether they represent a different population to those who have been followed-up (and included in the analysis). Unfortunately, given the minimal amount of data collected this analysis is not possible. If those 'lost to follow-up' were found to differ however, the generalisability of intervention effects to other populations including those with the characteristics of those 'lost to follow-up', would be difficult.

Figure 21 shows the births observed in each of the four RCT arms vs. those that can be expected given the populations under surveillance in the clusters of each arm and the Crude

[43] Campbell MK, Elbourne DR, Altman DG. CONSORT statement: extension to cluster randomised trials. *BMJ* 2004;328;702-708

Birth Rate (40 per 1000 population). As can be seen the observed births are broadly in-line with those expected, notwithstanding seasonal variation and a drop-off in 2010, especially towards the end. This is interesting, as the 25% loss-to-follow-up would suggest the observed

Figure 19: Loss to follow-up by cluster and RCT arm

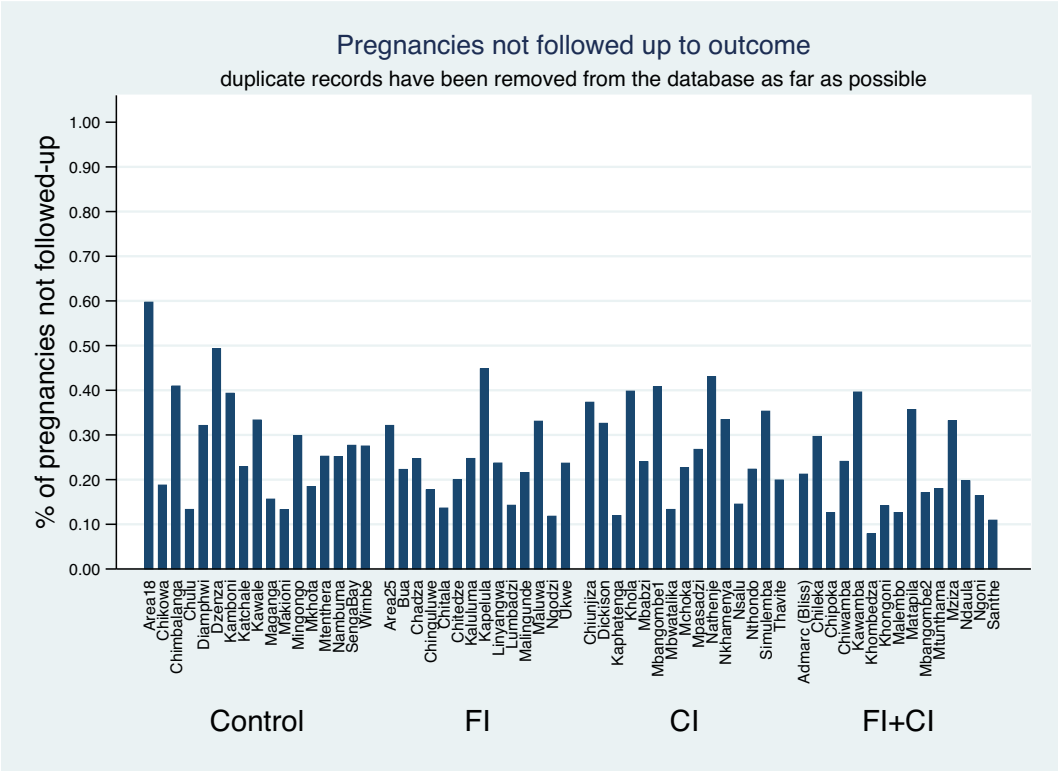
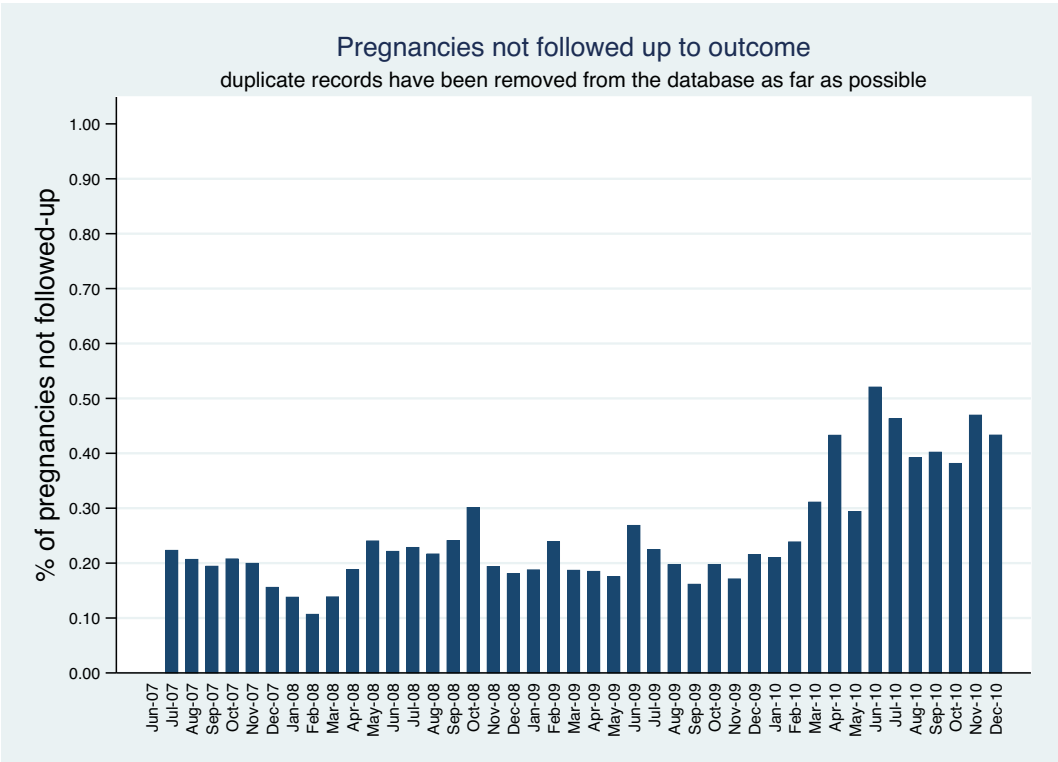


Figure 20: Loss to follow-up by month



births being too low. The fact the observed births are generally not too low suggests that many of those pregnancies 'lost-to-follow-up' may in fact not really have occurred as noted above and by Figure 22 which shows that far more pregnancies than could be expected were recorded in most of the clusters (the percentage of expected pregnancies missed is negative in most clusters).

Figure 21: Observed and expected births in each RCT arm

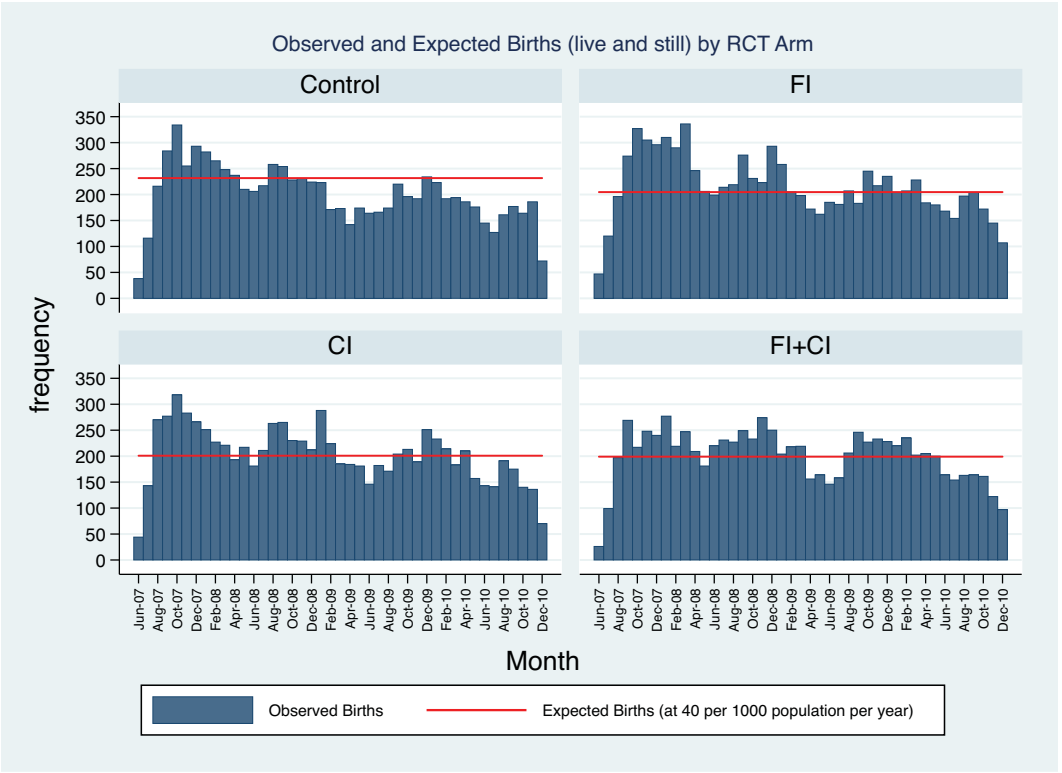


Figure 22: Proportion of expected pregnancies not recorded by KI

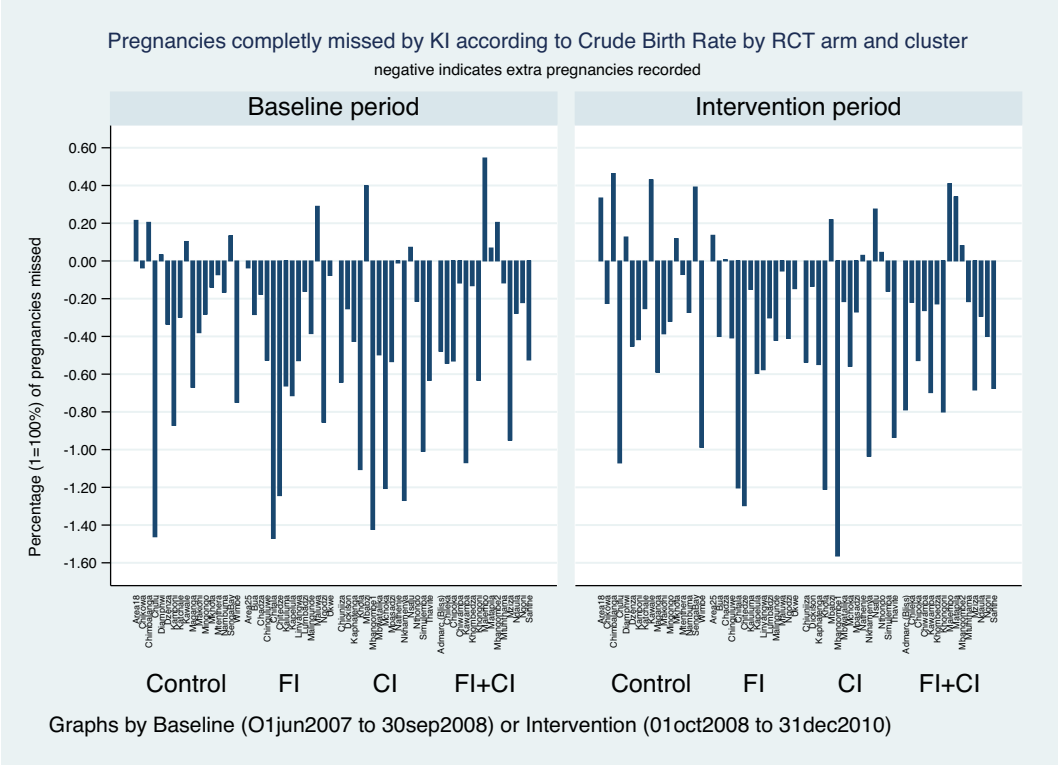
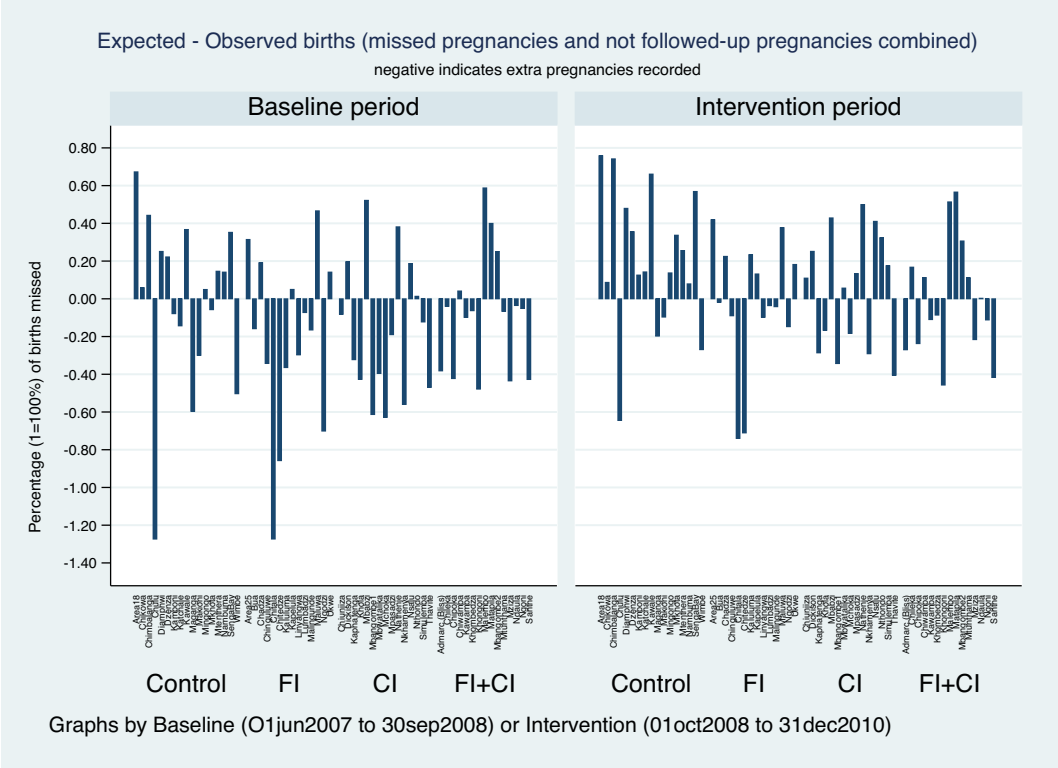


Figure 23 shows the difference between Expected and Observed births in all clusters, which although varying a lot between clusters (due to differences in follow-up etc.) does not seem to vary significantly by RCT arm.

Figure 23: Observed and expected births by cluster



4.1.1.2 *Percentage of maternal deaths with no MVA (no verification)*

Although only 51/102 (50%) Maternal Deaths had a Maternal Verbal Autopsy (MVA) all of the other 51 MD were verified by call-backs to the family in conjunction with the Key Informants and HSA later.

4.1.1.3 *Percentage of SB/NND with no PVA (no verification including of designation as either SB or NND).*

A total of 300/2088 (14.4%) Stillbirths and Neonatal Deaths remain unverified. This is despite a large catch-up verification campaign, which ultimately could not trace all women who were recorded as having stillbirths or neonatal deaths. Many stillbirths and neonatal deaths were not originally verified by verbal autopsy due to the large number of them and resource constraints. Whilst fuel shortages and other logistical difficulties hampered such original verification efforts, as was the case with the lack of original verification of maternal deaths (see above), planning and management of activities could also have been better. Figure 24 shows that the % unverified does not differ significantly by RCT arm although two clusters in the FI+CI RCT arm (Chileka and Chiwamba) have a higher percentage of SB and NND remaining unverified. Verification efforts ceased on 12th June 2011 with the relatives of the remaining unverified SB and NND being un-contactable (often due to the family moving out of the study area).

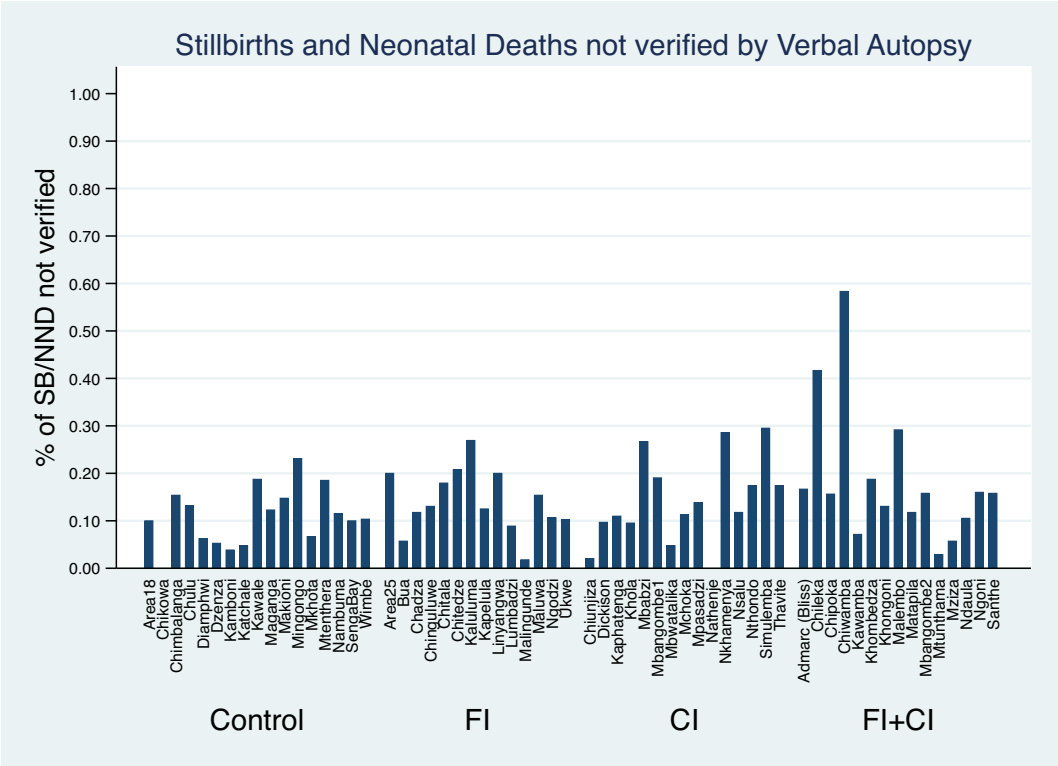
In some cases although a PVA may have been done meaning the death is verified, the categorisation of the death as either Macerated Stillbirth (MSB), Fresh Stillbirth (FSB), early (0-6 days) or late (7-28 days) Neonatal Death (ENND or LNND) may still not be possible due

a lack of information gained during the interview.[44] In other cases enough information may have been gained to categorise the death: as a stillbirth but not as either an MSB or an FSB; or categorise the death as an NND but not as an ENND or an LNND (again necessary for the calculation of PMR). Table 2 shows the number of stillbirths and neonatal deaths whose categorisation, as MSB, FSB, ENND or LNND was possible following PVA. It is split into 4 sections: one comparing FI vs. no FI, one for CI vs. no CI, one comparing all four arms, and one for all cases; each section contains 3 parts, the top one for the baseline period, the second and for the intervention period and the third for the whole time period. Table 2 shows that there are no significant differences between the percentage of SB and NND verified by FI vs. no FI, CI vs. no CI, or by RCT arm in either the baseline, intervention or total time periods. Therefore the potential for this lack of verification to majorly bias the outcomes of the NMR and Stillbirth (Perinatal mortality) RCT analyses is reduced.

However, it should be noted that small changes to SB and NND categorisation that could have resulted from the remaining verification, were it possible, could have changed the results. Typically 10-30% of deaths originally recorded as stillbirths can be reclassified as Neonatal deaths following PVA. If, say 10 more SB are reclassified as NND in the FI arm than in the no FI arm any previously erroneously observed effect on NMR of the FI could change to be above the p=0.05 significance level threshold. Similarly, the true effect could be revealed to be stronger rather than weaker following opposite changes resulting from the outstanding verification (which cannot be completed as stated above).

From the above data it is clear that the proportion of pregnancies lost to follow-up and the proportion of SB/NND that are verified do not vary significantly by RCT arm or direct FI vs. no FI and CI vs. no CI comparison. However, Table 3 shows that there is slightly less loss to follow-up in Salima than the other two districts. Given the lack of variation by RCT arm though, the results are less likely to be biased.

Figure 24: Verification of stillbirths and neonatal deaths by cluster and arm



[44] This is more likely following long delays between the death and the PVA as often occurred during the follow-up exercise; 68 cases in total had PVA from which no information on SB/NND categorisation could be gained.

Graphs showing observed vs. expected births, stillbirths, neonatal deaths, and maternal deaths (the expected figures for the deaths being based on both baseline estimates given expected births and baseline estimates given observed births) for each month for each of the clusters (health facility catchment areas) supervised by each of the 11 Monitoring and Evaluation Officers (MEO) were produced in order to investigate whether any bias may have resulted from inadequate supervision/follow-up on the part of any of the MEO. These 44 multi-panel graphs are contained in Appendix 19. It appears that generally there are no major inconsistencies that could not be explained by chance sampling variation or incorrect total population sizes being given initially (meaning the expected number of births being incorrect). However, in some instances there are notably fewer births and deaths recorded towards the end of the intervention period in 2010, suggesting an increase in loss-to-follow-up during this period as is also noted in Figure 21 above. Also, specific clusters like Area 18, which is urban with a more transient population and which had difficulty with Health Surveillance Assistants (supervisors of Key Informants), have recorded far fewer births than expected.

The graphs in Appendix 19 are also useful as a first step in a more detailed understanding of potential differences in effect by cluster, which may be dependent on the local dosage of the intervention and it's diffusion throughout surrounding areas. Due to time and money constraints we were not able to collected data on the location and density of Women's Groups and Task Forces (the two key components of the Community Intervention) in each cluster.

Table 2. Categorisation of death following PVA: proportion of stillbirths and neonatal deaths by RCT comparison and time period

	SB/NND categorised after PVA			
	RCT arm	**n**	**%**	**S.E. of %**
Baseline (Jun 1 2007 -	no QI	454	85%	2%
Sep 30 2008)	QI	432	81%	2%
Intervention (Oct 1	no QI	588	83%	2%
2008 - Dec 31 2010)	QI	596	82%	2%
Total (Jun 1 2007 -	no QI	1048	84%	1%
Dec 31 2010)	QI	1040	81%	1%
Baseline	no WG	451	84%	2%
	WG	435	81%	2%
Intervention	no WG	624	84%	1%
	WG	560	80%	2%
Total	no WG	1084	84%	1%
	WG	1004	80%	1%
Baseline	control	216	86%	2%
	QI	235	83%	2%
	WG	238	83%	2%
	QI+WG	197	78%	3%
Intervention	control	308	85%	2%
	QI	316	84%	2%
	WG	280	81%	2%
	QI+WG	280	79%	2%
Total	control	526	86%	2%
	QI	558	83%	2%
	WG	522	82%	2%
	QI+WG	482	78%	2%
Baseline	Total	886	83%	1%
Intervention	Total	1184	82%	1%
Total	Total	2088	82%	1%

Table 3. Follow-up and verification by district

	No follow-up		No PVA	
	mean	S.E. (mean)	mean	S.E. (mean)
Kasungu	29%	0%	15%	1%
Lilongwe	27%	0%	15%	1%
Salima	16%	0%	14%	2%
Total	25%	0%	15%	1%

4.1.2 Descriptive analyses

Here we show time trends annotated by baseline period (Jun-07 to Sep-08) and intervention period (Oct-08 to Dec-10) for each of the primary outcome measures by RCT arm. For each outcome and each comparison (FI vs. no FI; CI vs. no CI; all 4 arms) a graph with two time points only (one for baseline and one for intervention – weighted averages using cluster data) and a graph with monthly time points and a Lowess regression of the trend will be presented.

4.1.2.1 Maternal mortality graphs

Figure 25, Figure 27 and Figure 29, the baseline-intervention graphs for maternal mortality, clearly shows that MMR has gone down in all four RCT arms since the baseline period and that it appears to have gone down most in the control areas. It is interesting that MMR has also gone down in the control areas as this provides more evidence for a secular trend of decreasing MMR in Malawi (see section 4.2.2.2.3). Figure 26, Figure 28, and Figure 30, the lowess regression graphs of monthly maternal mortality data, provide more detail but confirm the trends in maternal mortality seen in the baseline-intervention graphs. None of the differences are even close to statistical significance though and we can conclude that there is no effect of either of the interventions (individually or in combination) on Maternal Mortality, as confirmed in the RCT analyses detailed below.

Given reviewers comments on the fact that, ranging between 343 and 562 maternal deaths per 100,000 the baseline maternal mortality ratio we observed (also see Table 4) is lower than previously reported MMR for Malawi (e.g. from the DHS 2004 [3, page 12], which shows an MMR of 984, or estimates from the WHO (1100)[45] or IHME (1140)[46] using modelling) we provide the following explanation as to why we think these are plausible figures and not the result of our community surveillance missing maternal deaths. This explanation is four-fold. Firstly, new modelling estimates from the WHO and UNICEF indicate that Malawi's MMR was likely to be 510 in 2008.[47] Secondly, the recent DHS 2010 [2, page 12] estimate of MMR in Malawi is 675 (showing a statistically significant decline from the 2004 DHS MMR, see section 4.2.2.2.3). Thirdly, MICS [48], another national survey, conducted in 2006 indicates that maternal mortality is higher in the southern region of Malawi (1029) than either the northern (543) or central (678) regions, meaning that given the new DHS MMR of 675 for the whole of Malawi, MMR in the central region, where our study was based, is likely to be lower, perhaps in the range we observed. Finally, unpublished data from a trial in Mchinji that UCL is also involved in, and that has a more detailed and rigorous

[45] WHO 2007. Maternal mortality in 2005 : estimates developed by WHO, UNICEF, UNFPA, and the World Bank.

[46] Hogan MC, Foreman KJ, Naghavi M, Ahn SY, Wang M, Makela SM, Lopez AD, Lozano R, Murray CJL. Maternal mortality for 181 countries, 1980–2008: a systematic analysis of progress towards Millennium Development Goal 5. Lancet. 2010 May 8; 375(9726):1609-23.

[47] WHO and UNFPA 2010 Maternal Mortality: 1990 to 2008: Estimates developed by WHO, UNICEF, UNFPA and The World Bank.

[48] National Statistical Office and UNICEF. 2008. Malawi Multiple Indicator Cluster Survey 2006, Final Report. Lilongwe, Malawi: National Statistical Office and UNICEF.

surveillance system with more checks that ours[9, page 15], shows baseline MMR for 2005-6 to be in the 400-500 range. We would like to take the opportunity here to also draw the readers attention to a forthcoming paper on trends in maternal mortality in Malawi over the last 30 years that we are involved in.

4.1.2.2 Neonatal mortality graphs

Figure 31, Figure 33, and Figure 35, the baseline-intervention graphs for neonatal mortality, are interesting as they respectively show that NMR has gone up in the no FI areas (from a higher baseline; no FI areas are CI only and control areas) and slightly down in the FI areas (FI only and FI+CI areas) from the baseline to the intervention period, and that it has gone up in the CI areas and slightly down in the no CI areas. Looking at all 4 arms (Figure 35), NMR has stayed roughly the same in the FI only and CI only areas but has gone up in the control areas and the FI+CI areas. The results of the RCT will depend on the variation in individual data within clusters as well as the variation in monthly data as detailed in Figure 32, Figure 34, and Figure 36. Figure 32, Figure 34, and Figure 36 are also interesting as they show that NMR appears to be going down in all four arms in the last 4 months, especially in the FI only arm; and that it also went up in the control arm in late 2009 and early 2010.

4.1.2.3 Perinatal mortality graphs

Figure 37 shows that the PMR has gone down in both FI areas and no-FI areas. Figure 38 shows that in both FI and no FI areas the PMR rises in the second half of 2007 and remains about the same in 2008 and 2009 both before falling slightly in 2010 with PMR falling in FI areas slightly more than no FI areas. These graphs show a lack of overall difference in PMR between FI and no FI, a fact borne out in the RCT results which are negative (see below). For CI vs. no CI, Figure 39 shows that PMR has gone down in CI areas and very slightly increased in no CI areas. Figure 40 shows that in no CI areas PMR actually increased from baseline into the intervention period, but then decreased in the last 6 months of 2010. For CI areas, PMR increases in the second half of 2007 before steadily decreasing through to the end of 2010; PMR is clearly lower throughout the whole intervention period, suggesting an effect of CI on PMR (which is confirmed in the RCT results – see below). For all 4 arms combined Figure 41 shows PMR to have dropped in the CI only arm and, less steeply, in the FI+CI arm, with the FI only arm and control arms showing increases in PMR, reflecting the conclusions from the other graphs above. Figure 42 echoes this with all the monthly variation shown, but again (like the NMR graph) shows a decline in all four arms in the last few months, which warrants further investigation as it could be a result of lack of follow-up (which is higher during these months).

Figure 25: Maternal mortality by baseline and intervention periods: FI vs. no FI

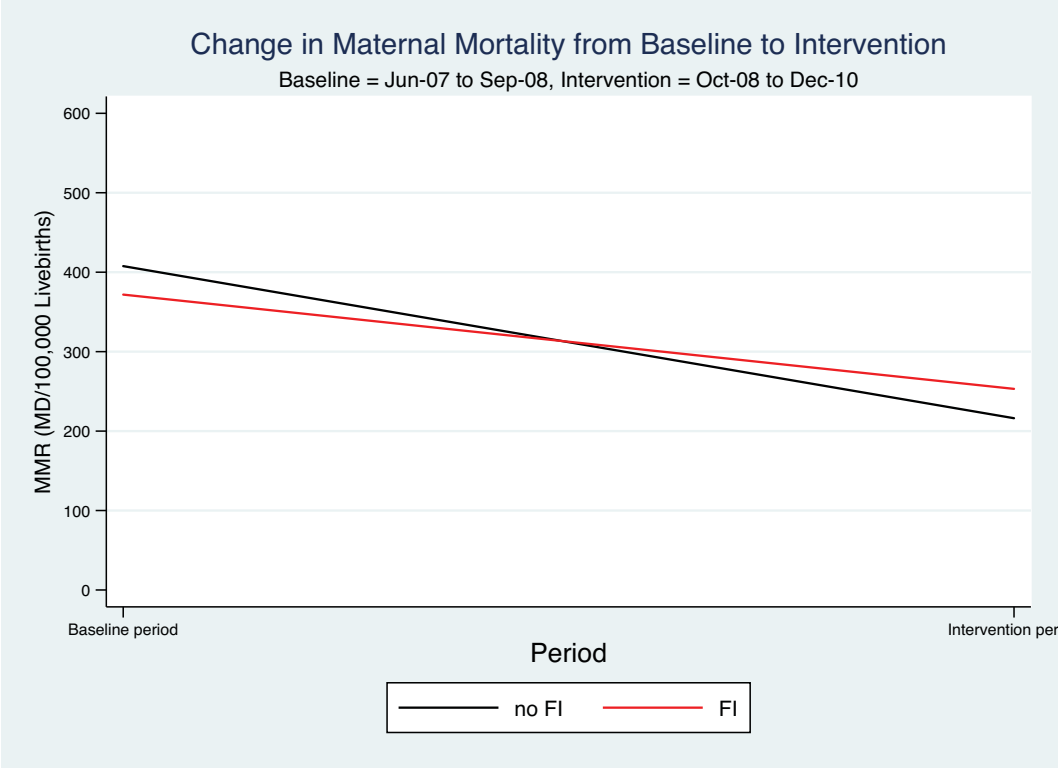


Figure 26: Maternal mortality by month: FI vs. no FI

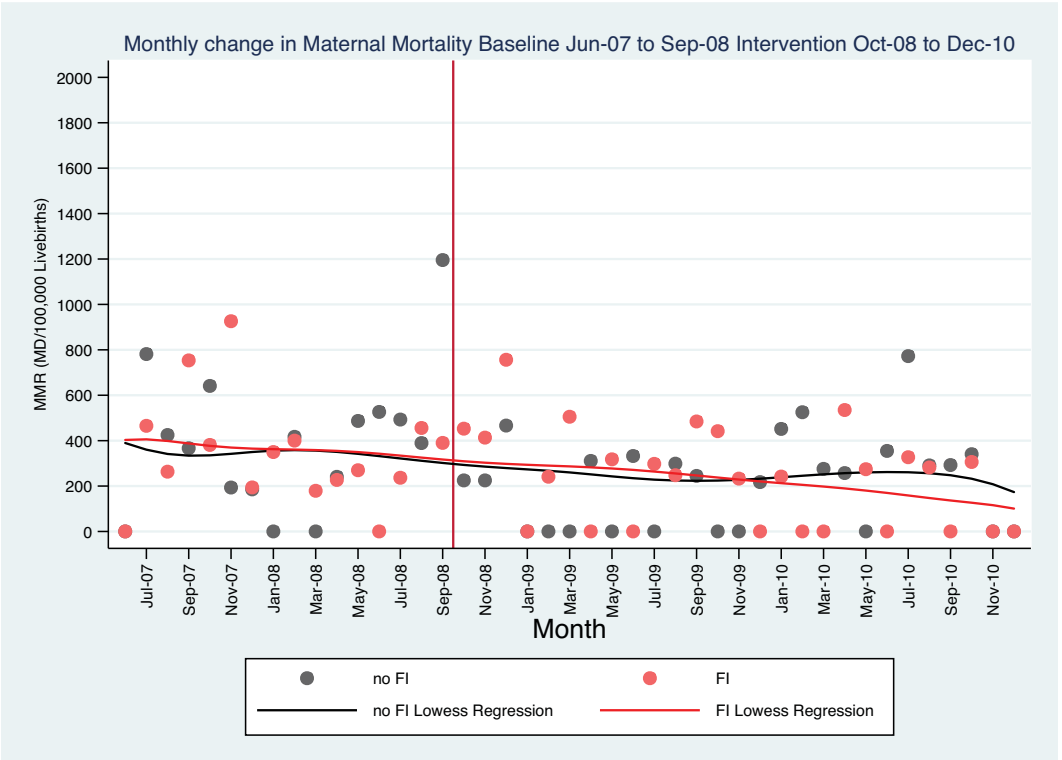


Figure 27: Maternal mortality by baseline and intervention periods: CI vs. no CI

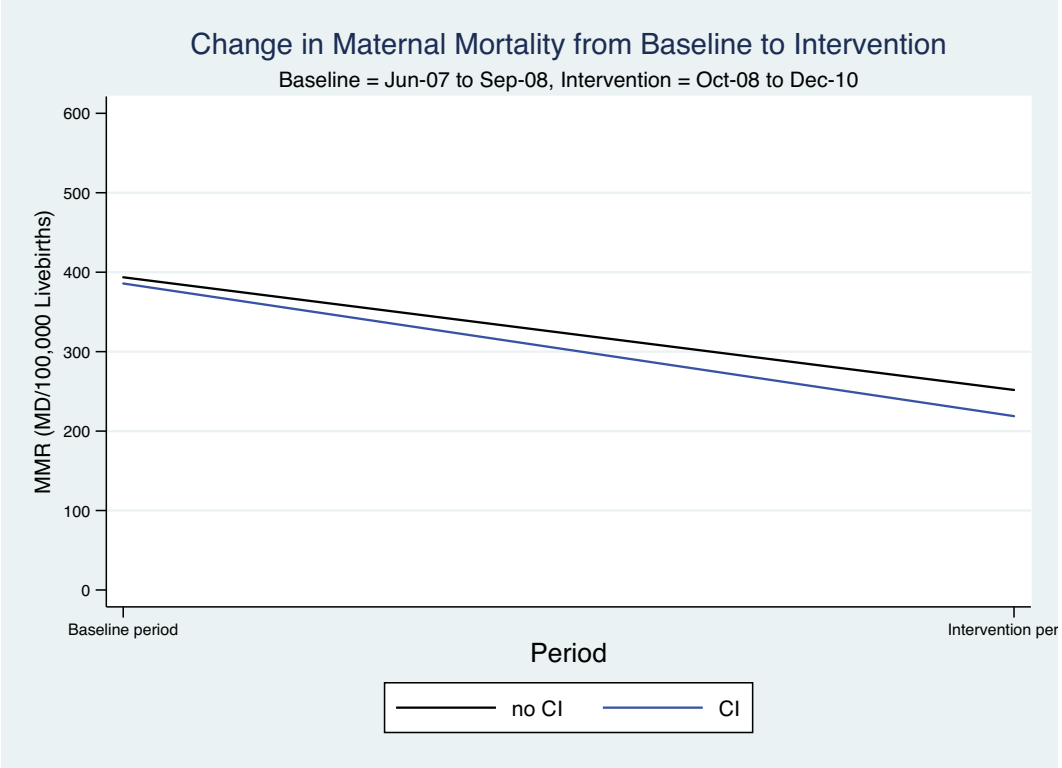


Figure 28: Maternal mortality by month: CI vs. no CI

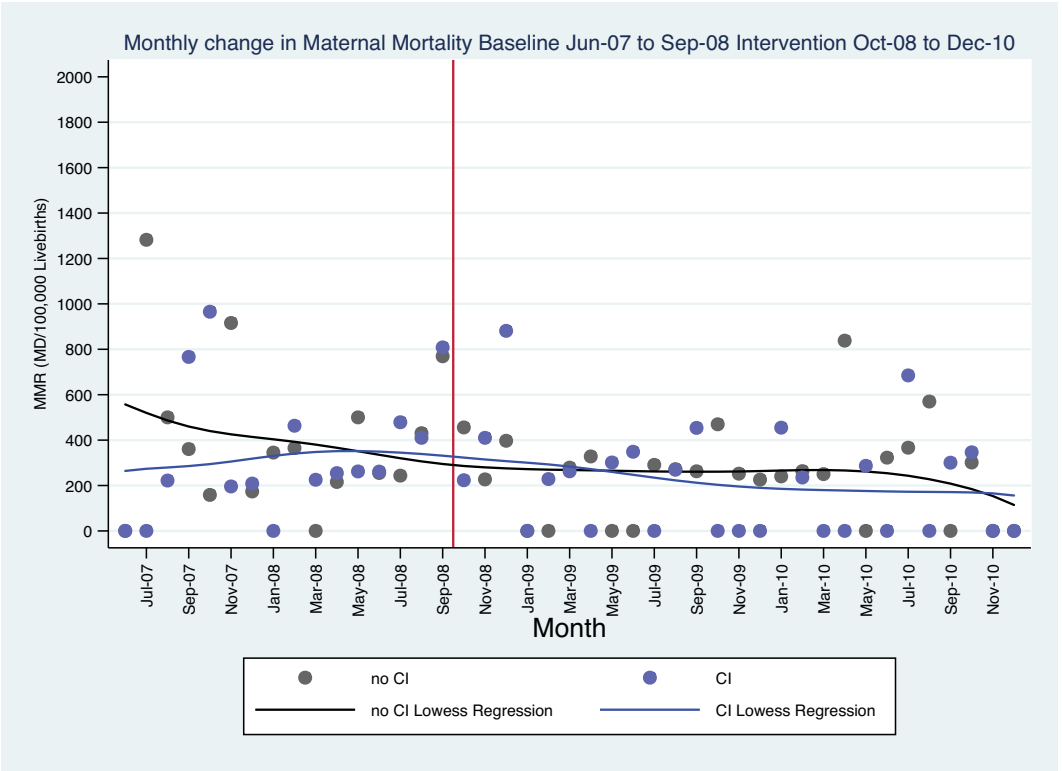


Figure 29: Maternal mortality by baseline and intervention periods: FI+CI vs. FI vs. CI vs. control

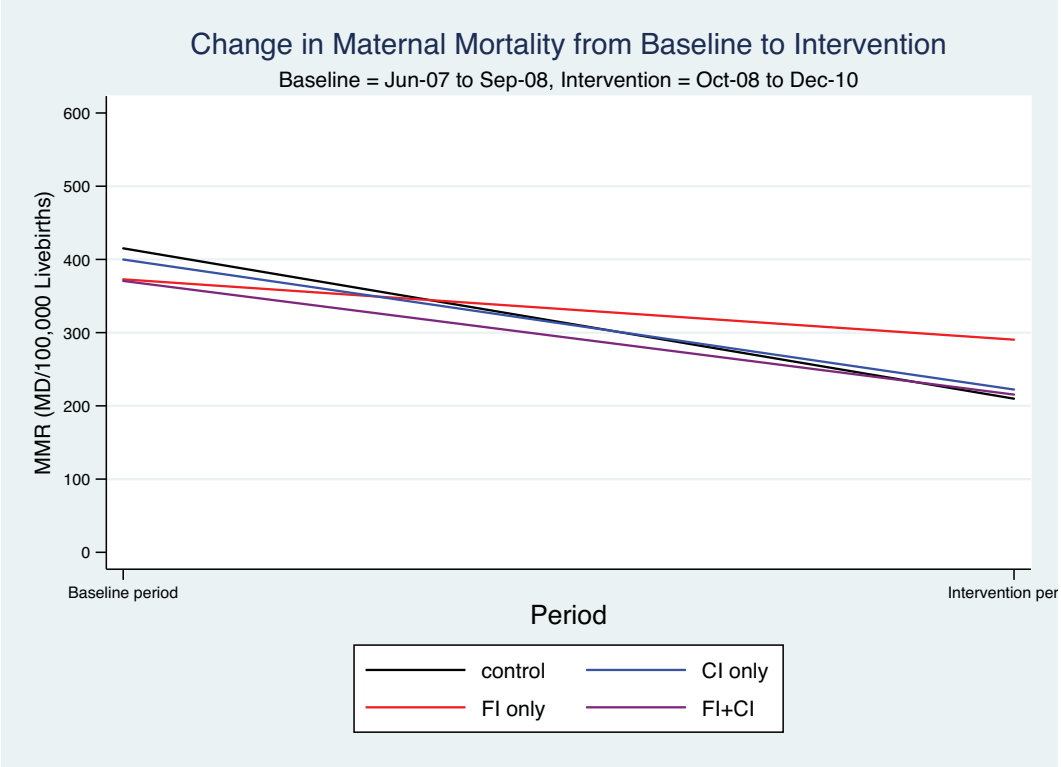


Figure 30: Maternal mortality by month: FI+CI vs. FI vs. CI vs. control

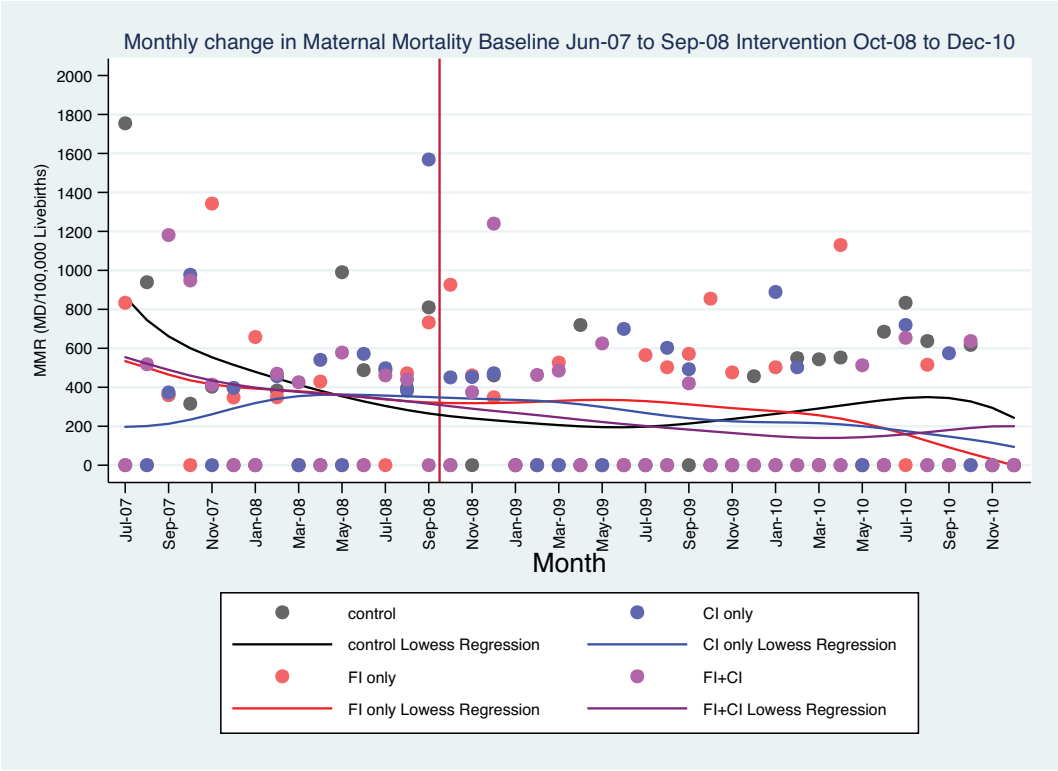


Figure 31: Neonatal mortality by baseline and intervention periods: FI vs. no FI

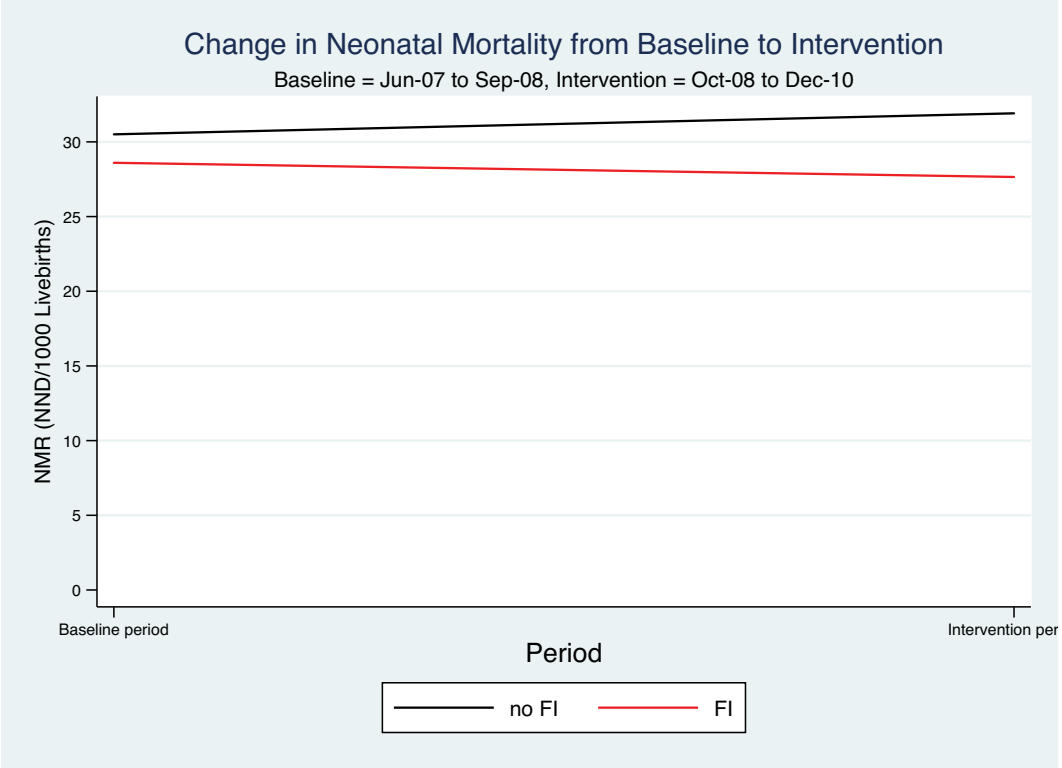


Figure 32: Neonatal mortality by month: FI vs. no FI

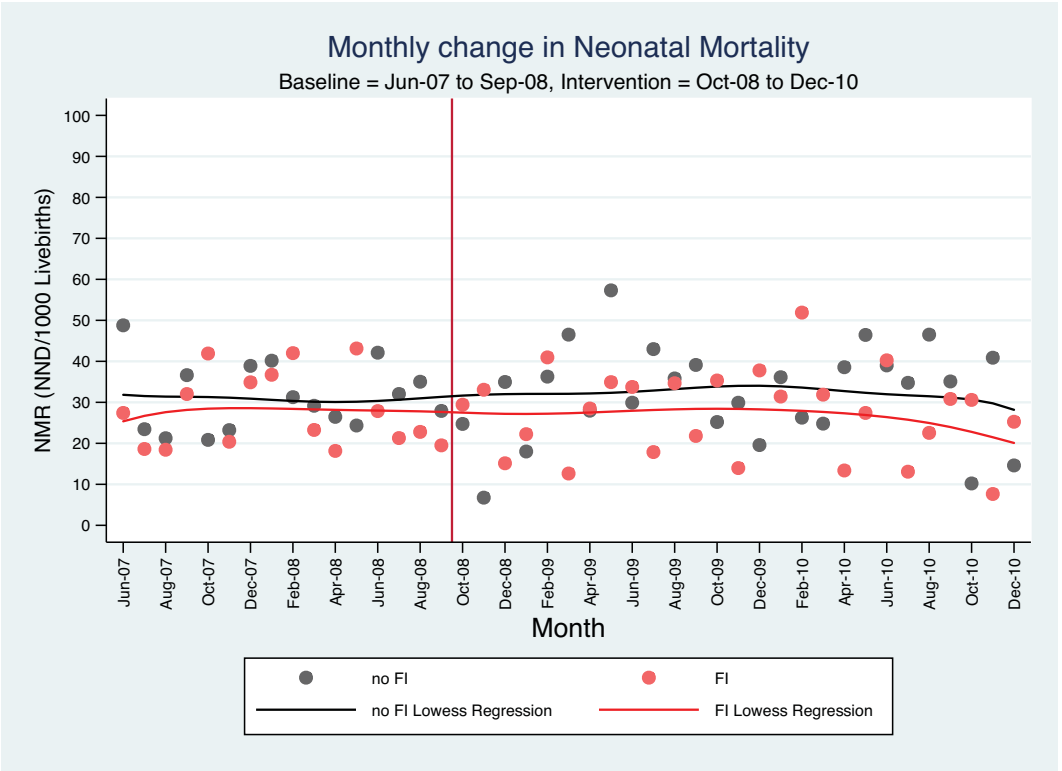


Figure 33: Neonatal mortality by baseline and intervention periods: CI vs. no CI

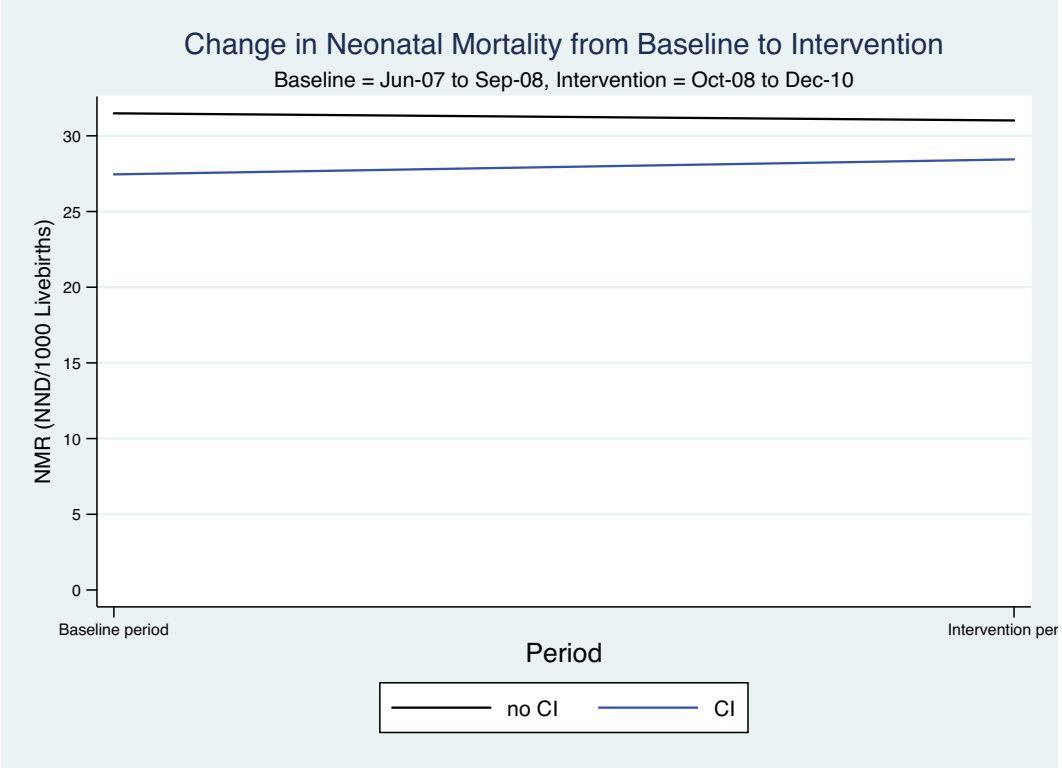


Figure 34: Neonatal mortality by month: CI vs. no CI

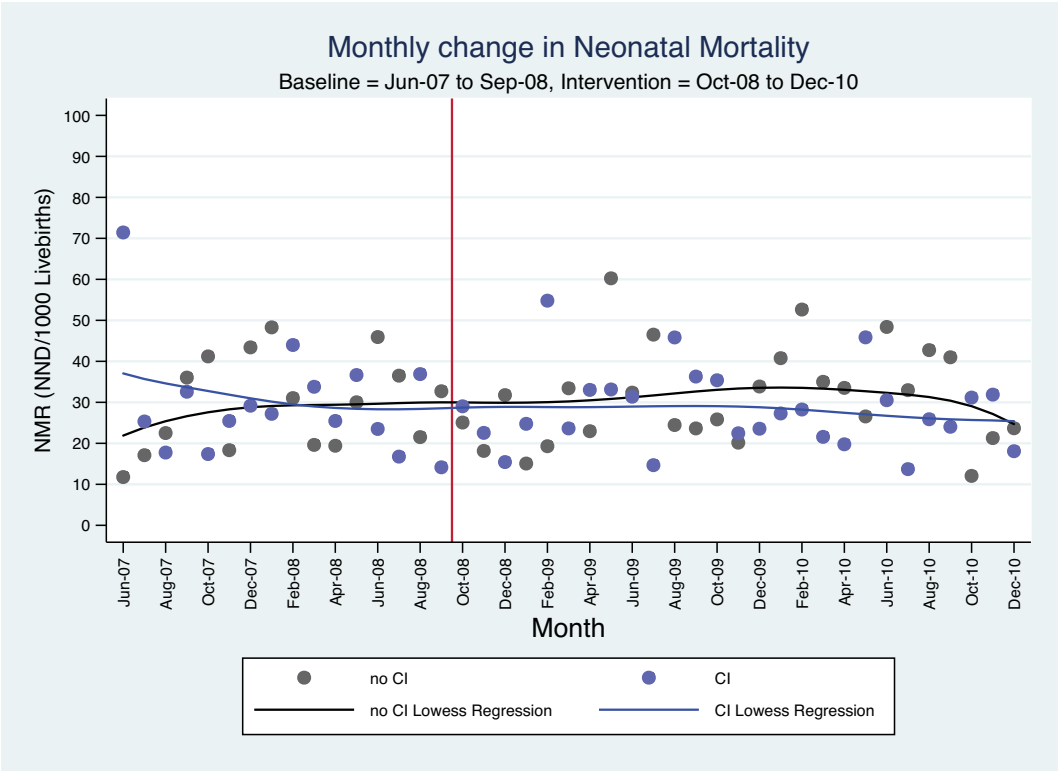


Figure 35: Neonatal mortality by baseline and intervention periods: FI+CI vs. FI vs. CI vs. control

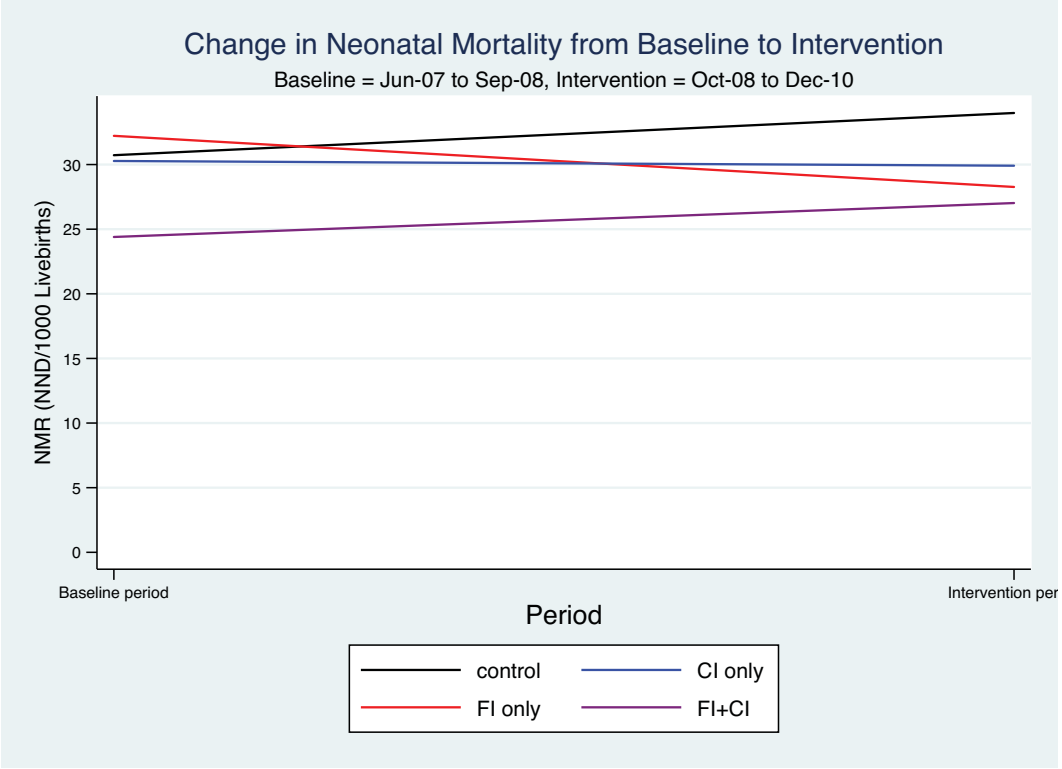


Figure 36: Neonatal mortality by month: FI+CI vs. FI vs. CI vs. control

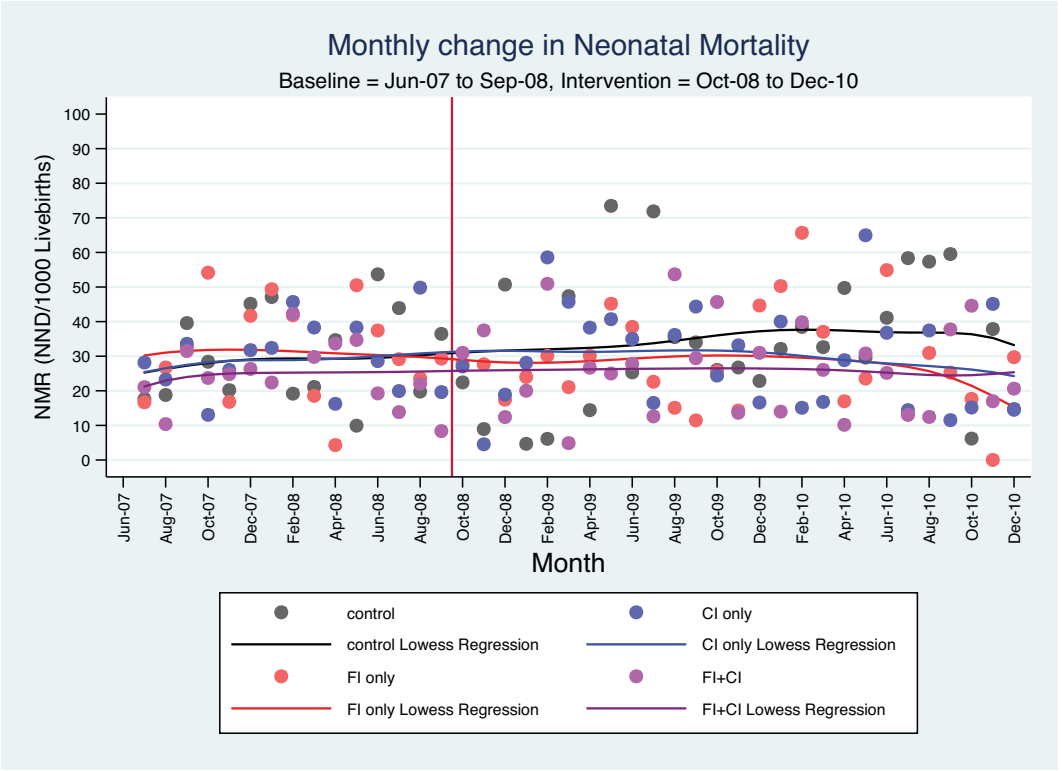


Figure 37: Perinatal mortality by baseline and intervention periods: FI vs. no FI

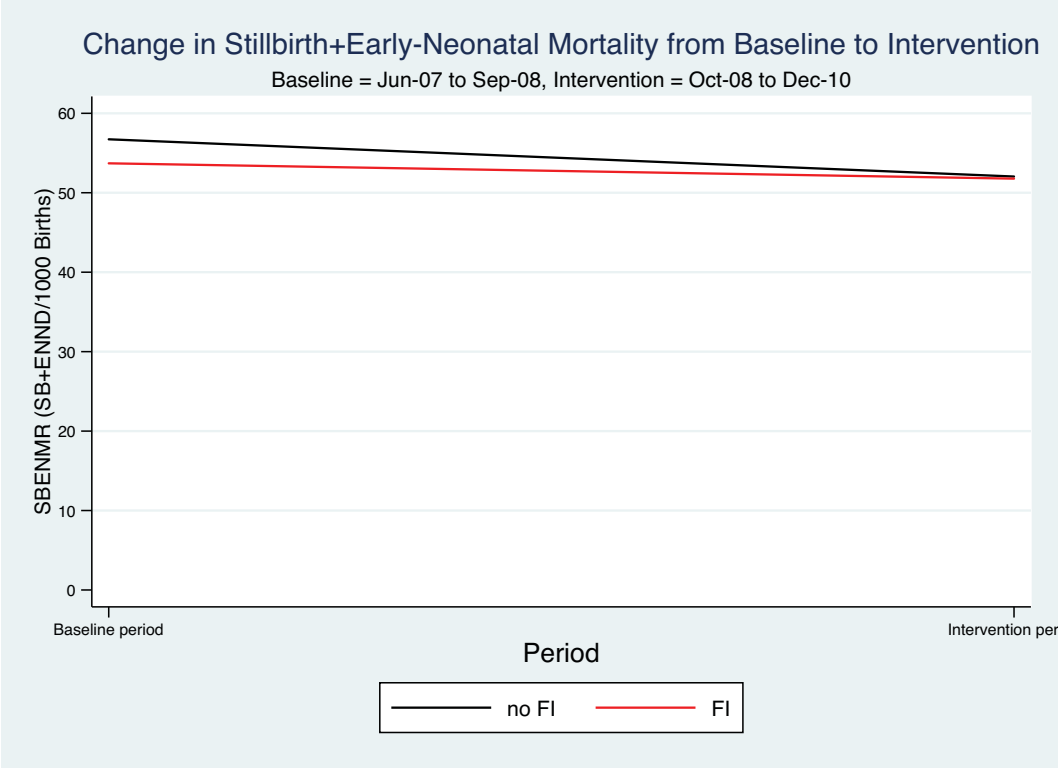


Figure 38: Perinatal mortality by month: FI vs. no FI

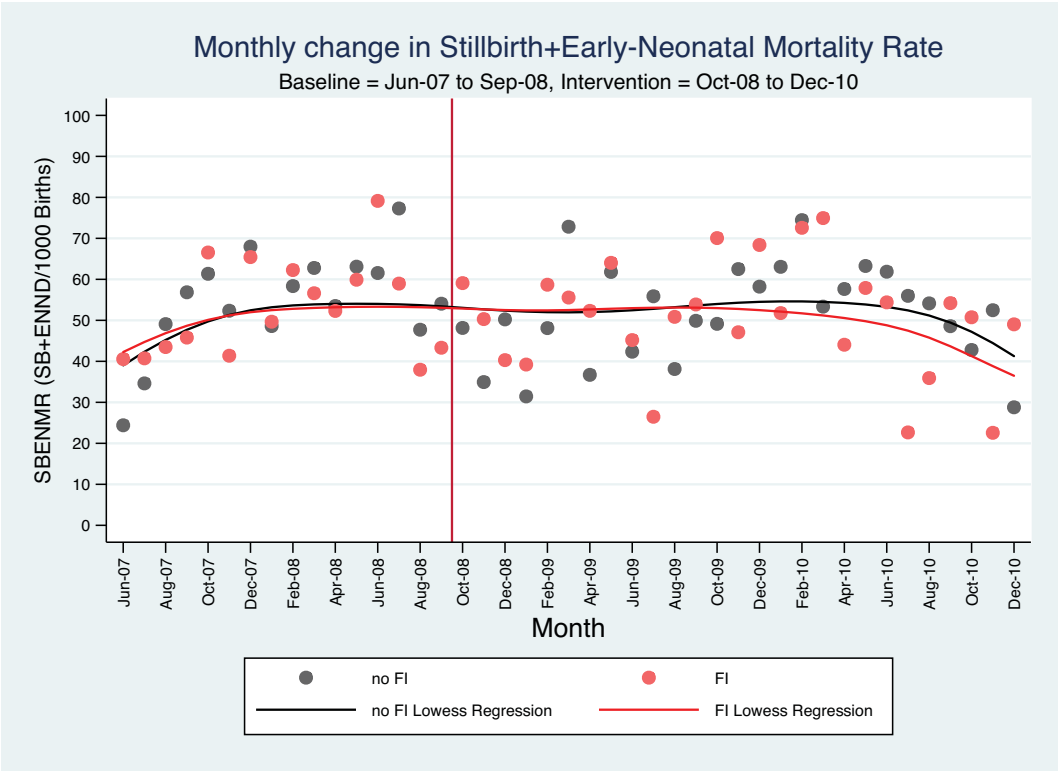


Figure 39: Perinatal mortality by baseline and intervention periods: CI vs. no CI

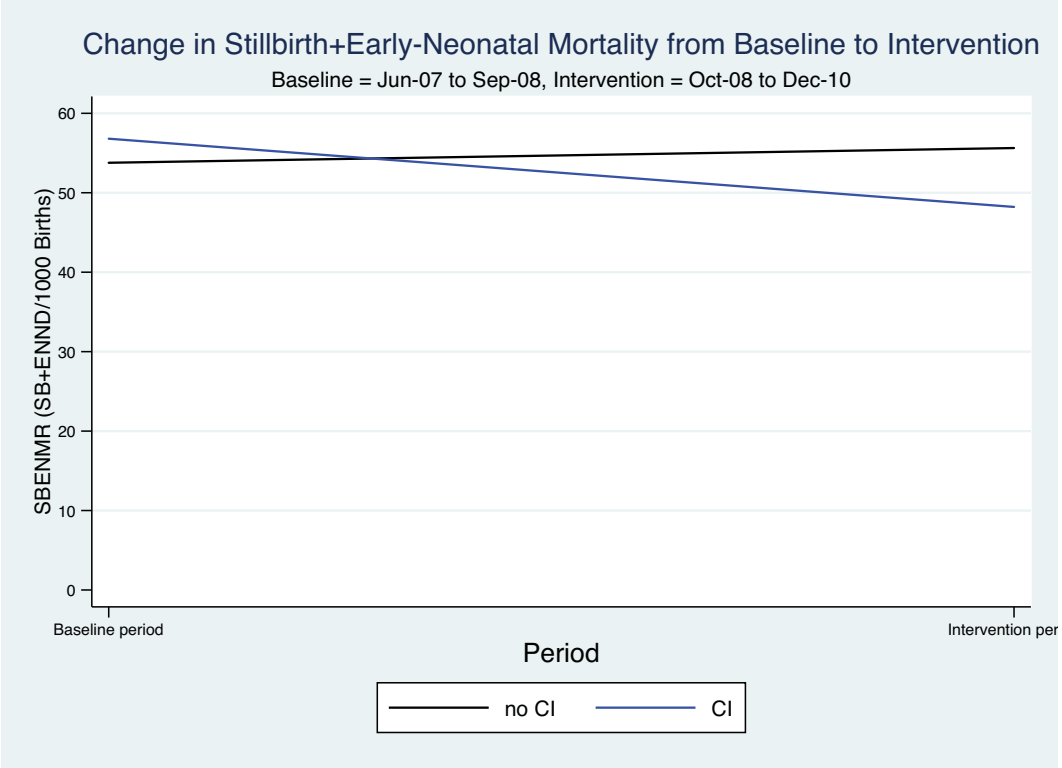


Figure 40: Perinatal mortality by month: CI vs. no CI

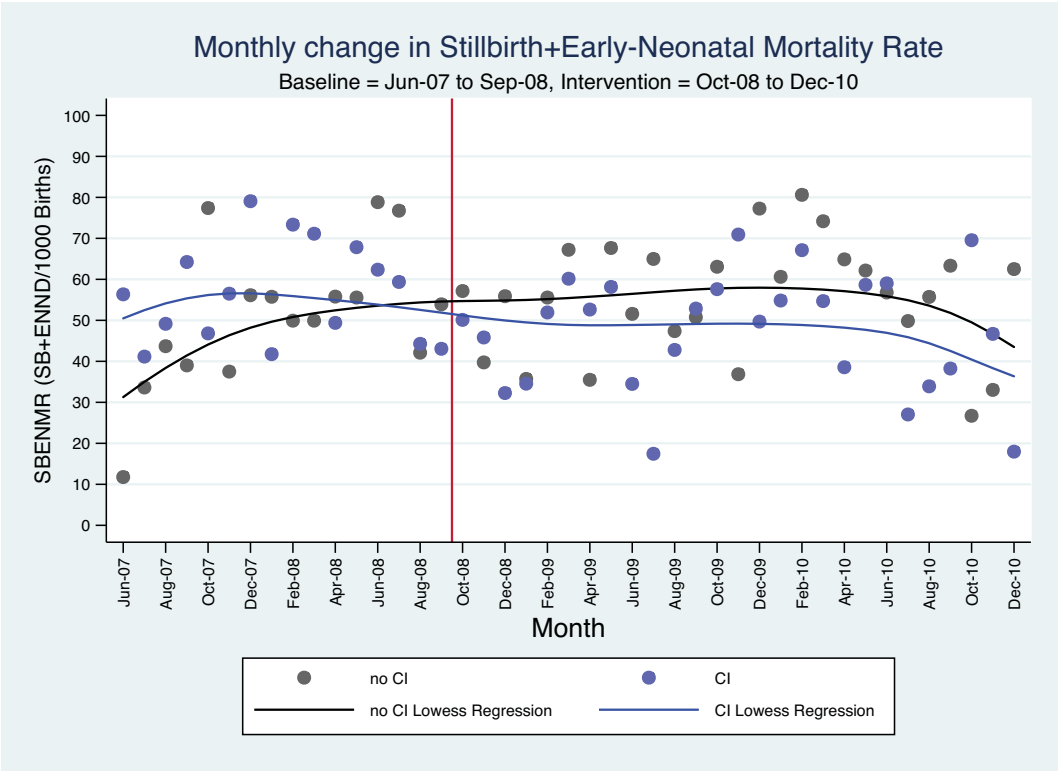


Figure 41: Perinatal mortality by baseline and intervention periods: FI+CI vs. FI vs. CI vs. control

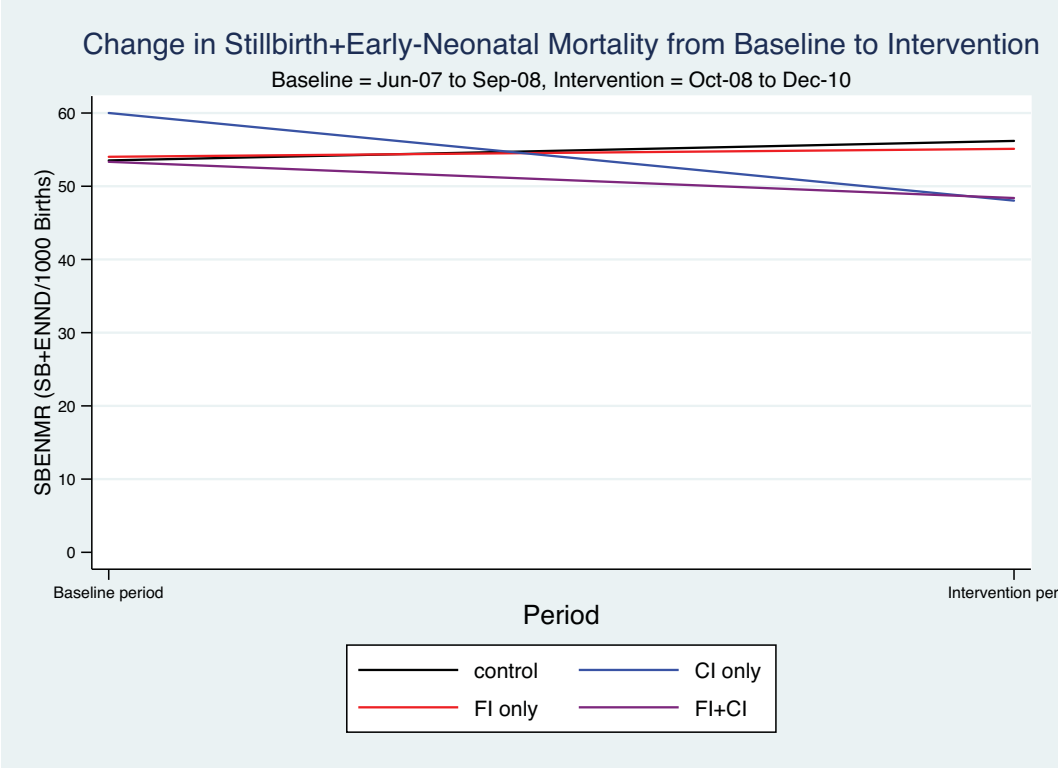
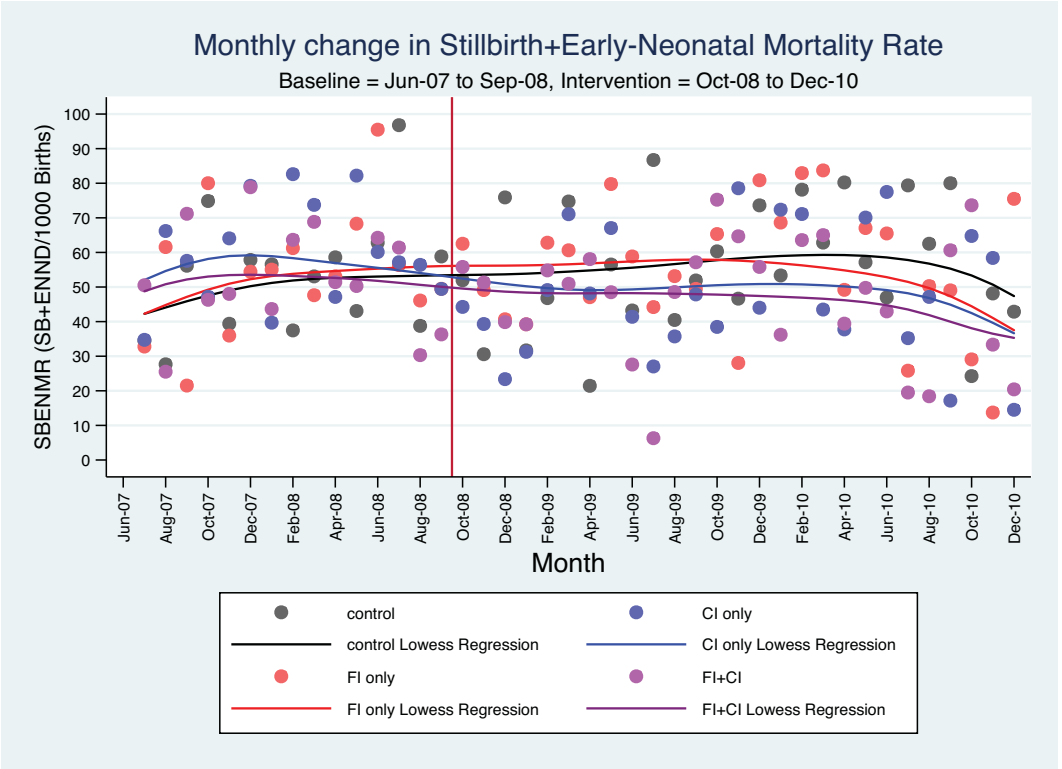


Figure 42: Perinatal mortality by month: FI+CI vs. FI vs. CI vs. control



4.1.2.4 Baseline and intervention period comparisons

The above figures of mortality by RCT arm can be used to assess whether there are large differences in mortality between the arms at baseline. Such pre-existing differences in the outcome of interest would likely bias the results and would need adjusting for in the final analysis. From the figures it is clear that the differences between the four arms are not large for any of the three outcomes (as was intended by the randomisation process). This is confirmed by Table 4, which provides the baseline figures by arm as well as their standard errors:

Table 4. Outcomes by arm at baseline

Baseline period		MMR	NMR	PMR	SBA
Control	mean	561	31.8	55.5	49.6%
	S.E. (mean)	147	4.2	5.9	4.8%
FI	mean	336	33.3	56.4	47.9%
	S.E. (mean)	104	4.1	5.2	5.6%
CI	mean	403	29.4	58.7	40.8%
	S.E. (mean)	160	2.6	7.5	3.5%
FI+CI	mean	298	24	52.9	52.2%
	S.E. (mean)	105	3.9	5.1	4.8%
Total	mean	406	29.6	55.8	47.7%
	S.E. (mean)	66	1.9	2.9	2.4%

MMR = Maternal Mortality Ratio: maternal deaths per 100,000 livebirths
NMR = Neonatal Mortality Rate: neonatal deaths per 1,000 livebirths
PMR = Perinatal Mortality Rate: perinatal deaths per 1,000 births
SBA = Skilled Birth Attendence: percentage deliveries at a health facility

Table 5 expands on this, looking at all potential confounding cluster-level variables for which we have data (see Box 3, section 2.1.11 for more details). As can be expected from the randomisation, there are not many large differences between the RCT comparison groups. It should also be borne in mind that differences in these variables between arms are only important if the variable is also associated with the outcome (intervention maternal, neonatal and perinatal mortality); in such cases, the variable is included in the adjusted model (see below).

Table 5. Balance of potential confounding variables between RCT comparison arms:

Variables[a]		no FI	FI Comments	no CI	CI Comments	control	FI	CI	FI+CI	range	Comments	Association with mortality outcomes (are differences important)
number of clusters	n	29	32 see right	29	32 see right	17	15	15	14	14 - 17	Slight imbalance - see 'Table 1: CONSORT Flowchart' for reasons	
Baseline MMR	mean[c]	487	316 see right	460	350 see right	561	336	403	298	336 - 561	Control is higher but there is a lot of uncertainty surrounding MMR due to small numbers of deaths in each arm	Yes (MMR)
	se(mean)	107	73	94	95	147	104	160	105			
Baseline NMR	mean	30.7	28.5 good balance	32.5	26.7 No CI slightly	31.8	33.3	29.4	24.0	24.0 - 33.3	FI+CI is lower than the others - but is the difference large enough to be important? (some of this difference could be due to less verification in FI+CI areas)	Yes (PMR)
	se(mean)	2.5	2.9	2.91	2.36 higher	4.2	4.1	2.6	3.9			
Baseline PMR	mean	57.0	54.6 No FI slightly	55.9	55.8 No CI slightly	55.5	56.4	58.7	52.9	52.9 - 58.7	FI+CI is lower than the others - but is the difference large enough to be important? (some of this difference could be due to less verification in FI+CI areas)	Yes (PMR)
	se(mean)	4.6	3.6 higher	3.9	4.5 higher	5.9	5.2	7.5	5.1			
Baseline Skilled Birth Attendance (%)	mean	45.5%	50.1% FI slightly	48.8%	46.5% good balance	49.6%	47.9%	40.8%	52.2%	40.8% - 52.2%	CI only is lower than the others - but is the difference large enough to be important?	No
	se(mean)	3.1%	3.6% higher	3.6%	3.1%	4.8%	5.6%	3.5%	4.8%			
Deliveries per month per nurse at nearest HC	mean	21.2	25.2 good balance	22.9	23.4 good balance	21.4	24.8	21.0	25.6	21.4 - 25.6	Good balance	No
	se(mean)	2.6	2.6	2.1	3.0	3.0	3.1	4.5	4.2			
Signal Function availability at HC (number of functions)	mean	1.66	1.81 Good balance	1.85	1.59 Good balance	1.72	2.04	1.58	1.59	1.58 - 2.04	Good balance	Yes (MMR)
	se(mean)	0.24	0.28	0.2	0.3	0.25	0.35	0.43	0.43			
Baseline staff psychology score (average of 19 questions on 1(=bad) - 5(=good) scale)	mean	2.40	2.46 Good balance	2.31	2.53 Good balance	2.29	2.35	2.52	2.54	2.29 - 2.54	Good balance	Yes (PMR)
	se(mean)	0.07	0.07	0.08	0.06	0.09	0.16	0.10	0.06			
Urban (=1), Peri-urban (=0.5), Rural (=0) setting	mean	0.16	0.19 Good balance	0.23	0.12 no CI slightly	0.18	0.29	0.13	0.10	0.10 - 0.29	FI slightly higher	Yes (MMR, PMR)
	se(mean)	0.06	0.06	0.07	0.05 higher	0.1	0.11	0.08	0.05			
Access by Tar Road (=1) or dirt road (=0)	mean	0.41	0.45 Good balance	0.39	0.47 Good balance	0.35	0.43	0.47	0.47	0.35 - 0.47	Control is lower than the others - but is the difference large enough to be important?	Yes (NMR)
	se(mean)	0.09	0.09	0.09	0.09	0.12	0.14	0.13	0.13			
Government (=1) or CHAM (=0) run	mean	0.22	0.14 No FI slightly	0.19	0.17 Good balance	0.18	0.21	0.27	0.07	0.07 - 0.27	FI+CI is lower than the others and CI is higher than the others- but are the difference large enough to be important?	No
	se(mean)	0.07	0.07 higher	0.07	0.07	0.1	0.11	0.12	0.07			
Tobacco Estates (=1) or not (=0)	mean	0.16	0.21 Good balance	0.16	0.20	0.18	0.14	0.13	0.27	0.13 - 0.27	Only in Kasungu; FI+CI is higher than the rest - but is the difference large enough to be important?	No
	se(mean)	0.07	0.08	0.07	0.07	0.1	0.10	0.09	0.12			

[a] Please note that no other data on characteristics of women (like tribe, age, socio-economic status, or parity) was collected due to the simple and low-cost nature of the community surveillance system

[b] Differences are not tested for statistical significance as, given the randomisation process, the null hypothesis of no difference is already true, and any significant differences that were found would be due to chance.

[c] Mean of cluster rates or ratios - applies to all variables. Table 12 contains the overall rates or ratios for each study arm or group of two arms

Table 6 provides the same information for the intervention period and is useful as it gives an indication of the likely effect (or lack of) of each of the interventions relative to the control, which will be explored below. However, unlike Figures 25-41 (odd), which present overall mortality rates, Table 6 (and Tables 7 and 8) presents average cluster-level mortality rates. Table 7 and Table 8, for FI vs. no FI at baseline and intervention and CI vs. no CI at baseline and intervention respectively, are also useful in giving an indication of the likely results.

Table 6. Outcomes by arm at intervention

Intervention period		MMR	NMR	PMR	SBA
Control	mean	334	33.1	57.1	67.0%
	S.E. (mean)	169	3.1	3.9	3.6%
FI	mean	272	27.9	54.1	66.5%
	S.E. (mean)	66	2.7	4.9	4.0%
CI	mean	185	30.3	46.1	58.0%
	S.E. (mean)	59	3.7	3.6	4.3%
FI+CI	mean	208	28.0	48.5	69.8%
	S.E. (mean)	70	2.4	4.1	3.7%
Total	mean	252	29.9	51.6	65.4%
	S.E. (mean)	54	1.5	2.1	2.0%

MMR = Maternal Mortality Ratio: maternal deaths per 100,000 livebirths
NMR = Neonatal Mortality Rate: neonatal deaths per 1,000 livebirths
PMR = Perinatal Mortality Rate: perinatal deaths per 1,000 births
SBA = Skilled Birth Attendence: percentage deliveries at a health facility

Table 7. Mortality outcomes at baseline and intervention for FI vs. no FI

Baseline period		MMR	NMR	PMR	SBA
No FI	mean	487	30.7	57.0	45.5%
	S.E. (mean)	107	2.5	4.6	3.1%
FI	mean	316	28.5	54.6	50.1%
	S.E. (mean)	73	2.9	3.6	3.6%
Total	mean	406	29.6	55.8	47.7%
	S.E. (mean)	66	1.9	2.9	2.4%
Intervention period					
No FI	mean	264	31.8	51.9	62.8%
	S.E. (mean)	93	2.4	2.8	2.9%
FI	mean	239	27.9	51.2	68.2%
	S.E. (mean)	48	1.8	3.2	2.7%
Total	mean	252	29.9	51.6	65.4%
	S.E. (mean)	54	1.5	2.1	2.0%

MMR = Maternal Mortality Ratio: maternal deaths per 100,000 livebirths
NMR = Neonatal Mortality Rate: neonatal deaths per 1,000 livebirths
PMR = Perinatal Mortality Rate: perinatal deaths per 1,000 births
SBA = Skilled Birth Attendence: percentage deliveries at a health facility

Table 8. Mortality outcomes at baseline and intervention for CI vs. no CI

Baseline period		MMR	NMR	PMR	SBA
No CI	mean	460	32.5	55.9	48.8%
	S.E. (mean)	94	2.9	3.9	3.6%
CI	mean	350	26.7	55.8	46.5%
	S.E. (mean)	95	2.4	4.5	3.1%
Total	mean	406	29.6	55.8	47.7%
	S.E. (mean)	66	1.9	2.9	2.4%
Intervention period					
No CI	mean	306	30.7	55.7	66.8%
	S.E. (mean)	96	2.1	3.0	2.6%
CI	mean	197	29.1	47.3	63.9%
	S.E. (mean)	45	2.2	2.7	3.0%
Total	mean	252	29.9	51.6	65.4%
	S.E. (mean)	54	1.5	2.1	2.0%

MMR = Maternal Mortality Ratio: maternal deaths per 100,000 livebirths
NMR = Neonatal Mortality Rate: neonatal deaths per 1,000 livebirths
PMR = Perinatal Mortality Rate: perinatal deaths per 1,000 births
SBA = Skilled Birth Attendence: percentage deliveries at a health facility

4.1.3 Cluster-level analyses

Here we present cluster-level analyses of intervention effects on NMR, MMR and PMR by Weighted T-Test. The cluster-level dataset was set up for analyses weighted by cluster size (number of births, the variable **hf** represents cluster) and for stratification by district[49] using the svyset command in Stata: **svyset hf [pweight=births], strata(strata)**.

The results of the weighted T-tests for FI vs. no FI; CI vs. no CI; and, FI+CI vs. FI only vs. CI only vs. control, are shown in Table 9. Please note that the factorial nature of the trial (FI in the presence of CI and vice versa) is not taken into account in these analyses, but is in the individual level analyses below. The commands used for the weighted T-test are of the form **svy: mean int_mmr, over(fi)** followed by **lincom [int_mmr]FI - [int_mmr]NoFI** to determine the mean difference in mortality rates and whether this difference is statistically significant.

The unadjusted analyses are presented in the first column of Table 9. An assessment of which baseline variables were correlated with the mortality outcomes during the intervention period at cluster level was done, following which models to estimate intervention effects adjusted for such potential confounders/effect modifiers (see Box 3) were built (details available from the authors). Model building strategies for the inclusion of multiple confounding variables vary. The strategy used here is that recommended by Hosmer and Lemeshow,[50] which is not favoured by Kirkwood and Sterne.[51] The results of the adjusted analyses are presented in the second column of Table 9.

[49] Although the randomisation was stratified by urban/rural as well as by district, this was not included in the survey set-up of the cluster-level data as Stata only allows stratification by one variable and the effect of the stratification of the three urban HC (2 control and one FI only) is unimportant (for example including i.urb as a variable in the regression models of the individual data did not change the results much at all).

[50] Hosmer DW, Lemeshow S. Applied Logistic Regression. New York: Wiley Series in Probability and Statistics. John Wiley & Sons, Inc.; 2000.

[51] Kirkwood B, Sterne J. Essential Medical Statistics. Wiley-Blackwell. 2003.

From Table 9, it is apparent that neither of the interventions has had any effect on Maternal Mortality; that there is little evidence for a slight trend towards an effect of the facility interventions on Neonatal Mortality (reducing mortality by 4.3 neonatal deaths per 1000, p=0.126), but an effect of both FI+CI combined on NMR (reducing mortality by 6.9 neonatal deaths per 1000 (95%CI: 13.8, 0.1), p=0.050); and, that there appears to be an effect of CI on Perinatal Mortality (reducing mortality by 7.2 perinatal deaths per 1000 (95%CI: 14.5, 0.1), p=0.054). The adjusted analyses tell a similar story apart from the fact that the combined FI+CI effect on NMR becomes less significant at p=0.126 (reduction of 5.4 neonatal deaths per 1000), and the effect of CI on PMR is slightly increased to a reduction of 7.7 perinatal deaths per 1000 (p=0.033).

Because these cluster-level results are not taking account of the factorial nature of the trial and they are also less accurate than the individual level analyses that take account of all of the variation in the data, the individual-level analyses presented below are the results of choice.

4.1.4 Individual-level analyses

Finally, in this section we present the results of individual-level analyses of intervention effects on NMR, MMR and PMR by logistic regression with stratum included as a covariate and adjustments for cluster baseline mortality and other potential confounding variables if necessary.

Logistic Regression assessing the effect (Odds Ratio, OR; see preface) of the intervention on the mortality outcome accounting for the effects of district (strata) and stratification of three urban HC (urb) and clustering by health facility catchment area with random effects was conducted using Stata's xtlogit command e.g. for the effect of both FI arms and both CI arms in the presences of each other (2x2 factorial design) on NMR: **xi: xtlogit nnd i.fi i.ci i.strata i.urb, or re i(hf)**. The following table summarises the results for maternal, neonatal and perinatal mortality by FI vs. no FI; CI vs. no CI; FI vs. CI. vs. FI+CI vs. control; FI vs. no FI and CI vs. no CI in the presence of the other intervention (2*2 factorial design); and, FI vs. no FI and CI vs. no CI in the presence of the other intervention (2*2 factorial design) with an interaction term to assess the synergy between the two (whether their effects are different with the other than without).[52]

First unadjusted analyses are presented in Table 10 (first column) and then adjusted analyses. The adjusted analyses include the variables (from those in Box 3, section 2.1.11) found to be significantly associated with the outcomes / improve the fit of the model significantly (as determined by likelihood ratio tests) in individual level logistic regressions with random effects by cluster also including stratification by district and the three urban HC (i.e. the final form of the model for analysis just excluding the intervention variable; see Appendix 20). Please note that the adjusted analyses could be altered depending on the model building strategy chosen for the possible inclusion of multiple confounding variables (currently each single potentially confounding variable was tested individually and no combinations have been tested). A comparison with the relevant p-values from the cluster-level analysis is provided in the final column (the broad similarity of the two sets of results should be noted).

From Table 10 it is apparent that there is a weak trends towards a weak effect on Neonatal Mortality of the Facilities Intervention (Odds Ratio=0.86 (95%CI: 0.72, 1.03; p=0.109), highlighted here because of an interim analyses showing a stronger trend). More strikingly, as the effect is larger and statistically significant, there appears to be an effect of both the interventions combined on NMR (Odds Ratio=0.78 (95%CI: 0.60, 1.01; p=0.057). Adjusting for the HC being accessible by tarmac road (baseline cluster NMR or skilled birth attendance

[52] The tests of interaction effects are under-powered for all outcomes and for all four arms are underpowered for maternal (see methods).

Table 9. Results of cluster-level analysis of RCT data

Unadjusted Analyses			95% Confidence Interval		
MMR		Mean	lower 95%	upper 95%	p-value sig.[a]
FI vs. no FI	no FI	226	127	325	
	FI	258	161	356	
	difference	32	-109	174	0.647 ns
CI vs. no CI	no CI	264	157	371	
	CI	220	132	309	
	difference	-43	-184	97	0.540 ns
FI vs. CI vs. FI+CI vs. control	control	227	69	385	
	FI	298	164	433	
	CI	225	116	334	
	FI+CI	216	76	357	
	difference FI	71	-132	275	0.486 ns
	difference CI	-2	-187	183	0.984 ns
	difference FI+CI	-11	-225	202	0.917 ns
NMR		Mean	lower 95%	upper 95%	p-value sig.[a]
FI vs. no FI	no FI	31.8	27.2	36.4	
	FI	27.5	24.2	30.8	
	difference	-4.3	-9.9	1.3	0.126 ns
CI vs. no CI	no CI	30.8	26.8	34.9	
	CI	28.4	24.3	32.4	
	difference	-2.4	-8.2	3.3	0.399 ns
FI vs. CI vs. FI+CI vs. control	control	33.8	28.1	39.6	
	FI	28.0	22.8	33.2	
	CI	29.8	22.9	36.8	
	FI+CI	26.9	23.0	30.8	
	difference FI	-5.8	-13.5	1.8	0.133 ns
	difference CI	-4.0	-13.1	5.0	0.376 ns
	difference FI+CI	-6.9	-13.8	-0.1	0.050 *
PMR		Mean	lower 95%	upper 95%	p-value sig.[a]
FI vs. no FI	no FI	52.1	47.8	56.4	
	FI	51.6	45.5	57.8	
	difference	-0.5	-8.0	7.0	0.895 ns
CI vs. no CI	no CI	55.4	49.9	61.0	
	CI	48.2	43.4	53.1	
	difference	-7.2	-14.5	0.1	0.054 ns
FI vs. CI vs. FI+CI vs. control	control	56.1	50.1	62.1	
	FI	54.7	45.7	63.8	
	CI	48.2	42.1	54.3	
	FI+CI	48.3	40.5	56.0	
	difference FI	-1.3	-12.0	9.3	0.801 ns
	difference CI	-7.9	-16.5	0.6	0.068 ns
	difference FI+CI	-7.8	-17.7	2.0	0.117 ns

[a] ns=not significant=p>0.05 *=p<0.05 **=p<0.01 ***=p<0.001

Adjusted Analyses (covariates[b])			95% Confidence Interval		
MMR (b_mmr, b_sbar)		Mean (residual)	lower 95%	upper 95%	p-value sig.[a]
FI vs. no FI	no FI	-10	-125	161	
	FI	8	-79	96	
	difference	18	-125	161	0.803 ns
CI vs. no CI	no CI	15	-86	115	
	CI	-16	-120	88	
	difference	-31	-177	115	0.674 ns
FI vs. CI vs. FI+CI vs. control	control	-28	-205	150	
	FI	54	-33	141	
	CI	8	-135	152	
	FI+CI	-41	-188	107	
	difference FI	82	-108	272	0.393 ns
	difference CI	36	-191	263	0.753 ns
	difference FI+CI	-13	-247	220	0.909 ns
NMR (tarmac)		Mean (residual)	lower 95%	upper 95%	p-value sig.[a]
FI vs. no FI	no FI	1.4	-2.9	5.8	
	FI	-2.2	-5.6	1.3	
	difference	-3.6	-9.1	1.9	0.196 ns
CI vs. no CI	no CI	0.4	-3.6	4.5	
	CI	-1.2	-5.2	2.7	
	difference	-1.7	-7.3	3.9	0.551 ns
FI vs. CI vs. FI+CI vs. control	control	2.8	-3.0	8.6	
	FI	-1.7	-7.2	3.7	
	CI	0.1	-6.5	6.7	
	FI+CI	-2.6	-6.6	1.4	
	difference FI	-4.5	-12.4	3.4	0.256 ns
	difference CI	-2.7	-11.4	6.1	0.547 ns
	difference FI+CI	-5.4	-12.4	1.6	0.126 ns
PMR (b_pmr)		Mean (residual)	lower 95%	upper 95%	p-value sig.[a]
FI vs. no FI	no FI	0.4	-3.7	4.6	
	FI	0.4	-5.6	6.4	
	difference	0.0	-7.3	7.3	0.995 ns
CI vs. no CI	no CI	4.2	-1.1	9.6	
	CI	-3.5	-8.1	1.1	
	difference	-7.7	-14.7	-0.7	0.033 *
FI vs. CI vs. FI+CI vs. control	control	5.1	-0.6	10.7	
	FI	3.4	-5.3	12.2	
	CI	-4.1	-9.6	1.4	
	FI+CI	-2.8	-10.3	4.7	
	difference FI	-1.6	-11.9	8.6	0.752 ns
	difference CI	-9.2	-17.0	-1.4	0.021 *
	difference FI+CI	-7.9	-17.4	1.7	0.105 ns

[b] b_mmr = cluster baseline MMR; i.urban2 = cluster rural/peri-urban/urban location; b_sbar = baseline skilled birth attendance (health facility delivery); tarmac = local health facility is accessible by tarmac road; b_pmr = cluster baseline PMR

Table 10. Results of individual-level analysis of RCT data

Logistic Regression of individual data, with random effects by cluster

Unadjusted Analyses			95% Confidence Interval				Cluster-level weighted T-Test p-value
MMR		Odds Ratio	lower 95%	upper 95%	p-value	sig.[a]	
FI vs. no FI	FI	1.19	0.67	2.11	0.564	ns	0.647
CI vs. no CI	CI	0.91	0.51	1.62	0.741	ns	0.540
FI vs. CI vs. FI+CI vs. control	FI	1.36	0.61	3.03	0.454	ns	0.486
	CI	1.07	0.45	2.54	0.876	ns	0.984
	FI+CI	1.08	0.46	2.57	0.854	ns	0.917
FI vs. no FI and CI vs. no CI (factorial)	FI	1.18	0.66	2.11	0.570	ns	
	CI	0.91	0.51	1.63	0.754	ns	
FI vs. no FI and CI vs. no CI and FI x CI (factorial with interaction)	FI	1.36	0.61	3.03	0.454	ns	
	CI	1.07	0.45	2.54	0.876	ns	
	FI x CI	0.75	0.23	2.38	0.619	ns	
NMR		Odds Ratio	lower 95%	upper 95%	p-value	sig.[a]	
FI vs. no FI	FI	0.86	0.72	1.03	0.109	ns	0.126
CI vs. no CI	CI	0.90	0.75	1.09	0.297	ns	0.399
FI vs. CI vs. FI+CI vs. control	FI	0.82	0.64	1.06	0.131	ns	0.133
	CI	0.86	0.67	1.12	0.262	ns	0.376
	FI+CI	0.78	0.60	1.01	0.057	ns	0.050
FI vs. no FI and CI vs. no CI (factorial)	FI	0.86	0.72	1.03	0.103	ns	
	CI	0.90	0.75	1.09	0.279	ns	
FI vs. no FI and CI vs. no CI and FI x CI (factorial with interaction)	FI	0.82	0.64	1.06	0.131	ns	
	CI	0.86	0.67	1.12	0.262	ns	
	FI x CI	1.10	0.76	1.58	0.623	ns	
PMR		Odds Ratio	lower 95%	upper 95%	p-value	sig.[a]	
FI vs. no FI	FI	0.99	0.85	1.15	0.882	ns	0.895
CI vs. no CI	CI	0.84	0.72	0.97	0.020	*	0.054
FI vs. CI vs. FI+CI vs. control	FI	0.96	0.78	1.18	0.695	ns	0.801
	CI	0.81	0.65	1.00	0.055	ns	0.068
	FI+CI	0.83	0.67	1.02	0.079	ns	0.117
FI vs. no FI and CI vs. no CI (factorial)	FI	0.99	0.85	1.15	0.881	ns	
	CI	0.84	0.72	0.97	0.020	*	
FI vs. no FI and CI vs. no CI and FI x CI (factorial with interaction)	FI	0.96	0.78	1.18	0.695	ns	
	CI	0.81	0.65	1.00	0.055	ns	
	FI x CI	1.06	0.79	1.43	0.681	ns	

[a] ns=not significant=p>0.05 *=p<0.05 **=p<0.01 ***=p<0.001

Adjusted Analyses[b] (covariates[c])		95% Confidence Interval				Cluster-level weighted T-Test p-value
MMR (b_mmr)		Odds Ratio	lower 95%	upper 95%	p-value	sig.[a]	
FI vs. no FI	FI	1.27	0.71	2.29	0.416	ns	0.803
CI vs. no CI	CI	0.83	0.46	1.48	0.524	ns	0.674
FI vs. CI vs. FI+CI vs. control	FI	1.33	0.59	2.97	0.488	ns	0.393
	CI	0.89	0.37	2.15	0.797	ns	0.753
	FI+CI	1.06	0.45	2.50	0.897	ns	0.909
	FI	1.26	0.70	2.26	0.435	ns	
FI vs. no FI and CI vs. no CI (factorial)	CI	0.84	0.47	1.50	0.548	ns	
FI vs. no FI and CI vs. no CI and FI x CI (factorial with interaction)	FI	1.33	0.59	2.97	0.488	ns	
	CI	0.89	0.37	2.15	0.797	ns	
	FI x CI	0.89	0.27	2.92	0.852	ns	
NMR (tarmac)		Odds Ratio	lower 95%	upper 95%	p-value	sig.[a]	
FI vs. no FI	FI	0.88	0.73	1.05	0.164	ns	0.196
CI vs. no CI	CI	0.93	0.77	1.13	0.473	ns	0.551
FI vs. CI vs. FI+CI vs. control	FI	0.85	0.66	1.10	0.216	ns	0.256
	CI	0.90	0.70	1.17	0.438	ns	0.547
	FI+CI	0.82	0.63	1.06	0.128	ns	0.126
	FI	0.88	0.73	1.05	0.155	ns	
FI vs. no FI and CI vs. no CI (factorial)	CI	0.93	0.77	1.12	0.440	ns	
FI vs. no FI and CI vs. no CI and FI x CI (factorial with interaction)	FI	0.85	0.66	1.10	0.216	ns	
	CI	0.90	0.70	1.17	0.438	ns	
	FI x CI	1.06	0.74	1.52	0.751	ns	
PMR (b_pmr i.urban2)		Odds Ratio	lower 95%	upper 95%	p-value	sig.[a]	
FI vs. no FI	FI	1.00	0.87	1.14	0.952	ns	0.995
CI vs. no CI	CI	0.87	0.76	1.00	0.050	*	0.033
FI vs. CI vs. FI+CI vs. control	FI	0.93	0.77	1.12	0.460	ns	0.752
	CI	0.81	0.67	0.99	0.041	*	0.021
	FI+CI	0.86	0.71	1.05	0.136	ns	0.105
	FI	0.99	0.87	1.13	0.909	ns	
FI vs. no FI and CI vs. no CI (factorial)	CI	0.87	0.76	1.00	0.050	*	
FI vs. no FI and CI vs. no CI and FI x CI (factorial with interaction)	FI	0.93	0.77	1.12	0.460	ns	
	CI	0.81	0.67	0.99	0.041	*	
	FI x CI	1.14	0.87	1.50	0.352	ns	

[b] Adjusted Analyses have slightly lower sample size due to data from confounding variables not always being available

[c] b_mmr = cluster baseline MMR; tarmac = HC is accessible by tarmac road; b_pmr = cluster baseline PMR; i.urban2 = cluster rural/peri-urban/urban location

DISCLAIMER: 14% of the SB and NND could not be verified. Therefore, the true results, which will remain unknown, may be different to those that are presented here using the available data. Given extensive assessment of the internal consistency of the data, however (see section 4.1.5 below), we are fairly confident that or results accurately describe the total population (see section 4.2.4.5) that they represents. We also undertook exploratory analyses excluding all of the unverified SB and NND and found the results to only change very slightly (odds ratio changed less than 1 percentage points, this was expected given the balance of loss to follow-up between RCT arms as shown in section 4.1.1 above; data not shown)

was not correlated with intervention cluster NMR and neither were any of the other nine potential confounding variables (see box 3, section 2.1.11) which we have data for, see Appendix 20), the effects for each intervention and both combined are weaker (this is because each of the intervention areas has a higher proportion of clusters with HC that are accessible by tarmac – see Table 5).

There is strong evidence suggesting an effect of the Community Intervention on Perinatal Mortality (Odd Ratio: 0.84, 95%CI: 0.72, 0.97; p=0.020). In contrast, there is no effect of the Facilities Intervention on PMR (OR = 1.00; p=0.882). The effect of the combined FI+CI on PMR falls short of p<0.05 significance presumably because of the lack of effect of the FI. Adjusting for baseline PMR and whether the cluster was peri-urban or urban (urban clusters were found to have higher perinatal mortality, see Appendix 20) the effect of the CI on PMR is less but still statistically significant (Odd Ratio: 0.87 (95%CI: 0.76, 1.00; p=0.050). Adjusting for baseline PMR results in a lesser effect because baseline PMR was lower in CI clusters and adjusting for whether the cluster was urban or not also results in a lesser effect as less of the CI clusters were urban (see Table 5).

To explain the different effects of FI and CI on NMR and PMR it is useful to look at the numbers of deaths (Table 12). Whilst there are fewer neonatal deaths in FI areas (284) than No FI areas (310) during the intervention period (when the RCT analysis applies) there are actually more stillbirths (312 in FI areas compared to 278 in No FI areas), so when these are combined into perinatal mortality[53] they cancel each other out. In Community Intervention areas there are fewer stillbirths (274) as well as fewer neonatal deaths (286) compared to no CI areas (316 stillbirths and 308 neonatal deaths; Table 12). In the following sub-section we provide detailed analyses showing how the community and facility intervention effects on stillbirths, and early and neonatal deaths are linked to yield the results on neonatal and perinatal mortality we have observed.

None of the analyses show any possibility of an effect of either of the interventions on Maternal Mortality. Given how close the Odds Ratios and p-values are to 1 (and in fact in many cases the OR are over 1), it is unlikely that there were effects that we have missed due to lack of statistical power (which was previously acknowledged as an issue for measuring effects on MMR – see section 2.1.3). In fact, using the binomial distribution and the observed births and deaths data, we can calculate the probability that there was really a 30% reduction (OR=0.70) in maternal mortality resulting from the facilities intervention, or from the community intervention. These probabilities are low at 1.3% and 27.9% respectively. The probabilities of there really being a (still relevant but less than aimed for) 20% reduction in MMR given the observed data for each of the facility and community interventions are 6.7% and 66.9% respectively (please note that these calculations do not take account of clustering, which is more apparent for the community intervention, and also don't consider overlap between the probability distributions of observing intervention and control area deaths and are therefore likely to be overestimates – details of calculations available from the authors).

We must acknowledge the imperfection of the data. As with most scientific studies one can only go so far in terms of knowing the true picture of what has happened. Sampling error has been accounted for via the use of statistical tests, but we must acknowledge that even a p=0.05 result still means there is a 5% chance that we observed the result due to chance sampling variation and that there may not in fact truly be an effect in the population.[54] In terms of non-sampling error we have exerted ourselves to ensure that it has been minimised.

[53] Which actually only includes early neonatal deaths; total neonatal deaths are highlighted though due to the FI+CI effect on neonatal mortality.

[54] This is why triangulation of the results of the RCT both with each other, and with additional evidence from the process evaluation, is so important. The more a coherent, evidence-based and triangulated story can be told, the less likely it is that the observed significant results were due to chance.

Table 11. Changes to the results on NMR and SBENMR following changes in the number of NND and SB following refinement of analysis and verification

				No clustering or factorial	Random effects individual level analysis (FI vs. no FI and CI vs. no CI (factorial))							No clustering or factorial (SB)	Random effects individual level analysis (FI vs. no FI and CI vs. no CI (factorial) (PMR))						
28/02/2011	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB+NND diff.	**Preliminary Report to THF.** 77 clusters still included
no FI	213	10000							332	9867								
FI	185	10718	-28	0.81	0.79	0.66	0.95	0.013	386	10509	54	1.09	0.99	0.85	1.15	0.890	26	
no CI	234	10871							393	10699								
CI	164	9847	-70	0.77	0.78	0.65	0.95	0.012	325	9677	-68	0.91	0.87	0.75	1.01	0.080	-138	
Change	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value		
no FI	15	573							28	559							0	
FI	2	426	-13	-0.03	-0.02	-0.03	0.00	0.004	14	414	-14	-0.03	-0.02	-0.02	-0.03	-0.236	-27	
no CI	3	418							13	407							0	
CI	14	581	11	0.04	0.03	0.01	0.05	0.042	29	566	16	0.03	0.03	0.03	0.04	0.101	27	
01/04/2011	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB+NND diff.	**Pre-DMC report.** 65 clusters - about 200 PVA added, final(?) community surveillance forms added
no FI	228	10573							360	10426								
FI	187	11144	-41	0.78	0.77	0.63	0.95	0.017	400	10923	40	1.06	0.97	0.83	1.12	0.654	-1	
no CI	237	11289							406	11106								
CI	178	10428	-59	0.81	0.81	0.66	1.00	0.054	354	10243	-52	0.95	0.90	0.78	1.05	0.181	-111	
Change	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value		
no FI	-4	-552							-13	-543							0	
FI	12	-510	16	0.06	0.06	0.04	0.08	0.078	-8	-490	5	0.01	0.04	0.04	0.04	0.298	21	
no CI	-2	-1037							-24	-1014							0	
CI	10	-25	12	-0.02	-0.03	-0.03	-0.03	-0.025	3	-19	27	-0.02	-0.05	-0.04	-0.06	-0.145	39	
14/04/2011	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB+NND diff.	61 clusters (final) - about 100 PVA added
no FI	224	10021							347	9883								
FI	199	10634	-25	0.84	0.83	0.67	1.03	0.094	392	10433	45	1.07	1.00	0.87	1.16	0.952	20	
no CI	235	10252							382	10092								
CI	188	10403	-47	0.79	0.78	0.62	0.97	0.029	357	10224	-25	0.92	0.85	0.74	0.99	0.036	-72	
Change	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value		
no FI	20	-9							0	12							0	
FI	12	-7	-8	-0.02	-0.02	-0.02	-0.03	-0.043	-1	6	-1	0.00	-0.01	-0.01	-0.02	-0.058	-9	
no CI	16	-10							1	6							0	
CI	16	-6	0	0.01	0.00	0.00	0.00	0.000	-2	12	-3	-0.01	0.00	0.00	0.00	-0.003	-3	
15/04/2011	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB+NND diff.	**Post-DMC report.** about another 100 PVA added
no FI	244	10012							347	9895								
FI	211	10627	-33	0.81	0.80	0.65	1.00	0.051	391	10439	44	1.07	0.99	0.86	1.14	0.894	11	
no CI	251	10242							383	10098								
CI	204	10397	-47	0.80	0.78	0.63	0.98	0.029	355	10236	-28	0.91	0.85	0.74	0.99	0.034	-75	
Change	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value		
no FI	79	-310							-65	-166							0	
FI	80	-306	1	0.03	0.04	0.06	0.00	0.003	-75	-150	-10	-0.01	0.01	-0.02	0.05	0.093	-9	
no CI	75	-281							-66	-141							0	
CI	84	-335	9	0.07	0.09	0.10	0.06	0.091	-74	-175	-8	-0.04	-0.07	-0.08	-0.05	-0.026	1	
18/05/2011	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB+NND diff.	**Final Report to THF.** Duplicate Records (n=1700) removed; another 1100 PVA done
no FI	323	9702							282	9729								
FI	291	10321	-32	0.85	0.84	0.71	1.00	0.054	316	10289	34	1.06	1.00	0.84	1.20	0.987	2	
no CI	326	9961							317	9957								
CI	288	10062	-38	0.87	0.87	0.73	1.04	0.121	281	10061	-36	0.88	0.78	0.66	0.94	0.007	-74	
Change	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value		
no FI	-6	-16							-8	-6							0	
FI	4	-21	10	0.03	0.03	0.02	0.03	0.068	-2	-9	6	0.02	0.04	0.04	0.05	-0.348	16	
no CI	-4	-18							-1	-13							0	
CI	2	-19	6	0.02	0.01	0.01	0.02	0.049	-9	-2	-8	-0.03	0.01	0.01	0.01	0.004	-2	
14/06/2011	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB+NND diff.	**Final Results.** Another 100 PVA processed. All verifications and data cleaning complete as far as possible.
no FI	317	9686							274	9723								
FI	295	10300	-22	0.88	0.87	0.73	1.04	0.123	314	10280	40	1.08	1.04	0.87	1.24	0.639	18	
no CI	322	9943							316	9944								
CI	290	10043	-32	0.89	0.88	0.74	1.05	0.170	272	10059	-44	0.85	0.79	0.66	0.95	0.011	-76	
Change	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value		
no FI	-3	3							0	0							0	
FI	-5	5	-2	-0.01	-0.01	-0.01	0.00	-0.012	0	0	0	0.00	-0.04	-0.01	-0.08	0.353	-2	
no CI	-6	6							0	0							0	
CI	-2	2	4	0.01	0.01	0.01	0.02	0.067	0	0	0	0.00	0.04	0.06	0.02	0.009	4	
12/10/2011	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB+NND diff.	**Final Results.** Minor error in calculation of NND corrected, definition of PMR changed from FSB+ENND to SB+NND. FINAL DATASET
no FI	314	9689							274	9723								
FI	290	10305	-24	0.87	0.87	0.72	1.03	0.110	314	10280	40	1.08	1.00	0.86	1.16	0.992	16	
no CI	316	9949							316	9944								
CI	288	10045	-28	0.90	0.90	0.75	1.07	0.237	272	10059	-44	0.85	0.84	0.72	0.97	0.020	-72	
Change	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value		
no FI	-4	-285							4	-9							0	
FI	-6	-317	-2	-0.01	-0.01	-0.01	0.00	-0.007	-2	-8	-6	-0.02	-0.01	-0.01	-0.01	-0.111	-8	
no CI	-8	-326							0	-13							0	
CI	-2	-276	6	0.01	0.01	0.00	0.01	0.042	2	-4	2	0.01	0.00	0.00	0.00	-0.001	8	
15/04/2013	NND	no NND	NND diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB	no SB	SB diff.	Odds Ratio	Odds Ratio	lower 95%	upper 95%	p-value	SB+NND diff.	**Published Results.** Minor error in denominators for MMR and NMR logistic regression analyses corrected, and baseline/intervention period split made consistent for deaths and non-deaths. FINAL DATASET
no FI	310	9404							278	9714								
FI	284	9988	-26	0.86	0.86	0.72	1.03	0.103	312	10272	34	1.06	0.99	0.85	1.15	0.881	8	
no CI	308	9623							316	9931								
CI	286	9769	-22	0.91	0.90	0.75	1.09	0.279	274	10055	-42	0.86	0.84	0.72	0.97	0.020	-64	

Nevertheless it is of course possible that such errors have also affected the results we have arrived at. The most notable source of such potential non-sampling error is the outstanding verification of 14% of SB/NND, which is now not possible. Table 11 illustrates changes to the results following successive rounds of data verification and refinements to the analysis following the Data Monitoring Committee meeting on 8th April 2011; and highlights the fact that differences in the range of 25 – 50 deaths between intervention arms do alter the results in terms of $p<0.05$ statistical significance. Nevertheless, despite these concerns, we show in the following sub-section and sections 4.2.3 and 4.2.4 that we are able to triangulate the results with each other fairly well, and to the activities, process and possible mechanisms of the interventions to a lesser extent. Therefore we are fairly confident that they are a fairly accurate picture of what really happened in the total population represented by the RCT.

4.1.5 Internal consistency of the RCT results

In this section we piece together the separate effects of each of the interventions on perinatal mortality (stillbirth mortality plus early neonatal mortality) and neonatal mortality (early neonatal mortality plus late neonatal mortality), bearing in mind the overlap between perinatal and neonatal mortality (early neonatal deaths) and the overlap between the interventions given the two-by-two factorial design of the RCT (Figure 7). The latter was accounted for when assessing the overall impact of each intervention (the two arms with the intervention vs. the two arms without the intervention) by including variables for both interventions in the individual level logistic regression models (i.e. controlling for the effect of the presence of the other intervention, which although being present in one of the two arms of the intervention being tested was also present in the comparison group (also as one of the two arms without the intervention in question); Figure 43). First, we present analyses detailing how consistent the results quantifying the effects of each of the two interventions on their own are with the results of the interventions in combination. We then give an overview of the observed significant effects (FI+CI on NMR and CI on PMR) broken down into the constituent parts of perinatal mortality (stillbirth and early neonatal mortality) and neonatal mortality (early and late mortality; also see section 4.2.3 on causes of death); before presenting an overview of all of the intervention effects on perinatal mortality, stillbirth, early neonatal mortality, late neonatal mortality and total neonatal mortality and how they all link together. We then finish with a consideration of the imperfection of the data.

Figure 43: The two-by-two factorial nature of the RCT and its analysis

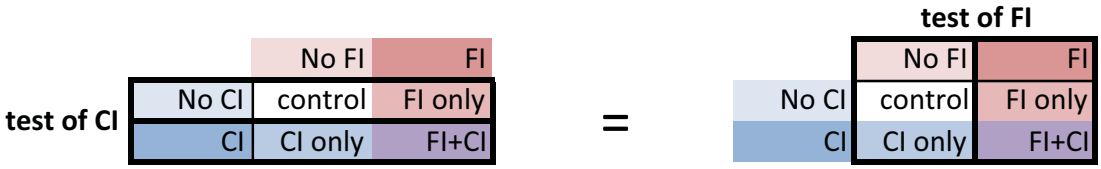


Table 13 presents the RCT results for perinatal mortality and neonatal mortality, including their constituent parts, the stillbirth rate, early neonatal mortality rate, and late neonatal mortality rate (the first two of the three sum to the perinatal mortality rate, and the second two of the three sum to the neonatal mortality rate; see Box 1 for definitions). The first white column '% change in mortality' shows the percentage decrease or increase in mortality that the odds ratio represents (e.g. 1.06 = 6%, and 0.81 = -19%; see preface); the second white column sums the separate FI and CI effects (e.g. 6% plus -19% equals -13%); the third column shows the combined FI+CI effect at a higher precision (e.g. FI+CI on the stillbirth rate = -14.1% = 14% (first white column) = an odds ratio of 0.86), and the fourth column subtracts the observed FI+CI effect from the calculated sum of the individual FI and CI effects (both for the two arm effects -see Figure 43- and the single arm effects) to calculate the discrepancy between the sum of the observed individual effects of the two interventions

Table 12. Baseline and intervention period births, deaths and mortality rates by RCT arm, unadjusted for clustering or the factorial nature of the trial

	Baseline (Jun 1 2007 - Sep 30 2008)								Intervention (Oct 1 2008 - Dec 31 2010)							
	No FI	FI	No CI	CI	control	FI only	CI only	FI+CI	No FI	FI	No CI	CI	control	FI only	CI only	FI+CI
Births	7351	7225	7587	6989	3718	3869	3633	3356	9992	10584	10247	10329	4912	5335	5080	5249
Livebirths	7114	6993	7368	6739	3613	3755	3501	3238	9714	10272	9931	10055	4766	5165	4948	5107
Stillbirths	237	232	219	250	105	114	132	118	278	312	316	274	146	170	132	142
Mascerated	44	42	39	47	20	19	24	23	58	49	59	48	33	26	25	23
Fresh	128	110	120	118	59	61	69	49	127	165	162	130	67	95	60	70
Neonatal Deaths	217	200	232	185	111	121	106	79	310	284	308	286	162	146	148	138
Early (0-6 days)	180	156	189	147	94	95	86	61	242	236	254	224	130	124	112	112
Late (7-28 days)	37	44	43	38	17	26	20	18	68	48	54	62	32	22	36	26
Perinatal Deaths	417	388	408	397	199	209	218	179	520	548	570	498	276	294	244	254
Maternal Deaths	29	26	29	26	15	14	14	12	21	26	25	22	10	15	11	11
Stillbirth rate per 1000 births	32.2	32.1	28.9	35.8	28.2	29.5	36.3	35.2	27.8	29.5	30.8	26.5	29.7	31.9	26.0	27.1
Neonatal mortality rate per 1000 livebirths	30.5	28.6	31.5	27.5	30.7	32.2	30.3	24.4	31.9	27.6	31.0	28.4	34.0	28.3	29.9	27.0
Early neonatal mortality rate per 1000 livebirths (0-6 days)	25.3	22.3	25.7	21.8	26.0	25.3	24.6	18.8	24.9	23.0	25.6	22.3	27.3	24.0	22.6	21.9
Late neonatal mortality rate per 1000 livebirths (7-28 days)	5.2	6.3	5.8	5.6	4.7	6.9	5.7	5.6	7.0	4.7	5.4	6.2	6.7	4.3	7.3	5.1
Perinatal mortality rate per 1000 births (stillbirths and early neonatal deaths)	56.7	53.7	53.8	56.8	53.5	54.0	60.0	53.3	52.0	51.8	55.6	48.2	56.2	55.1	48.0	48.4
Maternal mortality ratio per 100,000 livebirths	407.6	371.8	393.6	385.8	415.2	372.8	399.9	370.6	216.2	253.1	251.7	218.8	209.8	290.4	222.3	215.4

CI = Community Intervention; FI = Facility Intervention

and the observed effect of both the interventions together e.g. for the stillbirth rate -13.1% plus -14.1% equals 1.04% i.e. the observed combined FI+CI effect was 1.04 percentage points greater (a 1.04% greater reduction in stillbirths) than the sum of the observed individual effects. Inconsistencies of less than 2% were generally thought to be minor, and where inconsistencies of greater than +/-2% were apparent we indicate which single intervention effect was mainly responsible for the inconsistency with the observed combined effects of both (fifth white column). As can be seen, without exception, the single intervention effects that are responsible for the larger inconsistencies are generally not very certain at all, i.e. have wide 95%CI and high p-values (see preface). Finally, the right-most 5 columns of Table 13 show the results of formal tests of the interactions between the effects of each of the two interventions. The test of interaction indicates whether the effect of an intervention is modified by the presence of the other intervention i.e. whether the two interventions are synergistic –have a combined effect greater than the sum of the individual effects-, or antagonistic –have a combined effect lesser than the sum of the individual effects; statistically significant ($p<0.05$) odds ratios greater than one indicate that the interventions are synergistic whilst statistically significant odds ratios less than one indicate that the interventions are antagonistic. The results of the tests of interaction effects presented in Table 13 clearly show that there are no interactions between the facility and community intervention effects on any of the outcome measures.

Overall, given the inconsistencies between the observed individual effects and the combined effect of both interventions are either small or explained by non-significant effects on the whole,[55] and that tests of interaction, although they are underpowered (see section 4.1.4 above and section 2.1.11), show no hint of significance (have very high p-values), we can conclude that the RCT results are internally consistent. The analyses shown in Table 13 were repeated for the first intervention period (Oct-08 to Sep-09) and the second intervention period (Oct-09 to Dec-10) separately (tables in Appendix 21) with similar findings. We further explore the internal consistency of the results by mapping the intervention effects on perinatal and neonatal mortality with respect to effects on their constituent parts (stillbirth, early neonatal death and late neonatal death) below.

Figure 44 presents the observed significant effects of the RCT and their constituent parts: FI+CI on neonatal mortality and early and late neonatal mortality, and CI on perinatal mortality and stillbirth and early neonatal mortality, during the whole intervention period (Oct-08 to Dec-10), the first part of the intervention period (Oct-08 to Sep-09) and the second part of the intervention period (Oct-09 to Dec-10, see section 3.2 for rationale for this split of the intervention period). The middle of the boxes are the estimates of effect (odds ratios) and the tops and bottoms of the boxes are the upper and lower 95%CI respectively (see preface); the red line corresponds to no effect (an odds ratio of 1.00) with effects indicating reductions in mortality being below the red line and effects indicating increases in mortality being above the red line. Taking the intervention period as a whole (left hand side of Figure 44) it is apparent that the borderline significant effect of FI+CI on neonatal mortality (Odds ratio 0.78; 95%CI: 0.60, 1.01; first purple box) is made up of effects on both early neonatal mortality (Odds ratio 0.78; 95%CI: 0.60, 1.03; left magenta box) and late neonatal mortality (Odds ratio 0.77; 95%CI: 0.45, 1.30; left lavender box), but that these effects are just not significant (have upper 95%CI above 1.00) for early neonatal mortality (upper 95%CI: 1.03, p=0.083) and not significant for late neonatal mortality (upper 95%CI: 1.30, p=0.322). Given the low point estimate (0.77) the latter could be due to a too small sample size (greater uncertainty, see preface) than the absence of a real population effect. Moving on to look at the significant effect of CI on perinatal mortality during the whole intervention period (Odds ratio 0.84; 95%CI: 0.72, 0.97; first blue box) it is apparent that it is made up of effects on both stillbirth mortality (Odds ratio 0.81; 95%CI: 0.65, 1.02; left light blue box) and early neonatal mortality (Odds ratio 0.85; 95%CI: 0.70, 1.04; left dark blue box), both of which are close to significance (p=0.078 and p=0.113 respectively). The same information, split by the first (left hand side set of six boxes) and second (right hand side set of six boxes) intervention periods is

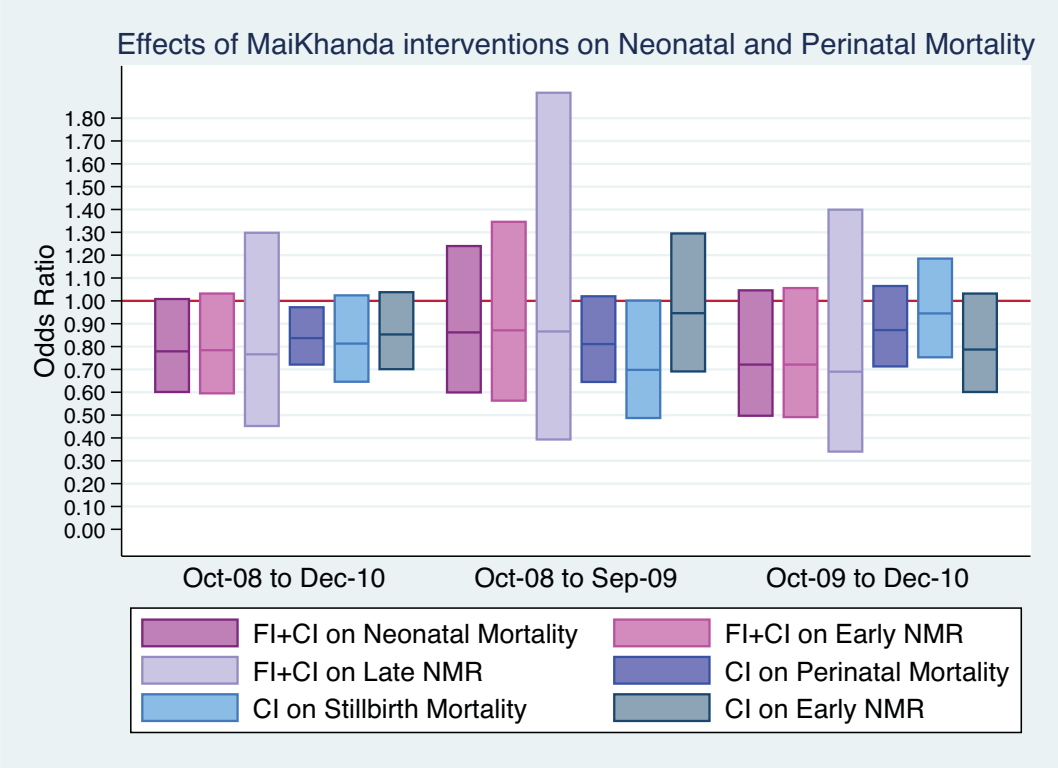
[55] There appears to be more inconsistency in the maternal mortality results. This, however, is likely to be an artifact of the small sample sizes in each of the four individual arms, including the FI+CI arm, which is the reference category from which we have assessed internal consistency. Please note that our conclusions regarding the intervention effects on maternal mortality detailed in section 4.1.4 still stand as they are based on the two-by-two comparisons which have higher sample sizes.

Table 13. Consistency between individual FI and CI effects and combined FI+CI effects

		RCT results: Intervention effects on mortality									Observed FIxCI interaction effect:				
Outcome	Intervention	Odds Ratio	lower 95%	upper 95%	p-value	sig.[a]	% change in mortality	Sum of FI and CI effects	Observed FI+CI effect	Inconsistency between observed sum and observed combined effects	For discrepancies over 2%: greatest Discrepancy in:	Odds Ratio	lower 95%	upper 95%	p-value	sig.[a]
Stillbirth rate	FI (FI only and FI+CI)	1.06	0.84	1.32	0.638	ns	6%									
	CI (CI only and FI+CI)	0.81	0.65	1.02	0.078	**	-19%	-13.1%		1.04%						
	FI only	1.04	0.76	1.43	0.790	ns	4%					1.02	0.65	1.61	0.917	ns
	CI only	0.80	0.58	1.12	0.192	*	-20%	-15.3%		-1.19%						
	FI+CI	0.86	0.62	1.19	0.354	ns	-14%		-14.1%							
NMR	FI (FI only and FI+CI)	0.86	0.72	1.03	0.103	*	-14%									
	CI (CI only and FI+CI)	0.90	0.75	1.09	0.279	ns	-10%	-23.7%		-1.57%		1.10	0.76	1.58	0.623	ns
	FI only	0.82	0.64	1.06	0.131	*	-18%									
	CI only	0.86	0.67	1.12	0.262	ns	-14%	-31.4%		-9.22%	CI effects (ns)					
	FI+CI	0.78	0.60	1.01	0.057	**	-22%		-22.1%							
early (0-6 day) NMR	FI (FI only and FI+CI)	0.92	0.75	1.11	0.373	ns	-8%									
	CI (CI only and FI+CI)	0.85	0.70	1.04	0.113	*	-15%	-23.1%		-1.50%		1.11	0.75	1.65	0.586	ns
	FI	0.87	0.67	1.14	0.308	ns	-13%									
	CI	0.81	0.61	1.07	0.131	*	-19%	-32.2%		-10.56%	FI effects (ns)					
	FI+CI	0.78	0.60	1.03	0.083	**	-22%		-21.6%							
late (7-28 day) NMR	FI (FI only and FI+CI)	0.67	0.46	0.97	0.035	***	-33%									
	CI (CI only and FI+CI)	1.14	0.78	1.66	0.498	ns	14%	-19.1%		4.26%		1.08	0.51	2.28	0.836	ns
	FI	0.64	0.37	1.11	0.112	*	-36%									
	CI	1.10	0.68	1.79	0.696	ns	10%	-25.5%		-2.16%	CI effects (ns)					
	FI+CI	0.77	0.45	1.30	0.322	ns	-23%		-23.4%							
Perinatal: Stillbirths + early NND	FI (FI only and FI+CI)	0.99	0.85	1.15	0.881	ns	-1%									
	CI (CI only and FI+CI)	0.84	0.72	0.97	0.020	***	-16%	-17.4%		-0.22%		1.06	0.79	1.43	0.681	ns
	FI	0.96	0.78	1.18	0.695	ns	-4%									
	CI	0.81	0.65	1.00	0.055	**	-19%	-23.0%		-5.77%	FI effects (ns)					
	FI+CI	0.83	0.67	1.02	0.079	**	-17%		-17.2%							
MMR	FI	1.18	0.66	2.11	0.570	ns	18%									
	CI	0.91	0.51	1.63	0.754	ns	-9%	9.3%		0.87%	FI and CI effects (both ns)	0.63	0.20	1.97	0.427	ns
	FI	1.36	0.61	3.03	0.454	ns	36%									
	CI	1.07	0.45	2.54	0.876	ns	7%	43.0%		34.54%	FI and CI effects (both ns)					
	FI+CI	1.08	0.46	2.57	0.854	ns	8%		8.5%							

[a] Given smaller sample size for some categories and the need to compare non-significant effects we have recoded significance as follows: ns = not significant = p>0.25 * = 0.25>p>0.1 ** = 0.1>p0.05 *** = 0.05>p>0.01 **** = p<0.01

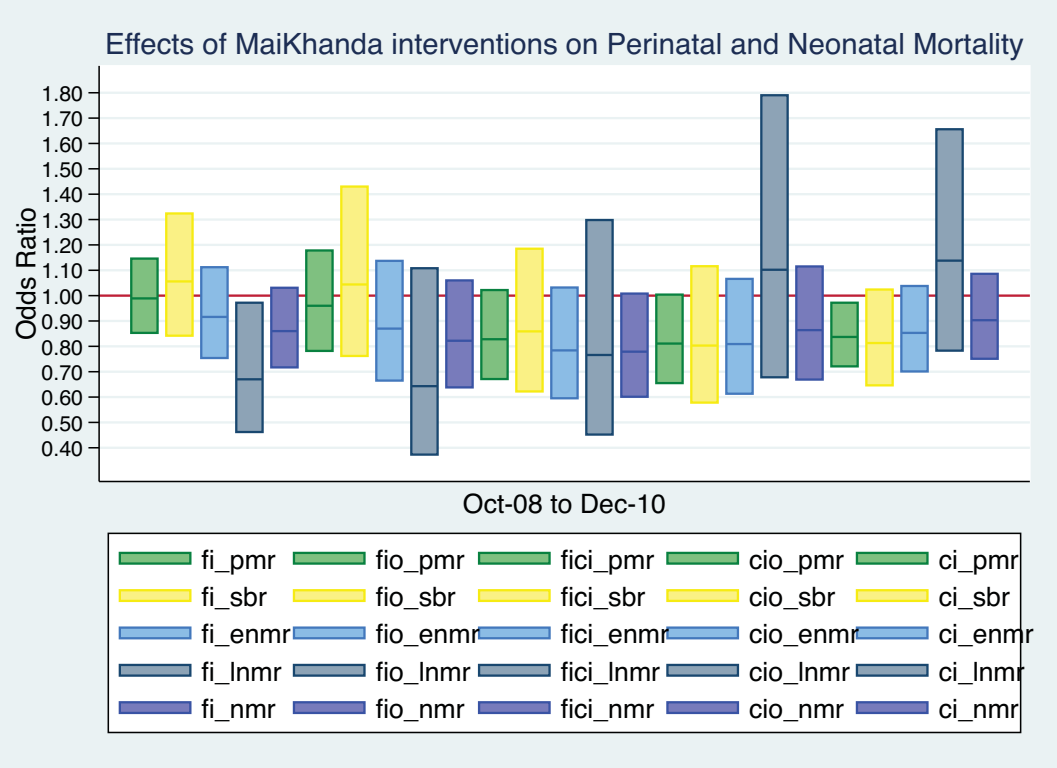
Figure 44: FI+CI effect on NMR, CI effect on PMR, and their constituent parts



interesting for two reasons. Firstly, it shows that the majority of the total effect of FI+CI on NMR (left purple boxes) seems to have occurred in the second intervention period rather than the first intervention period (the purple boxes on the right hand side are much lower with more of them below the red line than the purple boxes in the middle). Secondly, it shows that the total effect of CI on perinatal mortality seems to be mainly made up of an effect of CI on stillbirth mortality in the first intervention period (middle light blue box is low and mainly below the red line, whereas the middle dark blue box representing the effect of the CI on early neonatal mortality, the other component of perinatal mortality is almost centred on the red line indicating no effect), and an effect of CI on early neonatal mortality during the second intervention period (right hand side dark blue box is low and mainly below the red line, whereas the right hand side light blue box representing stillbirth mortality is higher with more of it above the red line). We explore these differences further, and with respect to the causes of neonatal and perinatal mortality, and possible effects of the interventions given their activities (which are detailed in section 4.2.1) below in section 4.2.3.

Apart from the significant effects of the interventions on mortality detailed above, it is also useful to look at the less significant and non-significant effects of all of the interventions and their combinations in order to build up a picture of how the intervention effects may be linked and answer questions such as: '*given the observed significant effect of the community intervention on neonatal mortality and the observed significant effect of the community intervention in combination with the facility intervention on neonatal mortality, and the fact that perinatal mortality and neonatal mortality are both made up of the same early neonatal deaths, how come there was no observed significant effect of the community intervention in combination with the facility intervention on perinatal mortality?*'. Figure 45 shows the effects of the facility and community interventions, both individually and in combination, on perinatal and neonatal mortality, split by their constituent parts, for the whole intervention period (Oct-08 to Dec-10). It is arranged in way intended to aid understanding of the overlaps between intervention effects (also see Table 13 and associated text above), and between

Figure 45: Individual and combined effects of the MaiKhanda interventions on NMR and PMR



the effects on perinatal mortality and neonatal mortality (which both include the same early neonatal mortality). The five blocks of five colour-coded boxes place the effects of FI (both FI arms – see Figure 43; fi_ in legend of Figure 45) as the left-most block of five boxes and the effects of CI (both CI arms; ci_ in legend) as the right-most block and then the effects of FI on its own (the FI only arm; fio_ in legend) second left and the effects of CI on its own (the CI only arm; cio_ in legend) second right, and finally place the effects of the combined FI+CI arm (fici_) as the middle block of five boxes. Each block of 5 boxes then has the effect of perinatal mortality (green box, pmr in legend) to the left followed by it's constituent parts: the effect on the stillbirth rate (yellow box, sbr in legend) second left, and the effect on the early neonatal mortality rate (light blue box, enmr in legend) in the middle; and then has the effect on neonatal mortality on the right (mid blue box, nmr in legend) with it's constituent parts to the left of it: the effect on late neonatal mortality (dark blue box, lnmr in legend, second to the right in the block of 5) and the effect on early neonatal mortality, which is the middle box (light blue) of the block of 5 and also a constituent part of perinatal mortality as described above. Readers are encouraged to spend some time studying the figure, and are referred to text associated with Figure 44, and the preface, for how to interpret the boxes with respect to their lower, mid and upper points and their placement in relation to the red line), however we provide the following summary. The effects of the FI (two arm, left-most boxes) appear to be mainly on late neonatal mortality (left dark blue box), with a resulting suggestion of an effect on overall neonatal mortality (left mid blue box), as do the effects of the FI on its own (one arm, second left block of boxes) which are more uncertain due to a smaller sample. On the other hand, there does not appear to be any effect of the CI (two arm, right-most boxes) on late neonatal mortality (dark blue box) and instead CI effects appear to mainly be on perinatal mortality (green) including both stillbirths (yellow) and early neonatal deaths (light blue), the latter of which also contributes to a slight suggestion of an effect on overall neonatal mortality (mid-blue) too. The effects of CI on it's own (one arm, second right block of boxes) appear

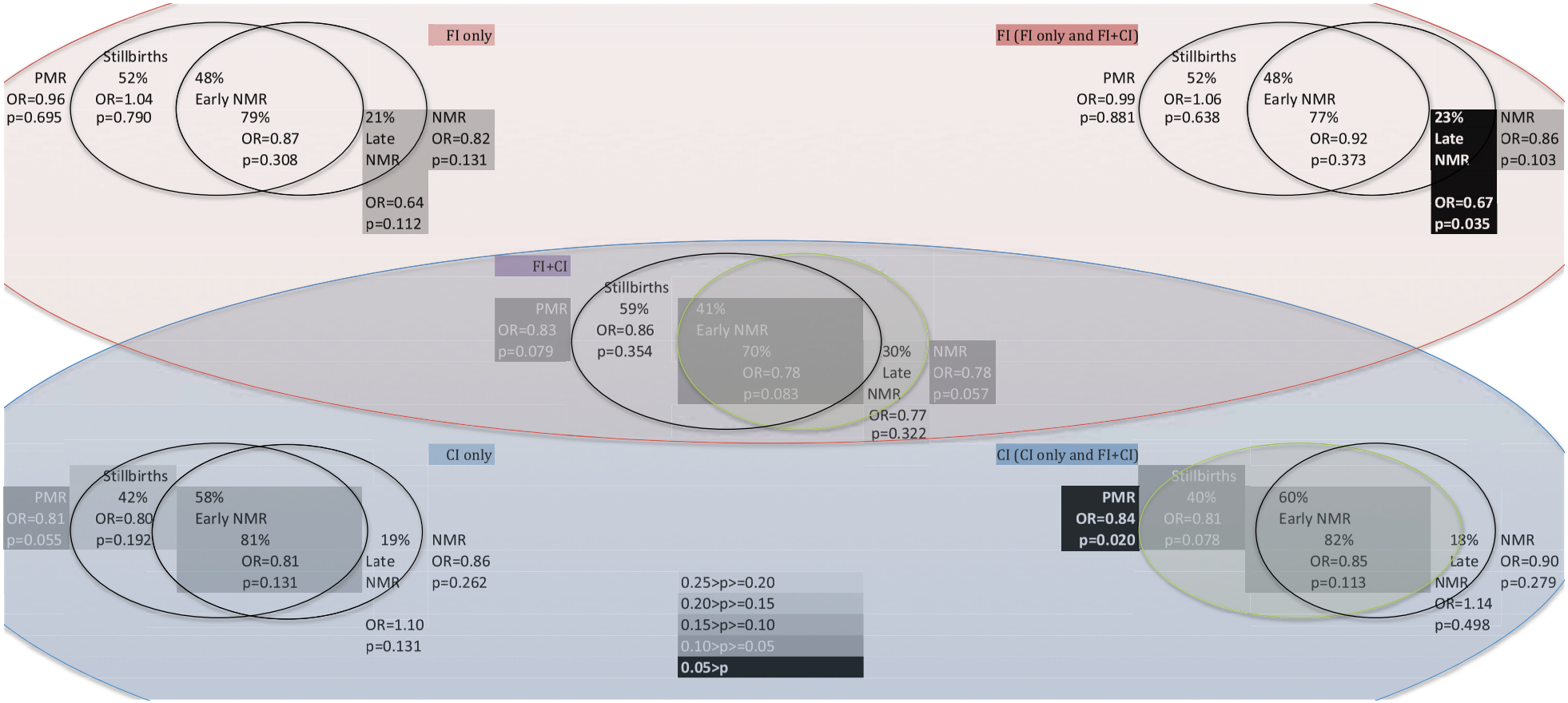
similar.[56] It therefore seems that the effects of CI and FI are complementary with CI acting on earlier mortality (stillbirths and early neonatal deaths) and FI acting on later mortality (perhaps early, but mainly late neonatal mortality). It is therefore not surprising, when we move on to look at the combined FI+CI effect (middle block of five boxes) that we find an effect on overall neonatal mortality (mid-blue box), which can be considered to be a combination of the CI effect on early mortality and the FI effect on late mortality. Coming back to the question posed at the beginning of this paragraph, we also actually *do* see a *suggestion* of an effect of the combined FI+CI on perinatal mortality (green box; which is also actually presented in Table 10). Looking at the numbers (Odds ratio: 0.83; 95%CI: 0.67, 1.02; p=0.079) it is apparent that this effect is not completely insignificant, and if we had a larger sample size to measure it, may actually be apparent in the population.[57] This also goes for the effect of FI+CI on early neonatal mortality (Odds ratio: 0.78; 95%CI: 0.60, 1.03; p=0.083), which is likely to be a combination of the (more significant and larger) effect of CI and the (less significant and smaller) effect of FI on this outcome. For interested readers we provide a further breakdown of the data shown in Figure 45 by first and second intervention periods, in Appendix 21. Given smaller sample sizes resulting from splitting the data, however, these figures add little to the story that we haven't already learnt from Figure 44 and Figure 45.

Figure 46 provides an alternative visualisation of the data presented in Figure 45 and goes one step further by quantifying the overlap of the intervention effects on perinatal and neonatal mortality via presenting the percentages of each of these effects that are due to effects on each of their two constituent parts (stillbirths and early neonatal mortality for perinatal mortality; and early and late neonatal mortality for neonatal mortality), represented by overlapping circles. The overlap between the interventions is also clearly shown by overlapping circles and the p-values of intervention effects are shading corresponding to the level of evidence of an effect that they indicate (starting with very weak evidence (p-values between 0.25 and 0.20 in very light grey, and moving sequentially in 5% intervals and darker shading to $p<0.05$ 'significant' effects in black shading and white text). From the figure it is apparent that the observed *effects on* perinatal mortality are roughly split 50:50, that the observed *effects on* neonatal mortality are roughly split 80:20, and that these splits do not differ very much between the different interventions (FI, FI only, FI+CI, CI only, and CI). From scrutiny of the grey scale shading indicating the significance of effects, the figure further shows that there may be more effects of the community intervention than the facilities intervention (i.e. it confirms the story already told above). Again, for interested readers, and for the sake of completeness we provide two additional versions of Figure 46, one for each of the first and second intervention periods, in Appendix 21. However, as before, this additional data does not appear to add to the story we are already aware of from the data already presented in this section; although perhaps it makes it clearer.

[56] This is as expected given the observed consistency between individual and combined intervention effects and a lack of interaction between them as described above in Table 13 and associated text.

[57] Although, by convention, all observed effects above the 5% significance level cut off (greater than p=0.05) are dismissed such dogmatic adherence to protocol may be unhelpful when attempting to triangulate results as we are here. It must be stressed however, that given the larger uncertainty surrounding greater p-values, further study with larger sample sizes is recommended before robust conclusions can be drawn regarding whether or not the less significant effects are really apparent.

Figure 46: Percentages of observed PMR and NMR reductions due to reductions in Stillbirth rate, Early NMR, and Late NMR by RCT comparison groups



4.2 Process Evaluation Results

This section describes the results of the process evaluation studies in the order with which their methods are described in chapter 2. Please refer to Figure 8 and Figure 9 in section 2.2 and Figure 17 and Figure 18 at the beginning of chapter 4 to place the individual studies in the context of the overall evaluation.

4.2.1 Intervention activities, processes and mechanisms

4.2.1.1 Facilities Intervention – specific quality improvement efforts

Successful changes focused on the identified key drivers of mortality should, when combined, lead to reduced mortality, via improvement of community and clinical processes and outcomes as shown in Figure 47. As part of the Deep Dive exercise (see section 2.2.6) all available data on specific quality improvement efforts and their associations with clinical process and outcomes was collated and analysed with respect to case-fatality rates at the facilities. These data include that on: PPH prevention, Asphyxia, Kangaroo Mother Care (KMC) and changes in maternal and neonatal case fatality rates with respect to specific quality improvement activities at the hospitals (CEmOCs); and, identification of High Risk Pregnant Women (HRPW) and Blood Donors, and, Emergency Obstetric Referrals (EOR), ,at the health centres. No data was collected or made available for evaluation on other important clinical processes and outcomes. In section 4.2.3 we attempt to link specific quality improvement efforts to population-level mortality i.e. all deaths, including those that occur outside of the facility, using data from the community based Verbal Autopsies (description of methods in section 2.1.8).

Figure 47: MaiKhanda key drivers of maternal and neonatal mortality diagram (March 2011)

AIM	Primary Drivers	Secondary Drivers	Processes/methods	execurtion
decrease in maternal and neonatal mortality	Patient demand for services and improved access to care	community based activities to foster demand and improve access	Supportive community	WG and TF
			Empowered women	WG and TF
		facility based activities to foster demand and improve access	Women Friendly Care	
	Safe, effective and timely routine care	Reliable care in the ANC	Identification of high risk mothers and referral to CEMOC for delivery	QI Teams and TF
		HC and CEMOC activities during labour	Partograph Use	QI Teams
			Prevention of PPH protocol	QI Teams
	Effective and safe movement of patients and information through the medical system	Patients in labour are rapidly assessed and triaged on arrival	Checklist for Emergency Obstetric Referrals	QI Teams
		good handoffs of information between sites (HC to CEMOC and HC to Community)	Checklist for Emergency Obstetric Referrals	QI Teams
		good handoff of information and responsiveness to emergency needs within the delivery facility	multiple opportunities for information transfer within facility	
	Safe, effective and timely care of the sick or vulnerable patient	effective management of the newborn	effective management of Asphyxia	QI Teams
			Neonatal Sepsis Protocol	QI Teams
			Kangaroo Mother Care	QI Teams
		effective management of the mother with complications	identification of high risk mothers, referral to CEmOC for delivery and follow up prior to due date to remind them	QI Teams and TF
	Effective support systems	Availability of supplies	identification of blood donors	QI Teams and TF
			changes to avoid stockouts/resources	
	Capacity of MoH to use QI methods to improve MCH	transfer of skills to MoH	training of MoH in QI skills ,mentoring of MoH staff and execution of change package.	
	Highly functional , independent NGO capable of attracting funding and MoH support.	well led, motivated , capacitated team	Strong SMT leadership, ED search, direction	
		plan to transform MaiKhanda in to independent NGO	Achievement of the milestones set out in Amy's document	

Overall the results presented in the section are inconclusive due to a lack of data. Inconsistent record keeping meant that for each specific QI effort the Data Deep Dive only uncovered data from some of the facilities MaiKhanda operated in and only for only some of the 2006-2010 time period. The available data for the hospitals suggest a possibility of some reductions in PPH incidence but not in PPH mortality (also see section 4.2.2.2.1 pie charts), some reduction in asphyxia case fatality rate at one hospital (St. Gabriel's), an unknown impact of KMC, and, a lack of obvious impact of any of the specific interventions on maternal or neonatal case fatality rates (also see Appendix 20). The limited available data for the health centres shows the identification of HRPW to not necessarily result in their delivery at the recommended place, some blood donors may have been identified, and a lack of obvious impact of the emergency obstetric referral checklist.

4.2.1.1.1 Hospital level

Figure 48 shows the results of 14 months of PPH Prevention work at Bwaila hospital. From the graph it is clear that after an initial increase followed by a decrease, adherence to the protocol stabilised at about 75% and incidence of PPH decreased slightly during the same time (although increased in September and October 2010 despite similar levels of adherence to the protocol). Deaths from PPH have been recorded as zero from Jan to Oct-10. However, it must be stressed that only women at high risk of PPH are included in Figure 48.

Figure 48: PPH prevention at Bwaila hospital

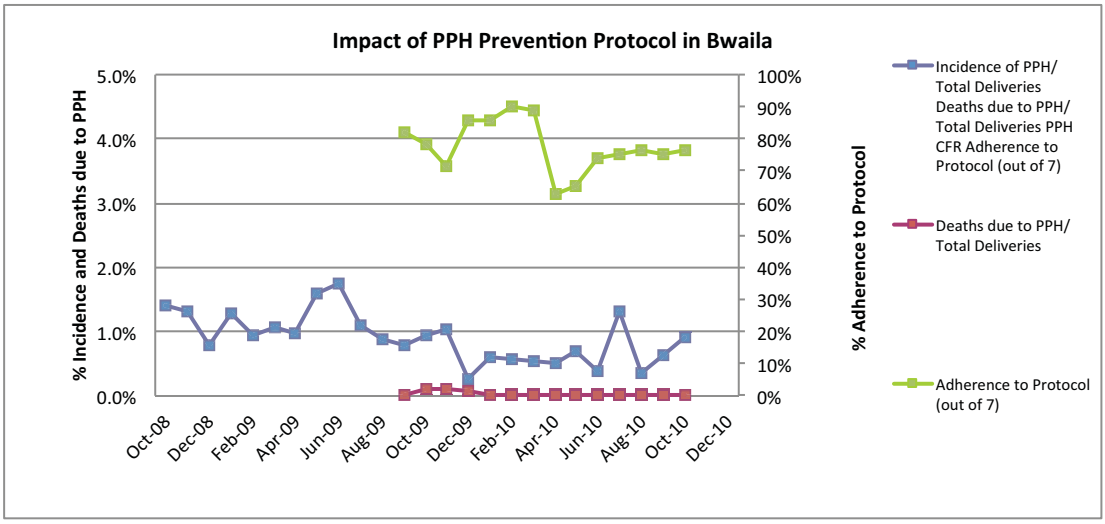


Figure 49, similarly, shows the same PPH prevention data from Kasungu District Hospital (KDH). As well as highlighting a decline in use of the protocol and an increase in PPH incidence at the end of the assessed time period, the graph is notable for the absence of PPH deaths in non-high risk women who were not recorded as part of the PPH prevention work. From the root-cause analysis data of maternal deaths for KDH, it is apparent that there were also deaths from PPH in December 2009 and July, August, October and December 2010 (data not shown). This clearly indicates that firstly, prevention is insufficient to stop PPH deaths (improvement of treatment and blood supply is also required) and secondly a focus on high-risk women only (even if it were consistent - and the data from KDH on protocol adherence presented in Figure 49 indicate that it is not always) is insufficient to impact on overall deaths from PPH.[58] Data from St. Gabriel's hospital re-enforce this conclusion: there were 6 deaths from PPH in 2010 (only 2 of which were recorded in the PPH prevention data) a rise from only 1 PPH death in 2009, despite the PPH prevention work starting in October

[58] In 2011 the FI team are now focusing PPH prevention efforts on all women.

Figure 49: PPH prevention at Kasungu District Hospital

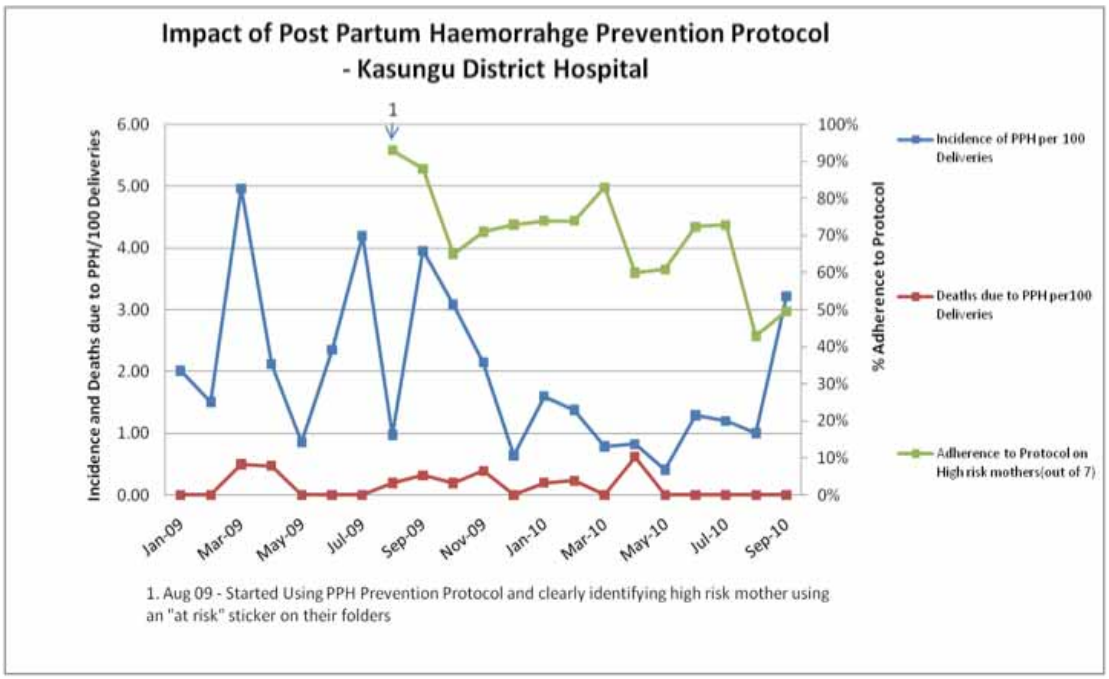
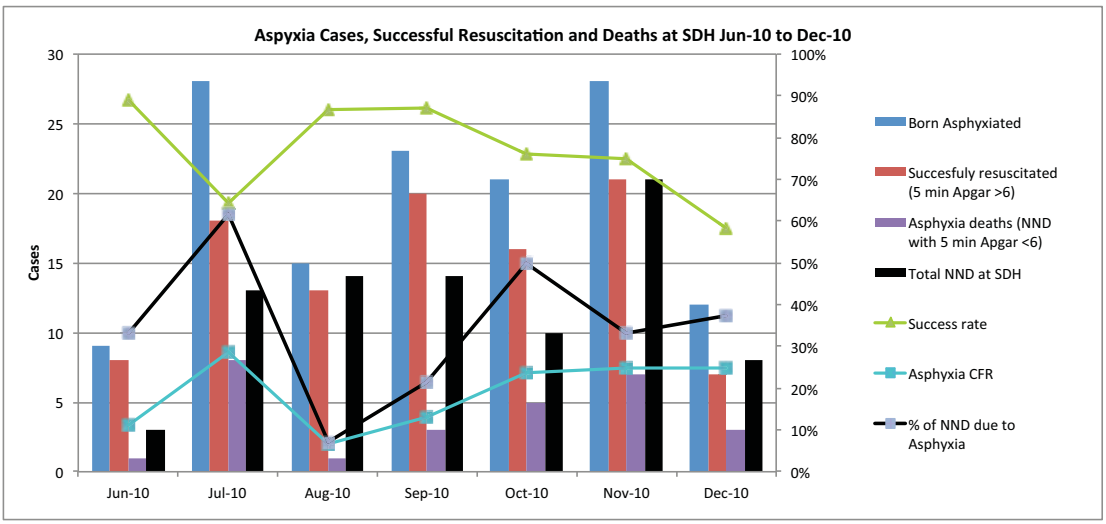


Figure 50: Asphyxia cases, successful resuscitation and deaths at SDH Jun-10 to Dec-10



2009. Other data on PPH prevention are available from Salima District Hospital (SDH; rise in protocol adherence, decline in PPH incidence), Kabadula (decline in protocol adherence, sporadic PPH incidence), Likuni (high protocol adherence but also high PPH incidence and continuing PPH deaths), Mitundu (increasing protocol adherence and decreasing but sporadic PPH incidence), Mlale (high protocol use, sporadic PPH incidence – low delivery numbers), and Daeung Luke (high protocol adherence but also high and sporadic PPH incidence).

Data on ***neonatal asphyxia*** are available from SDH and St. Gabriel's. Figure 50 shows the asphyxia CFR at SDH is high at around 25% and that the success rate for Resuscitation went down from around 80% to 60% towards the end of 2010.

At St. Gabriel's, Figure 51 shows the median asphyxia case fatality rate to have gone down from 42% (very high) between Jan-09 and Oct-09 to 14% between Nov-09 and Jun-11.[59] A case-study on asphyxia at St. Gabriel's conducted by the authors in August 2011, found the following. An in-house resuscitation drill for the staff, conducted every 2 weeks, using a resuscitation protocol and a scoring system on staff performance has been implemented at St. Gabriel since 2009 to tackle the high rate of asphyxia related neonatal deaths. The exercise was a team effort, involved all staff, including patient attendants, in the labour ward, with the target of completing the neonatal resuscitation within the golden minute. Training tools such as a resuscitation mannequin were provided to the staff and are available in the labour ward at all times for staff to practice, in addition to the fortnightly drills. A direct outcome of the intervention has been improvements in the competency and skills of the nursing staff in labour ward at St. Gabriel hospital to conduct neonatal resuscitation. Their target is to complete the drill within the first minute of birth-and the staff do feel competent enough to achieve that. The process has had a positive effect on their morale and confidence as well. Despite these improvements, around 1 in 5 babies asphyxiated at birth still die (the mean asphyxia CFR between Nov-09 and Jun-11 is 20%, data not shown), and there was an increase in the asphyxia CFR towards the end of period assessed suggesting it is hard for St. Gabriel's to 'hold the gains'. Further details of possible reasons for this are available in the case study report available from the authors upon request.

Data for ***Partograph use*** and other interventions aimed at ensuring adequate management of the second stage of labour are lacking.

For ***Kangaroo Mother Care*** (***KMC)***, data are available for KDH, St. Gabriel and SDH. Figure 52 shows the KMC data for SDH and indicates that admissions are usually only around 2 to 8 per month and that the CFR varies from 0% to around 30%, and doesn't seem to be related to the number of admissions (crowding). The data for St. Gabriel and KDH are similarly varied and, especially in the case of KDH where the death rate varies from 0 to 58%, do not seem to show any relationship between KMC protocol adherence and KMC related neonatal deaths (data not shown).

An interesting observation from the individual patient data available for SDH KMC babies only was that those discharged home has shorter stays (mean 4.4. days) and less weight gain (mean 2.6%) than those who absconded (mean stay of 6.4 days and mean weight gain of 7.3%). This suggests that the KMC protocol may not always have been followed properly at SDH with some babies perhaps being discharged too early. Although it could also be the case that those who absconded did so because their babies gained weight quicker than those who didn't and the mothers therefore felt their babies did not need to remain in KMC.

Another way of relating specific quality improvement intervention efforts to outcomes is to annotate outcome graphs with the timings of intervention processes. This was done for all CEmOCs for both NCFR and MCFR as part of the Data Deep Dive exercise (all graphs are provided in Appendix 22). Examples are provided below for MCFR at SDH (Figure 53) and NCFR at KDH (Figure 54). These graphs shows no noticeable changes in MCFR following the interventions indicated as M1 to M8 or NCFR following the interventions labelled N1 to N4, respectively. Looking at all of the other annotated MCFR and NCFR graphs (Appendix 20) there are also no clear changes in CFR following the interventions. Therefore, even though these micro-systems (individual CEmOCs) only have small numbers of deaths each month and hence a lot of data variability, it is difficult to conclude that the interventions have had any significant impact on overall CEmOC MCFR and NCFR. We return to this theme in the Chapter 5.

[59] A previous version of this report had incorrectly indicated that there were no asphyxia deaths between Sep-10 and Dec-10 at St. Gabriel's.

Figure 51: Asphyxiated babies, successful resuscitation and deaths at St. Gabriel's hospital

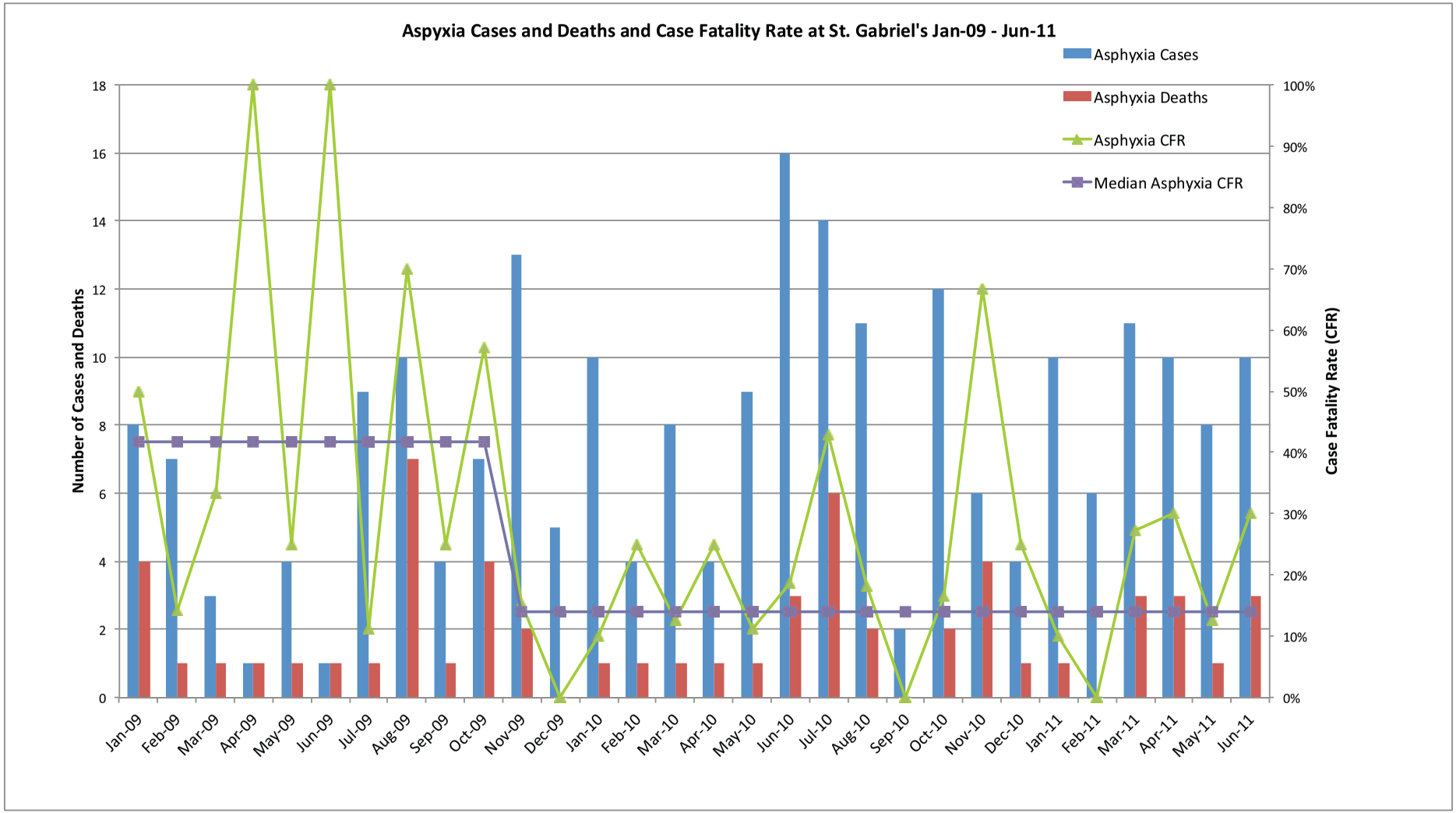


Figure 52: Kangaroo Mother Care at SDH

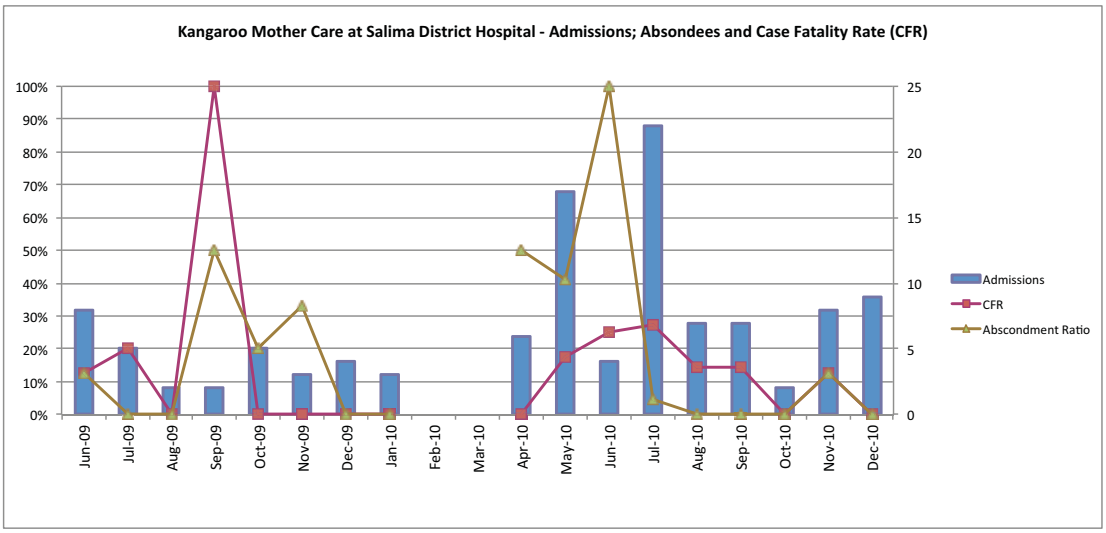
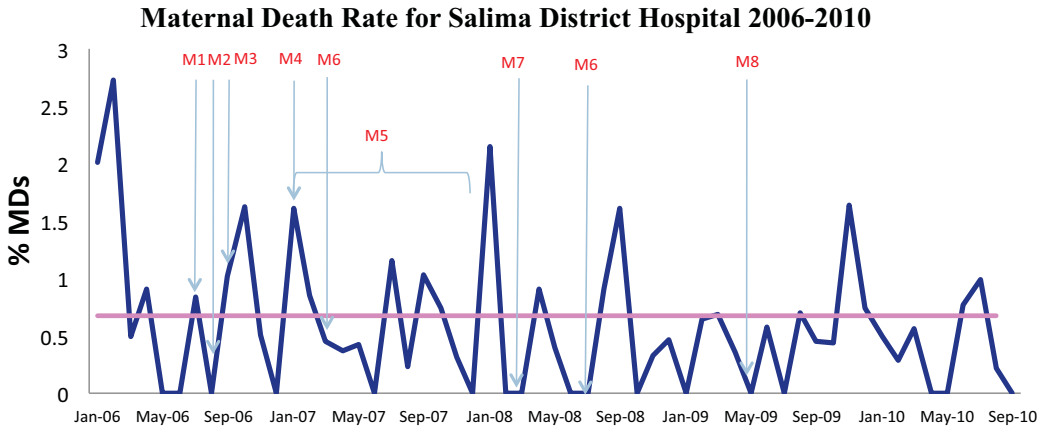
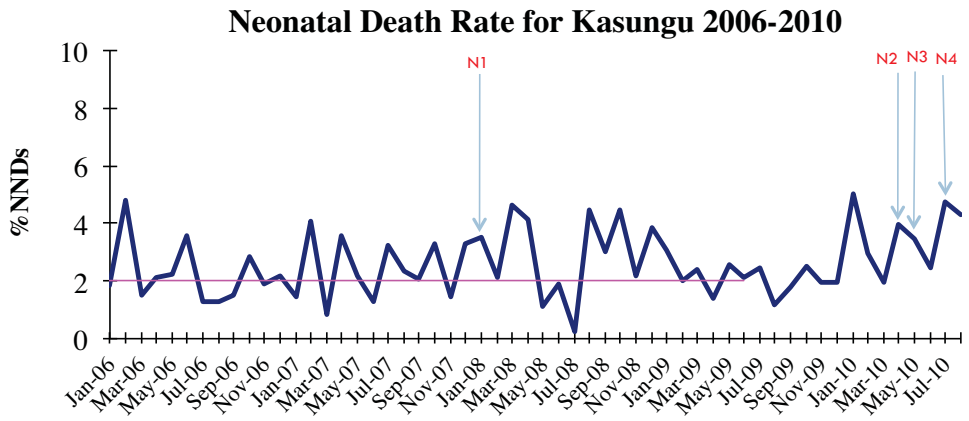


Figure 53: Example of annotated MCFR run chart: SDH



M1. July 06 - Encourage delivery in the facility
M2. <Aug 06 - Improved monitoring during 3rd and 4th stage of labour
M3. <Sept 06 - Reduce Peurperal Sepsis
M4. Jan 07 - Task shifting
M5. 2007 - Reduce time to Caesarean Section
M6. Mar 07, Jul 08 - Partograph training for midwives from all Health Centres
M7. Mar 08 - District Health Management Team's engagement in QI activity
M8. May 09 - Introduction of prevention of Post Partum Haemorrhage protocol

Figure 54: Example of an annotated NCFR run chart: KDH

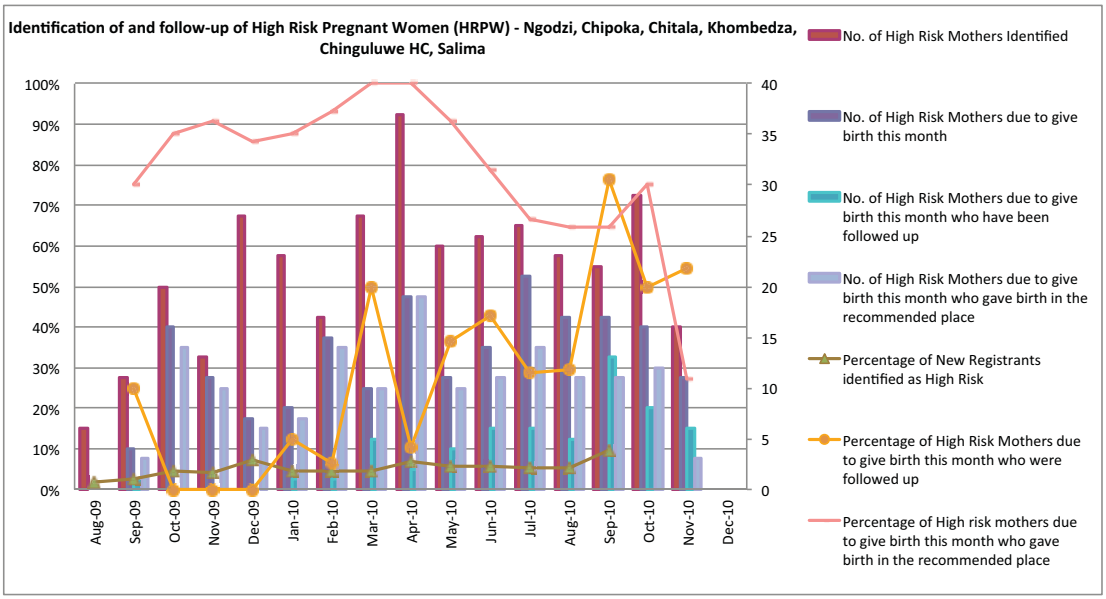


N1. ? Jan 08 - Use of Neonatal Sepsis protocol
N2 . Apr 10 - Resuscitation of the asphyxiated newborn training
N3. May 10 - Kangaroo Mother Care commences
N4. July 10 - Improved recording and use of Partographs; weekly neonatal death audits

4.2.1.1.2 Health Centre level

The identification of HRPW and encouraging them and following them up to delivery at a CEmOC has been one of the key Facilities Interventions at Health Centre level. Figure 55 details the key process measures documenting this work for 5 Health Centres in Salima combined. The percentage of new ANC registrants who were identified as high risk typically varies from 2% to 10% (6 to 37 women) for any given month, but there is missing data for some of the HC for some of the months.

Figure 55: Identification and follow-up of HRPW in 5 Salima HC

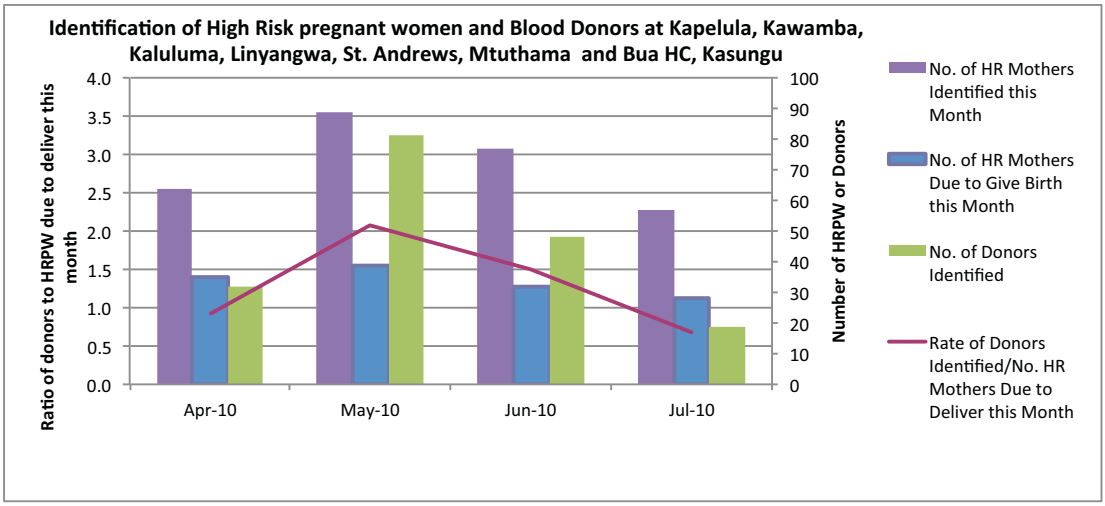


The percentage of HRPW giving birth in the recommended place rose from 75% to 100% from Sep-09 through Apr-10, but then declined to 65% by Sep-10 and to only 27% in Nov-10. There is also data for 7 HC in Lilongwe, which shows a similar picture but with a sharper recent decline in the percentage of HRPW followed-up and the percentage delivering at the

CEmOC (data not shown). It is important to note that this data does not give any insight into the consistency with which HRPW are being identified.

Figure 56 provides HRPW and blood donor identification data from 7 HC in Kasungu and shows, albeit with very limited data, that the identification of blood donors is correlated with the identification of HRPW as might be expected given each HRPW is supposed to identify a donor. However, there is no information on the number of identified donors who actually donate blood. From the root cause analysis of maternal deaths at KDH it is apparent that two deaths in Jul-10 and two deaths in Sep-10 resulted from a lack of blood (data not shown). Therefore, there is clearly still some way to go for this intervention to impact on facility maternal deaths. Going forward the new indicator being monitored will be requests for blood at the CEmOC that were not met due to a lack of blood availability.

Figure 56: Identification of HRPW and blood donors at 7 Kasungu HC



Moving on to look at the data on ***Emergency Obstetric Referrals*** (EOR) Figure 57 shows that EOR cases typically vary from 40 to 55 per month (data is missing from Jun-10 onwards for three of the HC). Checklist usage is low from Jun-09 to Jan-10 then it picks up to between 60% and 100% from Mar-10 to Dec-10 but there is missing data from 3 HC for these months. The percentage of women who are stable on departure is similar to that of the percentage for which the checklist was used up to Jun-10, after which the percentage who are stable on departure becomes much lower. The completeness of the checklist is apparently good when it is used (though again there is a lack of data). Overall, it is difficult to determine from this data what the impact of the use of the EOR checklist is.

Attempts were made to relate the work on EOR to changes in MCFR. Despite there being a perennial problem with getting feedback on the EOR cases that survived, some data was collected from KDH, enabling a comparison between the outcomes of referrals from FI HC (implementing work on EOR) and non-FI HC in Kasungu.

Figure 58 summarises this data which shows that, even ignoring plausible values extrapolated from the small number of cases (the 95%CI) that the MCFR for EOR from FI HC was no lower on average than the MCFR for EOR from non-FI HC, and in fact was slightly higher from the 3rd quarter of 2009 to the 1st quarter of 2010.

Figure 57: Emergency Obstetric Referrals from 5 HC in Salima

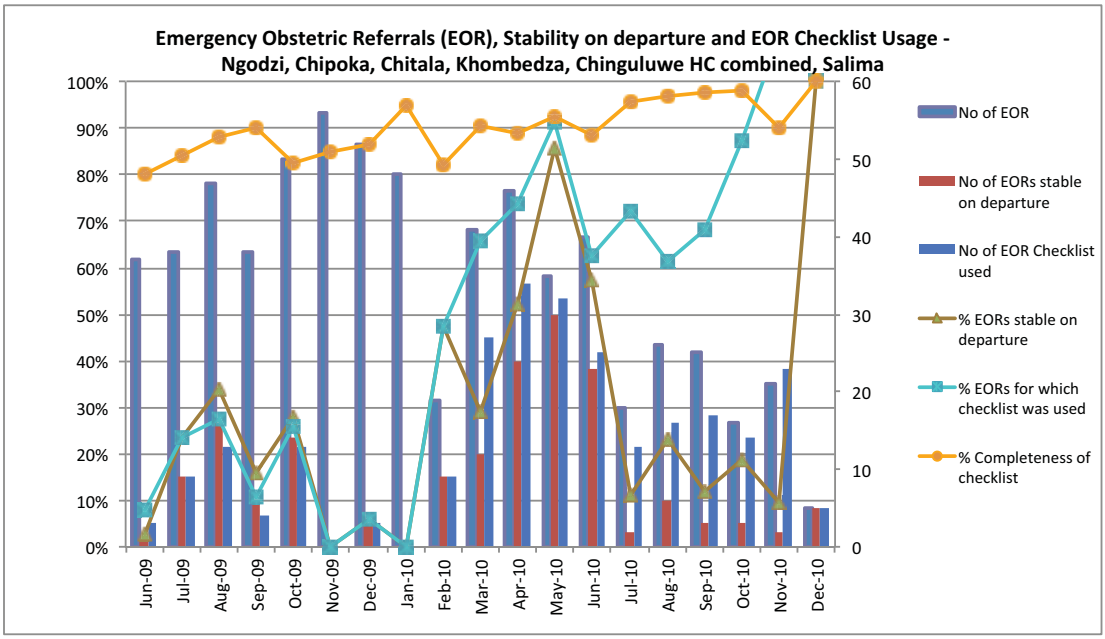
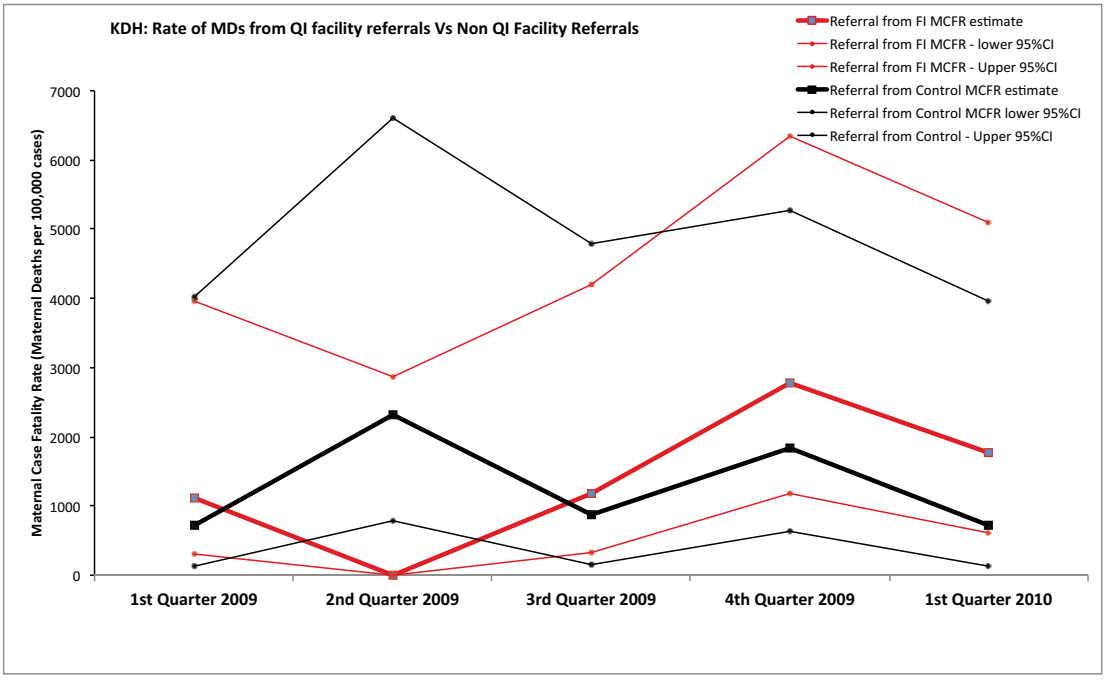


Figure 58: MCFR of EOR from FI HC and non-FI HC in Kasungu



4.2.1.2 Community Intervention activities process and mechanisms

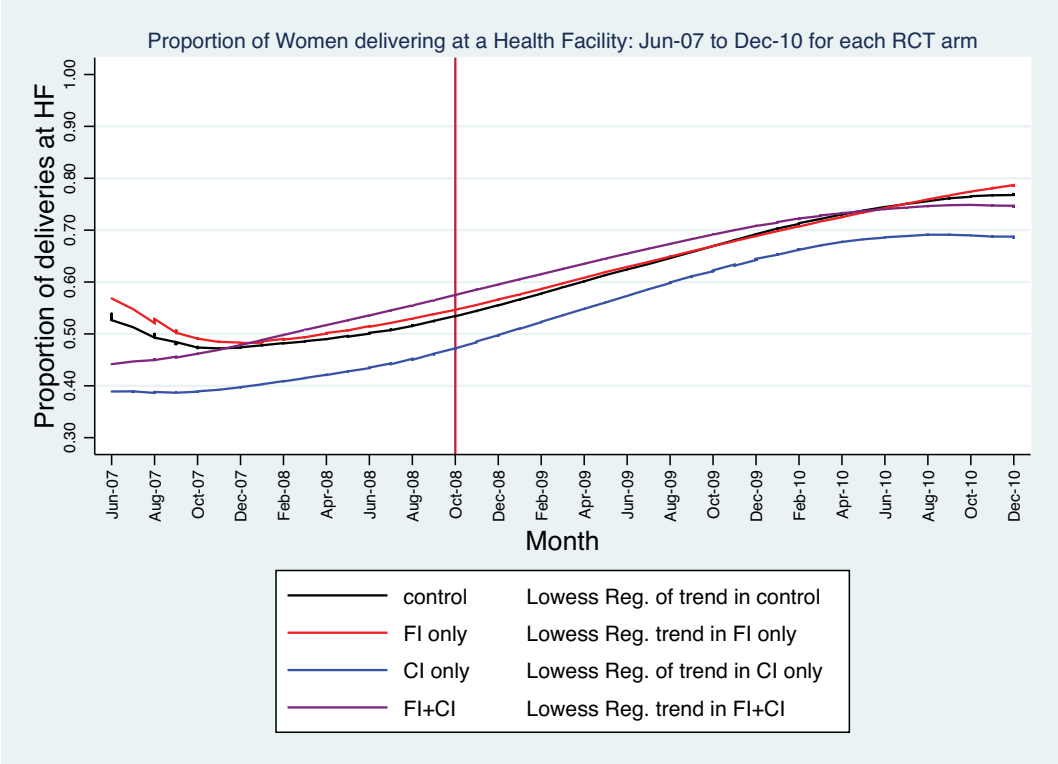
The headline results of the studies (described in section 2.2.1.2) undertaken to assess the activities, processes and mechanisms of the community intervention are as follows. The community intervention did not result in a greater increase in health facility deliveries, which went up dramatically in all areas (section 4.2.1.2.1); the population coverage of the women's groups was fairly low with only an estimated 10% of all pregnant women being group members in CI areas, and only 2% of women's group members were first time mothers (section 4.2.1.2.2); the strategies identified by the women's groups could have impacted on maternal and neonatal mortality but we do not have enough data to assess such potential

(section 4.2.1.2.3); and, MNH knowledge, attitude and practices were on the whole not any better in CI areas compared to no-CI areas (section 4.2.1.2.4).

4.2.1.2.1 Health facility delivery and health seeking behaviour

Figure 59 clearly shows that the proportion (multiply by 100 for percentage) of all women delivering at a health facility went up in all areas, including those without the community intervention and those without either the facility or the community intervention, with increases throughout the whole study period and particularly from mid-2008 onwards. This indicates that the community intervention did not lead to greater increases in health facility delivery than that that occurring in other areas anyway. Looking at the difference between the two CI arms and the two no CI arms, detailed in Table 8 (section 4.1), it is apparent that in CI areas the percentage of women delivering at a health facility increased from 46.5% during the baseline period (Jun-07 to Sep-08) to 63.9% during the intervention period (an increase of 17.4 percentage points); and that in areas without CI the percentage of women delivering at a health facility increased a very similar amount from 48.8% during the baseline period (Jun-07 to Sep-08) to 66.8% during the intervention period (an increase of 18.0 percentage points).

Figure 59: Increase in the percentage of women delivering at a health facility across all 4 RCT arms



When assessing the outcomes of the Community Intervention it is important to recognise that the initial intention of the intervention was to reduce Delay 1 and encourage skilled birth attendance, but that over the intervention period this has shifted to 100% delivery in the facility (with the TBA ban). Measurement of the effect of the CI on Delay 1 (the delay in the decision to seek care, and Delay 2, the delay in reaching appropriate care (see section 1.2.2) was attempted: admission records and partographs at Health Centres were examined to see whether it was possible to determine when the women arrived with respect to timing of the first/second stage of labour, and stable/critical condition. However, it was found that the time that the women actually arrived at the Health Centre was never recorded, only the time that

she was admitted to the labour ward was, therefore making it impossible to determine whether the women had in fact arrived at the HC in good time but had been kept waiting or whether she was admitted late because she had actually arrived late.

4.2.1.2.2 Composition of women's groups and population coverage

After accounting for some outliers, the average size of women's groups as of 2010, was 29 in Kasungu, 37 in Lilongwe, and 24 in Salima. However, the membership of groups in Lilongwe appeared more transient than in the other two districts, i.e. fewer of the same women were recorded as having attended each meeting. In addition, the women's group register does not record data during phase 3, the implementation phase of the women's group action cycle (see section 1.2.5.1). During this phase, women's group numbers are likely to increase, as is the participation of males within the community.

Table 14 uses data from the women's group registers on the average number of women per women's group in each district and the percentage of women's group members that are 15-49yrs old, to calculate the percentage of all pregnancies in areas covered by the MaiKhanda women's group intervention that are in women's group members. As can be seen from the data below, only around 10% of all pregnancies in WG areas are in WG members. This coverage level contrasts with higher coverage in MaiMwana in Mchinji and in other women's group programmes in India, Bangladesh and Nepal, and is the result of the relatively low density of women's groups in MaiKhanda (729 groups for a population of around 900,000 (the CI was in 29 less dense rural clusters of approximately 30,000 population each; Table 1): around 1 group per 1200 population), which is due to the women's group intervention being less intensive than in these other sites.

The most common age range of women's group members is 20-24 with older age groups making up a progressively smaller percentage of the total membership.

The data in the registers (Appendix 8) also show the average number of children the women attending the groups have is around 3.8. This increases from an average of 1 child in the under 20yr olds, 2 for 20-24yr olds, 3 for 25-29yr olds, 4 for 30-34yr olds, 5 for 35-39yr olds and around 6 for 40-59yr olds. There are no major differences in this data between Kasungu, Lilongwe and Salima. This data is useful for two reasons. Firstly, as the data is similar to the national population of Malawi, it verifies the quality of the register data. Secondly, it highlights that only 2% of WG members have no children. This is concerning as it means a lack of coverage of first time mothers who are more at risk of maternal, perinatal and neonatal complications.

Table 14. What proportion of all pregnancies in Women's Group areas are in Women's Group members?

District	Total Rural Population	Population in WG areas (half of total population)	Crude Birth Rate (births per 1,000 population per year) from MICS 2006	Expected births per year in WG areas	No. of WG	Population per WG	ave. no of Women per WG	total WG members	% WG members aged 15-49	WG members aged 15-49	Fertility Rate in 15-49yr olds (births per 1000 women) from MICS 2006	Expected births per year in WG members	% of all pregnancies in WG areas covered by a WG
Kasungu	608,917	304,459	44.5	13548	243	1253	29	7047	91.6%	6455	216	1394	10%
Lilongwe	1,206,842	603,421	44.5	26852	324	1862	37	11988	87.1%	10442	216	2255	8%
Salima	331,398	165,699	44.5	7374	162	1023	24	3888	86.9%	3379	216	730	10%
All	2,147,157	1,073,579	44.5	45520	729	1473	31	22923	88.4%	20275	216	4379	10%

Data from Women's Group Registers

Using the observed CBR from the surveillance alters the proportions of total pregnancies covered by WG slighty. In Salima it is lower as the observed CBR is higher than the Malawi 2004 DHS figure:

District	Surveillance Population	Observed Births in one year (Aug-07 - Jul-08)	Observed Crude Birth Rate (births per 1,000 population per year)	Expected births per year in WG areas	Expected births per year in WG members	% of all pregnancies in WG areas covered by a WG
Kasungu	90580	3992	44.1	13418	1394	10%
Lilongwe	151107	5916	39.2	23625	2255	10%
Salima	71278	3433	48.2	7981	730	9%
All	312,965	13,341	42.6	45764	4379	10%

4.2.1.2.3 MNH problems and strategies identified by Women's Groups

The top ten maternal/neonatal ***problems identified*** for all three MaiKhanda districts combined were:

1. Haemorrhage (APH or PPH)
2. Anaemia
3. Ruptured Uterus
4. Retained Placenta
5. Prolonged/Obstructed Labour
6. Tetanus
7. Malaria (/in pregnancy)
8. Neonatal Sepsis
9. Pneumonia
10. Malpresentation.

Differences in the problems identified by the women's groups of each district are minor. No clear trends are apparent from the data on the frequency with which each of the problems were estimated to be occurring.

The top ten ***strategies identified*** by the 292 women's groups across all three districts with data on strategies were:

1. Dimba (vegetable) gardens
2. Bicycle Ambulance
3. Health Education
4. Animal Rearing
5. Mobile Clinics
6. Insecticide Treated Bednets
7. Clean/safe water
8. Income Generating Activities
9. Village Fund
10. Health Post.

The strategies more reliant on local resources, such as Dimba Gardens, were generally perceived to have been implemented more successfully, whereas the strategies requiring more external inputs such as Mobile Clinics were less successfully implemented.

An analysis of how the strategies might overcome the identified problems was undertaken and the strategies thought most likely to have the most impact were deemed to be

- Bicycle Ambulances
- Health Education
- Mobile Clinics
- Health Post.

These may however, not be the most easily obtainable.

In addition to this data on the processes of the women's groups, a study of the impact of the different women's groups strategies was commissioned as part of the *Data Deep Dive* (section 2.2.6). The findings of this study are summarised in Table 15.

Table 15. Summary of strategy choice and implementation for 245 Women's Groups

Women groups' choice of strategy and implementation			
Strategy	**Total groups assessed**	**Choice in percentage**	**Implementation of choice in percentage**
Bicycle ambulance	245	91.4%	46.9%
Health Education on MNH	245	87.3%	98.1%
Rain-fed/ irrigation farming	245	85.7%	76.6%
Bed nets	245	61.6%	83.7%
Mobile clinic	245	42.0%	63.1%
Portable water	245	39.6%	50.5%
Adult literacy	245	37.9%	76.3%
Live stock production	245	35.5%	26.8%
VCT	245	31.4%	97.4%
Food processing	245	30.6%	54.7%
Village savings and Lending	245	21.8%	87.2%
Health Post	245	17.6%	30.2%
Drug Bank	245	9.0%	50.0%

The most popular strategies were Bicycle ambulance (chosen by 91% of 245 WG surveyed); Health Education on MNH (chosen by 87%); and Rain-fed/irrigation farming (chosen by 86%). The Bicycle Ambulance strategy was only implemented by 47% (105/224) of those groups that chose it, with reasons for the strategy not being implemented including:

—"We can't manage to buy Bicycle Ambulance because it's expensive"
—"Have contributed MK28, 000.00 but we do not know where to buy the bicycle ambulance"
—"One group around here received bicycle ambulance from MaiKhanda but we don't have access to it because their village headman denies us access to it and also that it is far away from here"

—"MaiKhanda have not given us Bicycle Ambulance"
—"Have not received Bicycle Ambulance from MaiKhanda though currently we have managed to contribute MK5000"

Cost is clearly an issue with one bicycle ambulance costing around MK50,000 (about £200). Those women's groups that received bicycle ambulances mainly received them as donations from Sacramenta with others from other NGOs such a CACET. The fact that the women's groups see the need for the bicycle ambulance and lobby for it is part of the empowerment approach of the intervention however, and means that the bicycle ambulances are likely to be taken care of and used properly as a result (as are bednets for malaria, another WG strategy – see Table 15). Indeed, the ownership of the bicycle ambulances in reflected by the fact that 91% of the WGs that have them also have established maintenance funds (minimum of MK200 and maximum of MK41000) for them. 98% of the bicycle ambulances are used for maternity cases, with 81% being used for other serious cases and 20% also used for non-serious cases. Given that the distance to the nearest Health Facility of the villages where the women's group members reside ranges from 1km to around 20km (average 9km) and roads and transport availability are typically very bad, the bicycle ambulances are clearly useful for overcoming Delay 2 (reaching the facility in time). However, we have no specific data on the impact of bicycle ambulances on Delay 2, or indeed on maternal, neonatal or perinatal mortality.

The Health Education strategy was the most successfully implemented strategy with 98% of the 87% of WG who chose the strategy managing to implement it (Table 15). The main providers of the Health Education on MNH were: Women's Group Facilitators (providers to 84% of WG who implemented the strategy), MNH Task Forces (providers to 59%; providing health education was the main reason the Task Forces were set up), and HSA (providers to 54%), with other NGOs being providers to 8%. The main target groups of the MNH messages were women (100% of implementing groups), and men (88% of implementing groups), with girls and boys only targeted by 5% of implementing groups. The MNH messages were typically disseminated at public meetings (97% of implementing groups), via posters and wall writing (86% of implementing groups), home visits (50%), drama (34%) and open days (31%); and usually on a monthly basis (86% of implementing groups), with 13% disseminating on a weekly basis.

The farming strategy was implemented by 77% of the 86% of WG that chose it (Table 15) with a variety of crops grown on plots ranging from 0.4 to 5 acres. The strategy is aimed at both generating money for the WG - to use for example on bicycle ambulances (see above) - and producing nutritious food for pregnant women. The main beneficiaries of the money generated were women's group members (68% of implementing WG); pregnant/lactating women (46%). the whole community (31%) and the MNHTF (25%) with men being beneficiaries in only 5% of cases, chiefs in 3%, and all the produce being eaten rather than sold in 3%. The main beneficiaries of the crops in terms of eating were also the women's group members (58% of implementing groups); pregnant/lactating women (56%), the whole community (41%), and MNHTF members (23%), with other women (12%), children (12%), men (8%) and chiefs (4%) also occasionally benefitting; only 2.5% of the groups sold all their produce. It is possible that eating iron rich green leafy vegetables from the Dimba gardens may reduce anaemia in pregnant women and that other nutritional gains from the gardens may reduce the likelihood of pregnancy complications including the risk of

low birth weight[60], however, we have no data to assess this. Future assessment could also be difficult, as it would require detailed analysis of the nutritional content of the food eaten by women in women's group and control areas with reference to the food they grow and measurement of anaemia via blood sampling, and other relevant pregnancy complications.

Four strategies; Health Education on MNH, VCT, Bed nets, and VSL (Village Saving and Lending) were the only strategies that over 80% of women groups that chose them have managed to implement (Table 15). This is perhaps because Health Education on MNH, VCT and Bed net strategies received direct support from the health system. Such support may in some cases have been precipitated by lobbying from the Women's Groups, and in other cases requests from the WG may have coincided with existing plans by the Health Facility to provide these services. The VSL strategy may have been implemented successfully by many women's groups because most of their members could see the direct or immediate impact this strategy could bring to them. In addition, many other NGOs in the area also encourage and assist set-up of VSL schemes making it a relatively easy strategy to implement.

The study also recorded which members of the community benefitted from each of the implemented strategies, and found that the beneficiaries of most of the strategies for most of the groups included pregnant/lactating mothers and children. The study also shows that communities are ready to contribute to the reduction of maternal and neonatal deaths through implementing strategies that directly contribute to this but they are challenged in some cases by lack of resources, lack of co-ordination by women's groups, local leaders and other members of the community, lack of leadership skills, and knowledge gaps, among other problems.

Overall, the involvement and buy-in of women's groups and communities into the Community Intervention is evident by them identifying and trying to implement, and often successfully implementing, the strategies, as detailed above. Whether the mobilisation of women and communities can be considered to be empowerment, is still uncertain however as we don't have specific measures of empowerment. During the *Data Deep Dive* it was also recognised that the engagement and involvement of traditional leaders in the community was of paramount importance for the success of the women's groups (see section 4.2.5.2.4.1).

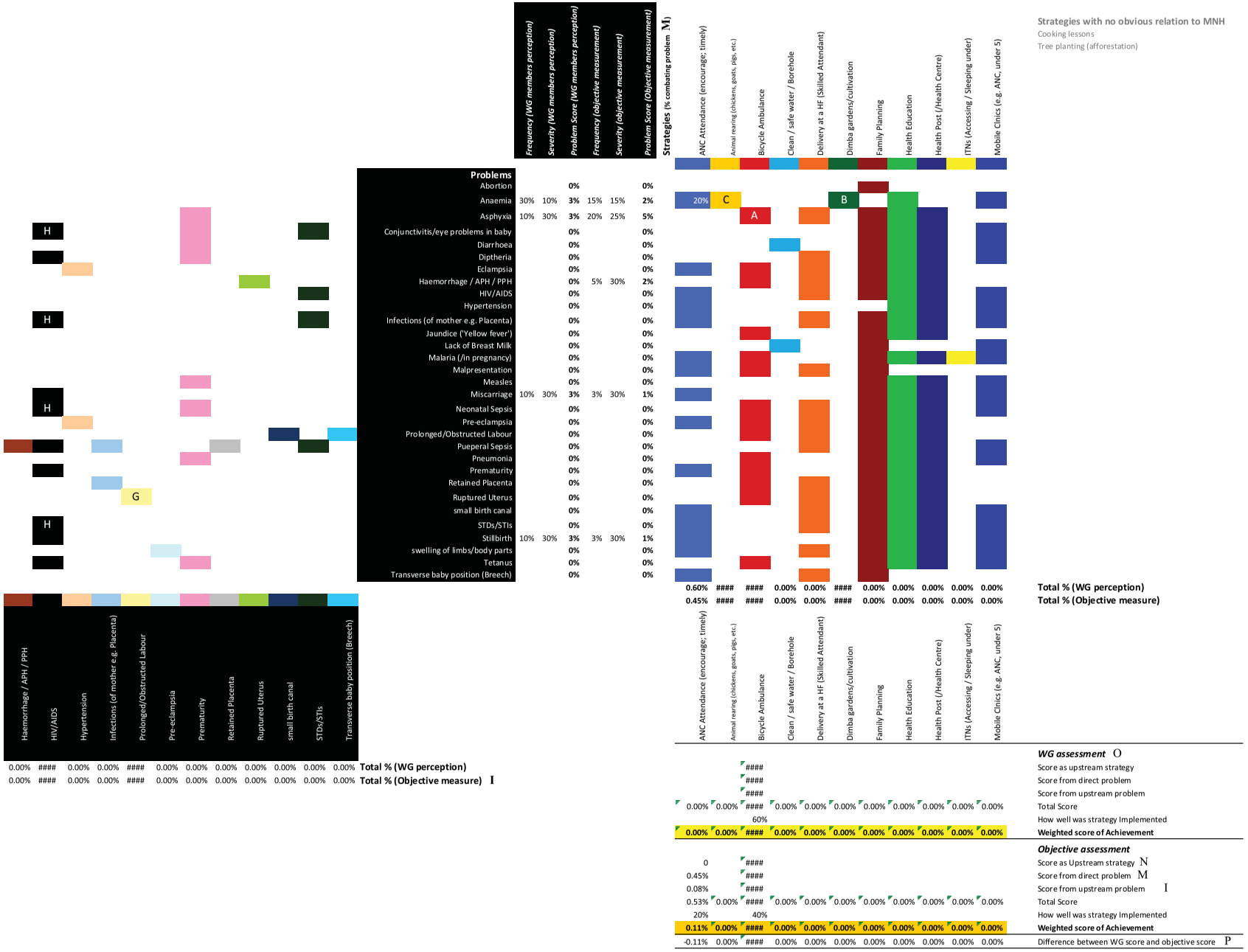
4.2.1.2.3.1 Linking strategy implementation to outcomes and impact

In order to determine how specific strategies might result in specific health outcomes, including the observed effect on perinatal mortality (see section 4.1) we would require objective data on the prevalence and severity of all MNH problems in the areas that the women's groups operate and data on how effective the strategies the women's groups chose and implement are in reducing the severity and prevalence of these problems. For example, by what percentage can a Bicycle Ambulance reduce maternal mortality from Haemorrhage? [A][61] By how much can Dimba gardens or Animal Rearing reduce the prevalence and severity of Anaemia? [B, C] In addition, the contribution of downstream strategies to the upstream strategies they help to realise needs to be estimated. For example, how effective are Dimba Gardens in raising money to purchase a Bicycle Ambulance? [D] How effective are other such Income Generating Activities? [E] How effective are Adult Literacy Classes in improving Health Education? [F] To further complicate matters, many of the identified MNH problems are also downstream problems to other MNH problems: for example, Prolonged/Obstructed Labour can lead to Ruptured Uterus [G] and HIV/AIDS can exacerbate a number of infections [H]. Therefore any strategies that impact on such problems, which are

[60] Rao S, Yajnik CS, Kanade A, Fall CHD, Margetts BM, Jackson AA, Shier R, Joshi S, Rege S, Lubree H, Desai B. Intake of Micronutrient-Rich Foods in Rural Indian Mothers Is Associated with the Size of Their Babies at Birth: Pune Maternal Nutrition Study. J. Nutr. April 1, 2001 vol. 131 no. 4: 1217-1224.

[61] Lettering in brackets refers to the letters on Figure 60, which is an example of the model of WG effectiveness being discussed.

Figure 60: Linking implementation of women's group strategies to health outcomes and mortality impact



also downstream of other problems, will also have indirect impacts [I] on these other upstream problems.

Despite the potential complexities of estimating such a model of WG effectiveness it would be a valuable exercise for unpacking the processes of the WG intervention that may lead to any reductions in maternal and neonatal morbidity and mortality that may be observed by the evaluation of MaiKhanda in due course. The main difficulties will be in gaining accurate and objective estimates of the prevalence [J] and severity [K] of all the MNH problems and their effects on other problems [L] and on the effectiveness of all downstream [M] and upstream [N] strategies in dealing with each of the MNH problems. Populating a simple model of the most important problems and strategies may be the first step.

The model could also be extended to incorporate how the women's groups themselves perceive the importance of the problems and how they perceive the effectiveness and successful implementation of the strategies [O]. A comparison between the objective data and the women's group self evaluation data [P] could then be made which would enable an estimation of how effective the WG are in combating objectively defined MNH problems. Of course, there is the question of what is an objectively defined problem – if the women themselves don't perceive something as a problem or perceive it to be less severe than it is 'objectively' determined to be then should interventions on their behalf be encouraged? Indeed, given that the women's group intervention is aimed at community empowerment and community-led solutions, are objective measurements necessary or required? At the level of mortality probably, but at other levels of severity, perhaps not.

4.2.1.2.4 MNH knowledge, attitudes and practice: results

4.2.1.2.4.1 Respondent characteristics

Table 16 provides details of the survey respondents socio-demographic characteristics. Respondents in No CI areas were slightly younger on average, were slightly less educated and slightly more illiterate; just over 90% were married in each group. Around three-quarters of each group were farmers, with a slightly higher percentage employed as labourers in the NoCI group; only 3% were unemployed. A slightly higher percentage of respondents' husbands were illiterate in the CI group (Table 16); and CI group husbands were also slightly less educated (data not shown). The occupation of respondents spouses showed an almost identical distribution in each group to that of the respondents (data not shown). On average, CI group respondents lived slightly further away to the nearest health facility (11.4km) than No CI respondents (10.9km) and a higher percentage in CI areas walked to the health centre (71%) than in No CI areas (62%; Table 16). Overall, respondents in CI areas were slightly worse off than respondents in No CI areas, something which should be borne in mind when interpreting the KAP results.

4.2.1.2.4.2 Antenatal care and danger signs during pregnancy

It is recommended that pregnant women receive at least 4 thorough, comprehensive and personalised Antenatal Care (ANC) visits, with one in the first trimester (<16 weeks).[62] Respondents were asked how many ANC visits a pregnant woman should receive and how many they had during their recent pregnancy (Table 17). 63% of respondents in No CI areas and 58% of respondents in CI areas indicated that the recommended number of ANC visits was either 4 or 5,[63]; and 56% of respondents in No CI areas and 47% of respondents in CI areas indicated that they had 4 or more ANC visits during their recent pregnancy (Table 17). Only 20% of respondents in No CI areas and 19% of respondents in CI areas indicated that

[62] JHPIEGO (2007) Focused Antenatal Care, Malaria in Pregnancy, Prevention of Mothers to Child Transition and Tuberculosis: Orientation Package for service providers.

[63] Although the recommended number of ANC visits is 4, we believe that thinking it is 5 will not be detrimental to the woman's health.

Table 16. Characteristics of respondents to MNH KAP survey

Respondent characteristic	No Community Intervention	Community Intervention	Total
Age of Respondents	**251 (100%)**	**345 (100%)**	**596 (100%)**
15 -19	31 (12.4%)	32 (9.3%)	63 (10.6%)
20 -29	144 (57.4%)	204 (59.1%)	348 (58.4%)
30 -39	58 (23.1%)	64 (18.6%)	122 (20.5%)
40 -49	2 (0.8%)	13 (3.8%)	15 (2.5%)
50 -59	2 (0.8%)	1 (0.3%)	3 (0.5%)
Don't Know	14 (5.6%)	31 (9.0%)	45 (7.6%)
Marital Status	**251 (100%)**	**345 (100%)**	**596 (100%)**
Not Married	22 (8.8%)	27 (7.8%)	49 (8.2%)
Married	229 (91.2%)	318 (92.8%)	547 (91.8%)
Education: Highest Class ever attended[64]	**251 (100%)**	**345 (100%)**	**596 (100%)**
None	73 (29.1%)	109 (31.6%)	182 (30.5%)
Std 1	9 (3.6%)	7 (2.0%)	16 (2.7%)
Std 2	19 (7.6%)	22 (6.4%)	41 (6.9%)
Std 3	15 (6.0%)	28 (8.1%)	43 (7.2%)
Std 4	20 (8.0%)	33 (9.6%)	53 (8.9%)
Std 5	34 (13.5%)	40 (11.6%)	74 (12.4%)
Std 6	17 (6.8%)	25 (7.2%)	42 (7.0%)
Std 7	20 (8.0%)	29 (8.4%)	49 (8.2%)
Std 8	16 (6.4%)	28 (8.1%)	44 (7.4%)
Form 1	4 (1.6%)	5 (1.6%)	9 (1.5%)
Form 2	16 (6.4%)	8 (2.3%)	24 (4.0%)
Form 3	3 (1.2%)	5 (1.4%)	8 (1.3%)
Form 4	5 (2.0%)	6 (1.7%)	11 (1.8%)
Post-secondary	0	0	0
Illiterate[65]	**96/251 (38%)**	**154/345 (45%)**	**250 (42%)**
Respondents main Occupation	**251 (100%)**	**345 (100%)**	**596 (100%)**
Labour	40 (15.9%)	40 (11.6%)	80 (13.4%)
Agriculture	184 (73.2%)	268 (77.7%)	452 (75.8%)
Private office employee	0 (0.0%)	1 (0.3%)	1 (0.16%)
Small Business	10 (4.0%)	10 (2.9%)	20 (3.4%)
Shopkeeper	3 (1.2%)	5 (1.4%)	8 (1.3%)
Unemployed	6 (2.4%)	10 (2.9%)	16 (2.7%)
Incapacitated	2 (0.8%)	0 (0.0%)	2 (0.3%)
Others	6 (2.4%)	11 (2.4%)	17 (2.9%)
Spouse Illiterate	**35/184 (18.5%)**	**52/251 (20.7%)**	**87/440 (20%)**
Mean distance to Health Facility	**10.9km**	**11.4km**	
Mode of Transport to HF			
Walking	156 (62.2%)	246 (71.3%)	402 (67.4%)
Bicycle	66 (26.3%)	77 (22.3%)	143 (24.0%)
Bus	24 (9.6%)	14 (4.1%)	38 (6.4%)
Other (e.g. car)	5 (2.0%)	8 (2.3%)	13 (2.2%)

[64] Junior Primary levels (Std 1-4), Senior Primary levels (std 5-8), Junior Secondary level (form 1-2), Senior secondary level (form 3-4)

[65] Those who do not know how to read and write or who have never attended school.

Table 17. Antenatal Care Knowledge, Attitude and Practice

Antenatal Care		No Community Intervention	Community Intervention	Total
Number of ANC Visits recommended	1	2.4%	8.1%	5.7%
	2	10.2%	3.6%	6.4%
	3	5.7%	9.3%	7.7%
	4	**32.9%**	**26.9%**	**29.4%**
	5	**30.9%**	**30.7%**	**30.8%**
	Don't Know	17.9%	21.5%	20.0%
Total		100.0%	100.0%	100.0%
Number of Visits made	1	1.6%	3.2%	2.6%
	2	8.6%	10.6%	9.8%
	3	32.2%	36.0%	34.4%
	4	**33.9%**	**30.1%**	**31.7%**
	5+	**21.6%**	**17.1%**	**19.0%**
	Don't Know	2.0%	2.9%	2.6%
Total		100.0%	100.0%	100.0%
Trimester of first ANC visit	**1st**	**20.1%**	**18.9%**	**19.4%**
	2nd	70.7%	69.2%	69.8%
	3rd	8.4%	10.1%	9.4%
	Don't Know	.8%	1.8%	1.4%
Total		100.0%	100.0%	100.0%

they had their first ANC visit in the first trimester as recommended; with the vast majority of respondents in both groups indicating that their first ANC visit was in the second trimester (Table 17). As expected, those starting ANC earlier were more likely to have more total visits (data not shown). Clearly differences in knowledge, attitude and practice towards ANC do not vary much between women in CI areas and women in no CI areas.

Data on place of ANC indicated that 58% of respondents went for ANC at health centres and 40% went to hospitals for ANC, with very small minorities going to health posts, mobile clinics or Traditional Birth Attendants (TBA).

In terms of services provided to respondents during their ANC visits, over 95% of respondents indicated that they received iron tablets and a Tetanus Toxoid (TT) vaccination and that their abdomen was examined and their weight measured; 84% indicated that they gave a blood sample; 74% that their blood pressure was measured, 72% that thy received de-worming tablets; 67% that their height was measured, and only 56% that they gave a urine sample. It was not recorded whether or not respondents were asked to give blood or urine samples and subsequently refused.

Respondents were also asked about the health talks they received during their ANC visits. Over 90% of respondents indicated that they received talks on: family planning, wrapping the newborn, TT vaccination, using a skilled birth attendant, breast-feeding immediately after birth, danger signs during pregnancy, and identifying emergency transport options. 84% and 71% of respondents respectively indicated that they received a talk on financial preparation for delivery, and arranging blood in case of emergency.

Knowledge of danger signs during pregnancy is also crucial. Respondents were asked whether they knew if the following were danger signs during pregnancy; the percentage who did is indicated in brackets for each: vaginal bleeding (any amount) (75%); severe lower abdomen pains (64%); severe headache (57%); convulsion (55%); blurred vision/swelling of hands/face (47%); others (10%). The number of danger signs respondents in each group knew

is provided in Table 18; 58% of respondents in No CI areas and 64% of respondents in CI areas knew of at least three dangers signs during pregnancy.

64% of respondents indicated that they had experienced at least one problem (danger sign) during pregnancy.

Table 18 also provides data on the number of danger signs experienced during pregnancy for women in No CI and CI areas. 34% of women in No CI areas and 37% in CI areas experienced no danger signs with a lower percentage of women experiencing only 1 danger sign and slightly higher percentages experiencing 2 to 6 danger signs in the CI group compared to the No CI group. Clearly there is no obvious impact of CI on reducing the number of danger signs experienced by pregnant women during pregnancy.

4.2.1.2.4.3 Place of delivery and danger signs during labour

The place where respondents recently delivered was also recorded as were attitudes towards delivery place and reasons for not delivering at a health facility. Table 19 shows that 86% of respondents in No CI areas and 88% of respondents in CI areas delivered at a health facility. The proportions of respondents in each group who were assisted by specific personnel during delivery were very similar with 74.4% of respondents in No CI areas and 77.3% of respondents in CI areas assisted by nurses, 12.0% in No CI areas and 10.2% in CI areas assisted by TBA, 9.6% in No CI areas and 9.3% in CI areas assisted by doctors/clinical officers, 1.6% in No CI areas and 0.9% on CI areas assisted

Table 18. Knowledge and experience of danger signs during pregnancy

Danger signs		No Community Intervention	Community Intervention	Total
Number of danger signs mentioned	0	13 (5.2%)	21 (6.1%)	34 (5.7%)
	1	53 (21.1%)	44 12.8%)	97 (16.3%)
	2	42 (16.7%)	58 (16.8%)	100 (16.8%)
	3	**32 (12.7%)**	**83 (24.1%)**	**115 (19.3%)**
	4	**34 (13.5%)**	**52 (15.1%)**	**86 (14.4%)**
	5	**67 (26.7%)**	**72 (20.9%)**	**139 (23.3%)**
	6	**10 (5%)**	**15 (4.2%)**	**25 (4.2%)**
Total		251 (100%)	345 (100%)	596 (100%)
Number of danger signs developed during pregnancy	**0**	**34.3%**	**37.4%**	**36.1%**
	1	29.1%	22.3%	25.2%
	2	16.3%	11.9%	13.8%
	3	15.5%	19.1%	17.6%
	4	4.0%	6.4%	5.4%
	5	.8%	2.0%	1.5%
	6		.9%	.5%
Total		100.0%	100.0%	100.0%

by patient attendants; 1.6% in No CI areas and 0.9% on CI areas assisted by friends/relatives, and 0.8% in No CI areas and 0.3% on CI areas assisted by patient attendants (data not shown). For Malawi as a whole, the recent 2010 DHS[2, page 12] indicates 60.6% were assisted by nurses and a higher percentage than in our survey were assisted by friends/relatives (8.7%) or gave birth on their own (2.6%), with percentages assisted by TBA (14.4%) and doctors/clinical officers (10.7%) similar.

The 77 respondents who did not deliver at the health facility gave the following reasons (some giving more than one response): 'other' reasons (mainly religious beliefs; 44%); no transportation (29%); facility not open (17%); no female provider at facility (10%); don't trust facility/ poor quality services (9%); not customary (6%); cost too much (4%);

husband/family did not allow (3%); and, not necessary (1%). Clearly, issues that need to be addressed at the facility are important, but equally transport and religious beliefs are also important factors preventing 13% of the surveyed women delivering at the facility.

Respondents were also asked why health facility delivery was important. Only 4% of respondents indicated that they thought health facility delivery was not important with 84% indicating that it was important so that the condition of the mother and baby could be examined, 62% because it enabled the easy management of complications, and 49% for infection-free delivery.

On attitudes towards health facility delivery only 2.4% of respondents in No CI areas and 0.9% of respondents in CI areas indicated that they agreed that it was not necessary to deliver at a health facility. However, 29.2% of respondents in No CI areas but only 15.0% of respondents in CI areas agreed that if they had another baby they would not deliver at a health facility; and 72.5% of respondents in No CI areas but 82.3% of respondents in CI areas agreed that all pregnant mothers in their community should deliver at a health facility. The latter results indicate that attitudes towards health facility delivery (but not practices – see Figure 59) in CI areas are more positive that in No CI areas.

Respondents were also asked about their knowledge of the following danger signs during labour; the percentage who did is indicated in brackets for each: excessive bleeding before or after delivery (81%); labour longer than 8 hours (69%); appearance first of any part of the baby that is not the head (69%); convulsion (63%); others (9%). 5.5% of respondents indicated that they didn't know any danger signs during labour.

36% of respondents indicated that they had experienced at least one problem (danger sign) during labour. Looking at the data on experience of labour complications by No CI and CI and by place of delivery (Table 20) shows that of the majority of women who delivered at a health facility, the percentages experiencing 0, 1, 2, 3 or 4 labour complications were very similar between those in No CI and those in CI areas. Of those delivering at a TBA, a higher percentage in CI areas experienced complications, however the numbers delivering at TBA are small as are numbers delivering at home and the numbers delivering at other places are too small to accurately assess differences between groups.

Table 19. Place of delivery of MNH KAP survey respondents

Delivery		No Community Intervention	Community Intervention	Total
Place of delivery	**Health Facility**	**216 (86.1%)**	**303 (87.8%)**	**519 (87.1%)**
	TBA	14 (5.6%)	17 (4.9%)	31 (5.2%)
	At Home	19 (7.6%)	17 (4.9%)	36 (6.0%)
	Others	2 (0.8%)	8 (2.3%)	10 (1.7%)
Total		251 (100.0%)	345 (100.0%)	596 (100.0%)

4.2.1.2.4.4 Postnatal care check-ups, maternal post-delivery problems, and immediate newborn care

Post-natal Care (PMC) by a health professional should ideally be given within 2-days of delivery and certainly within the first 7 days. In No CI areas 59% of women had a PNC check-up with a health professional within 7 days, whereas in CI areas only 47% of women did. The reasons given for women not having PNC within 7 days were as follows: didn't know they should have PNC (48%); thought PNC not necessary (24%); facility too far/no practice in the community/no service available nearby (18%); did not know who to ask for PNC (10%), felt it was unsafe to go (8%); received treatment from traditional healer (5%); family members do not allow (4%); and, will cost too much (4%). By 6-weeks after delivery 80% of women in No CI areas and 87% of women in CI areas had had a PNC check-up. Of

Table 20. Labour complications by place of delivery and No CI vs. CI

Complications	Place of delivery	Total

			Health Facility	TBA	At Home	Others	
No CI	Number of complications developed/ experienced	0	67.1%	50%	63%	50.0%	65.7%
		1	19.0%	21%	33%	50.0%	20.3%
		2	10.2%	7%	5%		9.6%
		3	2.8%				2.4%
		4	0.9%	21%			2.0%
	Total		216=100%	14=100%	19=100%	2=100%	251=100%
CI	Number of complications developed/ experienced	0	63.0%	47%	53%	62.5%	61.7%
		1	21.1%	41%	35%	12.5%	22.6%
		2	10.6%	6%	12%	12.5%	10.4%
		3	2.0%	6%			2.0%
		4	3.3%			12.5%	3.2%
	Total		303=100%	17=100%	17=100%	8=100%	345=100%

these women only 77% in CI areas and 71% in No CI areas took their baby to the PNC check-up (i.e. they were only going for themselves to be checked). However, at the PNC check-up, nearly all of the women received advice on newborn care (97%) and were counselled about breast-feeding (96%). In addition, 95% were counselled about family planning, 95% were counselled about immunisation, 89% had an examination of their abdomen and 83% were asked whether they had severe abdominal pain. For the women who brought their babies to PNC, 98% had their babies vaccinated, 96% had their babies weighed and 90% had their babies examined; 91% were asked about their babies feeding habits.

Respondents were also asked about their knowledge of the following post-delivery danger signs; the percentage who did in No CI areas and in CI areas is indicated in brackets for each: high fever (No CI: 58%; CI: 69%); pain in lower abdomen or smelling/vaginal discharge (No CI: 49%; CI: 63%); excessive bleeding (No CI: 73%; CI: 81%); severe headache (No CI: 47%; CI: 54%); convulsion and fit (No CI: 56%; CI: 59%); others (No CI: 8%; CI: 10%); don't know (No CI: 10%; CI: 9%). Clearly, women in CI areas have better knowledge of postnatal care problems.

The data on experience of postpartum (post-delivery) maternal complications shows that 40% of women in No CI areas experienced PNC problems whilst 30% in CI areas did. Table 21 details the specific postpartum maternal complications experienced by women in No CI and CI areas and indicates that higher percentages of women in No CI areas experienced each complication than the percentages of women in CI areas.

Immediate newborn care is crucial for all babies regardless of whether they were born healthy or at full term or not.[66] Key newborn care practices include not bathing the baby until at least 24hrs after birth; and breast-feeding the baby immediately and with the first liquid that comes from the breast (the colostrum).[67] Table 22 shows the percentages of women in No CI areas and CI with the correct knowledge of these practices, and who actually observed these practices with their recently delivered newborn babies. Although knowledge of the best time to bath the new-born being after 24hrs was equally low in both groups (49% in No CI and 47% in CI areas), similarly higher percentages of women in each group indicated that they did

[66] Beck D, et al (2004), saving newborn lives: Care of the newborn reference manual.

[67] Silvestre M.A. (2010), Essential Newborn Care: The DOH/WHO Protocol.

Table 21. Postpartum maternal complications in No CI and CI areas

Post-Partum maternal complication	No Community Intervention	Community Intervention	Total
So much bleeding that you feared it was life threatening	21.90%	15.10%	18.00%
High fever	23.50%	17.10%	19.80%
Severe lower abdominal pain	24.70%	17.40%	20.50%
Convulsions	13.50%	5.80%	9.10%
None of the above	59.40%	69.90%	65.40%

bath their recently delivered newborn after 24hrs (65% in No CI areas and 67% in CI areas). Practice of immediate breastfeeding was also higher than correct knowledge, with a higher percentage of women in No CI areas having correct knowledge of this practice (77% vs. 63% of women in CI areas) and actually breast-feeding their recent newborns within the first hour (83% vs. 72% in CI areas; Table 22). 90% of women in no CI areas and 87% in CI areas gave fed their babies the colostrum; and a higher percentage of women in No CI areas exclusively breastfed their babies in the first three days (90%) than in CI areas (87%), but a higher percentage of women in CI areas exclusively breastfed their babies in the first six months (58%%) than in no CI areas (50%). The differences between women in No CI areas and women in CI areas in newborn care practices are not large, but overall women in No CI areas provided slightly more optimal care to their newborns than women in CI areas.

4.2.1.2.4.5 Birth preparedness

Being prepared for childbirth and for complications reduces delays to obtaining skilled maternal and neonatal care.[68] An average of 76% had prepared for the delivery while they were pregnant, with a higher percentage of women surveyed in CI areas (80%) being prepared than in No CI areas (69%). Specific preparations included (percentages indicating they had prepared in this way in brackets): financial preparations (72%); food (51%); transport (46%); material for clean delivery (44%); birth attendant identification (37%); facility identification (30%); and, blood donor identification (19%). Table 23 shows the number of these seven items that women in No CI and CI areas had prepared before delivery, and also shows that women in CI areas were more prepared than women in No CI areas.

In terms of financial preparations Figure 61 shows that women in CI areas set aside more money on average than women in No CI areas (MK280 ≈ £1), although more respondents from No CI areas could not remember how much money they set aside.

The recently delivered women were also asked whether they had planned the place where they would deliver during their pregnancy. In No CI areas 90% of women indicated that they had and of those 96% indicated that they had planned to deliver at a health facility; in CI areas 84% of women indicated that they had and of those 97% indicated that they had planned to deliver at a health facility. It is interesting to note that the percentage who actually delivered at a health facility were lower (Table 19), though as also indicated above the discrepancy is likely due to health system or community factors beyond their control.

4.2.1.2.4.6 Summary

The survey on maternal and neonatal health knowledge, attitudes and practices has shown that there are only small differences between women in community intervention areas and women

[68] JHPIEGO (2004), monitoring birth preparedness and complication readiness: tools and indicators for maternal and newborn health.

Table 22. Knowledge and practice of immediate newborn care practices

Newborn care practice - **Knowledge**	Response **(correct)**	**No Community Intervention**	**Community Intervention**	**Total**
Bathing baby 24hrs after birth	Within 24hrs	31.5%	36.6%	34.5%
	After 24hrs	**48.8%**	**47.0%**	**47.7%**
	Should not be bathed	1.2%	0.6%	0.9%
	Other e.g. "After 3 days"	0.8%	0.6%	0.7%
	Don't know	17.6%	15.2%	16.2%
Immediate breast-feeding	**Start breast-feeding immediately**	**77.2%**	**62.9%**	**68.9%**
	Wait until placenta is out	9.6%	9.7%	9.7%
	After bathing baby	1.3%	6.3%	4.2%
	24hrs after birth	1.8%	3.8%	2.9%
	Other "After being given hot water"	0.0%	0.3%	0.2%
	Don't know	14.0%	17.1%	14.1%
Newborn care practice - **Practice**	Response **(correct)**	**No Community Intervention**	**Community Intervention**	**Total**
Bathing baby 24hrs after birth	Within 24hrs	28.6%	30.2%	29.5%
	After 24hrs	**64.5%**	**67.2%**	**66.0%**
	Don't know	6.9%	2.7%	4.5%
Immediate breast-feeding	**Start breast-feeding immediately (first hour)**	**82.6%**	**71.8%**	**76.4%**
	After 1 hour	14.5%	23.2%	19.5%
	Don't know	2.9%	5.0%	4.1%
Give first liquid coming out of breast	**Yes**	**89.6%**	**87.3%**	**88.3%**
	No	10.4%	12.7%	11.7%
Exclusive breast-feeding in first 3 days	**Yes**	**85.0%**	**76.3%**	**80.0%**
	No	15.0%	23.7%	20.0%
Exclusive breast-feeding in first 6 months (only asked to women with babies 6 months or older)	Give baby other food and drink in first month	14.4%	2.5%	7.9%
	Give baby other food and drink when 1-5 months old	26.9%	28.7%	27.7%
	Give baby other food and drink after 6+ months	**50.3%**	**57.8%**	**54.5%**
	Don't know when they started giving baby other food and drink	8.0%	11.1%	9.7%

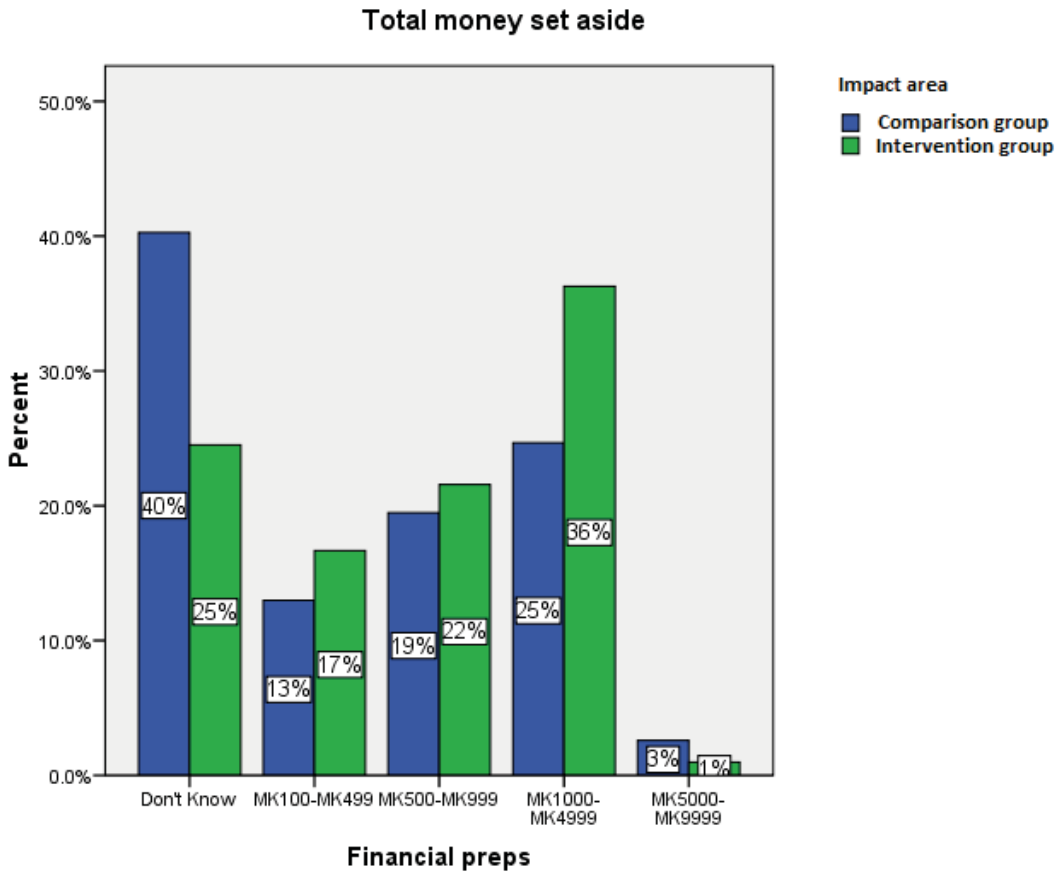
in areas without the community intervention. Knowledge of the recommended antenatal care appears very similar between the two groups, although knowledge of at least three danger signs during pregnancy is slightly higher in CI areas (64% vs. 58% in No CI areas) and the experience of no complications during pregnancy is slightly lower in CI areas (37% vs. 34% in No CI areas). In terms of place of delivery this survey corroborates the previously presented evidence (see section 4.2.1.2.1) that similarly high percentages of women are delivering at health facilities in intervention and control areas, and complications during delivery were also very similar between the two groups. A higher percentage of women in No CI areas (59%) had a postnatal check within 7 days than of women in CI areas (47%). However, women in CI areas had greater knowledge of postpartum maternal complications and also experienced less of each complication than women in No CI areas on average. In terms of postnatal newborn care however, women in No CI areas fared slightly better

although the differences between the groups were very small. Finally, in terms of birth preparedness, women in CI areas were found to have made more preparations (including setting larger sums of money aside) than women in No CI areas. How the, albeit small, observed differences between the MNH knowledge, attitudes and practices of women in CI areas and women in No CI areas identified in this survey may impact on the observed difference in perinatal mortality between the two groups (see section 4.1) requires further investigation.

Table 23. Birth preparedness of women in No CI and CI areas

Preparations for birth		No Community Intervention	Community Intervention	Total
Number of items prepared out of: finance, transport, food, birth attendant identification, facility identification blood donor identification, material for clean delivery.	0	31.8%	19.5%	25.1%
	1	8.4%	15.1%	12.2%
	2	21.1%	16.8%	18.6%
	3	15.1%	18.3%	16.9%
	4	8.8%	15.1%	12.4%
	5	8.8%	9.6%	9.2%
	6	0%	0%	0%
	All 7	6.0%	5.6%	5.6%

Figure 61: Financial preparations for childbirth by No CI and CI



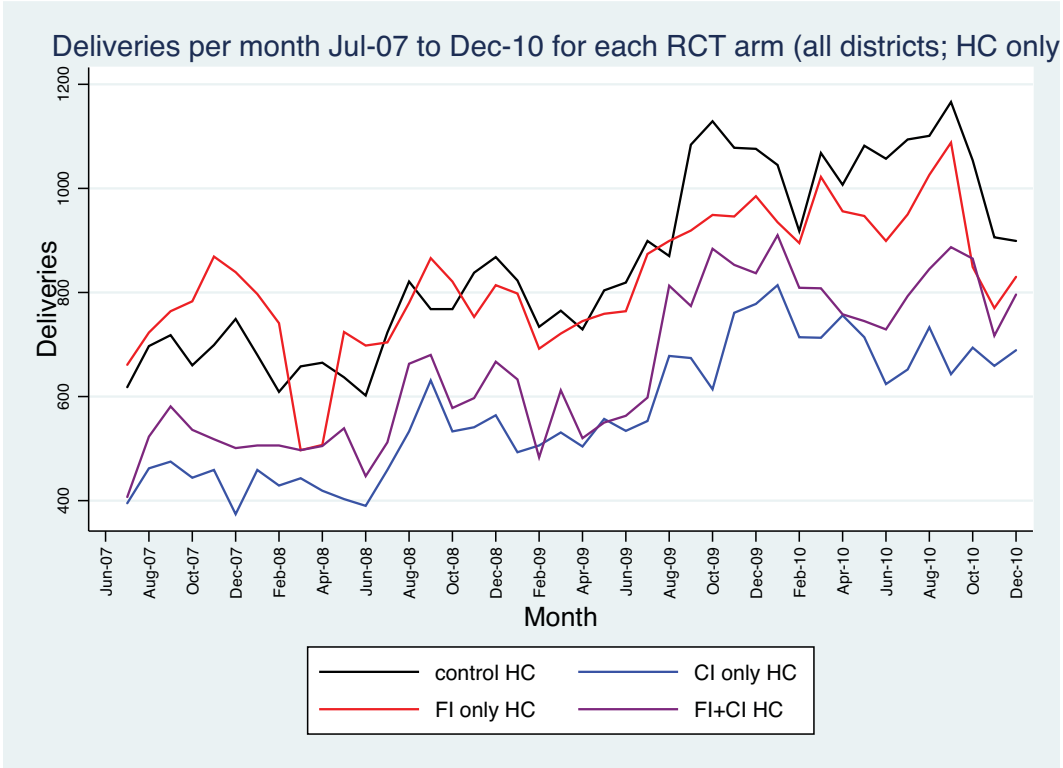
4.2.2 Health centre and hospital complications and case fatality rates

First we will present the data on maternal and neonatal case fatality and stillbirths, for the randomised Health Centres for the period June 2007 to December 2010, then we move on to present the case-fatality and cause of death data for the hospitals (CEmOCs) which were not part of the RCT.

4.2.2.1 Health Centre

Table 24 to Table 26 summarize the key HC indictors for FI and control HC in each of Kasungu, Lilongwe and Salima districts respectively. The tables compare the MaiKhanda Facilities Intervention (FI) HC with the HC that did not undergo the FI (control HC) and compare June-2007 – June 2008 (2007/8; considered as baseline) with July 2008 – July 2009 (2008/9; considered as intervention as the FI intervention officially re-started in the Health Centres in July 2008) and July 2009 – June 2010, to enable annual comparisons. First reported in Table 24 to Table 26 is the number of deliveries that are occurring at the HC. As is corroborated by the community surveillance results (see Table 7, Table 8, and Figure 59) all three tables clearly show a rise in HC deliveries from 2007/8 to 2008/9 to 2009/10 in both FI and control HC. Figure 63, Figure 65, and Figure 67, show the rise in the number of health centre deliveries graphically for all four arms of the RCT for all three districts. First, Figure 62 shows the increase in health facility deliveries for all four arms across all three districts.

Figure 62: Deliveries per month in Health Centres by RCT arm (all districts)



Maternal complications (see Appendix 10) are next reported. In Kasungu, the percentage of deliveries recorded with maternal complications reduced in both FI and non-FI health centres from 2007/8 to 2008/9 to 2009/10 (Table 24). In Lilongwe, maternal complications increased from 2007/8 to 2008/9 before decreasing in 2009/10 for both FI and non-FI health centres (Table 25). In Salima maternal complications were roughly constant throughout the evaluation period in FI health centres, but went down from 2007/8 to 2008/9 and then remained roughly constant in non-FI health centres (Table 26).

The Maternal Case Fatality Rate (MCFR) is difficult to assess at health centre level due to the small number of deaths. Table 24 to Table 26 suggests a decrease for all HC in 2008/9 and an

increase in control HC only in 2009/10. The fact the MCFR did not also increase in the FI HC in 2009/10 could be due to improved referrals, but given the small numbers could also be due to chance. In Salima HC there were only 4 maternal deaths in all HC for all time periods As is clear there are relatively very few maternal deaths in the HC compared to the hospitals; this is due to a high rate of referral and a high proportion of serious cases presenting directly at the hospitals without previously visiting the under-equipped (see section 4.2.1.1) health centres. The data from the CEmOCs – which account for around 90% of all facility maternal deaths is reported in section 4.1.2.2 below.

Moving on to look at neonatal complications (see Appendix 10) it is apparent that in Kasungu there has been little change in FI HC, but in non-FI HC the percentage of livebirths with neonatal complications increased from 2007/8 to 2008/9 before returning to a similar level in 2009/10 (Table 24). In Lilongwe, better recording of prematurity and low birth weight in 2008/9 lead to a large increase in neonatal complications; the rate then remained roughly the same in 2009/10 for both FI and non-FI HC (Table 25). In Salima FI HC, neonatal complications increased between 2007/8 and 2008/9 before remaining roughly constant; whereas in non-FI HC in Salima neonatal complications slightly decreased in control HC (Table 26).

Looking at the Neonatal Case Fatality Rate (NCFR), it is apparent that in Kasungu (Table 24), the NCFR rose substantially in both the FI and the control HC between 2007/8 and 2008/9 but then fell back to close to the 2007/8 level in 2009/10 in both FI and control HC. In Lilongwe the NCFR has changed less and has remained similar for all 3 years for both FI and control HC; at 3-4/1000 the NCFR is around half that of Kasungu HC though (Table 25). In Salima, there has been a fall in NCFR in both FI and control HC from 2007/8 to 2008/9 then a further fall in 2009/10 in FI HC but a slight increase in 2009/10 for control HC (Table 26); NCFR in Salima HC is similar to that of Lilongwe HC. As with MCFR, changes could also be the result of changes in referrals to the CEmOC, considering the NCFR is relatively very low (about one third or less) compared to that in the CEmOCs (see section 4.1.2.2 below).

The Fresh Stillbirth Rate (FSBR) is an important indicator of clinical care immediately before and during delivery. District-wise, Kasungu recorded a fall in FSBR in its FI HC from 2007/8 to 2008/9 and a slight rise in 2009/10, and a rise in the control facilities from 2007/8 to 2008/9 followed by a larger fall in 2009/10. It is interesting to note that in Kasungu the FSBR in control HC is 2-3 times that of FI HC in all time periods (Table 24, Figure 64); it is unclear why this should be the case. Lilongwe (Table 25) recorded a similar FSBR in FI facilities and a rise in control facilities from 2007/8 to 2008/9 followed by a fall in FI facilities and a slight rise in control facilities to 2009/10. Salima recorded a rise in FSBR in FI facilities, but a fall in control facilities between 2007/8 and 2008/9 followed by a large fall in FI HC and a fall in control HC to 2009/10. It should be noted here that as with the MCFR and NCFR none of these trends are statistically significant (the 95% confidence intervals (CI) which give an indication of the precision of the two estimates being compared, always overlap considerably meaning T-tests or analyses of variance comparing the two or more groups would not be significant at the 5% level; some overlap, equivalent to up to one-third of the mean to lower/upper confidence interval could still permit 5% statistical significance given that comparing two or more groups is equivalent to visualisations of 95%CI, for the purposes of assessing statistical significance, being reduced from +/- 1.96 standard errors surrounding the mean to around +/- 1.39 or 1.5 standard errors surrounding the mean depending on the imbalance of standard errors between the two groups.[69, 70]), and therefore could be arising due to chance happenings.

[69] Goldstein H, J. R. Healy MJR. The Graphical Presentation of a Collection of Means. Journal of the Royal Statistical Society. Series A (Statistics in Society), Vol. 158, No. 1 (1995), pp. 175-177.

[70] Wolfe R, Hanley J. If we're so different, why do we keep overlapping? When 1 plus 1 doesn't make 2. CMAJ JAN. 8, 2002; 166 (1) pp. 65-66.

Table 24. Kasungu Health Centre data summary and trends

Summary of Kasungu Health Centre data comparing FI and control between Jul-2007 - Jun-2008 (baseline) and Jul-2008 - Jun 2009 and Jul-2009 - Jun-2010 (intervention period)

Kasungu		**FI**							**control**						
		2007/8	**2008/9**	**2009/10**	**changes**			**comments**	**2007/8**	**2008/9**	**2009/10**	**changes**			**comments**
		A	**B**	**C**	**A->B**	**B->C**	**A->C**		**A**	**B**	**C**	**A->B**	**B->C**	**A->C**	
number of Health Centres		8	8	8	0	0	0	no change	7	7	7	0	0	0	no change
Deliveries[a]		**2,895**	**3519**	**3755**	22%	7%	30%	increase in 2008/9 then broadly the same in 2009/10	**2,166**	**2,371**	**3,378**	9%	42%	56%	increase in 2008/9 and again in 2009/10
Maternal Complications	number	392	355	293	-9%	-17%	-25%		210	219	257	4%	17%	22%	
	% of deliveries[b]	*13.5%*	*10.1%*	*7.8%*	-25%	-23%	-42%	lower in 2008/9 and even lower in 2009/10	*9.7%*	*9.2%*	*7.6%*	-5%	-18%	-22%	slightly lower in 2008/9 and much lower in 2009/10
Livebirths		**2,882**	**3,532**	**3,535**	23%	0%	23%		**2,136**	**2,347**	**3,402**	10%	45%	59%	
Neonatal Complications	number	368	469	449	27%	-4%	22%		235	339	381	44%	12%	62%	
	% of livebirths	*12.8%*	*13.3%*	*12.7%*	4%	-4%	-1%	little change - slight increase by 2009/10)	*11.0%*	*14.4%*	*11.2%*	31%	-22%	2%	higher in 2008/9 then back to baseline level in 2009/10
Availability of the 6 BEmOC signal functions															
no. (%) of health centres with:	0 functions	0 *0%*	0 *0%*	0 *0%*	*0%*	*0%*	*0%*	little change - slightly worse by 2009/10	1 *14%*	1 *14%*	1 *14%*	*0%*	*0%*	*0%*	little change from 2007/8 to 2008/9 then worse in 2009/10
	1 to 2 functions	5 *63%*	6 *75%*	6 *75%*	*13%*	*0%*	*13%*		3 *43%*	3 *43%*	6 *86%*	*0%*	*43%*	*43%*	
	3 to 4 functions	2 *25%*	1 *13%*	2 *25%*	*-13%*	*13%*	*0%*		3 *43%*	2 *29%*	0 *0%*	*-14%*	*-29%*	*-43%*	
	5 to 6 functions	1 *13%*	1 *13%*	0 *0%*	*0%*	*-13%*	*-13%*		0 *0%*	1 *14%*	0 *0%*	*14%*	*-14%*	*0%*	
Maternal Deaths		**2**	**1**	**1**	-1	0	-1		**4**	**1**	**4**	-3	3	0	
MCFR (deaths per 100,000 deliveries)	MCFR	69	28	27	-41	-2	-42	lower in 2008/9 and same in 2009/10	185	42	118	-142	76	-66	lower in 2008/9 then back to baseline level in 2009/10
	lower 95%CI	19	5	5				(not significant)	72	7	46				(not significant) (not significant)
	upper 95%CI	252	161	151					474	239	304				
Neonatal Deaths		**17**	**34**	**20**	17	-14	3		**15**	**31**	**26**	16	-5	11	
NCFR (deaths per 100,000 deliveries)	NCFR	5.9	9.6	5.7	4	-4	0	higher in 2008/9 but then back to baseline level in 2009/10 (not significant) (not significant)	7.0	13.2	7.6	6	-6	1	higher in 2008/9 but then back to baseline level in 2009/10
	lower 95%CI	3.7	6.9	3.7					4.3	9.3	5.2				(not significant) (not significant)
	upper 95%CI	9.4	13.4	8.7					11.6	18.7	11.2				
Fresh Stillbirths		**21**	**20**	**24**	-1	4	3		**31**	**50**	**35**	19	-15	4	
FSBR (FSB per 1000 deliveries)	FSBCFR	7.3	5.7	6.4	-2	1	-1	lower in 2008/9 then slightly higher in 2009/10 (not significant) (not significant)	14.3	21.1	10.4	7	-11	-4	higher in 2008/9 but then back below baseline level in 2009/10
	lower 95%CI	4.7	3.7	4.3					10.1	16.0	7.5				(not significant) (not significant)
	upper 95%CI	11.1	8.8	9.5					20.2	27.7	14.4				

MCFR = Maternal Case Fatality Rate; NCFR = Neonatal Caase Fatality Rate; FSBCFR = Fresh Stillbirth Rate

[a] ajustments made for missing data

[b] denominator is unadjusted number of deliveries (recorded deliveries i.e. those with data on complications)

Table 24 is continued on the next page

Table 24 continued

Kasungu		baseline comparison 2007/8 FI vs Control	intervention comparison 2008/9 FI vs Control	intervention comparison 2009/10 FI vs Control	2007/8	2008/9	2009/10	Total changes A->B	Total changes B->C	Total changes A->C	comments
number of Health Centres					15	15	15	0	0	0	no change
Deliveries[a]					**5,061**	**5,890**	**7,133**	16%	21%	41%	increase in 2008/9 and again in 2009/10
Maternal Complications	number				602	574	550	-5%	-4%	-9%	
	% of deliveries[b]	*higher in FI HC*	*slightly higher in FI HC*	*slightly higher in FI HC*	*11.9%*	*9.7%*	*7.7%*	-18%	-21%	-35%	lower in 2008/9 and even lower in 2009/10
Livebirths					**5,018**	**5,879**	**6,937**	17%	18%	38%	
Neonatal Complications	number				603	808	830	34%	3%	38%	
	% of livebirths	*higher in FI HC*	*about the same*	*slightly higher in FI HC*	*12.0%*	*13.7%*	*12.0%*	14%	-13%	0%	higher in 2008/9 then slightly lower in 2009/10
Availability of the 6 BEmOC signal functions											
no. (%) of health centres with:	0 functions	*about the same*	*about the same*	*slightly better in FI HC*	1 *7%*	1 *7%*	1 *7%*	*0%*	*0%*	*0%*	little change from 2007/8 to 2008/9 then worse in 2009/10
	1 to 2 functions				8 *53%*	9 *60%*	12 *80%*	*7%*	*20%*	*27%*	
	3 to 4 functions				5 *33%*	3 *20%*	2 *13%*	*-13%*	*-7%*	*-20%*	
	5 to 6 functions				1 *7%*	2 *13%*	0 *0%*	*7%*	*-13%*	*-7%*	
Maternal Deaths					**6**	**2**	**5**	-4	3	-1	
MCFR (deaths per 100,000 deliveries)	MCFR	*lower in FI HC*	*slightly lower in FI HC*	*lower in FI HC*	119	34	70	-85	36	-48	lower in 2008/9 then higher in 2009/10 (but still less than baseline)
	lower 95%CI	*(not significant)*	*(not significant)*	*(not significant)*	54	9	30				(not significant) (not significant)
	upper 95%CI				258	124	164				
Neonatal Deaths					**32**	**65**	**46**	33	-19	14	
NCFR (deaths per 100,000 deliveries)	NCFR	*lower in FI HC*	*lower in FI HC*	*slighty lower in FI HC*	6.4	11.1	6.6	5	-4	0	higher in 2008/9 but then back to baseline level in 2009/10
	lower 95%CI	*(not significant)*	*(not significant)*	*(not significant)*	4.5	8.7	5.0				(not significant) (not significant)
	upper 95%CI				9.0	14.1	8.8				
Fresh Stillbirths					**52**	**70**	**59**	18	-11	7	
FSBR (FSB per 1000 deliveries)	FSBCFR	*lower in FI HC*	*significantly lower*	*lower in FI HC*	10.3	11.9	8.3	2	-4	-2	higher in 2008/9 but then back below baseline level in 2009/10
	lower 95%CI	*(not significant)*	*in FI HC*	*(not significant)*	7.8	9.4	6.4				(not significant) (not significant)
	upper 95%CI				13.4	15.0	10.7				

MCFR = Maternal Case Fatality Rate; NCFR = Neonatal Caase Fatality Rate; FSBCFR = Fresh Stillbirth Rate

[a] ajustments made for missing data

[b] denominator is unadjusted number of deliveries (recorded deliveries i.e. those with data on complications)

good outcome
bad outcome
no change
data issue

Figure 63: Deliveries at Health Centres in Kasungu by RCT arm

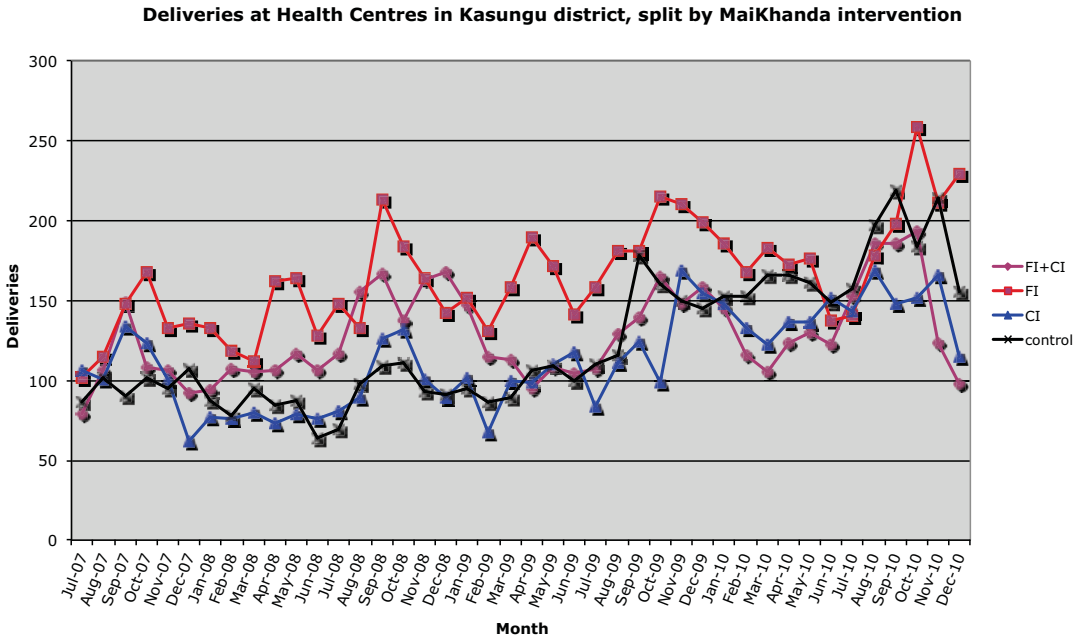


Figure 64: Fresh Stillbirth rate at Health Centres in Kasungu: FI vs. non-FI

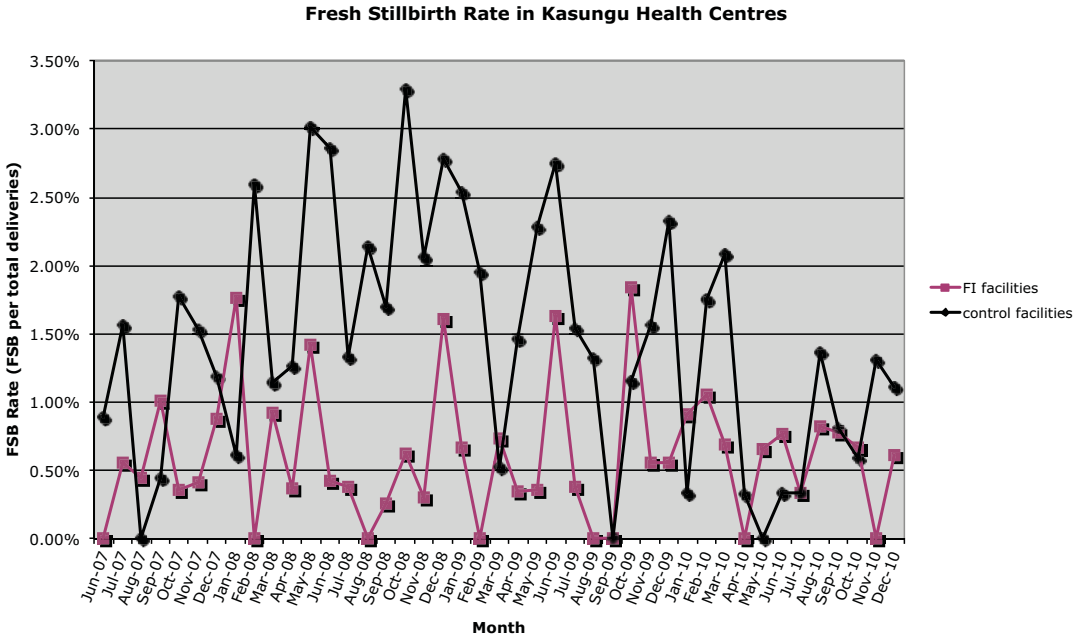


Table 25. Lilongwe Health Centre data summary and trends

Summary of Lilongwe Health Centre data comparing FI and control between Jul-2007 - Jun-2008 (baseline) and Jul-2008 - Jun 2009 and Jul-2009 - Jun-2010 (intervention period)

Lilongwe		**FI**							**control**						
		2007/8	**2008/9**	**2009/10**	**changes**			**comments**	**2007/8**	**2008/9**	**2009/10**	**changes**			**comments**
		A	**B**	**C**	**A->B**	**B->C**	**A->C**		**A**	**B**	**C**	**A->B**	**B->C**	**A->C**	
number of Health Centres		15	15	15	0	0	0	no change	19	19	19	0	0	0	no change
Deliveries[a]		**9,673**	**9617**	**13387**	-1%	39%	38%	increase in 2008/9 then large increase in 2009/10	**8,098**	**9,745**	**12,884**	20%	32%	59%	increase in 2008/9 and again in 2009/10
Maternal Complications	number	823	1033	1187	26%	15%	44%		825	1,039	1,092	26%	5%	32%	
	% of deliveries[b]	*8.5%*	*10.7%*	*8.9%*	26%	-17%	4%	back to baseline in	*10.2%*	*10.7%*	*8.5%*	5%	-21%	-17%	slightly lower in 2008/9 and much
Livebirths		**9,204**	**9,581**	**13,409**	4%	40%	46%		**7,949**	**9,668**	**12,797**	22%	32%	61%	
Neonatal Complications	number	381	1347	2002	254%	49%	425%	better recording of LBW	753	1253	1730	66%	38%	130%	better recording of LBW
	% of livebirths	*4.1%*	*14.1%*	*14.9%*	240%	6%	261%	and prematurity in 2008/9 and 2009/10	*9.5%*	*13.0%*	*13.5%*	37%	4%	43%	and prematurity in 2008/9 and 2009/10
Availability of the 6 BEmOC signal functions															
no. (%) of health centres with:	0 functions	5 *33%*	8 *53%*	5 *33%*	*20%*	*-20%*	*0%*	worse in 2008/9 then slightly better in 2009/10 but not as good as 2007/8	5 *26%*	11 *58%*	7 *37%*	*32%*	*-21%*	*11%*	worse in 2008/9 then slightly better in 2009/10
	1 to 2 functions	10 *67%*	6 *40%*	9 *60%*	*-27%*	*20%*	*-7%*		14 *74%*	7 *37%*	11 *58%*	*-37%*	*21%*	*-16%*	but not as good as 2007/8
	3 to 4 functions	0 *0%*	1 *7%*	0 *0%*	*7%*	*-7%*	*0%*		0 *0%*	1 *5%*	1 *5%*	*5%*	*0%*	*5%*	
	5 to 6 functions	0 *0%*	0 *0%*	1 *7%*	*0%*	*7%*	*7%*		0 *0%*	0 *0%*	0 *0%*	*0%*	*0%*	*0%*	
Maternal Deaths		**7**	**1**	**1**	-6	0	-6		**3**	**1**	**3**	-2	2	0	
MCFR (deaths per 100,000 deliveries)	MCFR	75	10	7	-65	-3	-68	lower in 2008/9 and same in 2009/10	38	10	23	-28	13	-14	lower in 2008/9 then back to baseline level in 2009/10
	lower 95%CI	37	2	1				(not significant)	13	2	8				(not significant) (not significant)
	upper 95%CI	156	59	42					111	58	68				
Neonatal Deaths		**45**	**41**	**59**	-4	18	14		**24**	**39**	**45**	15	6	21	
NCFR (deaths per 100,000 deliveries)	NCFR	4.9	4.3	4.4	-1	0	0	slightly lower in 2008/9 then same in 2009/10 (not significant) (not significant)	3.0	4.0	3.5	1	-1	0	higher in 2008/9 then lower in 2009/10
	lower 95%CI	3.7	3.2	3.4					2.0	3.0	2.6				(not significant) (not significant)
	upper 95%CI	6.5	5.8	5.7					4.5	5.5	4.7				
Fresh Stillbirths		**54**	**58**	**65**	4	7	11		**37**	**58**	**81**	21	23	44	
FSBR (FSB per 1000 deliveries)	FSBCFR	5.8	6.0	4.9	0	-1	-1	about the same in 2008/9 then lower in 2009/10	4.7	6.0	6.3	1	0	2	higher in 2008/9 then same in 2009/10
	lower 95%CI	4.5	4.7	3.8				significant)	3.4	4.6	5.1				(not significant) (not significant)
	upper 95%CI	7.6	7.8	6.2					6.4	7.7	7.8				

MCFR = Maternal Case Fatality Rate; NCFR = Neonatal Caase Fatality Rate; FSBCFR = Fresh Stillbirth Rate

[a] ajustments made for missing data; some HC are closed in some months and these are obviously counted as 0 deliveries

[b] denominator is unadjusted number of deliveries (recorded deliveries i.e. those with data on complications)

Table 25 is continued on the next page

Table 25 continued

Lilongwe		**baseline comparison 2007/8 FI vs Control**	**intervention comparison 2008/9 FI vs Control**	**intervention comparison 2009/10 FI vs Control**	**2007/8**		**2008/9**		**2009/10**		**Total changes A->B**	**B->C**	**A->C**	**comments**
number of Health Centres					34		34		34		0	0	0	no change
Deliveries[a]					**17,771**		**19,362**		**26,271**		9%	36%	48%	increase in 2008/9 and again in 2009/10
Maternal Complications	number				1,648		2,072		2,279		26%	10%	38%	
	% of deliveries[b]	*slightly lower in FI HC*	*higher in FI HC*	*slightly higher in FI HC*	*9.3%*		*10.7%*		*8.7%*		15%	-19%	-6%	lower in 2009/10
Livebirths					**17,153**		**19,249**		**26,206**		12%	36%	53%	
Neonatal Complications	number				1134		2600		3732		129%	44%	229%	better recording of LBW
	% of livebirths	*lower in FI HC*	*slightly higher in FI HC*	*higher in FI HC*	*6.6%*		*13.5%*		*14.2%*		104%	5%	115%	and prematurity in 2008/9 and 2009/10
Availability of the 6 BEmOC signal functions														
no. (%) of health centres with:	0 functions	*about the same*	*about the same*	*about the same*	10	*29%*	19	*56%*	12	*35%*	*26%*	*-21%*	*6%*	worse in 2008/9 then slightly better in 2009/10
	1 to 2 functions				24	*71%*	13	*38%*	20	*59%*	*-32%*	*21%*	*-12%*	but not as good as 2007/8
	3 to 4 functions				0	*0%*	2	*6%*	1	*3%*	*6%*	*-3%*	*3%*	
	5 to 6 functions				0	*0%*	0	*0%*	1	*3%*	*0%*	*3%*	*3%*	
Maternal Deaths					**10**		**2**		**4**		-8	2	-6	
MCFR (deaths per 100,000 deliveries)	MCFR	*higher in FI HC*	*slightly higher in FI HC*	*about the same*	58		10		15		-48	5	-43	lower in 2008/9 and same in 2009/10
	lower 95%CI	*(not significant)*	*(not significant)*	*(not significant)*	32		3		6					(not significant)
	upper 95%CI				107		38		39					
Neonatal Deaths					**69**		**80**		**104**		11	24	35	
NCFR (deaths per 100,000 deliveries)	NCFR	*higher in FI HC*	*lower in FI HC*	*higher in FI HC*	4.0		4.2		4.0		0	0	0	higher in 2008/9 but then back to baseline level in 2009/10
	lower 95%CI	*(not significant)*	*(not significant)*	*(not significant)*	3.2		3.3		3.3					(not significant) (not significant)
	upper 95%CI				5.1		5.2		4.8					
Fresh Stillbirths					**91**		**116**		**146**		25	30	55	
FSBR (FSB per 1000 deliveries)	FSBCFR	*higher in FI HC*	*higher in FI HC*	*slightly lower in FI HC*	5.3		6.0		5.6		1	0	0	higher in 2008/9 but then back below baseline level in 2009/10
	lower 95%CI	*(not significant)*	*(not significant)*	*(not significant)*	4.3		5.0		4.7					significant)
	upper 95%CI				6.5		7.2		6.5					

MCFR = Maternal Case Fatality Rate; NCFR = Neonatal Caase Fatality Rate; FSBCFR = Fresh Stillbirth Rate

[a] ajustments made for missing data; some HC are closed in some months and these are obviously counted as 0 deliveries

[b] denominator is unadjusted number of deliveries (recorded deliveries i.e. those with data on complications)

good outcome
bad outcome
no change
data issue

Figure 65: Deliveries at Health Centres in Lilongwe by RCT arm

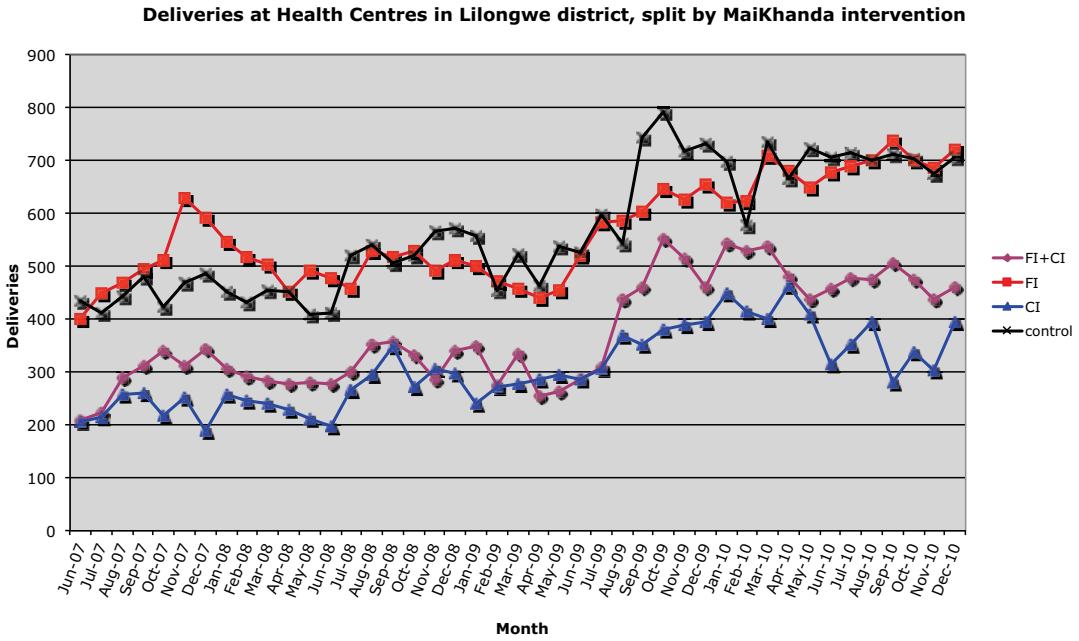


Figure 66: Fresh Stillbirth rate at Health Centres in Lilongwe: FI vs. non-FI

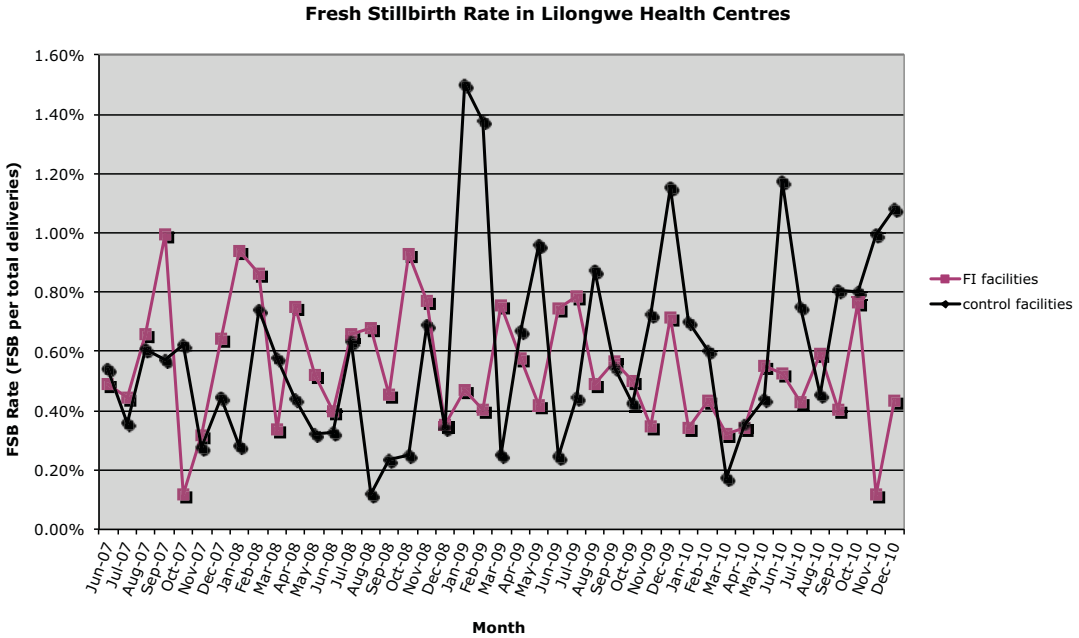


Table 26. Salima Health Centre data summary and trends

Summary of Salima Health Centre data comparing FI and control between Jul-2007 - Jun-2008 (baseline) and Jul-2008 - Jun 2009 and Jul-2009 - Jun-2010 (intervention period)

Salima		**FI**								**control**							
		2007/8		**2008/9**		**2009/10**		**changes**			**comments**	**2007/8**		**2008/9**		**2009/10**		**changes**			**comments**
		A		**B**		**C**		**A->B**	**B->C**	**A->C**		**A**		**B**		**C**		**A->B**	**B->C**	**A->C**	
number of Health Centres		6		6		6		0	0	0	no change	7		7		7		0	0	0	no change
Deliveries[a]		**2,493**		**3139**		**3760**		26%	20%	51%	increase in 2008/9 and in 2009/10	**3,034**		**3,730**		**4,470**		23%	20%	47%	increase in 2008/9 and again in 2009/10
Maternal Complications	number	200		260		334		30%	28%	67%		260		235		310		-10%	32%	19%	
	% of deliveries[b]	*8.0%*		*8.3%*		*8.9%*		3%	7%	11%	little change - slight increase by 2009/10)	*8.6%*		*6.3%*		*6.9%*		-26%	10%	-19%	slightly lower in 2008/9 and same in 2009/10
Livebirths		**2,487**		**3,155**		**3,472**		27%	10%	40%		**3,025**		**3,738**		**4,283**		24%	15%	42%	
Neonatal Complications	number	368		522		580		42%	11%	58%		396		452		547		14%	21%	38%	
	% of livebirths	*14.8%*		*16.5%*		*16.7%*		12%	1%	13%	slight increase in 2008/9 same in 2009/10	*13.1%*		*12.1%*		*12.8%*		-8%	6%	-2%	slight decrease in 2008/9 then same in 2009/10
Availability of the 6 BEmOC signal functions																					
no. (%) of health centres with:	0 functions	0	*0%*	0	*0%*	0	*0%*	*0%*	*0%*	*0%*	slightly better in 2008/9 and then again in 2009/10	0	*0%*	0	*0%*	0	*0%*	*0%*	*0%*	*0%*	no change
	1 to 2 functions	5	*83%*	4	*67%*	4	*67%*	*-17%*	*0%*	*-17%*		7	*100%*	7	*100%*	7	*100%*	*0%*	*0%*	*0%*	
	3 to 4 functions	1	*17%*	2	*33%*	2	*33%*	*17%*	*0%*	*17%*		0	*0%*	0	*0%*	0	*0%*	*0%*	*0%*	*0%*	
	5 to 6 functions	0	*0%*	0	*0%*	0	*0%*	*0%*	*0%*	*0%*		0	*0%*	0	*0%*	0	*0%*	*0%*	*0%*	*0%*	
Maternal Deaths		**1**		**0**		**1**		-1	1	0		**0**		**1**		**1**		1	0	1	
MCFR (deaths per 100,000 deliveries)	MCFR	40		0		28		-40	28	-12	lower in 2008/9 and same as baseline in 2009/10	0		27		23		27	-4	23	higher in 2008/9 then same in 2009/10 (only one death)
	lower 95%CI	7		0		5					(not significant)	0		5		4					(not significant) (not significant)
	upper 95%CI	227		122		158						126		152		127					
Neonatal Deaths		**16**		**13**		**12**		-3	-1	-4		**16**		**10**		**16**		-6	6	0	
NCFR (deaths per 100,000 deliveries)	NCFR	6.4		4.1		3.5		-2	-1	-3	lower in 2008/9 and slightly lower again in 2009/10	5.3		2.7		3.7		-3	1	-2	lower in 2008/9 and slightly higher in 2009/10
	lower 95%CI	4.0		2.4		2.0					(not significant)	3.3		1.5		2.3					(not significant) (not significant)
	upper 95%CI	10.4		7.0		6.0						8.6		4.9		6.1					
Fresh Stillbirths		**13**		**24**		**16**		11	-8	3		**24**		**27**		**25**		3	-2	1	
FSBR (FSB per 1000 deliveries)	FSBCFR	5.2		7.6		4.5		2	-3	-1	higher in 2008/9 then lower in 2009/10 (not significant) (not significant)	7.9		7.2		5.6		-1	-2	-2	slightly lower in 2008/9 and again in 2009/10
	lower 95%CI	3.0		5.1		2.8						5.3		5.0		3.8					(not significant)
	upper 95%CI	8.9		11.4		7.3						11.7		10.5		8.3					

MCFR = Maternal Case Fatality Rate; NCFR = Neonatal Caase Fatality Rate; FSBCFR = Fresh Stillbirth Rate

[a] ajustments made for missing data

[b] denominator is unadjusted number of deliveries (recorded deliveries i.e. those with data on complications)

Table 26 is continued on the next page

Table 26 continued

Salima		baseline comparison	intervention comparison	intervention comparison	Total						
		2007/8 FI vs Control	2008/9 FI vs Control	2009/10 FI vs Control	2007/8	2008/9	2009/10	changes A->B	changes B->C	changes A->C	comments
number of Health Centres					13	13	13	0	0	0	no change
Deliveries[a]					**5,527**	**6,869**	**8,230**	24%	20%	49%	increase in 2008/9 and again in 2009/10
Maternal Complications	number				460	495	644	8%	30%	40%	
	% of deliveries[b]	*about the same*	*higher in FI HC*	*higher in FI HC*	*8.3%*	*7.2%*	*7.8%*	-13%	9%	-6%	lower in 2008/9 and about the same in 2009/10
Livebirths					**5,512**	**6,893**	**7,755**	25%	13%	41%	
Neonatal Complications	number				764	974	1127	27%	16%	48%	
	% of livebirths	*higher in FI HC*	*higher in FI HC*	*higher in FI HC*	*13.9%*	*14.1%*	*14.5%*	2%	3%	5%	about the same
Availability of the 6 BEmOC signal functions											
no. (%) of health centres with:	0 functions	*about the same*	*slightly better in FI HC*	*better in FI HC*	0 *0%*	0 *0%*	0 *0%*	*0%*	*0%*	*0%*	little change from 2007/8 to 2008/9 then slightly better in 2009/10
	1 to 2 functions				12 *92%*	11 *85%*	11 *85%*	*-8%*	*0%*	*-8%*	
	3 to 4 functions				1 *8%*	2 *15%*	2 *15%*	*8%*	*0%*	*8%*	
	5 to 6 functions				0 *0%*	0 *0%*	0 *0%*	*0%*	*0%*	*0%*	
Maternal Deaths					**1**	**1**	**2**	0	1	1	
MCFR (deaths per 100,000 deliveries)	MCFR	*higher in FI HC*	*lower in FI HC*	*about the same*	18	15	25	-4	10	7	about the same in 2008/9 then higher in 2009/10 (not significant) (not significant)
	lower 95%CI	*(not significant)*	*(not significant)*		3	3	7				
	upper 95%CI				102	82	91				
Neonatal Deaths					**32**	**23**	**28**	-9	5	-4	
NCFR (deaths per 100,000 deliveries)	NCFR	*higher in FI HC*	*higher in FI HC*	*about the same*	5.8	3.3	3.6	-2	0	-2	lower in 2008/9 and then about the same in 2009/10 (not significant) (not significant)
	lower 95%CI	*(not significant)*	*(not significant)*		4.1	2.2	2.5				
	upper 95%CI				8.2	5.0	5.2				
Fresh Stillbirths					**37**	**51**	**41**	14	-10	4	
FSBR (FSB per 1000 deliveries)	FSBCFR	*lower in FI HC*	*about the same*	*lower in FI HC*	6.7	7.4	5.1	1	-2	-2	higher in 2008/9 but then back below baseline level in 2009/10 (not significant) (not significant)
	lower 95%CI	*(not significant)*		*(not significant)*	4.9	5.7	3.8				
	upper 95%CI				9.2	9.7	6.9				

MCFR = Maternal Case Fatality Rate; NCFR = Neonatal Caase Fatality Rate; FSBCFR = Fresh Stillbirth Rate

[a] ajustments made for missing data

[b] denominator is unadjusted number of deliveries (recorded deliveries i.e. those with data on complications)

good outcome
bad outcome
no change
data issue

Figure 67: Deliveries at Health Centres in Salima by RCT arm

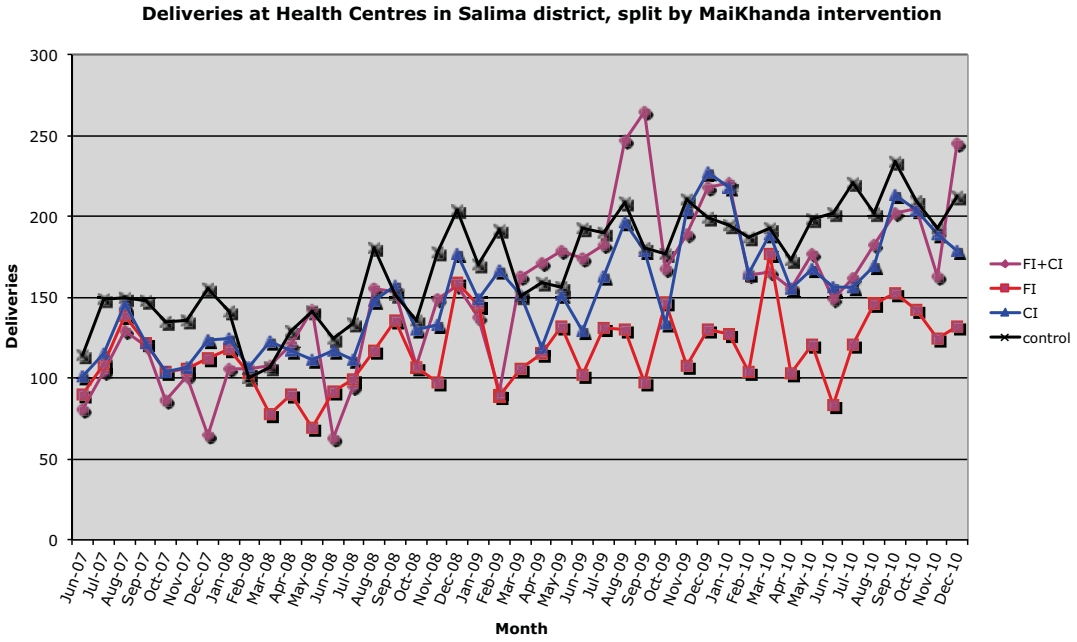
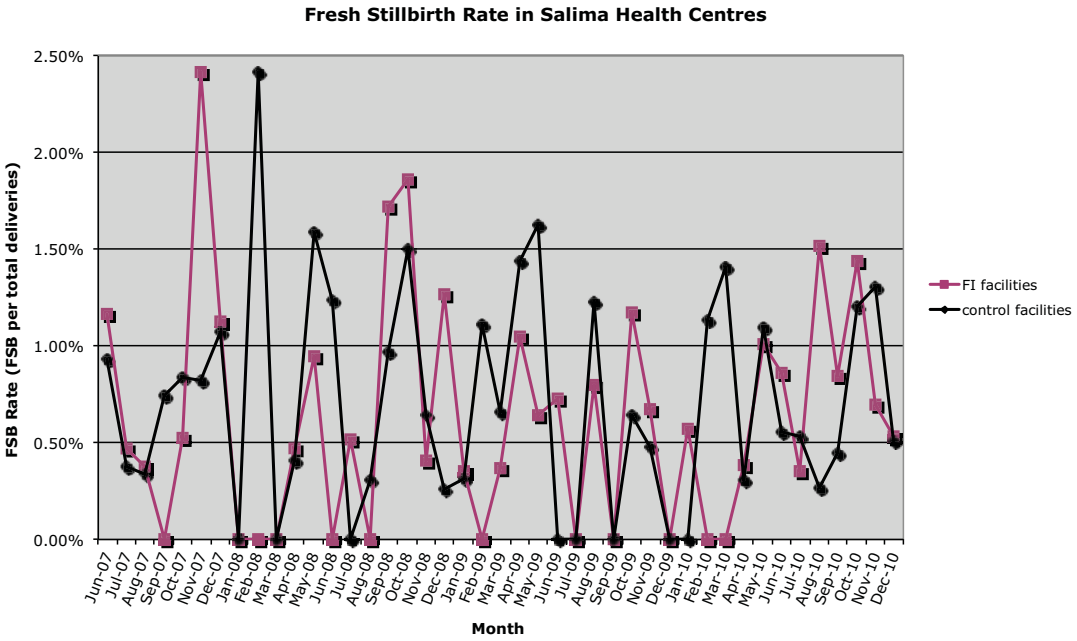


Figure 68: Fresh Stillbirth rate at Health Centres in Salima: FI vs. non-FI



For all districts combined and during the whole intervention period (Oct-08 to Dec-10) there was a slight, but statistically significant, effect of the FI on Fresh Stillbirth Rates: FI HC: 5.5 fresh stillbirths per 1000 births (95%CI: 4.9, 6.3); control HC: 7.8 fresh stillbirths per 100 births (95%CI: 7.0, 8.7; data not shown). Given the low rates in comparison to those in the community (section 4.2.3), hospitals (section 4.2.2.2), and total population (section 4.1.2) the absolute reduction in stillbirth mortality is small. The lack of observed effects on NCFR and MCFR at FI HC compared to control HC remain when looking at all districts and the whole intervention period.

Figure 69 to Figure 71 plot HC changes in FSBR, NCFR and MCFR by month by district and RCT arm with Lowess regression to provide a more detailed picture of the changes in case fatality rate described above.

Figure 69 shows that in Kasungu HC the FSBR is higher than in other districts for all RCT arms, and is highest in control HC (black line) where it rises in late 2008/early 2009; CI only HC (blue line) in Kasungu also have a slightly higher FSBR which is higher in 2008; the other arms have similar, lower, FSBR with no notable trends. The FSBR in both Lilongwe and Salima HC do not seem to diverge significantly by RCT arm and are uniformly low across the whole time period. The 'Total' graph (bottom right) in Figure 69 also shows no trends of note but should be interpreted with caution as it plots all 3 districts separately rather than the weighted average of all three, with the Lowess Regression line being drawn from all 3 districts points every month.

Figure 70 shows that NCFR is also higher in Kasungu HC than HC in the other districts, for all four RCT arms. It also shows an absence of significant trends in NCFR in Lilongwe and Salima for all four arms; with the Lowess Regressions of NCFR being uniformly low across the four arms in these districts; that is except for in Salima where the trend line increases for FI HC in late-2010 which is due to four NND being recorded in Chitala HC in Dec-10 (the outlying red dot; all 4 deaths were due to Asphyxia and were recorded with dates on the paper surveillance form). In Kasungu, there are some appreciable trends: NCFR in CI only HC (top left blue line) decreases in late 2007 before increasing in mid-2009 and then decreasing in 2010; NCFR in FI+CI HC remains fairly constant at an average of 10 NND/1000 livebirths before increasing in 2010; NCFR in FI only HC (red line) and control HC (black line) increases slightly in the second half of 2008 and first half of 2009 before decreasing approximately back to its 2007 baseline.

Figure 71 clearly highlights that Maternal Deaths in HC are isolated events and that consequently the trends in MCFR across RCT arm and district are all fairly flat.

Figure 69: Fresh Stillbirth Rate in Health Centres by RCT arm

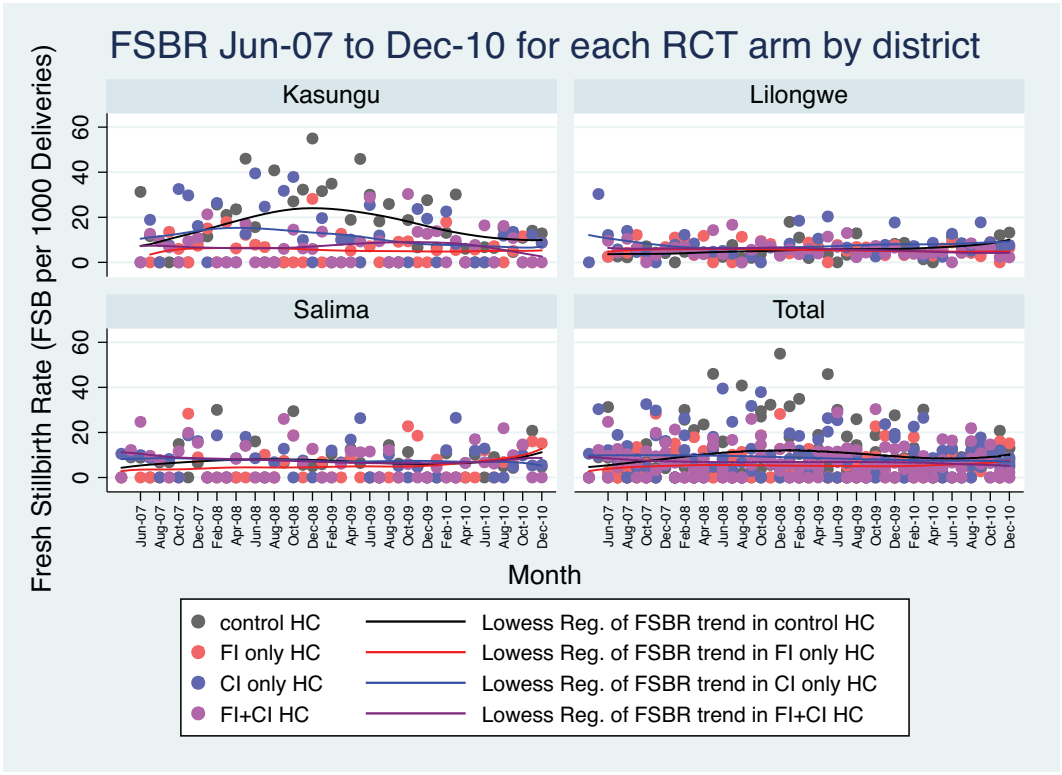


Figure 70: Neonatal Case Fatality Rate in Health Centres by RCT arm

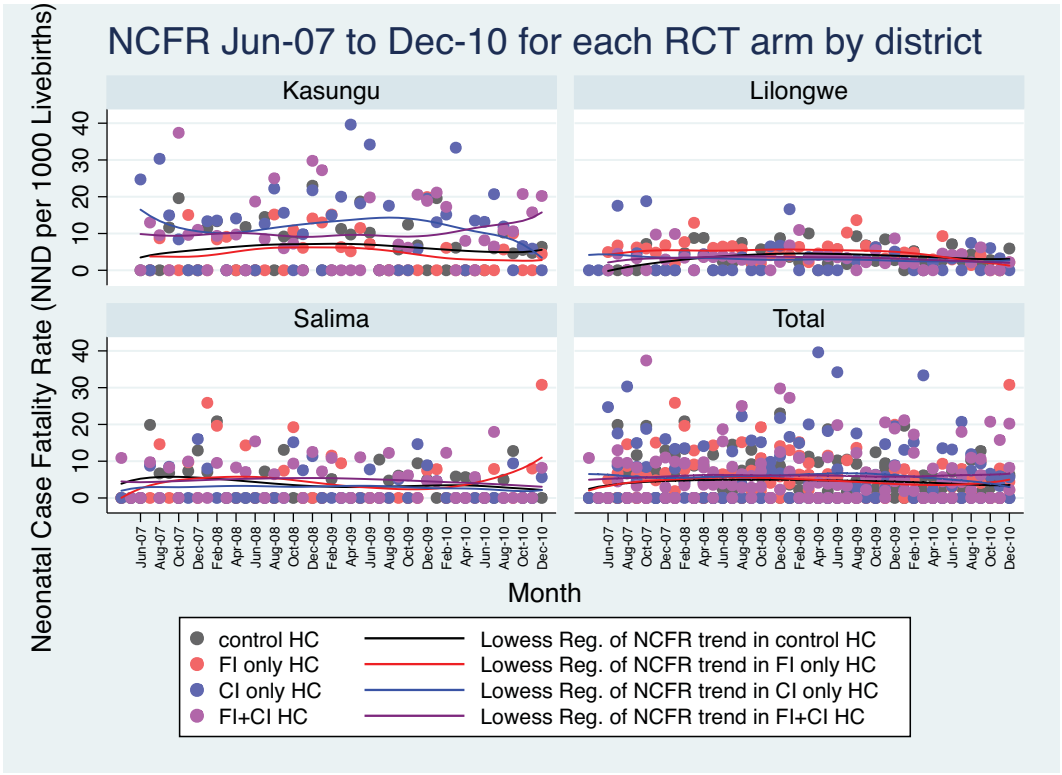
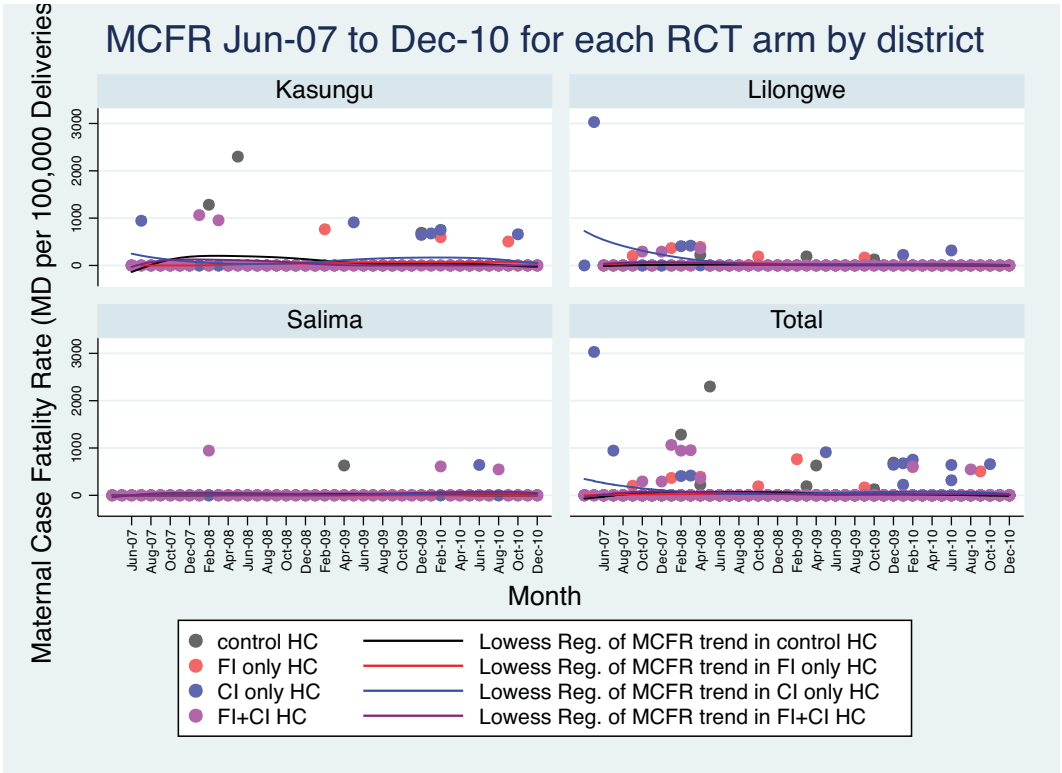


Figure 71: Maternal Case Fatality Rate in Health Centres by RCT arm



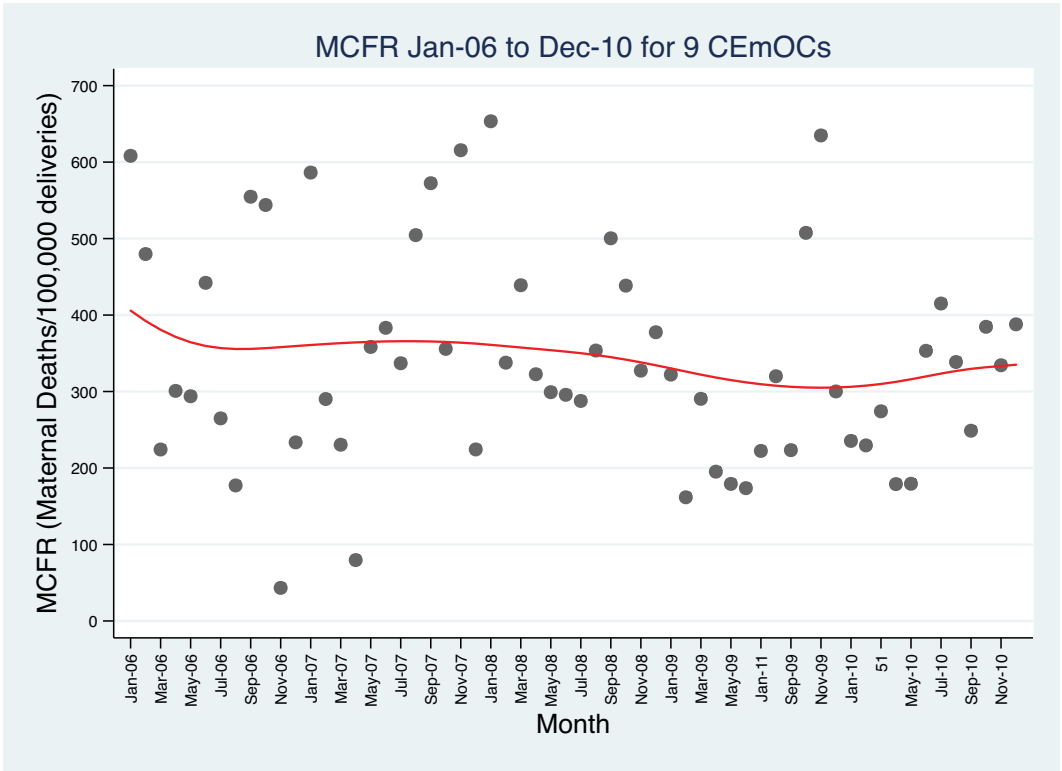
4.2.2.2 Hospital

4.2.2.2.1 Maternal Case Fatality Rate

Looking at the data on MCFR for the 9 CEmOCs where MaiKhanda has been working (Bwaila, Kabadula, Likuni, Mitundu, Mlale, Nkhoma, St. Gabriel's, SDH and KDH) we see the following (Figure 72, Figure 73, and Table 27): that MCFR (Maternal Deaths per 100,000 deliveries) during the 2006 baseline averaged 347 (median 297), that it increased in 2007, averaging 378 (median 357), that it remained similar in 2008, averaging 387 (median 346), that it decreased substantially in 2009, averaging 297 (median 257), and that it had the same average in 2010[71] (297) but a higher median (304). This represents an overall decline of 15% using annual averages or an increase of 2% using annual medians (which are often preferred when assessing QI initiatives as they discount outliers that may be due to periodic events that tip the system to a temporary 'out-of-control' state). Attributing the reduction in MCFR seen in 2009 to MaiKhanda does not fit with the conclusions from the dosage (section 3.2) and specific QI work (section 4.1.3) data, but more importantly does not fit with the fact that there was a rise in median MCFR in 2010 when the dosage of MaiKhanda was increased (see section 3.2), although it's possible that a threshold of overcrowding was reached during 2010 after a significant increase in health facility deliveries (see section 4.2.1.2.1) .

Since the use of annual means and medians and other such categorisation of time-trend data is to some extent arbitrary it is also useful to plot a trend line using regression techniques such as Lowess Regression, which is useful for making sense of data with a lot of variation as it produces smoothed trend lines. Figure 72 details a Lowess regression of the

Figure 72 MCFR in 9 CEmOCs, lowess regression



[71] This contrasts from the data presented in the third Deep Dive meeting and is the result of 6 more Maternal Deaths being found for 2009 and 1 more for 2010 when going through the Maternal Death Audits. It is unknown whether there would be more maternal deaths in 2006, 2007 and 2008 if a similar exercise was undertaken –if so the decline in 2009 would perhaps be larger. It should be noted however, that MaiKhanda is still capturing about twice as many Maternal Deaths as the Malawian MoH have in their EmOC report (see columns 9 and 10 of Table 29 below).

Figure 73: Maternal Case Fatality Rate at 9 CEmOCs combined, 2006-2010

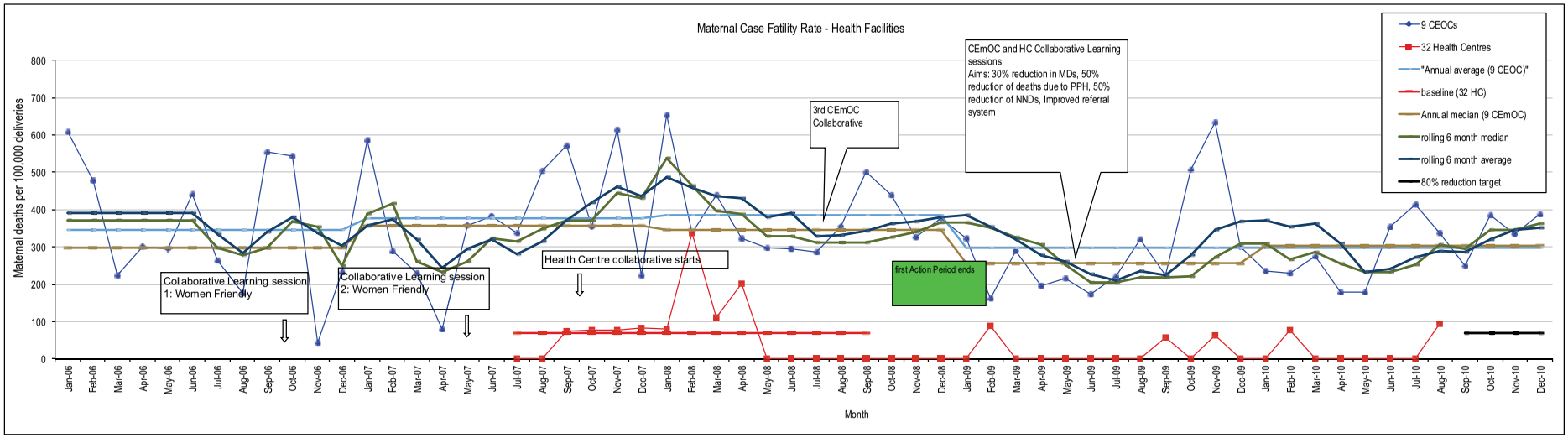


Table 27: Annual comparison of MCFR at CEmOCs, 2006-2010

MCFR (MD/100,000 deliveries) in MaiKhanda	2006	2007	annual % change	Change since 2006 baseline	2008	annual % change	Change since 2006 baseline	2009	annual % change	Change since 2006 baseline	2010	annual % change	Change since 2006 baseline
Deliveries 9 CEmOC	29,056	30,639	**5%**	**5%**	33,470	**9%**	**15%**	36,614	**9%**	**26%**	39,966	**9%**	**38%**
MD 9 CEmOCs	100	116	**16%**	**16%**	129	**11%**	**29%**	112	**-13%**	**12%**	119	**6%**	**19%**
MD KCH		44			28			35					
MD KCH assumed	30										30		
Annual average with KCH (rates much higher)	433	522	**21%**	**21%**	455	**-13%**	**5%**	391	**-14%**	**-10%**	364	**-7%**	**-16%**
Annual average (Jan-Dec 2006/7/8/9/10)	347	378	**9%**	**9%**	386	**2%**	**11%**	297	**-23%**	**-14%**	297	**0%**	**-15%**
Annual Median (Jan-Dec 2006/7/8/9/10)	297	357	**20%**	**20%**	346	**-3%**	**16%**	257	**-26%**	**-14%**	304	**18%**	**2%**

MCFR data from the 9 CEmOCs (excluding KCH) and whilst showing the increase in 2007 to be less marked shows the decline in 2009 followed by the rise in the second half of 2010.

Following quality improvement methodology, however, control charts should be used to assess the significance of changes in time-series data. Newly prepared control charts[72] were produced by the Institute for Healthcare Improvement (IHI; the technical partner behind the facilities intervention – see section 1.2) just prior to the submission of the final draft of this report. The control chart for CEmOC MCFR, which uses the same dataset as the two previous figures, except for data from 2006, which has been removed,[73] is provided as Figure 74, and can be explained (*text from IHI*) as follows.

The control charts show the variation and assess the stability of maternal and neonatal (see below sub-section) case fatality rates, with limits calculated as 3 standard errors on either side of the mean (as per the standard calculation of a U-chart). We used data from January 2007 to December 2010 for this analysis (data collected before January 2007 were thought to be unreliable[73]). A statistically significant change in performance in MCFR and NCFR (see Figure 80 below) occurred when we observed eight consecutive monthly values below the baseline mean as per control chart rules.[74] Using these criteria, we observed a MCFR baseline (381/100000 births) over the first 24 months of the study (Jan-07 to Dec-08) and a NCFR baseline (27.4/1000 live births) over the first 10 months of the study (Jan-07 to Oct-07). The denominator of live births was an average of 3,038; the U-Chart's control limits vary with monthly sample size.

Data falling outside of the control limits indicates the system is out of control, or is special cause variation. We determined special cause variation in MCFR to be November 2009, and in NCFR to be January, March and November 2010 in accordance with Shewhart's definitions[75,76] and Run Chart Rules.[77] Standard variation is inherent within the system and represents all other data points.

We recalculated the mean when the data indicated that there had been a change in performance, according to rules set down by Provost and Murray and consistent with the accepted usage of control charts.[74] Median MCFR decreased from a baseline of 381/100,000 births from January 2007 to December 2008 to 266/100,000 in the period from January 2009 to May 2010. Some worsening of this improved rate was detected from June 2010 to the end of the overservation period in November 2011, when the median rate was 310/100,000. Since none of the CEmOCs were included in the randomization design, we are not able to determine whether the apparent improvement after January was due to the initiation of QI interventions in the 9 non-randomized CEmOC facilities in July 2007 or to secular trends for improved MCFR throughout Malawi. The worsening of rates after May 2010 occurred during a time when there was a marked increase in rates of skilled delivery which may have reflected an inability of these poorly resourced failities to effectively manage the higher volume of patients.

On consideration of: the dosage of the facilities intervention at the hospital, which was low in 2008 (especially for neonatal) when the changes in MCFR and NCFR become

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[72] It is important to note that these are also new in the sense that they are different to previously produced charts tracking progress of the interventions throughout the 4 year evaluation period (these were run charts, see Figure 75), during the *Data Deep Dive* process (see section 2.6) and the nine months following the evaluation period (Jan-07 to Sep-11).

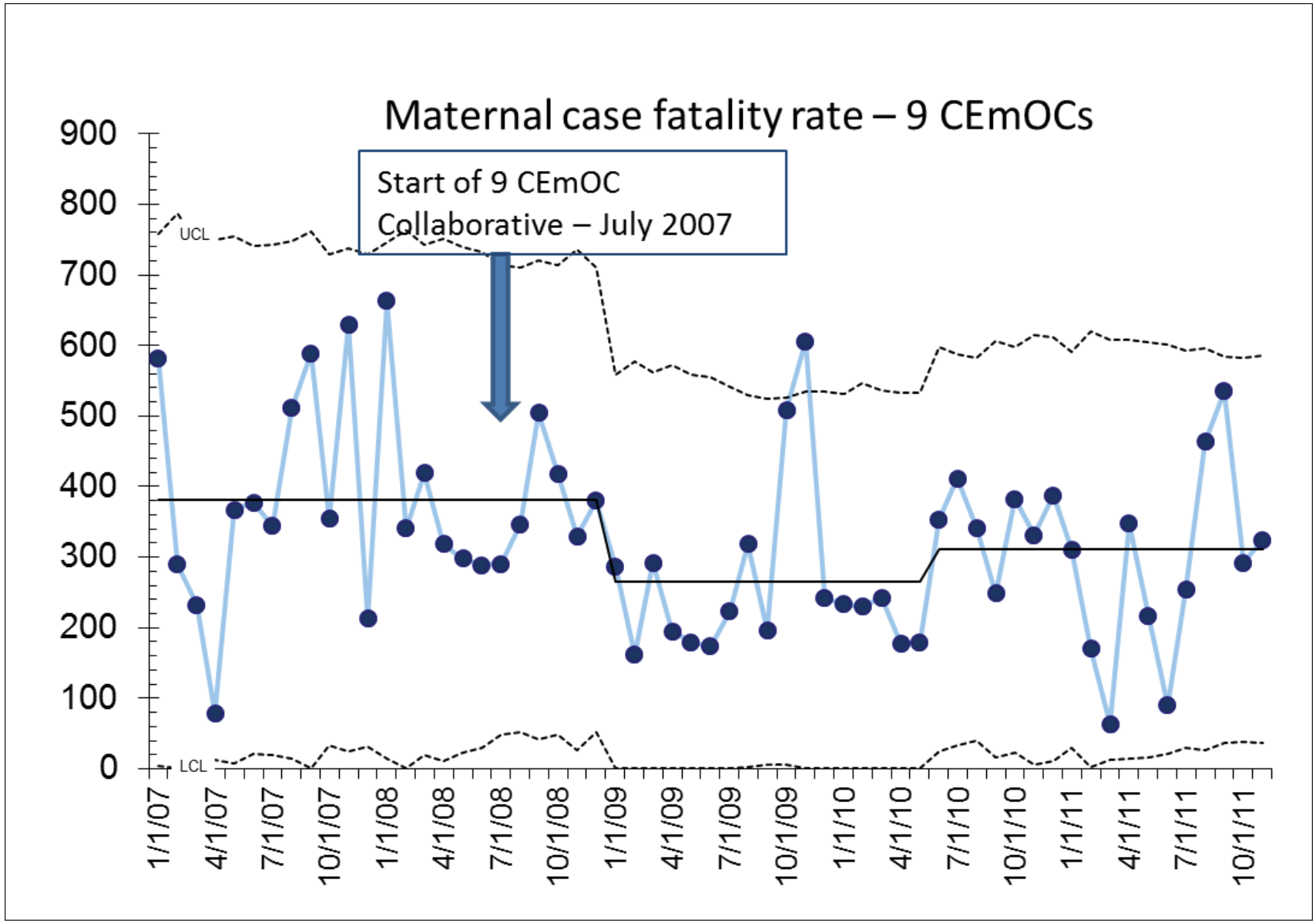
[73] This was not previously thought to be the case, and the facilities intervention did actually start in the CEmOCs in May 2006 so we are not convinced of this. Also, looking at the variation in the data it could be argued that all data before February 2008 is unreliable, and that it would be a useful exercise to make 26 versions of the control chart, each starting sequentially from a different month between January 2006 and February 2008 inclusive to see what difference that makes to the median lines plotted.

[74] Provost LP, Murray S. The Health Care Data Guide: Learning from Data for Improvement. San Francisco: Jossey-Bass; 2011.

[75] Shewhart, Walter Andrew. Economic Control of Quality of Manufactured Product. D. Van Nostrand Company, Inc, 1931

[76] Deming, W.E. The New Economics for Industry, Government & Education. Cambridge: Massachusetts Institute of Technology Center for Advanced Engineering Study.1993

Figure 74: Control chart of MCFR at the 9 CEmOCs, from Jan-07 to Nov-11



apparent on the control charts, and which only increased in late 2009 (section 3.2; we feel the single annotation provided on the new control charts needs to be unpacked); the available process data, which admittedly is patchy (see above); data on causes of death, which don't appear to change despite specific efforts of the facilities intervention (presented below); and, data on secular trends (acknowledged by IHI); we believe that the facilities intervention (and the community intervention) are unlikely to have been responsible for the observed changes. Indeed it is our belief that the available data (for examples see sections 3.2.2.1 and 4.1.3 above, the following text, and sections 4.2.2.3 and 4.2.5.1 below) indicate that the large and complex 9 CEmOC system was not under the control of MaiKhanda, but instead was influenced primarily by the many other factors outside the control of MaiKhanda.

Figure 75, produced using run-chart rules[77], which are less stringent[78] and more commonly used than control chart rules in quality improvement, provides further evidence in support of this notion by highlighting the increase in maternal case-fatality rate at the 9 CEmOCs in late 2010 as significant and showing that the increased rate has continued to November 2011.[79] This chart is the same as that used by the MaiKhanda facilities intervention to track progress and is the latest available before going to press.

Comparing the cause of death data over time to determine whether changes in the causes of death could be related to specific interventions targeting these causes of death, we observed the following. From the available data (Bwaila: maternal deaths for Feb-09, and Sep-09 to Mar-10; Nkhoma: all maternal deaths in 2009; KDH and St. Gabriel's: all maternal, deaths in 2009 and 2010; SDH: all maternal deaths from Oct-09 to Nov-10' Likuni: all maternal deaths in 2010; total 71% of all maternal deaths each year), it is apparent (Figure 76 and Figure 77) that firstly, there are many different causes of maternal death that have to be addressed, with the top four causes (PPH, Sepsis, Anaemia and Eclampsia), making up just over half of all deaths[80], and secondly that the facilities intervention, which only focused on a sub-set of these causes during the evaluation period (see section 3.2), seems unlikely to have effected the case mix given it's focuses. For example, Figure 76 and Figure 77 show that the percentage of deaths from PPH actually slightly increased in 2010 as compared to 2009 despite the facilities intervention work on PPH in 2010. Given there were 529 recorded cases of PPH in the 9 CEmOCs in both 2009 and 2010 (data not shown), this clearly illustrates the lack of impact of the PPH prevention work (section 4.1.3) on PPH deaths.

Finally, it is worth looking at how each of the Three Delays contribute to the maternal deaths at the CEmOCs (Figure 78). In 2009 the delay in the decision to seek care (Delay 1) was associated with 55% of maternal deaths, whilst delay in reaching treatment (including delayed referrals, Delay 2) was associated with 14% of deaths and delay in receiving adequate care (Delay 3) was associated with 31% of deaths. In 2010, the proportion that Delay 1 was associated with declined to 42% whilst the proportion Delay 3 was associated with increased to 40%. Whilst it is important to bear in mind that this data is only for approximately half of all the maternal deaths that happened in each year, it is also possible that this data represents a shift in responsibility for deaths away from the community and towards the hospital, something that is important to bear in mind in the analysis of the RCT data with respect to attempts to control for the influence of the un-randomised CEmOCs (see section 4.2.4.5) and when considering how the MaiKhanda interventions may have contributed to changes in the place of death (see section 4.2.4), although we do not have data on which RCT arm, if any, each of these deaths came from. Given that the death review

[77] Perla RJ, Provost LP, Murray SK. The run chart: a simple analytical tool for learning from variation in healthcare processes. BMJ Qual Saf 2011; 20: 46-51

[78] Significant changes are taken as those following 6 points below/above the previous median rather than 8 points below/above.

[79] Although the evaluation period stopped in December 2010, there is no reason to not report data in 2011 given the CEmOCs were not in a trial framework and that quality improvement is a continuous endeavor that recommends making inferences from on-going time-series data rather than distinct whole time-periods with cut-offs (see footnotes 78 and 81 for refs).

[80] We can assume that the 8 deaths that were audited each year but for which the causes of death was not determined (grey) were not caused by any of these 4 common killers. It should be noted that where multiple causes of death exist for one woman the one death was divided into these factors e.g. a women dying of sepsis and eclampsia would contribute 0.5 sepsis deaths and 0.5 eclampsia deaths.

Figure 75: Run chart of MCFR at the 9 CEmOCs Jan-06 to Nov-11

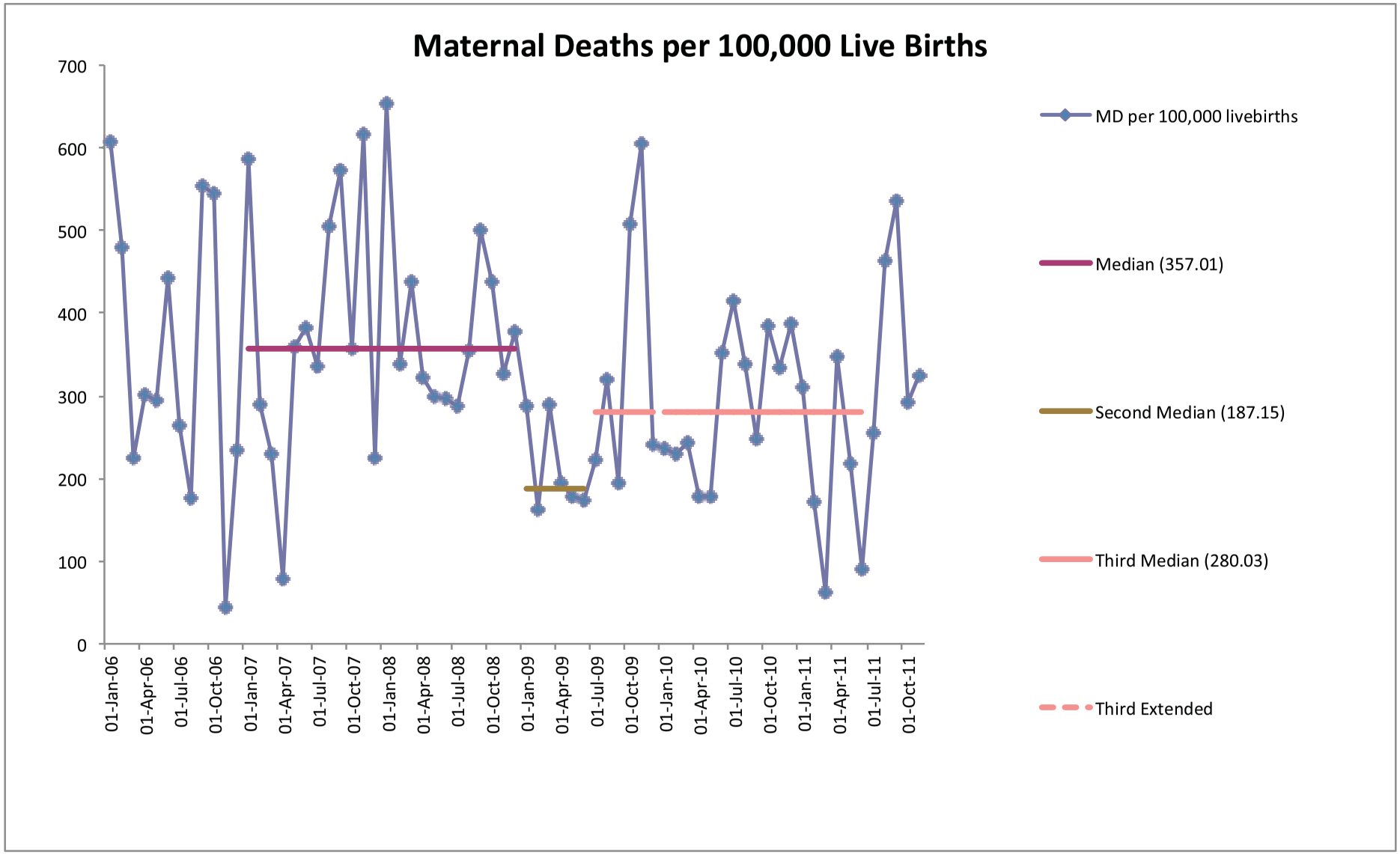


Figure 76: Causes of maternal deaths at the 9 CEmOCs – 2009

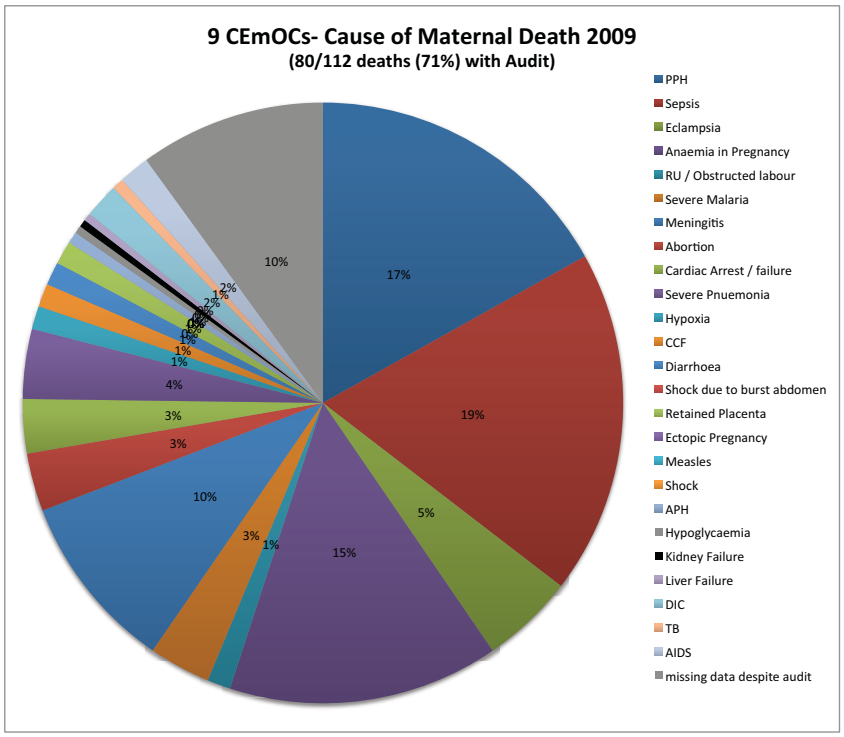
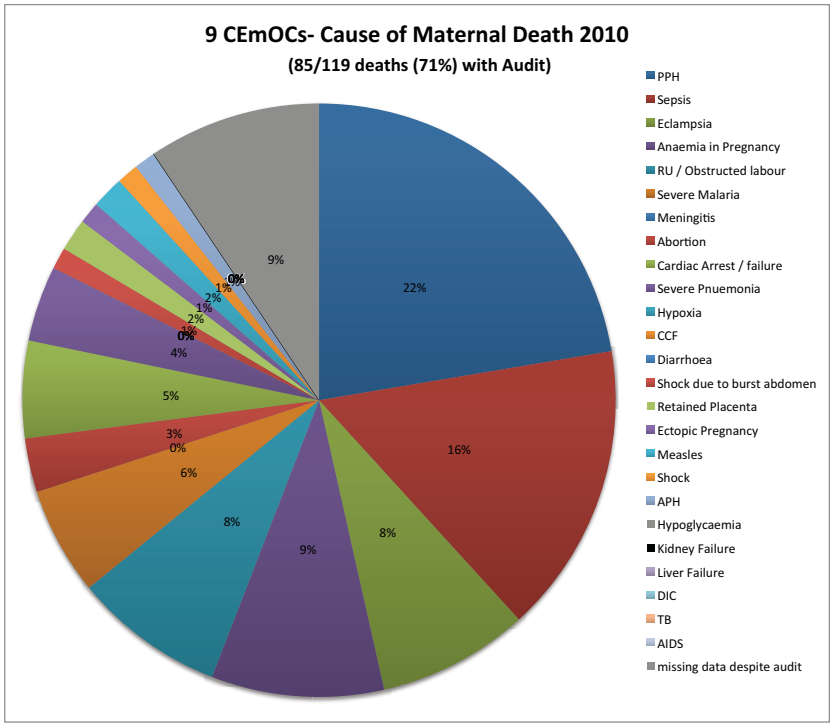
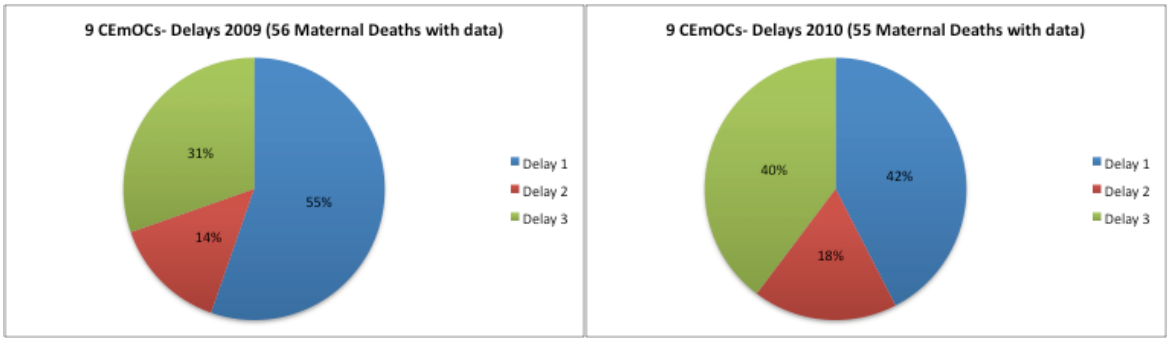


Figure 77: Causes of maternal deaths at the 9 CEmOCs - 2010



(audit) process requires honesty and a blame free culture, it is also possible (though we have no evidence) that the death review teams at the hospitals may have taken more responsibility for the deaths in 2010 rather than just pushing the blame on the communities.

Figure 78: Contribution of the Three Delays to maternal deaths in 9 CEmOCs in 2009 and 2010



4.2.2.2.2 Neonatal Case Fatality Rate

Moving on to look at NCFR at the CEmOCs, given the dosage (section 3.1) and specific QI work (section 4.1.3) data we may perhaps expect an impact of the CEmOC FI on NCFR in 2010 when the neonatal interventions were stepped up, although the data on specific QI work is patchy and a link to any impact on NCFR is unclear, especially from the annotated run charts for individual CEmOCs (Appendix 20).

Looking now at the data for the 9 CEmOCs where the FI was focused (Figure 79 and Table 28) we see that the NCFR (Neonatal Deaths per 1000 livebirths) during the May-December 2006 baseline[81] averaged 29 (median 26), that it decreased slightly in 2007, averaging 27 (median 26), that it decreased substantially in 2008, averaging 21 (median 20), that it remained at this lower level in 2009, averaging 20 (median 20), and that it increased substantially in 2010 but not to baseline levels, averaging 25 (median 23). This represents an overall decline of 14% using annual averages or of 10% using medians of the monthly data.

As introduced in the above sub-section, Figure 80 shows the recently calculated[64] control chart for neonatal case fatality rates. We also disagree with IHI's interpretation of this chart (that the change was due to the MaiKhanda interventions – see italic text 5 pages back) for the following reasons. Attributing the reduction in NCFR seen in 2008 (from Nov-07 in the control chart) and sustained in 2009 to MaiKhanda does not fit with the above conclusions from the dosage and specific QI work data, as there was little MaiKhanda neonatal work happening in 2008 and although it started in 2009 was not up to full dosage until 2010, when in fact as Figure 79 and Table 28 show the NCFR increased, when we would have expected it to decrease if it were dependent on the effects of the MaiKhanda FI.[82] As is noted, in Table 28, the effects of not including KCH are likely to be limited in the case of NCFR. Figure 81, produced using run-chart rules and used in MaiKhanda internal monitoring (see above text accompanying Figure 75) provides further evidence supporting the conclusion that the MaiKhanda facilities intervention was not in control of the system responsible for neonatal case fatality in the 9 CEmOCs (and was unlikely to be responsible for the lower rate in 2008)

[81] Data for January to April 2006 is unreliable with data for Bwaila, which has one of the highest NCFR, also missing for these months, so it was not included in the baseline estimate.

[82] There is an argument that the increased MaiKhanda FI neonatal interventions in 2010 lead to better recording of deaths and consequently pushed up the NCFR (the same could also be said for MCFR). However, we feel that this is unlikely for two reasons. Firstly the data improvement work of MaiKhanda started earlier, in 2007 (and was sustained throughout the intervention period); and, secondly, the variation in the data does not seem to be extreme for NCFR ever since it was deemed accurate in May 2006 (and as previously noted, the variation decreases in February 2008 for MCFR).

Figure 79: Neonatal Case Fatality Rate at 9 CEmOCs combined, 2006 to 2010

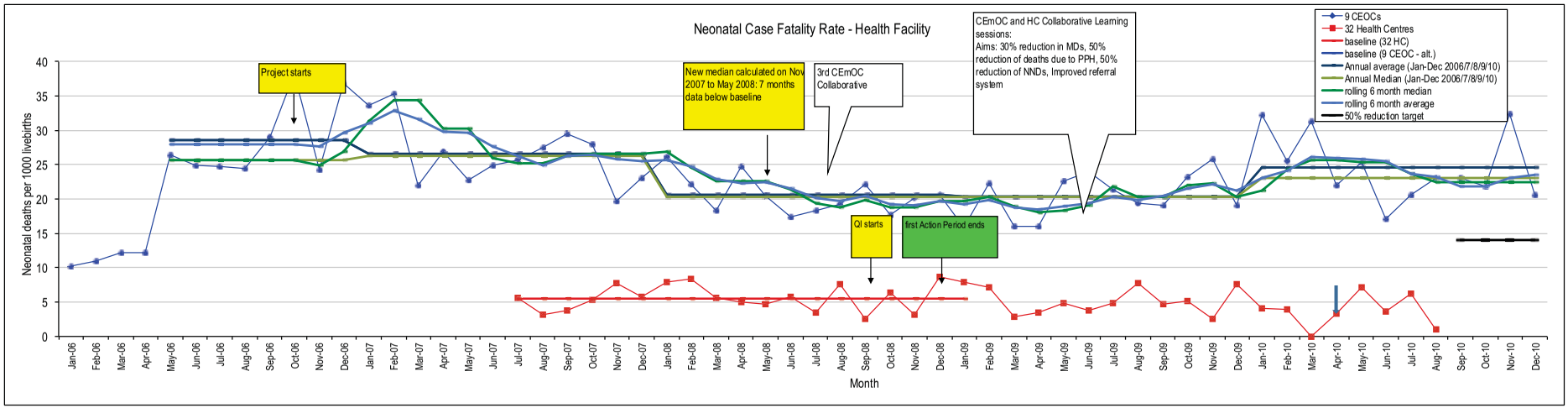


Table 28. Annual comparison of NCFR at CEmOCs, 2006-2010.

NCFR in MaiKhanda CEmOCs	May-Dec 2006	2007			2008	*annual % change*	Change since 2007	2009	*annual % change*	Change since 2007	2010	*annual % change*	Change since 2007
Livebirths 9 CEmOC	20,255	30,560			33,735	***10%***	**10%**	36,523	***8%***	**20%**	40,064	***10%***	**31%**
NND 9 CEmOCs	580	805			691	***-14%***	**-14%**	748	***8%***	**-7%**	981	***31%***	**22%**
NND KCH													
NND KCH assumed													
Annual average KCH assumed (rates higher?)													
	May-Dec 2006	2007	*change*	since 2006	2008	*change*	since 2006	2009	*change*	since 2006	2010	*change*	2006 baseline
Annual average (Jan-Dec 2006/7/8/9/10)	29	27	**-7%**	**-7%**	21	***-22%***	**-28%**	20	***-1%***	**-29%**	25	***21%***	**-14%**
Annual Median (Jan-Dec 2006/7/8/9/10)	26	26	***2%***	**2%**	20	***-23%***	**-21%**	20	***0%***	**-21%**	23	***13%***	**-10%**

Figure 80: Control chart of NCFR at the 9 CEmOCs, from Jan-07 to Dec-10

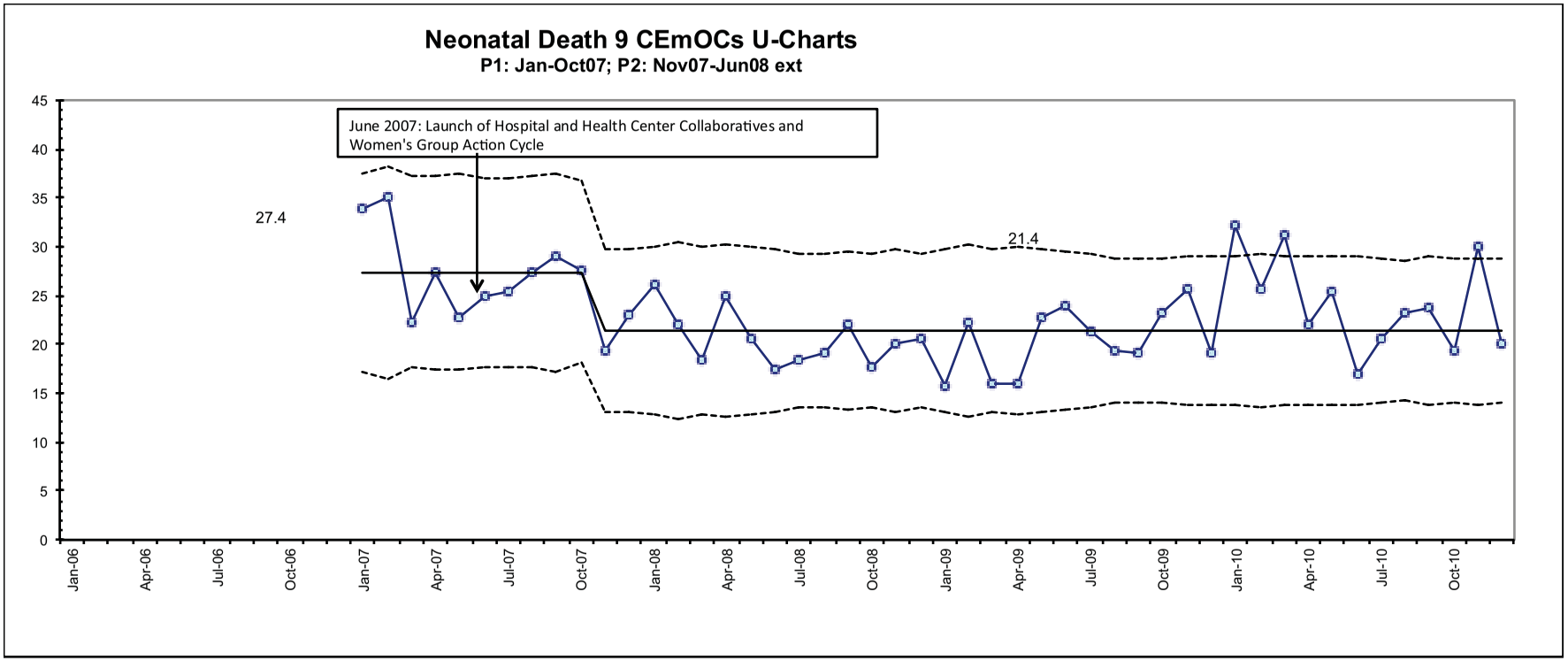
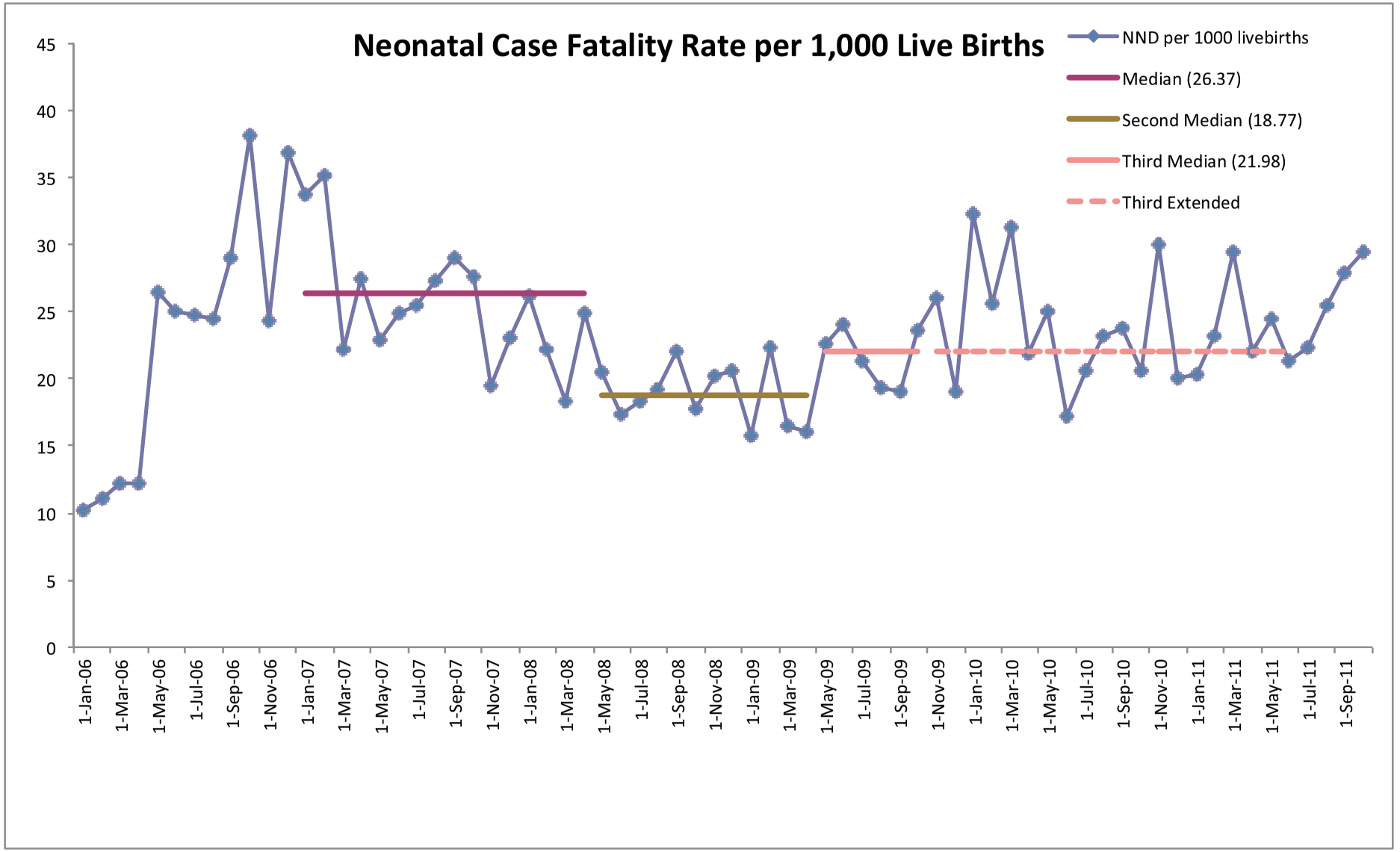


Figure 81: Run Chart of NCFR at the 9 CEmOCs Jan-06 to Oct-11



by indicating a significant increase in May 2009 (following 6-points above the previous median) that continued to October 2011 with the last 4 months showing a rising trend.

A plot of the Lowess Regression of the NCFR trend at the 9 CEmOCs combined is provided in Figure 82, also shows the decline in NCFR in 2007-2009, followed by and increase in late-2009 and 2010.

Although the MaiKhanda FI was not specifically tasked with reducing the Fresh Stillbirth Rate (FSBR; expressed as Fresh Stillbirths per 1000 deliveries) it might reasonably be assumed that improvements in partograph use and management of the second stage of labour may lead to reductions in fresh stillbirths. Accordingly, we have provided the trend in FSBR for all 9 CEmOCs combined in Figure 83 below, which shows that the FSBR increased throughout 2006 and 2007 before remaining approximately the same in 2008 and then reducing in 2009 and 2010 to around the original baseline 2006 level. It is unclear whether the initial rise was due to better recording of data or whether, given the lack of process data on partograph use and management of obstructed labour etc., the decrease can be related to the MaiKhanda FI work.

Figure 82: NCFR in 9 CEmOCs, lowess regression

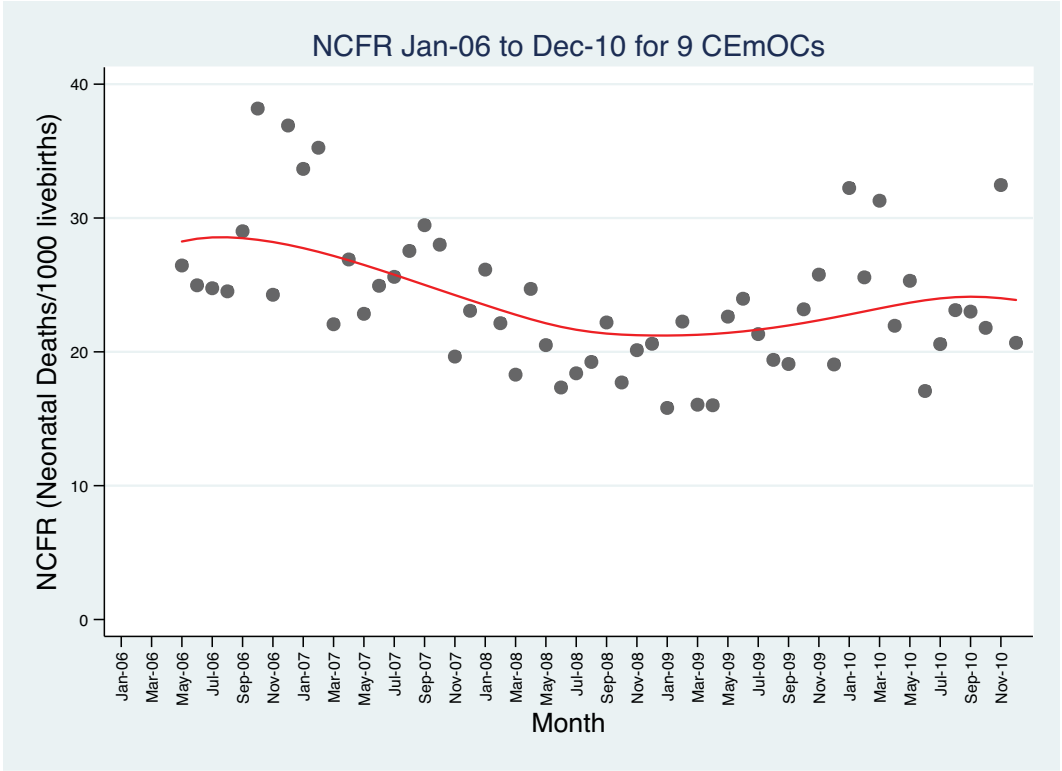
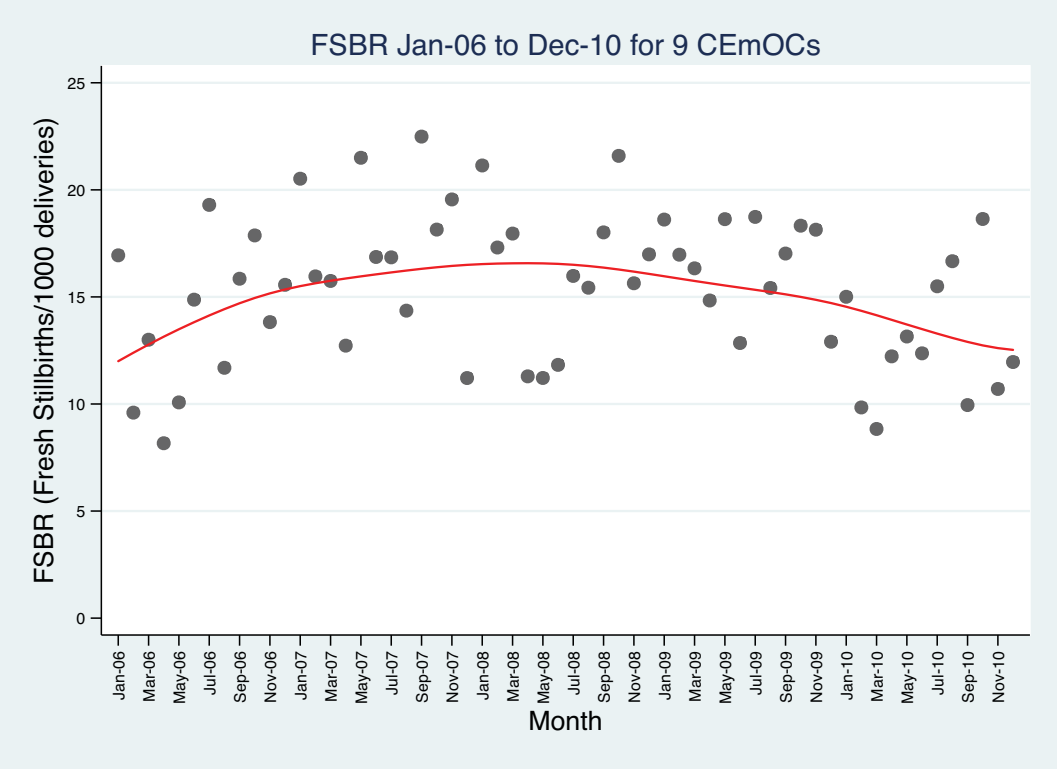


Figure 83: FSBR in 9 CEmOCs, lowess regression



4.2.2.2.3 Secular trends in maternal and neonatal hospital case fatality and population mortality in Malawi

Despite the other evidence indicating that there probably has been no overall effect of the MaiKhanda FI work at the CEmOCs, it is still important to examine secular trends in case fatality in other CEmOCs throughout Malawi, and in mortality in the population of Malawi as a whole. These give an indication of background rates of change that could possibly have masked effects of the MaiKhanda FI (or alternatively, if there was found to be an association of declining CFR with MaiKhanda FI activity, could give an indication as to whether the change could in fact also be explained, given the absence of a control group without the intervention, as a secular trend). Although an IHI intern was tasked with gathering CFR data from other hospitals in Malawi in mid-2011, this was not achieved. Therefore the only two sources of data the authors are aware of for this task are a report on CEmOC functioning by Sharan *et al* (2010) which includes data for 2007, and the 2010 EmOC assessment from the Malawian MoH which evaluates all EmOC facilities in Malawi between June 2009 and May 2010. Using the available data in these reports it is possible to roughly assess plausible trends in CEmOC MCFR (but not NCFR) as detailed in Table 29. From this analysis, which is admittedly rough and uncertain, it seems that there is likely to have been a secular trend towards decreasing MCFR in CEmOCs in Malawi from 2007 to 2010; a claim which is also echoed by the MoH 2010 EmOC report which states that the Direct Obstetric Complication Fatality Rate (DOCFR)[83] went down from 3.4% in 2005 to 2% in 2009/10. This secular trend matches the decrease we have observed in the CEmOCs of Kasungu, Lilongwe and Salima during the same period (to May 2010, see Figure 73).

Finally, the DHS 2010 results show a statistically significant 31% fall in overall population maternal mortality throughout Malawi from an MMR of 984 maternal deaths per 100,000 livebirths (95%CI: 804, 1164) during 1999-2004 to an MMR of 675 maternal deaths per 100,000 livebirths (95%CI: 570, 780) during 2005-2010.[2, page12] For neonatal mortality, the

[83] The proportion of all maternal complication cases that die, which is related to the MCFR.

Table 29. Analysis of available data on secular trends in CEmOC MCFR in other districts of Malawi.

2010 EmOC survey - data for Jun-09 to may-10. Tables 3.8 and 3.14 EmONC Facilities assume all MaiKhanda CEmOCs are here?

District	Number of births attended in facilities[3]	our data	discrepancy with our data	Number of births attended in EmONC facilities	our data	discrepancy with our data	Number of women with direct complications[1]	Number of maternal deaths by direct cause[1]	our data (CEmOCs)	Discrepancy with our data	DOCFR[2]
Blantyre	32549			11,549			3532	133			3.8%
Dedza	17751			5,107			828	3			0.4%
Dowa	14394			7,946			1013	19			1.9%
Kasungu	16824	13328	21%	6,881	6,004	13%	1409	26	35	-35%	1.8%
Lilongwe	56804	87629	-54%	21,781	33,210	-52%	2973	40	89	-123%	1.3%
Salima	11536	17591	-52%	5,072	4,829	5%	1079	13	24	-85%	1.2%
Zomba	24930			6,644			1137	16			1.4%

1. Direct complications and direct causes of maternal death include: APH, PPH, obstructed/prolonged labour, ectopic pregnancy, severe abortion complications, retained placenta, ruptured uterus, postpartum sepsis, severe pre-eclampsia/eclampsia. Excludes "other" direct complications or causes of death including non-severe abortion complications. Weighted for total number of health centres.

Sharan *et al* (2010) Data for 2007. Figure 21

District	MCFR	our data	Discrepancy with our data	CFR for obstetric complications	2007 to 2010 change	Our CEmOC deliveries 2007	Our CEmOC MD 2007	Our CEmOC MCFR data 2007	Our change in MCFR 2007 to 2010	Absolute % change discrepancy with our data	Plausible lower 2007 to 2010 change given possible discrepancy	Plausible upper 2007 to 2010 change given possible discrepancy	Lower and upper estimates of change say change from 2007 to 2010 was likely to be a:
Blantyre	1152			6.9%	-45%						-67%	-3%	Decrease
Dedza	59			1.8%	-80%						-102%	-38%	Decrease
Dowa	239			2.8%	-33%						-55%	9%	Decrease or slight increase
Kasungu	378	583	-54%	4.0%	-54%	4193	36	859	-32%	-22%			Decrease
Lilongwe	184	268	-46%	1.3%	3%	23886	104	435	-38%	42%			slight increase or Decrease
Salima	256	497	-94%	1.5%	-20%	3440	20	581	-15%	-5%			Decrease
Zomba	241			2.2%	-36%						-58%	6%	Decrease or slight increase

weight	CEmOC	Sharan 2010 CFR	Our 2007 data deliveries	deaths	MCFR	% if Bwaila = 1.0%	Discrepancy with our data
0.52	Bwaila/KCH	1.0%	11127	20	180		
0.10	Nkhoma	3.7%	2113	23	1088	6.1	-39%
0.13	St. Gabriel	0.5%	2755	9	327	1.8	-72%
0.16	Likuni	1.0%	3344	5	150	0.8	20%
0.09	Mitundu	2.0%	1955	2	102	0.6	251%
	Lilongwe weighted	**1.3%**	21294				

Given the data (of which there are serious differences with ours) we can conlcude that there probably has been a decline in other districts from 2007 to 2010.

DHS shows an non-statistically significant increase in neonatal mortality from 27 neonatal deaths per 1,000 (95%CI: 23, 31) during 1999-2004 (DHS 2004), to 31 neonatal deaths per 1,000 (95%CI: 28, 35) during 2005-2010 (DHS 2010). However, it is possible that the data from the 2004 DHS (but not the 2010 DHS) are biased downwards, due to discrepancies in reporting the year of death, as discussed in the DHS 2004 report. An additional national survey, the Multiple Indicator Cluster Survey, conducted in 2006 and not suffering from serious potential bias, observed NMR to be 33 neonatal deaths per 1,000 (95%CI: 29, 38) between 2001 and 2006, which means there could have been a slight, but non-significant decline in NMR in Malawi during the 2007-2010 evaluation period. Further sources of data were used to model trends in NMR in Malawi from 2000-2010 as part of work that the authors were involved in, forthcoming in the journal *Health Policy and Planning*. This suggests (although is still in the peer review process) a (non-significant) decline in NMR from 2000-2010 (although the 95% confidence limits for the 2007 to 2010 data (the time of the evaluation period) are also compatible with an increase in NMR).

In summary, national level data shows that in all probability there has been a decline in maternal case fatality and mortality in Malawi throughout the evaluation period, making it difficult to attribute any changes in MCFR to MaiKhanda, even if there wasn't data already suggesting otherwise; but that we don't know what the secular trends in neonatal hospital case-fatality rates were and we are uncertain as to the trend in population neonatal mortality during the evaluation period (meaning that our conclusions regarding the likely effect of MaiKhanda on hospital NCFR remain the same).

4.2.2.3 Percentage of maternal deaths that were audited

Table 30 shows that of the very few maternal deaths recorded at the health centres (see section 4.2.1.1.2) around half had death audits in the baseline period (Jun-07 to Jul-08). Although LSTM did some work at the health centres during this period (see section 3.1) maternal deaths audits were taking place in control health centres at roughly the same rate too indicating Ministry of Health involvement, which is perhaps unsurprising given MoH commitment to maternal death reviews/audits as detailed in their Road Map for accelaertaing the reduction of maternal and neonatal mortality and morbidity in Malawi (see section 1.1.4). During the intervention periods (Jul-08 to Jun-09 and Jul-09 to Jun-10) only 1 of the 17 maternal deaths at the facility intervention and control health centres combined was recorded (on the health facility surveillance form, see Appendix 10 and section 2.2.2) to have been audited (Table 30). We do not have any details of any of the maternal death audits conducted at the health centres.

Although the same health facility surveillance form (Appendix 10) was used to collect data at the hospitals (CEmOCs) the CEmOC database (maintained by the MaiKhanda facilities intervention team) did not record numbers of maternal death audits. Therefore the only information available on the number of maternal death audits conducted at the CEmOCs is that from the analysis of the maternal death audit data (reported above in the last two paragraphs of section 4.2.2.2.1). This indicates that 71% of maternal deaths occurring at the 9 CEmOCs were audited in each of 2009 (80/112) and 2010 (85/119). It is unclear how many of the death audits occurred as a result of the MaiKhanda facilities intervention and how many occurred as a result of the Ministry of Health adhering to their own protocols on maternal death reviews/audits as detailed in their Road Map (see section 1.1.4).

Table 30. Maternal deaths and maternal death audits at FI and control health centres

Maternal Deaths and Maternal Death Audits at Health Centres							
District	RCT arm	Jul-07 to Jun-08		Jul-08 to Jun-09		Jul-09 to Jun-10	
Kasungu	FI	2	0	1	0	1	0
	Control	4	2	1	0	4	1
Lilongwe	FI	7	5	1	0	1	0
	Control	3	3	1	0	3	0
Salima	FI	1	0	0	0	2	0
	Control	0	0	1	0	1	0
Total	FI	10	5	2	0	4	0
	Control	7	5	3	0	8	1

4.2.3 Differences in causes of perinatal and neonatal deaths

The RCT results showed that the CI intervention reduced perinatal mortality by 16% and that the combined FI+CI intervention reduced neonatal mortality by 22% (sections 4.1.4 and 4.1.5). We provide a summary of the results here again for convenience in Table 31. This summary also includes a breakdown of intervention effects on the stillbirth rate, early neonatal mortality rate and late neonatal mortality which can be used with reference to differences in cause of death in the early and neonatal periods (as also presented in section 4.1.5) to aid our understanding of possible mechanisms of the interventions. In addition we also provide a breakdown of mortality rates by the first intervention period (Oct-08 to Sep-09) and the second more intensive intervention period (Oct-09 to Dec-10 – see section 3.2) in Table 32, which we compare to a breakdown of causes of mortality in the different RCT areas during these time periods.

First we will look at the difference in causes of perinatal deaths between CI areas and No CI areas during baseline and intervention periods to try to explain the effects of the CI on perinatal mortality. Then we will look at the differences in neonatal deaths between FI+CI areas and control areas during baseline and intervention periods to try to explain the effects of the combined FI+CI on neonatal mortality.

Table 31. Summary of RCT results including effects on stillbirths, and early and late NND

	Intervention period (Oct 1 2008 - Dec 31 2010)					
Primary ouctomes	2 x 2 factorial trial[a]				4 arm comparison[b]	
Secondary outcomes	FI vs. no FI		CI vs. no CI		FI+CI vs. control	
	OR (95%CI)	p-value	OR (95%CI)	p-value	OR (95%CI)	p-value
Stillbirth rate per 1000 births	1.06 (0.84, 1.32)	0.638	0.81 (0.65, 1.02)	0.078	0.86 (0.62, 1.19)	0.354
Neonatal mortality rate per 1000 livebirths	**0.86 (0.72, 1.03)**	**0.103**	**0.90 (0.75, 1.09)**	**0.279**	**0.78 (0.60, 1.01)**	**0.057**
Early neonatal mortality rate per 1000 livebirths (0-6 days)	0.92 (0.75, 1.11)	0.373	0.85 (0.70, 1.04)	0.113	0.78 (0.60, 1.03)	0.083
Late neonatal mortality rate per 1000 livebirths (7-27 days)	0.67 (0.46, 0.97)	0.035	1.14 (0.78, 1.66)	0.498	0.77 (0.45, 1.30)	0.322
Perinatal mortality rate per 1000 births (all stillbirths)	**0.99 (0.85, 1.15)**	**0.881**	**0.84 (0.72, 0.97)**	**0.020**	**0.83 (0.67, 1.02)**	**0.079**
maternal mortality ratio per 100,000 livebirths	**1.18 (0.66, 2.11)**	**0.570**	**0.91 (0.51, 1.63)**	**0.754**	**1.08 (0.46, 2.57)**	**0.854**

[a] CI x FI interaction term not included as study underpowered to detect interactions

[b] FI only vs. control and CI only vs. control results not shown

CI = Community Intervention; FI = Facility Intervention

4.2.3.1 Causes of perinatal mortality in CI and no CI areas

Figure 84 and Figure 85 show changes in the Cause Specific Mortality Fractions[84] of the perinatal deaths observed[85] in CI areas and No CI areas respectively between the baseline period and the intervention period. Figure 84 shows that the percentage of perinatal deaths that were stillbirths declined in CI areas from the baseline period (38.3% fresh stillbirth; 14.7% macerated) to the intervention period (30.6% fresh stillbirth; 10.7% macerated) as did the percentage that were due to asphyxia (from 12.7% to 7.5%), whereas there were increases in the percentage that were due to pneumonia and sepsis (from 20.1% to 27.4%) and the percentage that were due to meningitis (from 0.8% to 6.9%) and there was a slight increase in the percentage that were due to prematurity (from 10.5% to 12.9%). In No CI areas, as Figure 85 shows, the percentage of perinatal deaths that were due to stillbirths increased slightly from the baseline period (27.7% fresh stillbirth; 11.3% macerated) to the intervention period (31.8% fresh stillbirth; 12.1% macerated) as did the percentage that were due to prematurity (from 12.8% to 15.1%), whereas there was a in decrease in the percentage that were due to asphyxia (from 14.7% to 11.3%) and very slight decreases in the proportions due to pneumonia/sepsis, meningitis and other causes. Comparing the intervention periods (the right hand sides of Figure 84 and Figure 85), as was done in the analysis of the RCT data, it is apparent that there were slightly less stillbirths in CI areas than No CI areas and lower percentages of perinatal deaths due to prematurity and asphyxia in CI areas, but that slightly more of the perinatal deaths in CI areas were due to pneumonia/sepsis, meningitis and other causes than in No CI areas.

Bearing in mind that perinatal deaths are all stillbirths and early neonatal deaths, and considering Table 31 which indicates that a larger part of the CI effect on perinatal mortality was on stillbirths (a 'non-significant' 19% reduction: Odds Ratio: 0.81 (95%CI: 0.65, 1.02; p=0.078) than on early neonatal deaths (Odds Ratio: 0.85 (95%CI: 0.70, 1.04; p=0.113), the information in Figure 84 and Figure 85 indicate that the CI may have reduced perinatal mortality by reducing both macerated and fresh stillbirths. The figures also indicate that it is possible that some of the CI effect on perinatal mortality may have been mediated by the CI reducing early neonatal deaths due to asphyxia, which decreased in CI areas from baseline to intervention periods as well as being lower than in No CI areas in the intervention period as a whole. The fact that in the intervention period there are less perinatal deaths due to prematurity in CI areas than in No CI areas is a less clear cut indicator that the effect of CI on perinatal mortality may also be mediated by an effect on prematurity because of the fact that the percentage of perinatal deaths due to prematurity increased in CI areas from baseline to intervention periods. However, it also increased in No CI areas, meaning that the CI could have stopped it from increasing more in CI areas.

Splitting the intervention period into two and plotting the causes of death as mortality rates to give an indication of the changes and differences in absolute rather than relative mortality due to specific causes (Figure 86, and Figure 87 individually and together) shows the following. In the first intervention period there was a much lower mortality from stillbirths (including undefined as either macerated as fresh: CI: 18.2 stillbirths per 1000 births; No CI: 22.5 stillbirths per 1000 births; also confirmed in Table 32: Odds Ratio: 0.70 (95%CI: 0.49, 1.00; p=0.051)) and from asphyxia (CI: 2.6 deaths per 1000 births; No CI: 5.1 deaths per 1000 births)[86] in CI areas than No CI areas, but the perinatal mortality from other causes was similar between CI areas and No CI areas (Table 32 shows that, overall, the CI did

[84] Cause Specific Mortality Fractions are the percentage of all deaths caused by a specific cause of death, and therefore always add up to 100%. The graphs therefore provide no information on the differences in mortality rates between baseline and intervention periods and between RCT arms as this information is already known and taken account of in the observed intervention effects which these graphs are trying to explain.

[85] Only deaths with verbal autopsy information are included in the graphs. Between 10% and 18% of stillbirths and 3% and 6% of neonatal deaths in the 4 categories analysed had no verbal autopsy information.

[86] Mortality rates calculated for available data on cause of death, please note there are extra NND without cause of death data (grey on areas on graphs) and also that InterVA (used to assign cause of death – see section 2.1.8) does not always account for 100% of the death when assigning probabilities of first, second and third likely cause of death. Therefore the true mortality rates for specific causes will be around 20-30% higher.

Table 32. Summary of RCT results including effects on stillbirths, and early and late NND, splitting the intervention period into two

	1st Intervention period (Oct 1 2008 - Sep 30 2009)						2nd Intervention period (Oct 1 2009 - Dec 31 2010)					
Primary ouctomes	**2 x 2 factorial trial[a]**				**4 arm comparison[b]**		**2 x 2 factorial trial[a]**				**4 arm comparison[b]**	
Secondary outcomes	**FI vs. no FI**		**CI vs. no CI**		**FI+CI vs. control**		**FI vs. no FI**		**CI vs. no CI**		**FI+CI vs. control**	
	OR (95%CI)	**p-value**	**OR (95%CI)**	**p-value**	**OR (95%CI)**	**p-value**	**OR (95%CI)**	**p-value**	**OR (95%CI)**	**p-value**	**OR (95%CI)**	**p-value**
Stillbirth rate per 1000 births	1.18 (0.83, 1.69)	0.360	0.70 (0.49, 1.00)	0.051	0.82 (0.50, 1.36)	0.454	0.97 (0.77, 1.21)	0.767	0.94 (0.75, 1.18)	0.621	0.91 (0.66, 1.25)	0.576
Neonatal mortality rate per 1000 livebirths	**0.82 (0.63, 1.06)**	**0.124**	**1.05 (0.81, 1.36)**	**0.700**	**0.86 (0.60, 1.24)**	**0.423**	**0.90 (0.69, 1.17)**	**0.431**	**0.80 (0.61, 1.04)**	**0.098**	**0.72 (0.50, 1.05)**	**0.084**
Early neonatal mortality rate per 1000 livebirths (0-6 days)	0.92 (0.67, 1.26)	0.599	0.95 (0.69, 1.29)	0.727	0.87 (0.56, 1.35)	0.534	0.92 (0.70, 1.19)	0.516	0.79 (0.60, 1.03)	0.083	0.72 (0.49, 1.06)	0.093
Late neonatal mortality rate per 1000 livebirths (7-28 days)	0.54 (0.31, 0.92)	0.025	1.62 (0.93, 2.80)	0.089	0.87 (0.39, 1.91)	0.722	0.83 (0.49, 1.39)	0.473	0.81 (0.48, 1.37)	0.432	0.69 (0.34, 1.40)	0.303
Perinatal mortality rate per 1000 births (all stillbirths)	**1.04 (0.83, 1.31)**	**0.719**	**0.81 (0.65, 1.02)**	**0.074**	**0.85 (0.61, 1.17)**	**0.309**	**0.94 (0.77, 1.15)**	**0.555**	**0.87 (0.71, 1.06)**	**0.179**	**0.82 (0.62, 1.09)**	**0.171**
maternal mortality ratio per 100,000 livebirths	**1.91 (0.82, 4.48)**	**0.135**	**1.37 (0.60, 3.09)**	**0.455**	**3.62 (0.77, 17.07)**	**0.105**	**0.74 (0.32, 1.69)**	**0.476**	**0.58 (0.24, 1.39)**	**0.223**	**0.40 (0.11, 1.54)**	**0.184**

[a] CI x FI interaction term not included as study underpowered to detect interactions

[b] FI only vs. control and CI only vs. control results not shown

CI = Community Intervention; FI = Facility Intervention

Figure 84: Changes in perinatal death CSMF in CI areas between baseline and intervention periods

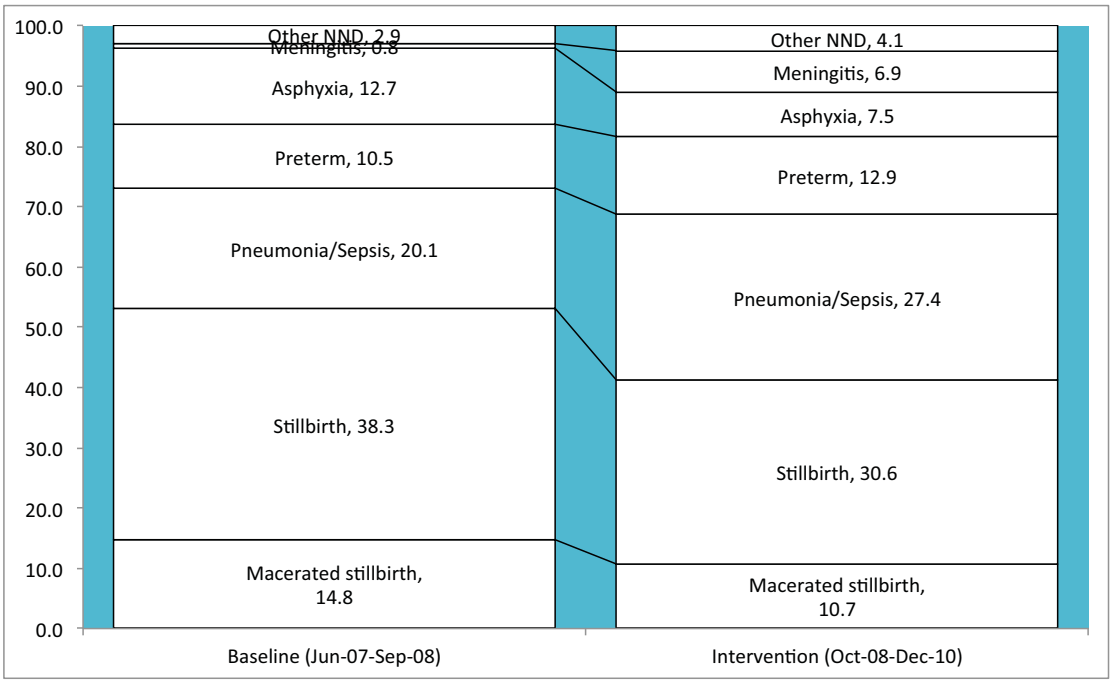
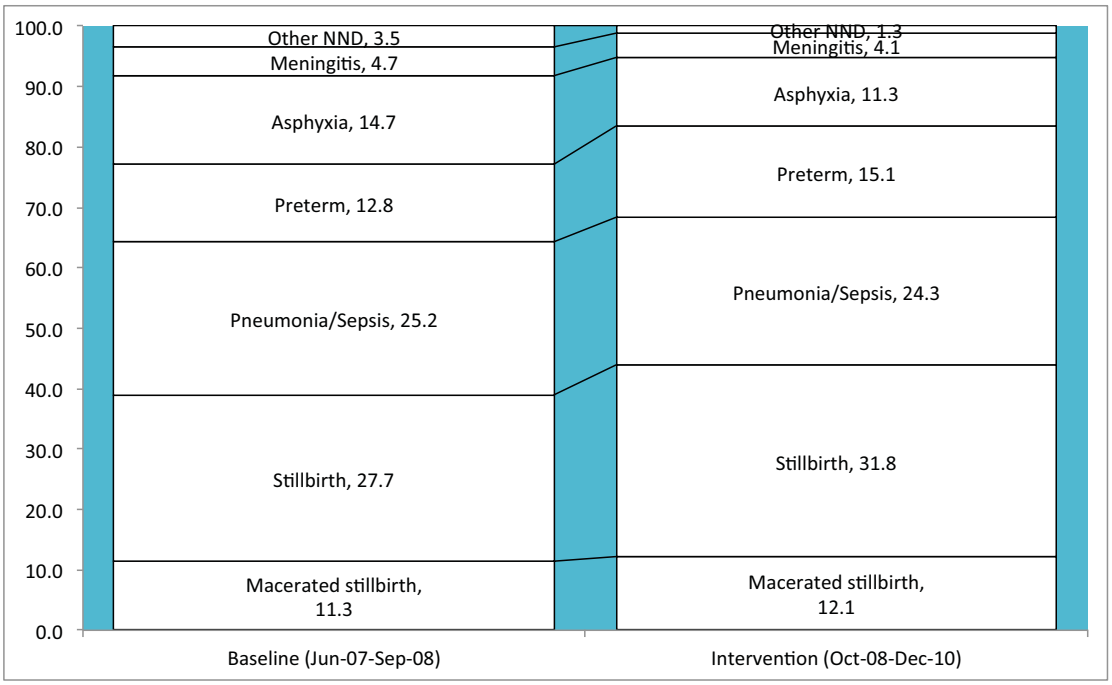


Figure 85: Changes in perinatal death CSMF in No CI areas between baseline and intervention periods



not reduce the early neonatal mortality part of perinatal mortality in the first intervention period: Odds Ratio: 0.95 (95%CI: 0.69, 1.29; p=0.727)). In the second intervention period the mortality from stillbirths increased in both CI and No CI areas and was slightly greater in No CI areas than CI areas (including undefined as either macerated as fresh: CI: 22.8 stillbirths per 1000 births; No CI: 25.0 stillbirths per 1000 births; but the difference was not statistically

Figure 86: Causes of perinatal mortality in CI areas over time

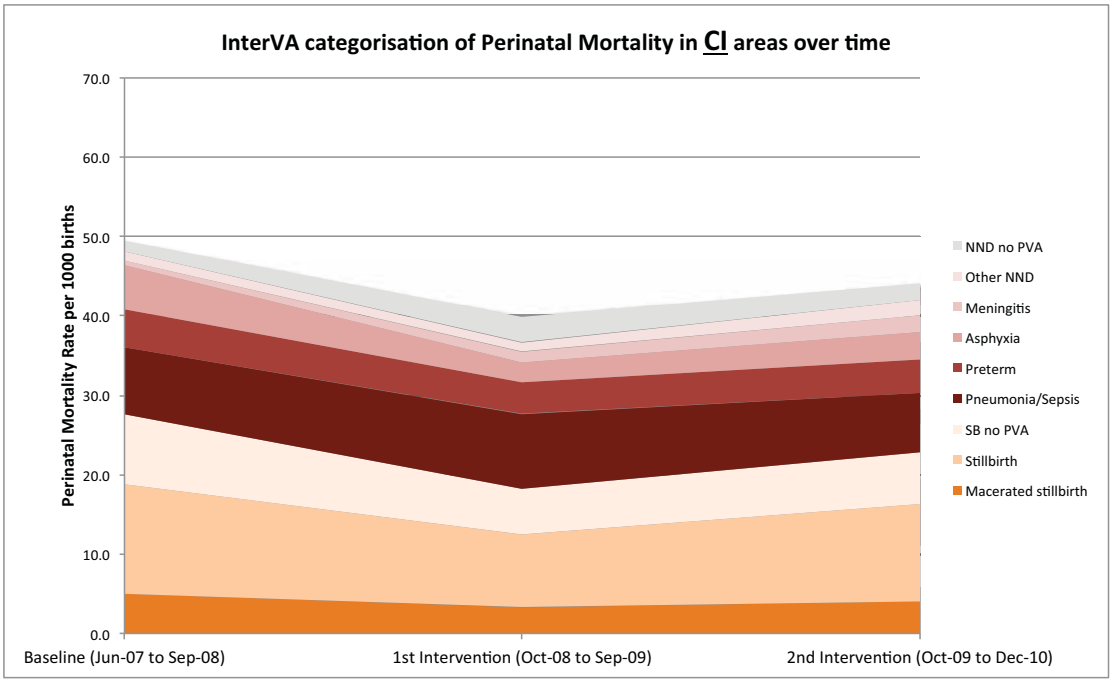
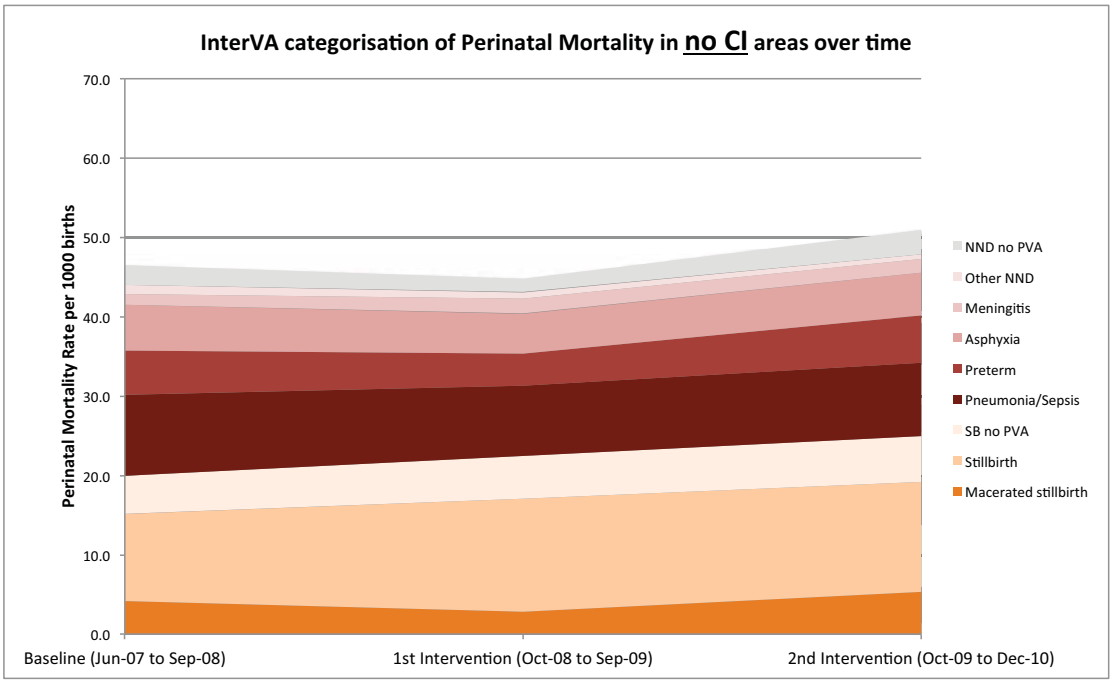


Figure 87: Causes of perinatal mortality in No CI areas over time



significant: Odds Ratio: 0.94 (95%CI: 0.75, 1.18; p=0.621; Table 32); whereas the (early neonatal) mortality from pneumonia/sepsis, prematurity and asphyxia was lower in CI areas than No CI areas (pneumonia/sepsis: CI: 7.5 deaths per 1000 births; No CI: 9.3 deaths per 1000 births; prematurity: CI: 4.2 deaths per 1000 births; No CI: 5.9 deaths per 1000 births; asphyxia: CI: 3.4 deaths per 1000 births; No CI: 5.4 deaths per 1000 births;[86] and the early neonatal mortality was lower overall: Odds Ratio: 0.79 (95%CI: 0.60, 1.03;p=0.083; Table 32). For the community intervention (CI) the first intervention period was when there were no task forces and when the strategies were newly implemented, whereas the second intervention

period was when the MNH task forces were functional and when the strategies had had more time to take effect (see Chapter 3).

In summary, it appears that the community intervention has reduced perinatal mortality during the whole of the intervention period mainly by reducing stillbirths in the first intervention period and early neonatal deaths due to sepsis, prematurity and asphyxia in the second intervention period. Given the community intervention evolved to include MNH task forces in the second intervention period it is possible that these could have influenced early neonatal deaths due to sepsis, prematurity and asphyxia. It is also possible that the effect of the community intervention on stillbirths during the first intervention period could have been mediated by improved nutrition of women during pregnancy (perhaps as a results of the dimba gardens – see section 4.2.1.2.3, though we have no evidence linking the two) or improved antenatal care (although again evidence is lacking for this – see section 4.2.1.2.4). It is also possible that the imbalance in baseline stillbirth rates (which were higher in CI areas than No CI areas; Figure 86, and Figure 87) and early neonatal death rates (which were lower in CI areas than No CI areas, therefore balancing the overall perinatal mortality rates which were balanced at baseline between CI and No CI areas at baseline; Figure 86, and Figure 87) could have played a role i.e. rates regressing to the mean over time. We examine data on place of death (facility or community; see section 4.2.4) to further investigate the effects of the community intervention on perinatal mortality (see Chapter 5).

4.2.3.2 Causes of neonatal mortality in FI+CI and control areas

Figure 88 and Figure 89 show changes in the Cause Specific Mortality Fractions of the neonatal deaths observed in FI+CI areas and control areas respectively between the baseline period and the intervention period. Figure 88 shows that the percentage of neonatal deaths that were due to prematurity declined in FI+CI areas from the baseline period (20.3%) to the intervention period (11.8%) as did the percentage that were due to asphyxia (from 11.7% to 7.5%), whereas there was an increase in the percentage of neonatal deaths in FI+CI areas that were due to meningitis (from 5.8% to 17.6%). In control areas (the comparison group for the observed effect of FI+CI on NMR), as Figure 89 shows, there were only small changes in neonatal mortality CSMFs from baseline to intervention periods, with slight increases in the percentage of neonatal deaths due to pneumonia/sepsis, prematurity, asphyxia, and meningitis and a slight decrease in the percentage of neonatal deaths due to other causes. Comparing the intervention periods (the right hand sides of Figure 88 and Figure 89), as was done in the analysis of the RCT data, it is apparent that in FI+CI areas the percentage of neonatal deaths due to prematurity (11.8% vs. 19.7%) and asphyxia (7.5% vs. 10.0%) were lower than in control areas, whereas the percentages due to meningitis (17.6% vs. 10.5%) and other causes (7.5% vs. 3.1%) were higher; and there was little difference in the percentages due to pneumonia/sepsis which made up more than half of the neonatal deaths in each area.

Bearing in mind that neonatal deaths can be split into early and late neonatal deaths, and considering Table 31, which indicates that the FI+CI effect on neonatal mortality included effects on both early neonatal mortality (Odds Ratio: 0.78 (95%CI: 0.60, 1.03; p=0.083) and late neonatal mortality (Odds Ratio: 0.77 (95%CI: 0.45, 1.30; p=0.322; effects not significant due to smaller sample sizes), the information in Figure 88 and Figure 89 indicate that the FI+CI may have reduced neonatal mortality by reducing: early deaths due to asphyxia (as deaths due to asphyxia always occur in the early 0-6 day period), perhaps due to improved intrapartum care in the facility/community and/or improved resuscitation efforts at the facility; and, deaths due to prematurity/low birth weight in the early/late neonatal period, perhaps due to kangaroo mother care at the facility and also postnatal care practices in the community. We do not have enough data, however, to prove these hypotheses (see sections 4.2.1.1. and 4.2.1.2.4).

Splitting the intervention period into two and plotting the causes of neonatal death as mortality rates to give an indication of the changes and differences in absolute rather than relative mortality due to specific causes (Figure 90 and Figure 91, individually and together) shows the following. In the first intervention period there was lower mortality from

Figure 88: Changes in neonatal death CSMF in FI+CI areas between baseline and intervention periods

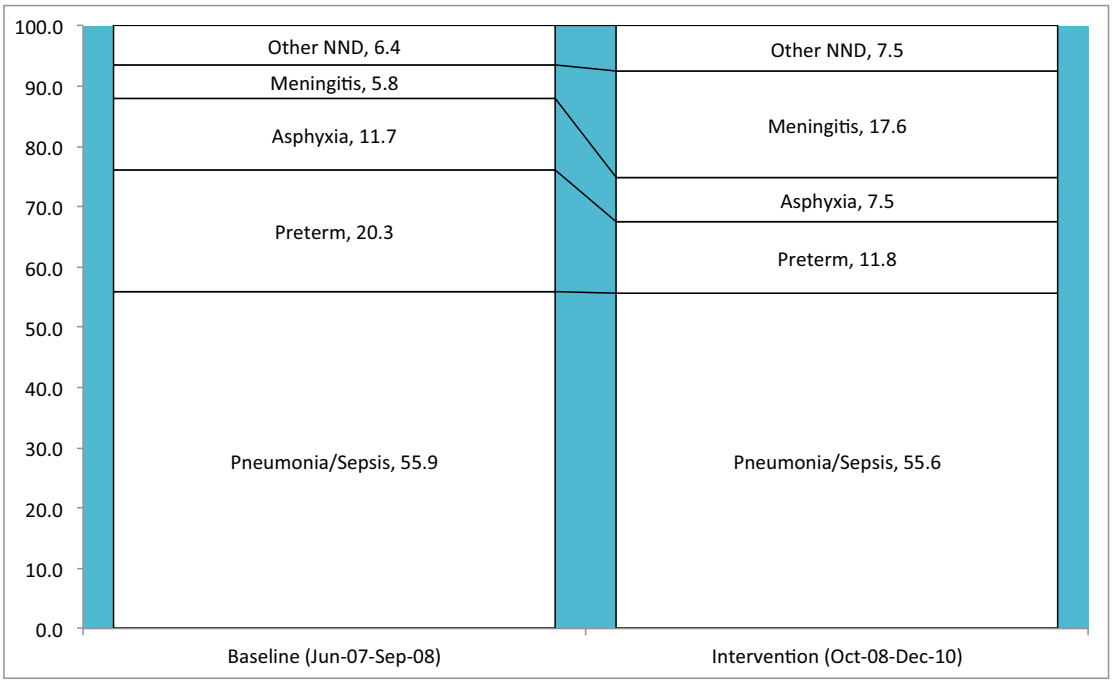
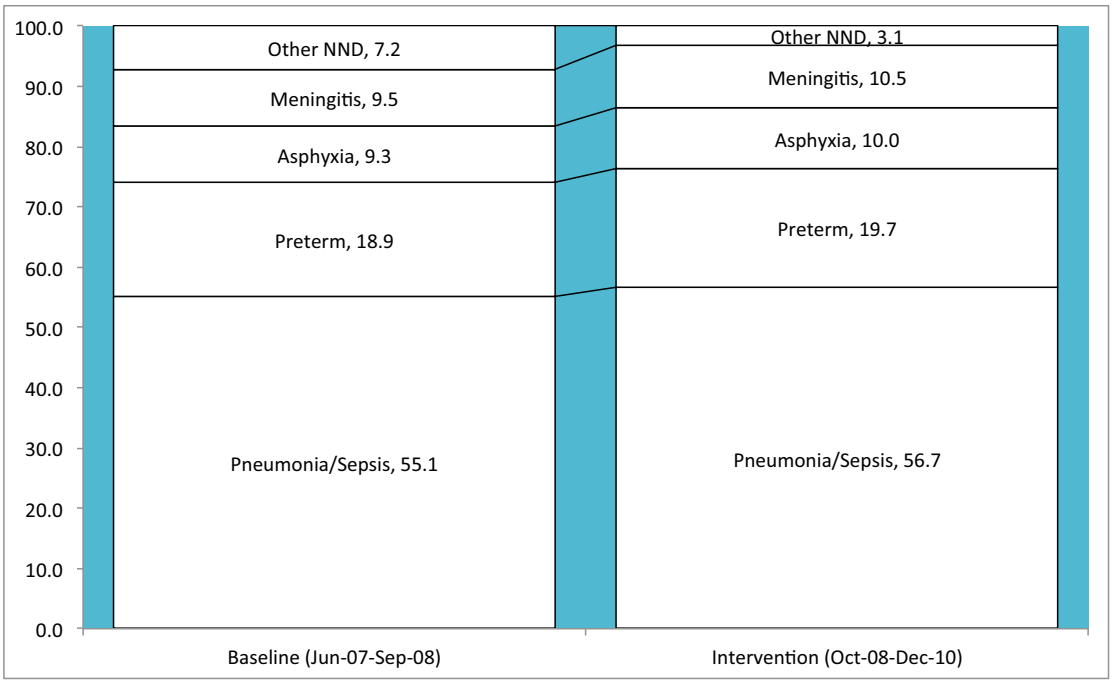


Figure 89: Changes in neonatal death CSMF in control areas between baseline and intervention periods



prematurity and asphyxia in FI+CI areas than control areas (prematurity: FI+CI: 2.3 neonatal deaths per 1000; control: 4.4 neonatal deaths per 1000 livebirths; asphyxia: FI+CI: 1.6 neonatal deaths per 1000 livebirths; control: 2.1 neonatal deaths per 1000 livebirths)[86] and slightly higher mortality from meningitis and other causes (meningitis: FI+CI: 3.2 neonatal deaths per 1000; control: 2.1 neonatal deaths per 1000 livebirths; other causes: FI+CI: 1.5 neonatal deaths per 1000 livebirths; control: 0.6 neonatal deaths per 1000 livebirths)[86], with

Figure 90: Causes of neonatal Mortality in FI+CI areas over time

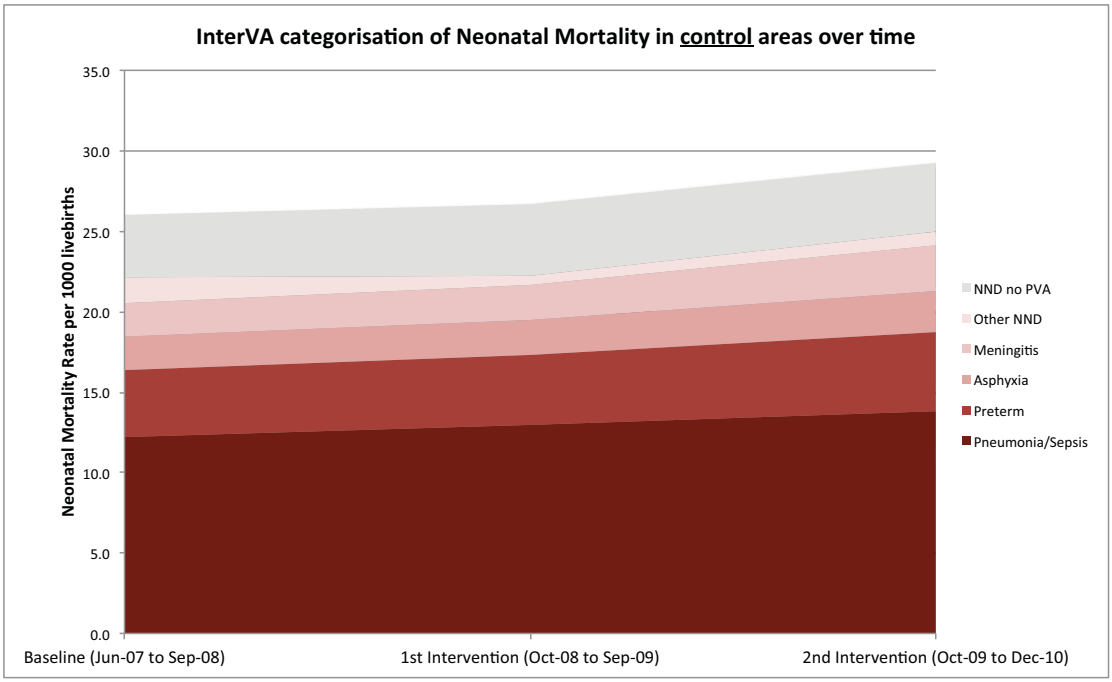
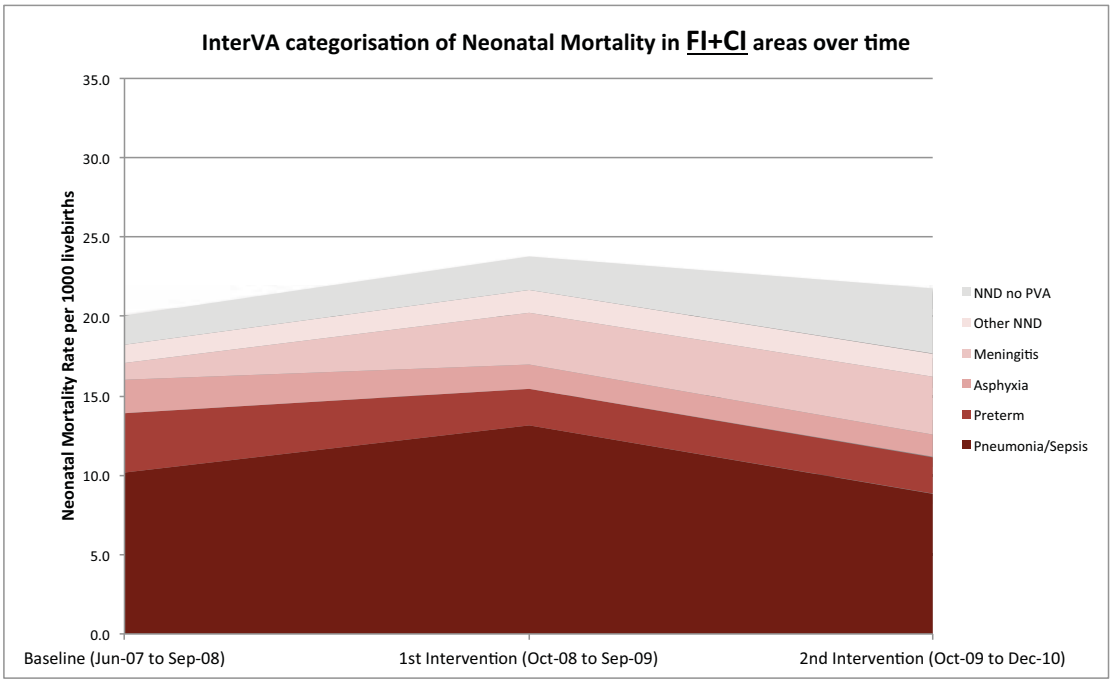


Figure 91: Causes of neonatal mortality in control areas over time



pneumonia/sepsis mortality being similar (FI+CI: 13.2 neonatal deaths per 1000 livebirths; control: 12.9 neonatal deaths per 1000)[86], i.e. the differences between FI+CI and control in neonatal mortality in the first intervention period are the same as for the whole intervention period – see above. In the second intervention period neonatal mortality from prematurity and asphyxia was also lower in FI+CI areas than control areas, and neonatal mortality from meningitis and other causes was also slightly higher, but there was also much lower mortality from pneumonia/sepsis in FI+CI areas (8.8 neonatal deaths per 1000 livebirths) than in

control areas (13.8 neonatal deaths per 1000 livebirths). This additional mortality reduction in the second intervention period can be looked at in conjunction with the measures of effect in each intervention period provided in Table 32. Table 32 shows that during the first intervention period the FI+CI did not really have much effect on either early or late NMR[87] and that most of the observed effect on NMR during the whole intervention period is likely to have occurred in the second intervention period and to have been on both early and late NMR.[88] For the community intervention (CI) the second intervention period was when half of the women's groups had MNH task forces and when the strategies had had more time to take effect; and for the facilities intervention the second intervention period was when MaiKhanda had more staff and more intensive visits to the hospitals and randomised health centres (see Chapter 3).

To further explore the FI+CI effect on NMR we can look at the changes and differences in the causes of both early and late neonatal mortality separately in both FI+CI areas and control areas (Figure 92).[89] As expected (given asphyxia deaths occur around the time of birth), Figure 92 shows that the lower asphyxia mortality in FI+CI areas is in early neonatal mortality (and in the second intervention period as discussed above). The lower mortality from prematurity in FI+CI areas compared to control areas is also concentrated in early neonatal deaths, but is in apparent in both the first and second intervention periods (Figure 92). Finally, the lower mortality from pneumonia/sepsis in FI+CI areas compared to control areas is in both early and late neonatal deaths but appears more concentrated in the second intervention period (Figure 92).

In summary, it appears the combined facility and community intervention has reduced early neonatal mortality due to asphyxia and early and late neonatal mortality due to sepsis during the second part of the intervention period when the interventions were both more concentrated, and has reduced early neonatal mortality due to prematurity throughout the whole intervention period. These observations should be considered along with hypothesised mechanisms of intervention effect (see end of last paragraph) and data on place of death (facility or community; see section 4.2.4) to further investigate the effects of FI+CI on neonatal mortality (see Chapter 5).

4.2.4 Differences in place of death

Overall, only 42% of all stillbirths and 43% of all neonatal deaths occurred in the facilities (352/843 stillbirths and 398/931 neonatal deaths with data).[90] Clearly there is a limit to the utility of facility case-fatality rate data (see section 4.2.2) and the burden of deaths in the community, as captured by our community surveillance and perinatal verbal autopsy system, needs to be considered.

In this section we present analyses of the place of death (community or facility or missing data (.)) by type (perinatal, early/late/total neonatal, stillbirth) and cause (see section 4.2.3 above) of death; and results of analyses of place of death with reference to place of birth. First we focus on perinatal mortality in community intervention (CI) areas and areas

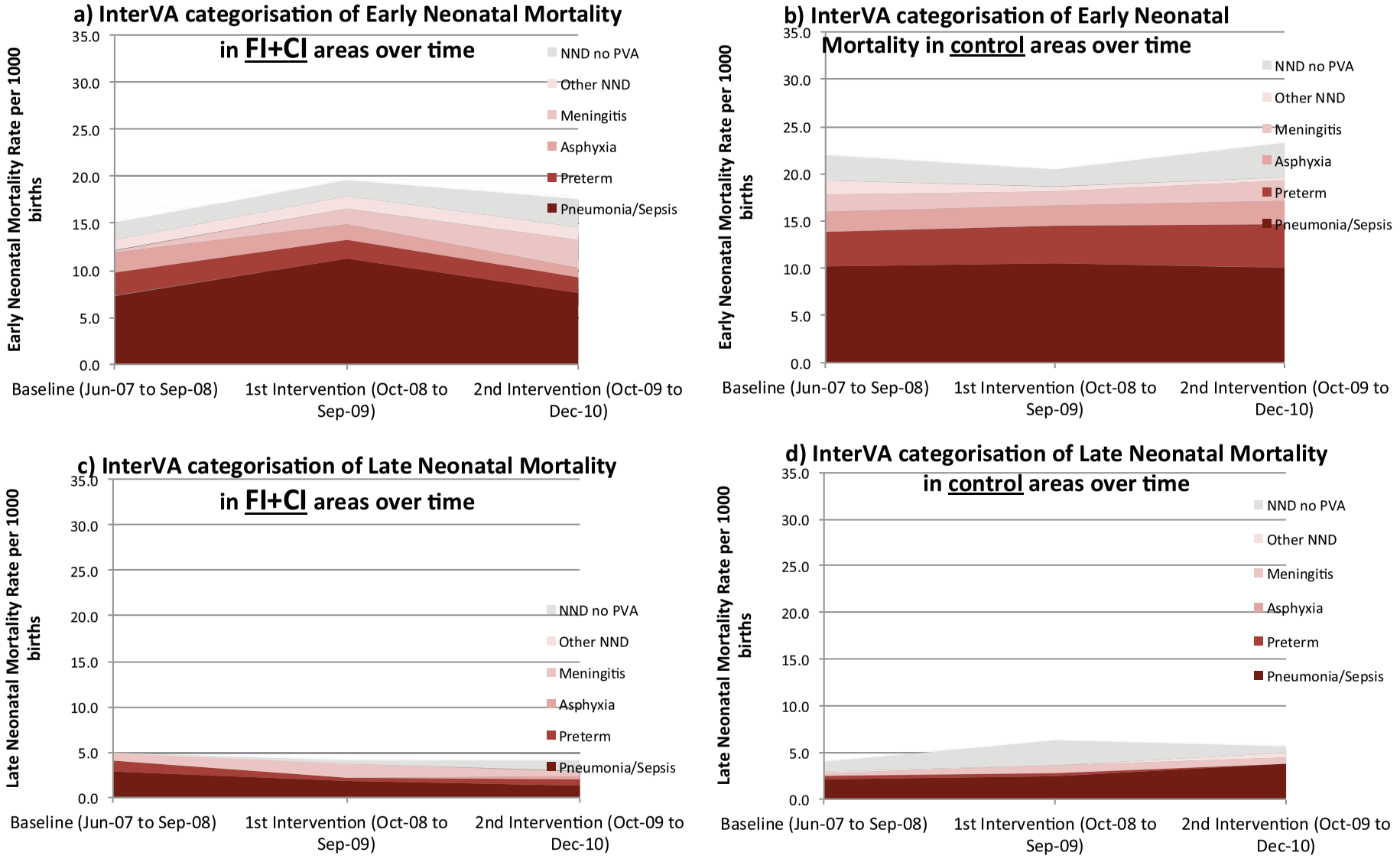
[87] First Intervention period: Early NMR: Odds Ratio: 0.87 (95%CI: 0.56, 1.35; p=0.534); late NMR: Odds Ratio: 0.87 (95%CI: 0.39, 1.91; p=0.722; total NMR: Odds Ratio: 0.86 (95%CI: 0.60, 1.24; p=0.423); also notice overall NMR (see above footnote for caveat) during the first intervention period is not that much less in FI+CI areas (26.0 neonatal deaths per 1000 livebirths) than in control areas (23.2 neonatal deaths per 1000 livebirths)

[88] Second Intervention period Early NMR: Odds Ratio: 0.72 (95%CI: 0.49, 1.06; p=0.093); late NMR: Odds Ratio: 0.69 (95%CI: 0.34, 1.40; p=0.303; total NMR: Odds Ratio: 0.72 (95%CI: 0.50, 1.05; p=0.084); also notice overall NMR (see two footnotes previous for caveat) during second intervention period is less in FI+CI areas (21.1 neonatal deaths per 1000 livebirths) than in control areas (28.3 neonatal deaths per 1000 livebirths).

[89] Please note that late neonatal mortality is rarer than early neonatal mortality (typically only 10-20% of neonatal deaths are in the late, 7-28 day period) so the lower late neonatal mortality rates area as expected.

[90] Although less relevant given the lack of impact of the interventions on maternal mortality, readers may be interested to know that of the 53/103 maternal deaths with data 8 (15%) occurred at home; 6 (11%) occurred at the TBA, 4 (8%) occurred on the way to treatment; 27 (54%) occurred in hospital, 7 (13%) occurred in another health facility in the district, and 1 (2%) occurred in another health facility outside the district. Therefore around two-thirds occurred in facilities and one-third occurred in the community.

Figure 92: Causes of early and late neonatal mortality in FI+CI areas and control areas over time

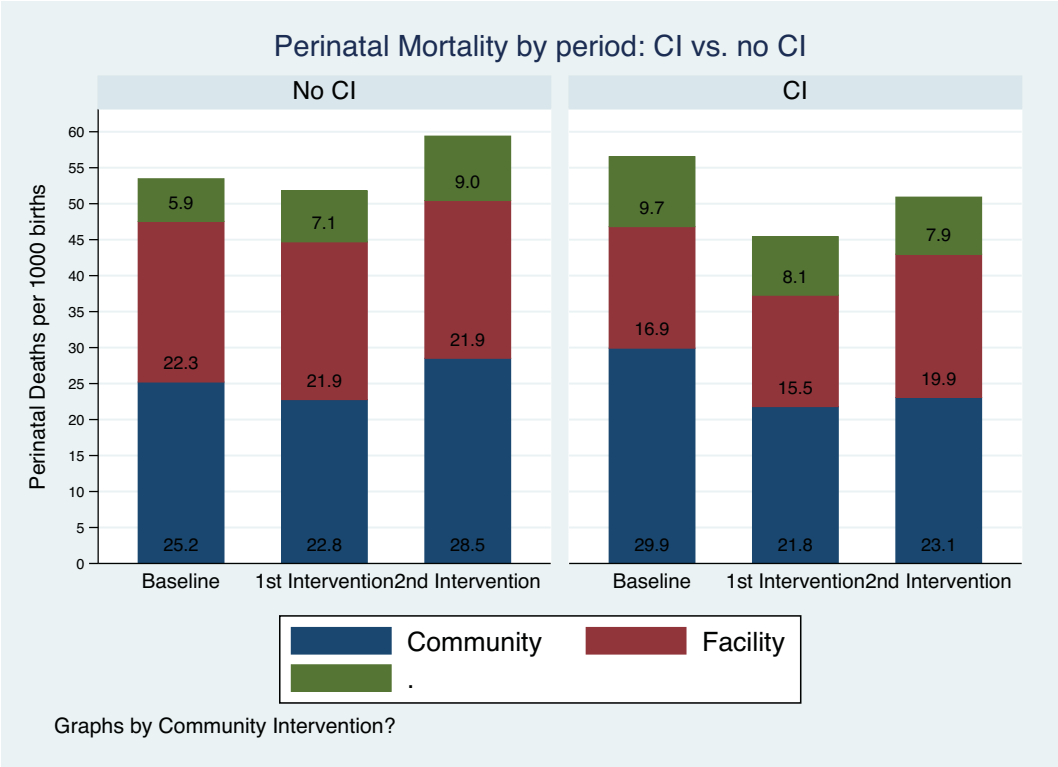


without the community intervention (No CI), bearing in mind the community intervention was shown to reduce perinatal mortality by 16% in the intervention period (section 4.1.4) and also the specific causes of perinatal mortality that the community intervention may have impacted on during specific time periods (section 4.2.3 above). Then, we focus on neonatal mortality in areas with both the facility intervention and the community intervention (FI+CI) and areas with neither intervention (control), bearing in mind the combination of the facilities intervention and the community intervention was shown to reduce neonatal mortality by 23% in the intervention period (section 4.1) and also the specific causes of neonatal mortality that the combined intervention may have impacted on during specific time periods (section 4.2.3 above). The analyses of place of death (community/facility, and facility type) by place of birth (community/facility) are then presented.

4.2.4.1 Place of perinatal mortality in CI and No CI areas

Figure 93 shows perinatal mortality rates[91] (perinatal deaths per 1000 births) split by occurrence at the health facility or occurrence at the community during each time period, in CI and No CI areas. In CI areas, whilst the perinatal mortality occurring in the facility increased (perhaps as a result of increased facility delivery – see section 4.2.1.2.1), the perinatal mortality occurring in the community decreased (Figure 93). It therefore appears that the reduced mortality in the first (Jun-07 to Sep-08) and second (Oct-08 to Dec-10) intervention periods (lower total bar heights) mainly occurred in the community in CI areas. In contrast, perinatal mortality increased in No CI areas (increased bar heights), and the

Figure 93: Changes in place of perinatal mortality in CI and No CI areas



[91] Rates are given for more accurate comparisons, which take account of differences in the number of births (exposures, or opportunities to death; likely different due to the time periods being of different lengths and the two populations being of different sizes), which the total number of deaths does not. The numbers of perinatal deaths in each group, in the order that the groups are laid out on the graph are as follows: No CI: baseline: 405; 1st Intervention: 248; 2nd Intervention: 325; CI: Baseline: 395; 1st Intervention: 223; 2nd Intervention: 276. Clearly, these numbers are fairly large so the differences between groups are less likely to be due to random chance sampling error. As a rough guide, each 1 per 1000 mortality rate on the graphs represents around 5-7 deaths (see Appendix 23).

amount of perinatal mortality occurring in the facility was similar in baseline and intervention periods, and the amount occurring in the community was less in the first intervention period, than the baseline period but more in the second intervention period (Figure 93). When considering these results it is important to bear in mind that the perinatal mortality occurring in the community in No CI areas appears less at baseline (25.2 perinatal deaths per 1000 births) than that in CI areas (29.9 perinatal deaths per 1000 births). Differences between categories in the amount of perinatal mortality with missing data on place of death could also be a concern, however we have no reason to believe that deaths with missing data on place of death (i.e. no verbal autopsy – see section 2.1.8) are more likely to have occurred in a particular place.

4.2.4.1.1 Place of death by cause of death

Here we present a breakdown of perinatal mortality by stillbirths and early neonatal deaths and by specific causes of death. The place of death for stillbirth mortality occurring during baseline (Jun-07 to Sep-08), first intervention (Oct-08 to Sep-09) and second intervention (Oct-09 to Dec-10) periods in CI and No CI areas is shown in Figure 94. This shows a similar picture to that for total perinatal deaths (Figure 93) except that stillbirths occurring in both the community and the facility are lower in the first intervention period in CI areas. Data on the place of death for the early neonatal death part of perinatal mortality (Figure 95) also shows a similar pattern to that for overall perinatal mortality (Figure 93), except that in CI areas the reduction of early neonatal mortality that happened in the community is slightly less pronounced (the pattern of data for No CI areas is very similar).

Moving on to look at specific causes of death, the patterns in place of death seen in place of stillbirth (Figure 94) are similar for each of macerated and fresh stillbirths, although the numbers of macerated stillbirths in each category are small (Appendix 23). In terms of each of the causes of the early neonatal death part of perinatal mortality the pattern for pneumonia/sepsis is also similar to that for overall perinatal mortality, although the proportion of mortality that is in the community goes down slightly more in the 2nd

Figure 94: Changes in place of stillbirth part of perinatal mortality in CI and No CI areas

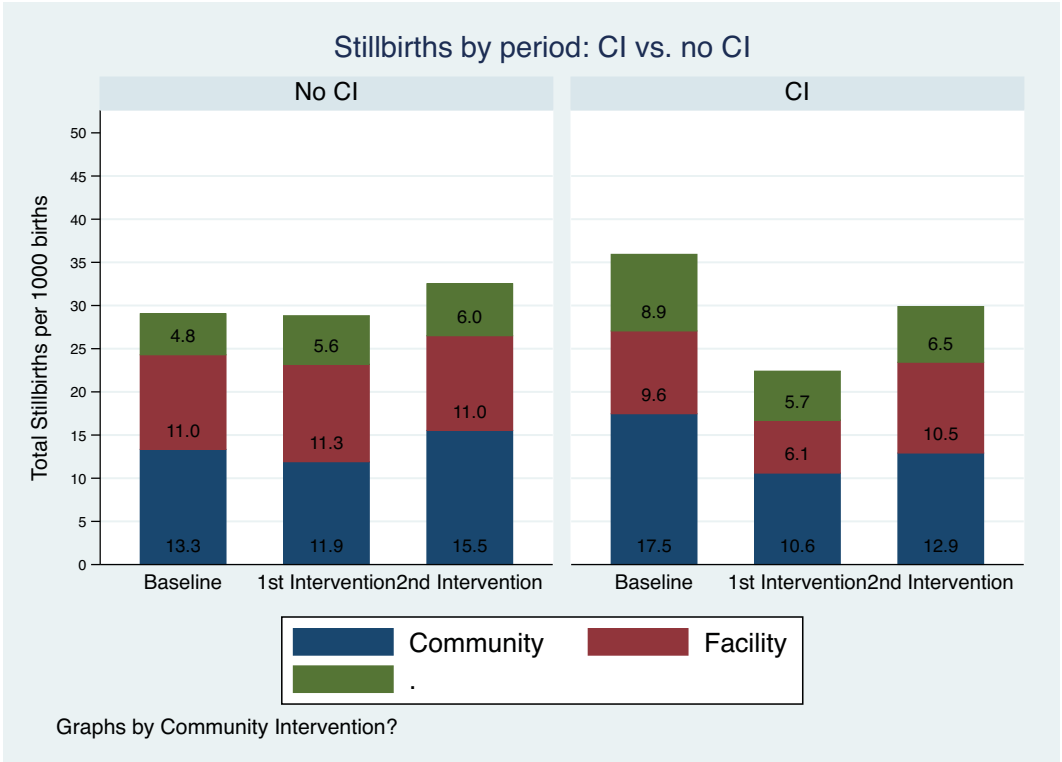
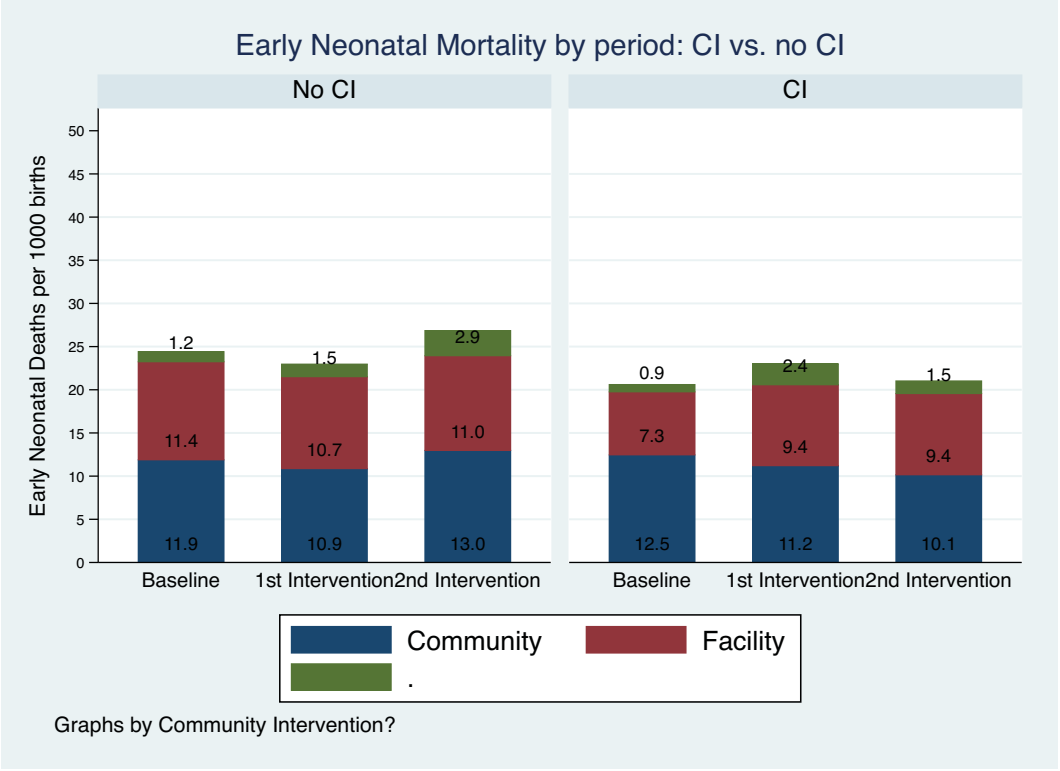


Figure 95: Changes in place of early NND part of perinatal mortality in CI and No CI areas



intervention period than the first intervention period (Appendix 23, although numbers are small). The pattern for perinatal mortality due to prematurity is similar to that for all perinatal deaths in No CI arms (with less community deaths in the first intervention period and more in the second intervention period), but different in CI areas, where community rates were the same (range 2.9 to 3.1 perinatal deaths per 1000 birth) in all three time periods, but facility rates were lower in both intervention periods, though numbers were low making these comparisons error prone (Appendix 23). The pattern for asphyxia mortality broadly matches that for total perinatal mortality too, with asphyxia mortality rates in the community being lower in CI areas in both intervention periods (Appendix 23). In No CI areas asphyxia mortality occurring in the community is lower and that occurring in the facility is higher in the first intervention period. The mortality rates for perinatal deaths caused by meningitis and other causes of early neonatal death are too small to assess by place of death, intervention period and No CI vs. CI, however, the figures are provided in Appendix 23 for reference.

In summary, it appears that the reductions in perinatal mortality due to stillbirth, sepsis and asphyxia seen in CI areas were more often the result of the result of reductions in the numbers of deaths occurring in the community than the result of a reduction of deaths in the facility.

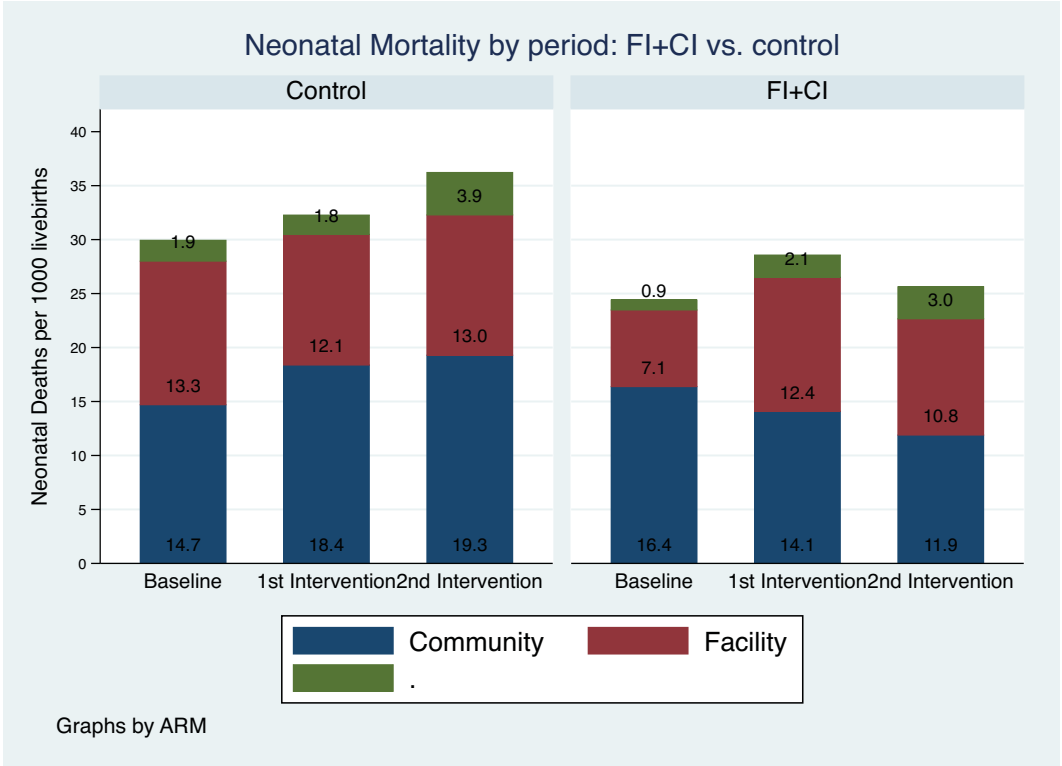
4.2.4.2 Place of neonatal mortality in FI+CI and control areas

Figure 96 shows neonatal mortality rates[92] (neonatal deaths per 1000 births) split by occurrence at the health facility or occurrence at the community during each time period, in

[92] As for perinatal mortality (see previous footnote), rates are given for more accurate comparisons. The numbers of neonatal deaths in each group, in the order that the groups are laid out on the graph are as follows: control: baseline: 108; 1st Intervention: 72; 2nd Intervention: 92; FI+CICI: Baseline: 79; 1st Intervention: 69; 2nd Intervention: 69. Although not as large as the numbers of perinatal deaths, these numbers are still fairly large so the differences between groups are less likely to be due to random chance sampling error. As a rough guide, each 1 per 1000 mortality rate on the graphs represents around 2-3 deaths (see Appendix 23).

control and FI+CI areas. In control areas, neonatal mortality in the community has gone up from 14.7 neonatal deaths per 1000 livebirths in the baseline period (Jun-07 to Sep-08) to 18.4 and then 19.3 neonatal deaths per 1000 livebirths in the first (Oct-08 to Sep-09) and second (Oct-09 to Dec-10) intervention periods respectively; whereas neonatal mortality occurring in health facilities remained roughly the same (range 12.1 to 13.3 neonatal deaths per 1000 livebirths). In areas with the combined facility and community interventions (FI+CI) however it appears that neonatal mortality in the community has gone down (from 16.4 neonatal deaths per 1000 in the baseline period to 14.1 and then 11.9 neonatal deaths per 1000 livebirths in the first and second intervention periods respectively); whereas neonatal mortality occurring in the facilities was similar in both intervention periods to that in control areas (matching the observed lack of difference in health centre neonatal case-fatality rates between health centres in FI+CI areas and health centres in control areas – see Figure 70, although numbers of deaths were low in the health centres – and consideration of whether the facility was a health centre or a hospital – see section 4.2.4.2.2 below - also needs to be given). Given that most of the FI+CI effect on NMR is likely to have occurred during the second intervention period (Table 32) it is also interesting to note that the difference in community neonatal mortality between control and FI+CI areas is most striking in the second intervention period (control: 19.3 neonatal deaths per 1000; FI+CI: 11.9 neonatal deaths per 1000), when also during this period facility neonatal mortalities are similar between the two groups (13.1 and 9.3; Figure 96). Overall, the evidence in Figure 96 indicates that most of the effect of the combined facility and community intervention on neonatal mortality may have been the result of the interventions reducing deaths occurring in the community. Baseline differences and missing data are less of a concern in this analysis than they are for the perinatal death analysis above, although there is a baseline difference in the split between early and late neonatal deaths (see below).

Figure 96: Changes in place of neonatal mortality in FI+CI and control areas



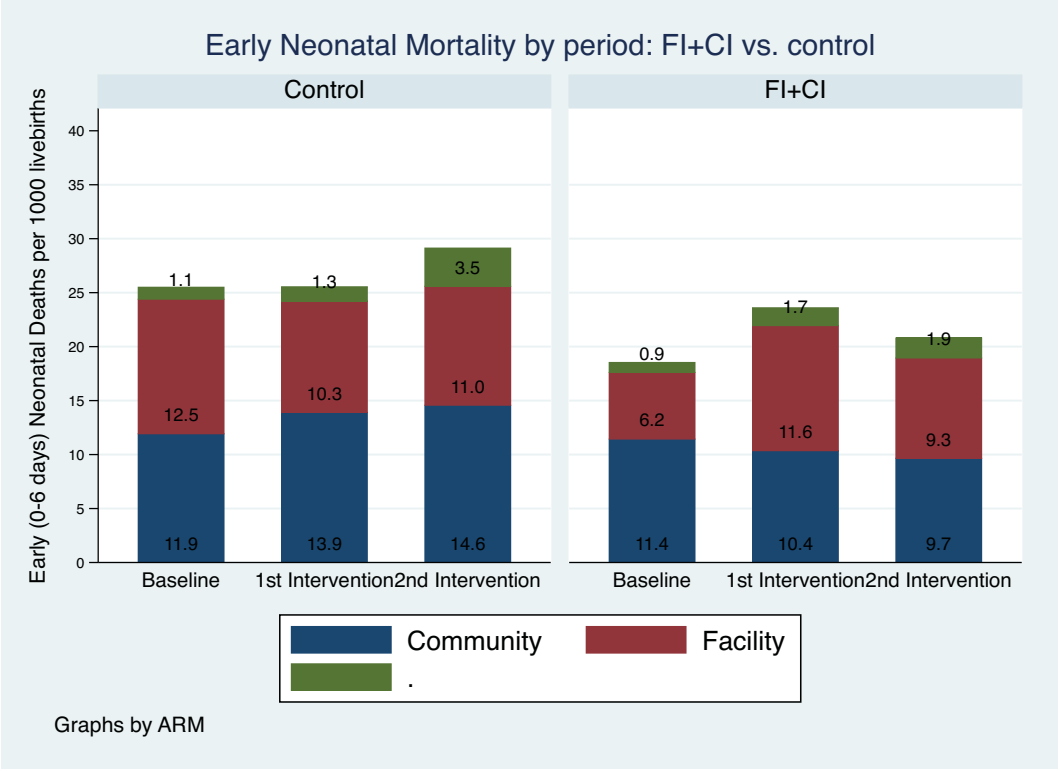
4.2.4.2.1 Place of death by cause of death

Breaking down neonatal mortality into early (0-6 days) and late (7-28 days) mortality, it can be seen (Figure 97 and Figure 98) that in FI+CI areas during the baseline period there was a higher late neonatal mortality rate an a lower early neonatal mortality rate (though a similar overall mortality rate) than in control areas. The differences in community-based early neonatal mortality between FI+CI and control areas during the first and second intervention periods, however, are fairly large, reflecting the pattern of overall neonatal deaths described above. Late neonatal deaths also show a similar pattern, though the numbers are very small.[69] so it is not really possible to assess trends.

Moving on to look at specific causes of death, the numbers are also small, with the exception of those for pneumonia/sepsis, for which the pattern of place of death observed for all neonatal deaths (Figure 96) holds true (Appendix 23). Although, the numbers of death are too small to make judgments regarding possible differences in place of death, graphs for prematurity, asphyxia, meningitis and other causes area also provided in Appendix 23 for reference.

In summary, it appears that the reductions in neonatal mortality, including those from sepsis (see section 4.2.3.1), seen in FI+CI areas were, like the reductions in perinatal mortality seen in CI areas (see above), more often the result of the result of reductions in the numbers of deaths occurring in the community than the result of a reduction of deaths in the facility.

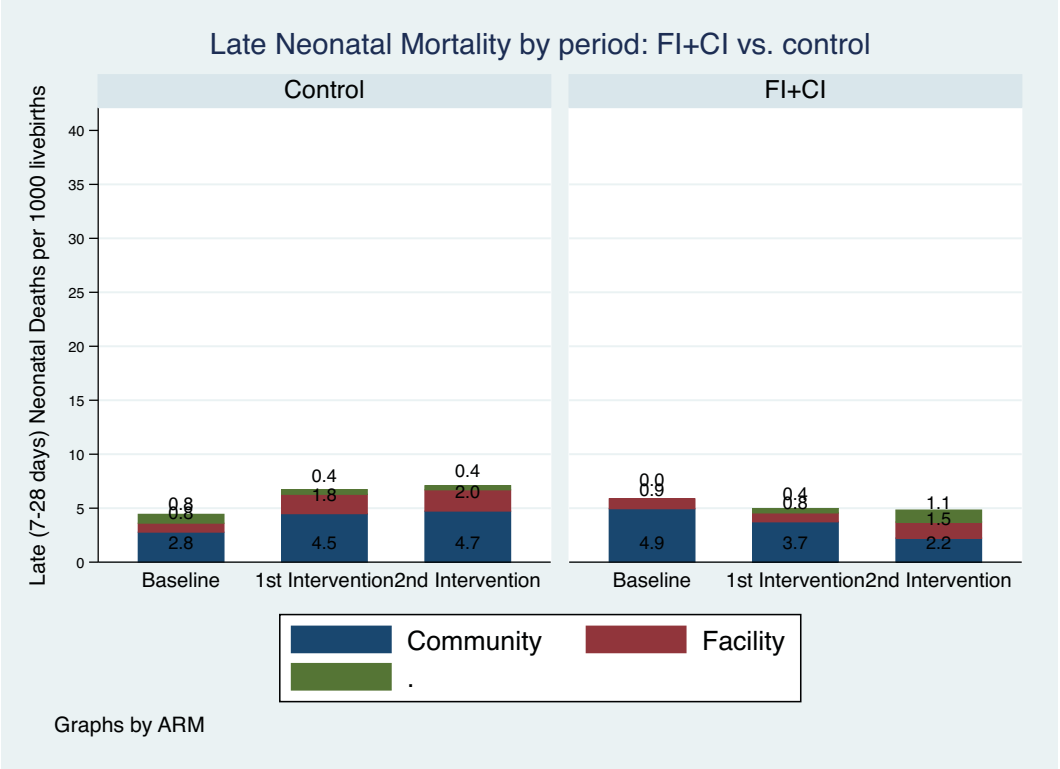
Figure 97: Changes in place of early neonatal part of neonatal mortality in FI+CI and control areas



4.2.4.3 *Place of death by place of birth*

The perinatal verbal autopsies recorded the place of death of the baby, including the name of the facility, from which we could determine the facility type (see Appendices 6 and 7). A total of 1774 (85.0%) of the 2078 PVA provided place of death information and of these 1024 (57.7%) deaths (stillbirths and neonatal deaths) were in the community and 750 (42.3%) were

Figure 98: Changes in place of late neonatal part of neonatal mortality in FI+CI and control areas



in a health facility. Place of birth was recorded on the community surveillance form (Appendix 3) without the name or type of health facility being recorded (see section 4.2.1.2.1 for trends in health facility delivery; we focus hear on the place of birth of only the babies that died). In this section we first provide a simple summary of place of death given place of birth and how it may result to the RCT results. We then present a more complicated summary, which includes type of facility where the death occurred. Using this information we then present an overview of referrals to CEmOCs where MaiKhanda worked, by RCT arm, in an attempt to assess the impact of the CEmOC work on the RCT results; and an overview of deaths that occurred in different randomised health centres to that of the cluster where the woman was from by arm, in an attempt to provide a measure of 'contamination' between RCT arms. Table 33 summarises the percentage of community (blue) births with place of death data that went on to die in the facility (orange), and the percentage of facility births with place of death data that went on to die in the facility,[93] by RCT comparison group, for stillbirths, neonatal deaths, and both combined, during the intervention period (when the RCT comparisons were made). Looking at the stillbirth data (red) it is apparent that there are some inaccuracies in the data as the place of death should always be the same as the place of birth for stillbirths. A total of 46/554 (8.3%) of stillbirths had this problem. Given the more intensive nature of the verbal autopsies (section 2.1.8) as compared to the community surveillance (sections 2.1.4 and 2.1.5) we are more inclined to believe the place of death data meaning that the previous analyses on place of death presented above should still stand (see footnote to Table 33). Whilst bearing in mind it is likely that a similar proportion (8%) of the neonatal deaths also have incorrect places of birth, it is still useful to examine the data as we have no reason to believe there would be higher percentages of inaccurate cases in particular RCT comparison groups. Looking at the percentage of neonatal deaths that were born in the

[93] The percentages that die in the same place (community or facility) that they were born in can be calculated from 100% minus the percentages that died in the other place (shown in the table).

community that died in a facility by RCT arm it is apparent that, whilst there is some variation, the percentages are small across all arms (CI only: 6%, control: 10%, FI only: 14%; and, FI+CI: 13%). Given that 40% of the neonatal deaths (234/604) that we observed during the intervention period occurred in the first day of life, and a further 14% (87) occurred on the second day, 9% (57) on the third day and a further 18% (106) on days 4 to 7, it may not always have been possible for a mother to seek care for her baby at the facility before the baby died. Nevertheless, especially for the later neonatal deaths, this data does highlight the fact that care-seeking behaviour in communities may be sub-optimal. It is also possible however, that many of the babies (and especially those that died later in the neonatal period) were in fact brought to the facility but were not admitted/were discharged and then went on to die in the community. Data on post-natal care was collected in the PVA (Appendix 6, section 6 of the questionnaire), however was omitted from the short-form PVA (Appendix 7; section 2.1.8) meaning that we only have data on postnatal care for 402 (40%) of the neonatal deaths. Of these, only 117 (29%) had a postnatal check-up for the baby before the baby died. Of the 72 cases that were born and died in the community during the intervention period and had data on whether or not the baby had a postnatal check-up first, only 18 (25%) did have a postnatal check-up; furthermore of the 34 of the 72 where the baby died on third day or later, only 12 (35%) had a check-up. It is therefore likely that care-seeking practices in the

Table 33: Place of death by place of birth for stillbirths and neonatal deaths by RCT comparison group during the intervention period

Intervention period: 1st Oct 2008 to 31st Dec 2010

			SB					NND			
RCT arm	**Birth in:**	**Births**	**Stillbirth in:**	**SB**	% with data	**Birth in:**	**Births**	**NND in**	**NND**	% with data
control	Community	67	Facility	4	**7%**	Community	86	Facility	8	**10%**
	Facility	68	Community	9	**16%**	Facility	74	Community	19	**28%**
FI only	Community	80	Facility	5	**8%**	Community	68	Facility	8	**14%**
	Facility	85	Community	14	**21%**	Facility	78	Community	17	**23%**
CI only	Community	72	Facility	1	**2%**	Community	69	Facility	4	**6%**
	Facility	50	Community	5	**13%**	Facility	78	Community	20	**29%**
FI+CI	Community	71	Facility	3	**6%**	Community	63	Facility	7	**13%**
	Facility	61	Community	5	**10%**	Facility	72	Community	16	**24%**
No CI	Community	147	Facility	9	**7%**	Community	154	Facility	16	**12%**
	Facility	153	Community	23	**19%**	Facility	152	Community	36	**25%**
CI	Community	143	Facility	4	**4%**	Community	132	Facility	11	**9%**
	Facility	111	Community	10	**11%**	Facility	150	Community	36	**26%**
No FI	Community	139	Facility	5	**4%**	Community	155	Facility	12	**9%**
	Facility	118	Community	14	**15%**	Facility	152	Community	39	**28%**
FI	Community	151	Facility	8	**7%**	Community	131	Facility	15	**13%**
	Facility	146	Community	19	**17%**	Facility	150	Community	33	**23%**

Should be zero as 'birth' and 'stillbirth' should be the same i.e. you can't give births somewhere and have a stillbirth somewhere else.

Given we trust the PVA data more (i.e. we trust the date of death data more than we trust the date of birth data), and the percentage of facility stillbirths with data occuring in the community is higher than the other way round, could this be evidence for some inflation of claims of facility delivery. Or is it more likely that women who had a stillbirth would be more likely to claim they had it at the facility to the key informant (compared to ordinary women)? (but then why wouldn't they also claim this to the MEO doing the PVA? because of more probing?). Perhaps the most likley explanation is a mismatch of these cases in the database i.e. the PVA being linked to the wrong women in the database. This is unlikley to have effected the RCT results however as the links to the correct village and cluster of the verbal autopsies was checked (i.e. wrong links are likely to be only for different women within the same village).

community remained poor. We do not have enough data to assess differences by RCT arm in care-seeking behaviour among mothers of babies that were born and died in the community.

Moving on to look at the percentage of facility births that subsequently died in the community, it is apparent that the percentages are similar between RCT comparison arms (CI only: 23%; FI+CI: 24%; control: 28%; FI only: 29%; Table 33) during the intervention period, meaning that the interventions are unlikely to have affected them. These percentages are important, however, in that they highlight a gap in care. Perhaps facilities are discharging babies too early? Or women are failing to return to the facility as requested? Both explanations require further investigation so that efforts can be made to reduce such mortality.

Looking at the comparisons relevant to the RCT results (bold borders in Table 33; see section 4.1 for the RCT results), the differences in community deliveries that died in facilities and facility deliveries that died in the communities were not large. It is therefore unlikely that either of the interventions worked by mechanisms linking the community and the facility. Indeed, although this was to be a part of MaiKhanda in FI+CI areas the amount of work conducted in this area was limited (and the process data on such linkages non-existent, as identified by the *Data Deep Dive* – see section 2.2.6).

Table 34 provides a breakdown of place of death by facility type by place of birth for all neonatal deaths during the intervention period, including those with missing data. The facilities where the babies died were categorised as health centres within the RCT and outside the RCT, and hospitals where MaiKhanda worked and hospitals where MaiKhanda wasn't working, with the remaining 'Facility – other unspecified' category reserved for deaths where the name of the facility was not given but the fact the baby died in a facility was given (see question 1.3 of the PVA questionnaires in Appendices 6 and 7). From Table 35 it can be ascertained that of the facility 197 neonatal deaths with data on facility type (i.e. not including the 'Facility – other unspecified' category), 88 (44.6%) occurred at a health centre within the RCT, only 3 (1.5%) occurred in a health centre outside the RCT, 106 (53.8%) occurred at one of the hospitals (CEmOCs) that MaiKhanda worked in (see section 4.2.1.1.1) and zero occurred in other hospitals. This indicates that it is possible that the relative contribution of the health centres to overall mortality may be larger than originally though from analyses of case-fatality rates at health centres and hospitals (see section 4.2.1.1). This could be the result of the hospitals mainly catering to their local catchment populations that were not included in the RCT. Indeed, Evidence presented in section 4.2.4.5 below suggests that this may indeed be the case, and may be the result of many of the hospitals being in urban populations rather than from more remote rural areas where the majority of the community surveillance and RCT populations were located. This evidence (see section 4.2.4.5 and Table 37) suggests that the RCT population and the CEmOC population are distinct, and only overlap by around 15-20% (for stillbirths and neonatal deaths), meaning that the imbalance in the proportion of total facility deaths that are at the health centre (around 10%) and at the hospital (around 90%) identified earlier by analyses of case-fatality rates (see section 4.2.2) is not reflected in the RCT population, which is a (mainly rural) subset of the total population.

Although the numbers become small when sub-dividing by RCT arm, and there is a lot of missing data, it is still useful to look at the type of facility for all facility stillbirths and neonatal deaths by RCT arm to check for major imbalances. Table 35 shows this information and given indicates no major differences between the RCT arms, although there is a suggestion (but the numbers are very small) that the proportion of neonatal deaths in CI arms that occur in RCT health centres is less than in No CI arms.

4.2.4.4 Contamination of RCT arms due to between arm migration

We can also use the health facility name data from the perinatal verbal autopsies to estimate the proportion of stillbirths and neonatal deaths that occurred outside of the cluster (health centre catchment area) the woman was from (was registered to have been pregnant in). This can then be used as a proxy measure for the contamination of the RCT by movement of women from clusters of one arm of the RCT to clusters of a different arm. In total 647 (31%) out of the total 2087 stillbirths and neonatal deaths recorded throughout the whole community

Table 34: Place of death including facility type by place of birth for neonatal deaths during the intervention period

Deaths: NND **RCT arm:** all **Time period:** 01oct2008 to 31dec2010 (Intervention)

Community/Facility split

Birth in:	n	%
Community	286	100

Death in:	n	% with data	%
Community	228	89%	80%
Facility	27	**11%**	9%
Total with data	255	100%	89%
missing death place	31		11%
Total	286		100%

Birth in:	n	%
Facility	302	100

Death in:	n	% with data	%
Community	72	**26%**	24%
Facility	207	74%	69%
Total with data	279	100%	92%
missing death place	23		8%
Total	302		100%

Birth in:	n	%
missing birth place	16	100

Death in:	n	% with data	%
Community	9	64%	56%
Facility	5	36%	31%
Total with data	14	100%	88%
missing death place	2		13%
Total	16		100%

Total Births in:		
Total		
n	%	
588	97%	with birth place
16	3%	without birth place
604	100%	Total

Total Deaths in:	n	% with data	%
Community	309	56%	51%
Facility	239	44%	40%
Total with data	548	100%	91%
missing death place	56		9%
Total	604		100%

Facility Type breakdown for Place of Death (type of facility was not recorded for births)

Birth in:	n	%
Community	286	100

Death in:	n	% with data	%
Community	228	89%	80%
Health Centre within RCT	13	5%	5%
Health Centre outside RCT	1	0%	0%
Hospital - MaiKhanda FI	8	3%	3%
Hospital - other	0	0%	0%
Facility - other unspecified	5	2%	2%
Total with data	255	100%	89%
missing death place	31		11%
Total	286		100%

Birth in:	n	%
Facility	302	100

Death in:	n	% with data	%
Community	72	26%	24%
Health Centre within RCT	72	26%	24%
Health Centre outside RCT	2	1%	1%
Hospital - MaiKhanda FI	96	34%	32%
Hospital - other	0	0%	0%
Facility - other unspecified	37	13%	12%
Total with data	279	100%	92%
missing death place	23		8%
Total	302		100%

Birth in:	n	%
missing birth place	16	100

Death in:	n	% with data	%
Community	9	64%	56%
Health Centre within RCT	3	21%	19%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	2	14%	13%
Hospital - other	0	0%	0%
Facility - other unspecified	0	0%	0%
Total with data	14	100%	88%
missing death place	2		13%
Total	16		100%

Total Births in:		
Total		
n	%	
588	97%	with birth place
16	3%	without birth place
604	100%	Total

Total Deaths in:	n	% with data	%
Community	309	56%	51%
Health Centre within RCT	88	16%	15%
Health Centre outside RCT	3	1%	0%
Hospital - MaiKhanda FI	106	19%	18%
Hospital - other	0	0%	0%
Facility - other unspecified	42	8%	7%
Total with data	548	100%	91%
missing death place	56		9%
Total	604		100%

surveillance period (Jun-07 to Dec-10) combined had a perinatal verbal autopsy indicating facility death and had the name of the facility where the death occurred recorded. Of these, 43 (6.6%) were facilities that were different to the facility that the mother was originally recorded, by the community surveillance, to reside in; and among these, 29 (4.5% of the 647 with data) were facilities randomised to receive a different intervention in the RCT (were in a different RCT arm). Using the individual facility names we determined net movement from each arm to each other arm and calculated net contamination rates for each arm accordingly, as laid out in Table 36.[94] From the table, it is apparent that net contamination of each arm[95] is likely to have been low at between 1% and 4% for each arm. Whilst we are assuming this data can be extrapolated to apply to movement of all births and deaths between the four arms of the RCT, it is important to acknowledge that this data is for stillbirths and neonatal deaths only and not births. However, given that deaths are more important that births in their influence on the RCT outcomes we can be fairly confident that the results presented in Table 36 indicate that there was little contamination of the RCT resulting from movement of women between arms. It is still possible that there was contamination as a result of interventions spreading between arms, however we have no evidence to suggest that this happened (see section 2.1.9).

4.2.4.5 The influence of the CEmOCs on the RCT

As alluded to earlier in the report on several occasions and detailed in Table 34 and Table 35, the hospitals (CEmOCs) are an additional destination for movement of women and babies from specific RCT arms, and are therefore another potential source of bias influencing the RCT (especially if the MaiKhanda FI has influenced outcomes at the CEmOCs, however this doesn't appear to be the case – see section 4.2.1.1.1). Table 34 indicates that only 19% (106/604; bottom left corner of table) of all neonatal deaths observed throughout the intervention period of the RCT in all arms combined occurred at the non-randomised CEmOCs also implementing the MaiKhanda facilities intervention. This percentage varied little between the four RCT arms (control: 17%; FI only: 17%; CI only: 22%; FI+CI: 22%; Appendix 24 contains tables like Table 34 for all eight RCT comparison groups) indicating that the CEmOC work is less likely to have affected specific arms of the RCT more than others. Table 37 details the places of death, including the individual MaiKhanda CEmOC for all of the stillbirths and neonatal deaths that occurred in each of the four RCT arms during the entire evaluation period (Jun-07 to Dec-10). As for neonatal deaths during the intervention period (Table 34 and Table 35; Appendix 24) the percentages that occurred in the MaiKhanda CEmOCs in each arm are low (control: 19%; FI only: 15%; CI only: 15%; FI+CI: 17% (range 18-21% for non-missing data)). The impact of the MaiKhanda CEmOC work on the RCT neonatal and perinatal mortality rates is therefore likely to be minimal. Table 37 is also useful as it shows that, with very few exceptions, the CEmOC deaths occurred within a CEmOC that was in the same district that the women resided in (as recorded in the community surveillance, see section 2.1.4). Apart from five stillbirths/neonatal deaths in Salima District Hospital from Linyangwa (which is in Kasungu), one death in Bwaila and one in KCH (Lilongwe) from Senga Bay (Salima), one death in Bwaila from Chipoka (Salima), and one death in Bwaila from Mtumthama (Kasungu), all other CEmOC deaths were babies originating in the same district. Overall, only 9 (2.6%) of the total 346 CEmOC deaths originated from other districts. Table 37 also shows that specific CEmOCs tend to cater more towards specific health centres and that some clusters have relatively less CEmOC deaths (and more community deaths). The former health centres tend to be nearby to the CEmOC

[94] We calculate net rates as we assume one case starting in the control arm and finishing in the FI only arm and another case starting in the FI only arm and finishing in the control arm cancel each other out. Obviously the amount of time spent in each arm is also important. However, with data for only 29 cases that changed arms we do not have enough information to estimate time effects, although assume that they cancel out overall in a similar fashion to the cases as laid out in the table.

[95] Net change in movement of cases to and from the arm divided by the number of cases in that arm with PVA data on the name of the health facility where the death occurred.

Table 35. Breakdown of facility of death by randomised health centres and MaiKhanda hospitals by RCT arm

RCT arm	Facility Type where death occurred	SB	% of facility deaths with facility type known	NND	% of facility deaths with facility type known
All	**Health Centre within RCT**	79	**49%**	88	**45%**
	Health Centre outside RCT	1	1%	3	2%
	Hospital - MaiKhanda FI	80	**50%**	106	**54%**
	Hospital - other	0	0%	0	0%
	Total with facility type data	160	100%	197	100%
control	**Health Centre within RCT**	23	**49%**	27	**51%**
	Health Centre outside RCT	0	0%	1	2%
	Hospital - MaiKhanda FI	24	**51%**	25	**47%**
	Hospital - other	0	0%	0	0%
	Total with facility type data	47	100%	53	100%
FI only	**Health Centre within RCT**	**22**	**52%**	**30**	**54%**
	Health Centre outside RCT	1	2%	2	4%
	Hospital - MaiKhanda FI	**19**	**45%**	**24**	**43%**
	Hospital - other	0	0%	0	0%
	Total with facility type data	42	100%	56	100%
CI only	**Health Centre within RCT**	**18**	**56%**	**14**	**32%**
	Health Centre outside RCT	0	0%	0	0%
	Hospital - MaiKhanda FI	**14**	**44%**	**30**	**68%**
	Hospital - other	0	0%	0	0%
	Total with facility type data	32	100%	44	100%
FI+CI	**Health Centre within RCT**	**16**	**41%**	17	**39%**
	Health Centre outside RCT	0	0%	0	0%
	Hospital - MaiKhanda FI	**23**	**59%**	27	**61%**
	Hospital - other	0	0%	0	0%
	Total with facility type data	39	100%	44	100%
No CI	**Health Centre within RCT**	45	**51%**	57	**52%**
	Health Centre outside RCT	1	1%	3	3%
	Hospital - MaiKhanda FI	43	**48%**	49	**45%**
	Hospital - other	0	0%	0	0%
	Total with facility type data	89	100%	109	100%
CI	**Health Centre within RCT**	34	**48%**	31	**35%**
	Health Centre outside RCT	0	0%	0	0%
	Hospital - MaiKhanda FI	37	**52%**	57	**65%**
	Hospital - other	0	0%	0	0%
	Total with facility type data	71	100%	88	100%
No FI	**Health Centre within RCT**	**41**	**52%**	**41**	**42%**
	Health Centre outside RCT	0	0%	1	1%
	Hospital - MaiKhanda FI	**38**	**48%**	**55**	**57%**
	Hospital - other	0	0%	0	0%
	Total with facility type data	79	100%	97	100%
FI	**Health Centre within RCT**	**38**	**47%**	**47**	**47%**
	Health Centre outside RCT	1	1%	2	2%
	Hospital - MaiKhanda FI	**42**	**52%**	**51**	**51%**
	Hospital - other	0	0%	0	0%
	Total with facility type data	81	100%	100	100%

Table 36: Contamination of RCT arms due to between-arm movement

Arm	Cluster (health centre)	SB+NND	SB+NND in another facility	Other facility	Other arm	control +	control -	FI +	FI -	CI +	CI -	FI+CI +	FI+CI -
Control	Area18	10	3	Area 25 (all 3)	FI		3	3					
	Chikowa	31											
	Chimbalanga	13											
	Chulu	53											
	Diamphwi	32											
	Dzenza	19	2	Area 25 (both)	FI		2	2					
	Kamboni	26											
	Katchale	21	1	Maluwa	FI		1	1					
	Kawale	16											
	Maganga	57	1	Chipoka	FI+CI		1					1	
	Makioni	61											
	Mingongo	26											
	Mkhota	30											
	Mtenthera	27											
	Nambuma	26											
	SengaBay	20											
	Wimbe	58	2	St. Andrews & Mtumthama	FI+CI		2					2	
	Total	**526**											
FI	Area25	20	1	Lumbadzi	same								
	Bua	35	1	Mziza	FI+CI				1			1	
	Chadza	17											
	Chinguluwe	46	1	Khombedza	FI+CI				1			1	
			1	Kaphatenga	CI				1	1			
	Chitala	39	2	Santhe	FI+CI				2			2	
			1	Makioni	control	1			1				
	Chitedze	53	1	Kaphatenga	CI				1	1			
	Kaluluma	52	1	Nkhamenya	CI				1	1			
	Kapelula	56	1	Bua	same								
			1	Wimbe	control	1			1				
	Linyangwa	40											
	Lumbadzi	45	1	Mbangombe1	CI				1	1			
	Malingunde	56											
	Maluwa	13	1	Chadza	same								
	Ngodzi	47	1	Lifeline	outside				1				
	Ukwe	39											
	Total	**558**											
CI	Chiunjiza	49											
	Dickison	31											
	Kaphatenga	82											
	Khola	21	1	Santhe	FI+CI						1	1	
	Mbabzi	15	1	Kawale	control	1					1		
	Mbangombe1	42	1	Ngoni	FI+CI						1	1	
	Mbwatalika	21	1	Nthondo	same								
	Mchoka	53											
	Mpasadzi	29	6	Nkhamenya	same								
	Nathenje	12											
	Nkhamenya	42											
	Nsalu	17											
	Nthondo	23	1	Chileka	FI+CI						1	1	
	Simulemba	61	2	Nkhamenya	same								
	Thavite	23	1	Kaphatenga	same								
	Total	**521**											

Table 36 continues on next page

Table 36 continued:

Arm	Cluster (health centre)	SB+NND	SB+NND in another facility	Other facility	Other arm	control +	control -	FI +	FI -	CI +	CI -	FI+CI +	FI+CI -
FI+CI	Admarc (Bliss)	42											
	Chileka	24											
	Chipoka	64	1	Mchoka	CI					1			1
	Chiwamba	36											
	Kawamba	42											
	Khombedza	16											
	Khongoni	46											
	Malembo	24											
	Matapila	17	1	Maluwa	FI			1					1
	Mbangombe2	19											
	Mtunthama	35	1	St. Andrews	same								
	Mziza	35	1	Bua	FI			1					1
	Ndaula	38											
	Ngoni	25	1	Dzenza	control	1							1
	Santhe	19	1	Linyangwa	FI			1					1
	Total	**482**			Totals	**4**	**9**	**9**	**11**	**5**	**4**	**10**	**5**
					Net change	**-5**		**-2**		**1**		**5**	
					Total SB+NND	526		558		521		482	
					no. with hf name data	**182**		**182**		**143**		**140**	
					% change (contamination)	**-2.7%**		**-1.1%**		**0.7%**		**3.6%**	

and the latter further away (data not shown), which along with the district data, lends additional support to the notion, introduced in the previous sub-section, that the CEmOC tend to cater more towards their local catchment populations rather than to women from further afield.[96]

For the 53 /103 (51%) maternal deaths with data on place of death, 27 (51%) died in MaiKhanda CEmOCs, with the following breakdown by RCT arm: control: 7/15 (47%); FI only: 9/17 (53%); CI only: 5/7 (71%); FI+CI: 6/14 (43%). Whilst these numbers are small, it appears that the percentage of maternal deaths occurring in the CEmOCs is higher than the percentage of stillbirths and neonatal deaths, but that the percentages do not differ dramatically between the RCT arms (given the small numbers). The numbers are too small to assess the movement between districts and clusters. Overall, we can conclude that there may be a greater influence of the CEmOCs on the RCT results for maternal mortality. However, given the lack of evidence of an impact of the MaiKhanda facilities intervention at CEmOC level (see section 4.2.1.1.1), i.e. the likely absence of a separate intervention effect diluting the RCT maternal mortality results by effecting both intervention areas (FI only, CI only and FI+CI) and control areas equally, we can conclude that the RCT results showing an absence of effect of either the community or the facilities interventions (at the randomised health centres) on maternal mortality are robust.

Overall, the potential of the MaiKhanda CEmOC facilities intervention work to bias the stillbirth and neonatal mortality results of the RCT is low for two reasons: because the CEmOC interventions are unlikely to have significantly reduced neonatal mortality (see section 4.2.1.1) and because the influence of the CEmOCs (regardless of what happened there) is relatively low and doesn't appear to be different in different RCT arms. And the potential of the MaiKhanda CEmOC facilities intervention work to bias the maternal mortality results of the RCT is low for one reason: because the CEmOC interventions are unlikely to have significantly reduced maternal mortality (see section 4.2.1.1). It is also important to note (as we did extensively for neonatal deaths above) that a significant fraction of maternal deaths were delivered in a facility only to die in the community later. For the 35 maternal deaths with data on place of delivery who delivered at a facility, ten (29%) died later in the community, and although the numbers are very small 5/19 (26%) in FI areas that were delivered in a facility also died in the community.

[96] Please note that this data provide an additional check on the quality of the community surveillance and perinatal verbal autopsy data (i.e. the movement patterns match what may be expected and are not random noise).

Table 37. Place of stillbirth and neonatal death by RCT cluster and arm, including each CEmOC individually

District	Kasungu	Lilongwe	Salima				MaiKhanda CEmOC																
Arm	Cluster (Health Centre)	SB+NND	Community	Same Health Centre	Other RCT Health Centre (Table 33)	Health Centre outside RCT	Kasungu DH	Salima DH	Bwaila	KCH	Kabudula	Likuni	Mitundu	Mlale	Nkhoma	St. Gabriel	Total	MaiKhanda CEmOC %	Other CEmOC	Other unspecified facility	Missing death place
Control	Area18	10	5	1	3												0	0%			1
	Chikowa	31	13	5					4	2	4	1					11	35%		2	
	Chimbalanga	13	9	1											1		1	8%			2
	Chulu	53	22	9			14										14	26%			8
	Diamphwi	32	7	7		1									11		11	34%		4	2
	Dzenza	19	15		2												0	0%	1		1
	Kamboni	26	18	4			2										2	8%		1	1
	Katchale	21	14		1				2				2				4	19%		1	1
	Kawale	16	12						1								1	6%			3
	Maganga	57	22	6	1			13									13	23%		8	7
	Makioni	61	24	17				8									8	13%		2	10
	Mingongo	26	11	2												5	5	19%		2	6
	Mkhota	30	22				5										5	17%		1	2
	Mtenthera	27	9	5											7		7	26%		1	5
	Nambuma	26	8	7					2	1							3	12%		5	3
	SengaBay	20	6	1				7	1	1							9	45%			4
	Wimbe	58	39	5	2		5										5	9%		1	6
	Total	**526**	**256**	**70**	**9**	**1**	**26**	**28**	**10**	**4**	**4**	**1**	**2**	**0**	**19**	**5**	**99**	**19%**	**1**	**28**	**62**
FI	Area25	20	10	2	1				3								3	15%			4
	Bua	35	27		1		5										5	14%			2
	Chadza	17	5	7					1								1	6%		2	2
	Chinguluwe	46	14	7	2			17									17	37%			6
	Chitala	39	12	13	3			3									3	8%		1	7
	Chitedze	53	27	5	1				3								3	6%		5	12
	Kaluluma	52	26	3	1		8										8	15%			14
	Kapelula	56	31	3	2	1	7										7	13%		4	8
	Linyangwa	40	16	3			6	5									11	28%		2	8
	Lumbadzi	45	27	5	1				4	1							5	11%		3	4
	Malingunde	56	39	1								11					11	20%		2	3
	Maluwa	13	6		1								1				1	8%		2	3
	Ngodzi	47	11	16	1	3		6									6	13%		5	5
	Ukwe	39	13	8					1		3						4	10%		9	5
	Total	**558**	**264**	**73**	**14**	**4**	**26**	**31**	**12**	**1**	**3**	**11**	**1**	**0**	**0**	**0**	**85**	**15%**	**0**	**35**	**83**

Table 37 continues on next page

Table 37 continued:

District	Kasungu	Lilongwe	Salima					MaiKhanda CEmOC																
Arm	Cluster (Health Centre)	SB+NND	Community	Same Health Centre	Other RCT Health Centre (Table 33)	Health Centre outside RCT		Kasungu DH	Salima DH	Bwaila	KCH	Kabudula	Likuni	Mitundu	Mlale	Nkhoma	St. Gabriel	Total	MaiKhanda CEmOC %	Other CEmOC	Other unspecified facility	Missing death place	
CI	Chiunjiza	49	29							3	1			7	3			14	29%		5	1	
	Dickison	31	22	2						1								1	3%		2	4	
	Kaphatenga	82	41	11		1			19									19	23%		1	9	
	Khola	21	17		1													0	0%		1	2	
	Mbabzi	15	4	3	1					2								2	13%		1	4	
	Mbangombe1	42	29	1	1													0	0%		3	8	
	Mbwatalika	21	12	4	1					1							2	3	14%			1	
	Mchoka	53	32	7					7									7	13%		1	6	
	Mpasadzi	29	12	1	6			5										5	17%		1	4	
	Nathenje	12	3	2						4						3		7	58%				
	Nkhamenya	42	13	7				6										6	14%		4	12	
	Nsalu	17	9	1						2		1						3	18%		2	2	
	Nthondo	23	14		1												3	3	13%		1	4	
	Simulemba	61	32	5	2			4										4	7%			18	
	Thavite	23	9	2	1			1	3									4	17%		2	5	
	Total	**521**	**278**	**46**	**14**	**1**		**16**	**29**	**13**	**1**	**1**	**0**	**7**	**3**	**3**	**5**	**78**	**15%**	**0**	**24**	**80**	
FI+CI	Admarc (Bliss)	42	18						16									16	38%		1	7	
	Chileka	24	4	4													5	5	21%		1	10	
	Chipoka	64	27	13	1				10	1								11	17%		2	10	
	Chiwamba	36	10	3							1							1	3%		1	21	
	Kawamba	42	23	10				4										4	10%		2	3	
	Khombedza	16	4	5					4									4	25%			3	
	Khongoni	46	25	1						2		3					1	6	13%		6	8	
	Malembo	24	7	1								1						1	4%		8	7	
	Matapila	17	7	1	1					2						1		3	18%		3	2	
	Mbangombe2	19	6	1													4	4	21%		5	3	
	Mtunthama	35	22	1	1			7		1								8	23%	1	1	1	
	Mziza	35	18	3	1	1		9										9	26%	1		2	
	Ndaula	38	26							1	1		1				4	7	18%		1	4	
	Ngoni	25	17		1					1	1							2	8%		1	4	
	Santhe	19	12		1			3										3	16%			3	
	Total	**482**	**226**	**43**	**6**	**1**		**23**	**30**	**8**	**3**	**4**	**1**	**0**	**0**	**1**	**14**	**84**	**17%**	**2**	**32**	**88**	
Overall Total		2087	1024	232	43	7		91	118	43	9	12	13	10	3	23	24	346	17%	3	119	313	

4.2.5 Context: description and assessment of intervention effects

4.2.5.1 Facility level

4.2.5.1.1 Availability of resources

Figure 99 gives an overview of the number of nursing staff, the number of deliveries per month, the number of deliveries per nurse per year, and Case Fatality Rates (fresh stillbirths, maternal and neonatal) for each of the 37 health centres in Lilongwe for the period July 2009 to June 2010 (colour coded by MaiKhanda intervention: grey=control red=FI only, blue=CI only, purple=FI+CI). The health centres are grouped into three categories: those which are urban and have access by tarmac road, have mains electricity and piped water; those which are peri-urban with easy access to town and have mains electricity and piped water, and those that are rural with poor road access, poor water supply system (generally boreholes) and solar electricity. From the graph it is clear that the more urban the health centre is the more nurses it has and the lower nurse to delivery ratio it has. This is unsurprising on consideration of the preferences of most health centre clinicians for work in more urban areas with their amenities and access to better schools for their children etc. In terms of case fatality rates the picture is more mixed but it appears that there are slightly higher fresh stillbirth rates in the more rural health centres. It is important to consider these differences between the health centres given that they may have an effect on how successful the MaiKhanda interventions are. The randomisation process, however, has ensured that such differences are roughly balanced out between those health centres receiving each intervention (see distribution of colours, representing the RCT arms, throughout each of Figure 99, Figure 100 and Figure 101).

In Kasungu and Salima, health centres are generally more rural, though the same differences with respect to peri-urban and more disadvantaged rural areas generally apply (Figure 100 and Figure 101). It should be noted that Salima health centres appear less disadvantaged than those in Lilongwe and Kasungu though, with more of them having access to electricity, mains water and tar roads, lower nurse/delivery ratios and lower Case Fatality Rates (Figure 101).

Table 38 presents information collected on other key health centre resources grouped by district and MaiKhanda intervention allocation. From this table it is clear that health centres are very under-resourced in general with the minority having functional ambulances, some not even having functional clocks in their labour ward or functional BP apparatus and most not having clinical officers available at night and some not even having nurses available at night, to name but a few indicators.

In terms of comparisons between districts there are some slight differences such as Kasungu HC having fewer deliveries per labour and post-natal bed per month; Salima having fewer health centres with functional ambu bags but more with functional car ambulances, and more with functional clocks in their labour wards; Lilongwe having fewer health centres with functional radio communication; and Salima having fewer health centres with nurses and medical assistants always available in the day but more with clinical officers available in the night. Some of these differences may be due to biases in the way the forms were filled in different districts. Nevertheless such differences between districts are taken account of in the RCT analysis which is stratified by district given that the RCT design was stratified by district.

It is interesting to note that whilst Figure 101 shows that Salima health centres are generally better off than Kasungu (Figure 100) and Lilongwe (Figure 99) health centres with respect to electricity, water and deliveries per nurses per year; but they are worse off with regards to many other indicators including deliveries per bed as evidenced by the data in Table 38. There are no major differences between the health centres in each arm of the RCT (Table 38). The lack of signal functions (see Box 2)[97] is also a problem as shown by the data

[97] Signal functions data was actually collected as part of the Health Facility Surveillance (see section 4.2.1.1.2 and Appendix 10).

Figure 99: Categorisation of Lilongwe Health Centres

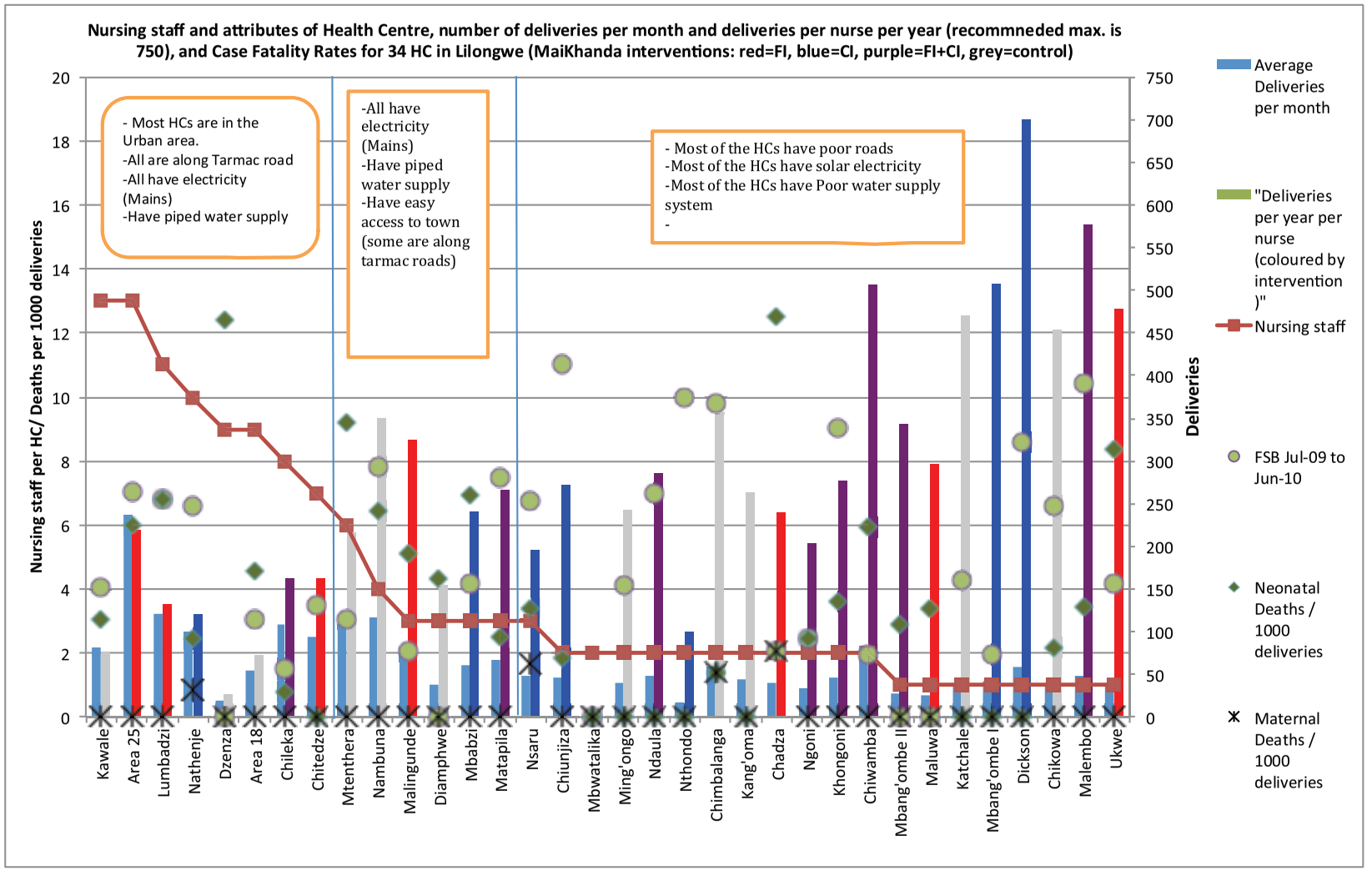


Figure 100: Categorisation of Kasungu Health Centres

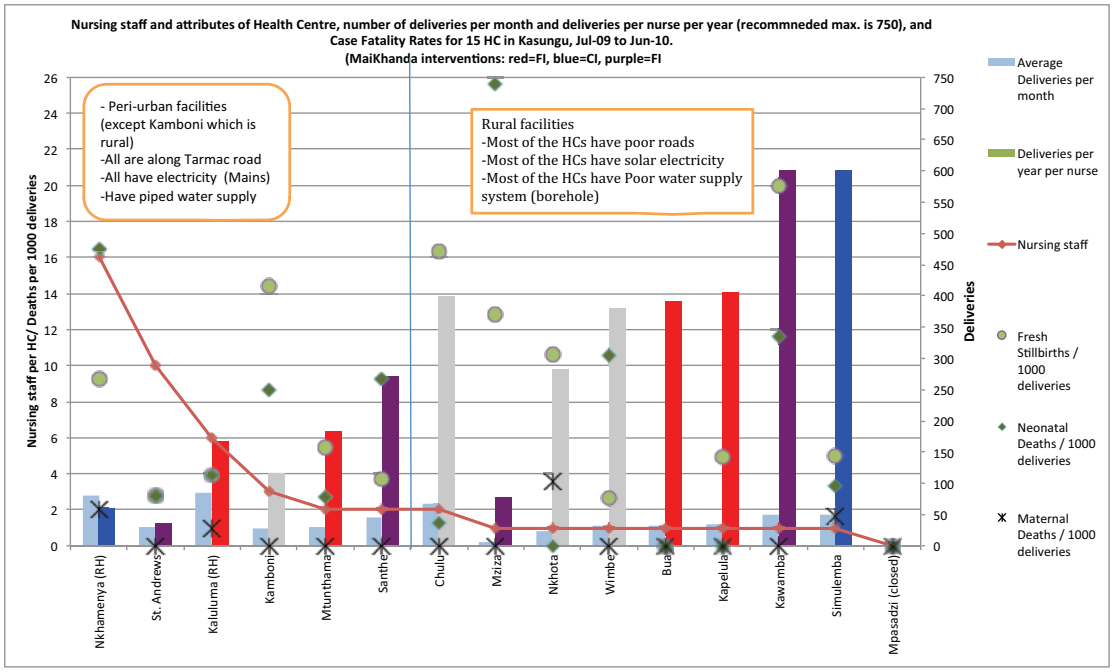
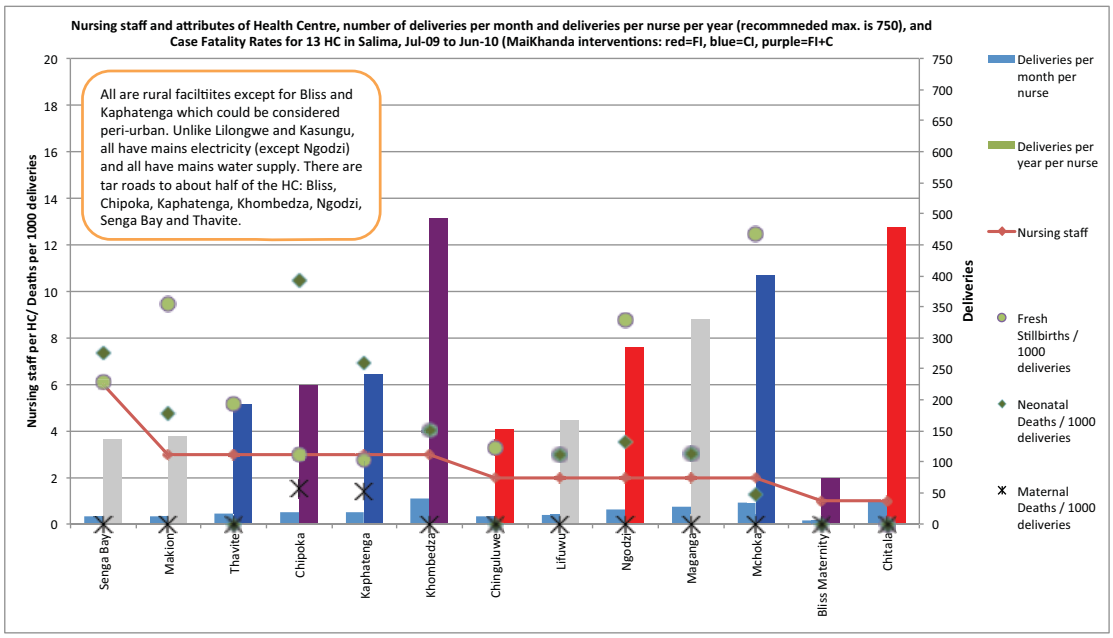


Figure 101: Categorisation of Salima Health Centres



in Table 39. This data also shows that Lilongwe health centres, with an average of 1.0 of the six BEmOC signal functions available in any given health centre in any given month between July 2009 and December 2010, are worse off than Kasungu health centres (average of 2.3) which are worse off than Salima health centres (average of 2.9). Table 39 however, shows that differences in signal function availability between the RCT comparison groups are small, indicating that signal function availability is unlikely to have biased the results of the RCT. The lack of signal function availability at the health centres could well have been a reason for the observed lack of effect of both the community and the facilities interventions on maternal mortality.

Table 38. Comparison of Health Centre resources by district and RCT arm

Category[1]	no. of HC[2]	Deliveries per month per labour ward bed[3]	Deliveries per month per post-natal ward bed	Percentage of Health Centres (HC) with: Functional Ambu Bag	Functional Ambulance	Functional Bicycle Ambulance	Functional BP aparatus	Functional clock in labour ward	Ave. Days a week open	Functional Radio comm.	Any Type of Nurse always available in the day[4]	Any Type of Nurse always available in the night	Clinical Officer always available in the day	Clinical Officer always available in the night	Medical Assistant always available in the day	Medical Assistant always available in the night
Kasungu HC	**15**	**16**	**7**	**85%**	**31%**	**15%**	**69%**	**46%**	**5.3**	**92%**	**85%**	**85%**	**15%**	**8%**	**92%**	**77%**
FI	8	13	6	75%	38%	25%	63%	75%	5.0	100%	100%	100%	25%	13%	100%	75%
no FI	7	20	9	100%	20%	0%	80%	0%	5.8	80%	60%	60%	0%	0%	80%	80%
CI	7	11	5	80%	40%	20%	80%	60%	3.6	100%	80%	80%	20%	20%	100%	80%
no CI	8	15	7	88%	25%	13%	63%	38%	6.4	88%	88%	88%	13%	0%	88%	75%
FI only	4	18	9	75%	25%	25%	50%	75%	6.0	100%	100%	100%	25%	0%	100%	75%
CI only	3	25	8	100%	0%	0%	100%	0%	2.0	100%	0%	0%	0%	0%	100%	100%
FICI	4	9	4	75%	50%	25%	75%	75%	4.0	100%	100%	100%	25%	25%	100%	75%
control	4	13	6	100%	25%	0%	75%	0%	7.0	75%	75%	75%	0%	0%	75%	75%
Lilongwe HC	**34**	**31**	**12**	**78%**	**19%**	**19%**	**67%**	**59%**	**6.7**	**67%**	**88%**	**85%**	**8%**	**8%**	**85%**	**68%**
FI	15	37	16	75%	17%	17%	75%	50%	6.4	67%	92%	83%	0%	0%	92%	82%
no FI	19	26	9	80%	20%	20%	60%	67%	7.0	67%	86%	86%	14%	14%	79%	57%
CI	16	22	12	67%	25%	8%	67%	50%	7.0	67%	91%	82%	0%	0%	82%	73%
no CI	17	41	12	87%	13%	27%	67%	67%	6.5	67%	87%	87%	14%	14%	87%	64%
FI only	7	53	18	83%	17%	33%	83%	67%	5.8	83%	83%	83%	0%	0%	100%	100%
CI only	8	19	10	67%	33%	17%	67%	67%	7.0	83%	80%	80%	0%	0%	80%	80%
FICI	8	26	14	67%	17%	0%	67%	33%	7.0	50%	100%	83%	0%	0%	83%	67%
control	11	34	9	89%	11%	22%	56%	67%	7.0	56%	89%	89%	22%	22%	78%	44%
Salima HC	**13**	**29**	**9**	**38%**	**46%**	**0%**	**77%**	**77%**	-	**92%**	**62%**	**31%**	**15%**	**23%**	**62%**	**69%**
FI	6	30	9	67%	33%	0%	67%	83%	-	83%	50%	50%	17%	17%	50%	50%
no FI	7	28	9	14%	57%	0%	86%	71%	-	100%	71%	14%	14%	29%	71%	86%
CI	6	36	11	50%	50%	0%	67%	67%	-	83%	50%	33%	17%	0%	50%	50%
no CI	7	23	7	29%	43%	0%	86%	86%	-	100%	71%	29%	14%	43%	71%	86%
FI only	3	23	7	33%	0%	0%	100%	100%	-	100%	67%	33%	0%	33%	67%	67%
CI only	3	35	10	0%	33%	0%	100%	67%	-	100%	67%	0%	0%	0%	67%	67%
FICI	3	37	12	100%	67%	0%	33%	67%	-	67%	33%	67%	33%	0%	33%	33%
control	4	23	8	25%	75%	0%	75%	75%	-	100%	75%	25%	25%	50%	75%	100%
All HC	**62**	26	10	**70%**	**28%**	**13%**	**77%**	**60%**	**6.3**	**79%**	**81%**	**71%**	**12%**	**12%**	**81%**	**71%**
FI	29	27	11	73%	27%	15%	73%	65%	5.9	80%	85%	81%	12%	8%	85%	72%
no FI	33	26	9	67%	30%	11%	81%	56%	6.7	78%	77%	62%	12%	15%	77%	69%
CI	29	23	11	65%	35%	9%	78%	57%	6.0	77%	77%	68%	9%	5%	77%	68%
no CI	32	30	10	73%	23%	17%	77%	63%	6.5	80%	83%	73%	14%	17%	83%	72%
FI only	14	34	13	69%	15%	23%	85%	77%	5.9	92%	85%	77%	8%	8%	92%	83%
CI only	14	25	11	50%	30%	10%	100%	60%	6.3	90%	67%	44%	0%	0%	78%	78%
FICI	15	22	10	77%	38%	8%	62%	54%	5.8	67%	85%	85%	15%	8%	77%	62%
control	19	26	8	76%	29%	12%	71%	53%	7.0	71%	82%	71%	18%	24%	76%	65%

[1]Differences not tested for statistical significance as null hypothesis of no difference is true i.e. due to randomisation any significant differences that happen to be present are purely the result of chance (Hayes and Moulton, 2009).

[2]There are also 14 further areas that don't have HC that were randomised to receive CI or no CI - see Randomisation flow diagram in Methods section.

[3]Only 3/15 iKasungu HC, 9/37 Lilongwe HC and 3/13 Salima HC have pre-natal beds so data not presented on this indicator.

[4]There are no doctors at any of the HC. Types of Nurse include: Enrolled Nruse Midwives, Enrolled Nurse Technicians, Enrolled Community Nurses, State Registered Nurses, State Registered Nurse Midwives and Auxillary Nurses.

Table 39. Comparison of signal function availability at HC by district and RCT arm

Category[1]	no. of HC[2]	Percentage of months between Jul-09 and Dec-10 where signal functions were available at Health Centres (HC equally weighted): BEmOC signal functions (Vacuum and Breech are counted as one)							CEmoC functions		No. of the 6 BEmOC signal functions available on average
		Manual removal of placenta	Manual vacuum aspiration (MVA)	Vacuum Extraction	Breech deliveries	Parenteral antibiotics	Magnesium sulphate	Oxytocic drugs (ergometrine or oxytocin)	Caesarian Section	Blood transfusion	
Kasungu HC	**15**	**20%**	**22%**	**19%**	**42%**	**56%**	**41%**	**57%**	**3%**	**10%**	**2.3**
FI	8	18%	19%	16%	42%	59%	33%	60%	4%	6%	2.2
no FI	7	22%	25%	22%	42%	52%	51%	55%	1%	14%	2.4
CI	7	17%	22%	22%	48%	56%	37%	59%	5%	20%	2.3
no CI	8	22%	21%	16%	37%	56%	45%	56%	1%	1%	2.3
FI only	4	25%	24%	18%	40%	64%	44%	60%	0%	1%	2.5
CI only	3	26%	33%	33%	54%	57%	57%	57%	0%	33%	2.8
FICI	4	11%	14%	14%	43%	55%	22%	59%	8%	10%	1.9
control	4	19%	18%	14%	33%	49%	46%	53%	1%	0%	2.1
Lilongwe HC	**34**	**7%**	**7%**	**10%**	**22%**	**21%**	**12%**	**35%**	**0%**	**0%**	**1.0**
FI	15	9%	7%	19%	23%	18%	14%	44%	0%	0%	1.1
no FI	19	6%	7%	4%	22%	23%	12%	27%	0%	0%	0.9
CI	16	3%	13%	7%	15%	10%	5%	23%	0%	0%	0.7
no CI	17	11%	2%	13%	29%	31%	19%	45%	0%	0%	1.3
FI only	7	12%	5%	34%	34%	27%	22%	53%	0%	0%	1.5
CI only	8	0%	17%	8%	18%	9%	5%	11%	0%	0%	0.5
FICI	8	6%	8%	6%	12%	10%	6%	36%	0%	0%	0.8
control	11	11%	0%	0%	26%	33%	17%	39%	0%	0%	1.1
Salima HC	**13**	**46%**	**9%**	**7%**	**76%**	**80%**	**16%**	**98%**	**0%**	**0%**	**2.9**
FI	6	49%	19%	16%	77%	83%	28%	98%	0%	0%	3.2
no FI	7	44%	1%	0%	76%	78%	6%	98%	0%	0%	2.7
CI	6	40%	20%	16%	75%	81%	32%	98%	0%	0%	3.2
no CI	7	52%	0%	0%	78%	79%	2%	98%	0%	0%	2.7
FI only	3	61%	0%	0%	81%	87%	2%	98%	0%	0%	2.9
CI only	3	43%	2%	0%	78%	83%	11%	98%	0%	0%	2.8
FICI	3	37%	39%	31%	72%	80%	54%	98%	0%	0%	3.6
control	4	44%	0%	0%	75%	74%	3%	99%	0%	0%	2.6
All HC	**62**	**19%**	**11%**	**12%**	**38%**	**42%**	**20%**	**54%**	**1%**	**2%**	**1.7**
FI	29	20%	13%	18%	39%	43%	22%	60%	1%	2%	1.9
no FI	33	18%	9%	7%	38%	41%	19%	48%	0%	3%	1.6
CI	29	14%	16%	13%	35%	36%	19%	47%	1%	5%	1.6
no CI	32	22%	6%	11%	41%	47%	22%	59%	0%	0%	1.8
FI only	14	26%	9%	22%	46%	50%	24%	65%	0%	0%	2.0
CI only	14	15%	17%	12%	38%	36%	17%	39%	0%	7%	1.6
FICI	15	14%	16%	13%	32%	36%	20%	55%	2%	3%	1.7
control	19	20%	4%	3%	38%	45%	20%	55%	0%	0%	1.7

[1]Differences not tested for statistical significance as null hypothesis of no difference is true i.e. due to randomisation any significant differences that happen to be present are purely the result of chance (Hayes and Moulton, 2009).
[2]There are also 14 further areas that don't have HC that were randomised to receive CI or no CI - see Randomisation flow diagram in Methods section.

4.2.5.1.2 Staff psychology results

Analysis from the staff psychology survey conducted across 57 health centres between January and May 2008 found that staff were often willing to work and interested in their work, but were less motivated due to poor salary, staff shortages and other problems with support systems. Such problems also contributed to poor morale among staff too (however, morale was on average good). Staff mainly reported good working relations with superiors, although leadership was often felt to be too distant. Links between health centres need to be improved. In the context of the potential for PDSA-based quality improvement work there is evidence of initiative in terms of staff coming up with new ideas, but these ideas were often not tested due to a lack of support from superiors. The results were analysed by various subgroups and it was found that staff in Lilongwe were worse off in the majority of the psychological indicators measured than staff in other districts. Staff over 30, those working at government facilities (rather than CHAM), nurses (rather than Medical Assistants), and those working at urban facilities as opposed to rural facilities, were also all found to be worse off. The balance in overall staff psychology scores between the RCT comparison groups at baseline was fairly good (see Table 5, section 4.1)

4.2.5.1.3 Provider knowledge survey results

Table 40 presents a summary of all the results of the provider knowledge questionnaire (Appendix 14). Firstly it presents the results of the Emergency Obstetric care scenario questions. Of the 52 completed questionnaires, the vast majority (42) are from nurses, 5 are from medical assistants, 1 is from a clinical officer, and 4 are from other staff (clinical technician; clinical officer intern and nurse midwife technician). The questionnaires reflect both BEmOC and CEmOC care: 35 in total were from health centres, 2 from rural hospitals (both of which are included as part of the 62 randomised health facilities); and 15 from CEmOCs. In terms of district breakdown, 20 are from Kasungu (7 of which are from health centres) and 20 are from Salima (18 of which are from health centres); The 12 from Lilongwe all come from health centres.

On average respondents got 70% of the questions correct (Clinical Officer, 92%, Nurses 69%, Medical assistants 70%) There was a significant difference between staff at CEmOCs who answered 86% of questions correctly and staff at BEmOCs who got only 64% correct. Whilst this may be explained by CEmOC staff encountering more obstetric complications than their BEmOC colleagues, the questions were designed to be answered by those with even a basic understanding of obstetric care. The BEmOC results are particularly alarming in view of numerous life threatening responses (20%), which may help to explain observed case fatality rates.

Table 40. Provider knowledge survey results

	Average % correct		
Questions (no.)	**BEmOC staff (n=37)**	**CEmOC staff (n=15)**	**Total (n=52)**
Emergency Obstetric Care (13)	64%	86%	70%
Monitoring of routine Labour (5)	36%	33%	35%
Management of routine Labour (11)	78%	84%	80%
Neonatal Care (5)	56%	64%	58%
	Average % ideal		
	BEmOC staff (n=37)	**CEmOC staff (n=15)**	**Total (n=52)**
Staff-Patient interactions (10)	48%	28%	42%
	Average % of questions correct		
Confidence	**BEmOC staff (n=37)**	**CEmOC staff (n=15)**	**Total (n=52)**
not at all confident	66%	61%	64%
very confident	60%	70%	62%
	Average % of questions correct		
Study	**BEmOC staff (n=37)**	**CEmOC staff (n=15)**	**Total (n=52)**
Never studied	47%	57%	50%
studied in last year	54%	66%	57%

The figures show that knowledge of the correct frequency of monitoring patients in routine labour is equally lacking in BEmOCs and CEmOCs with an average of only 36% and 33% correct responses respectively, with no significant difference between clinicians' designation. Knowledge of foetal heart rate monitoring (at least every 30 minutes) was the best-answered question, with 79% answering correctly.

In response to questions on management of routine labour, overall 80% of responses were correct with little difference between health facilities or staff designation.

Knowledge of Neonatal Care, with an average of only 58% correct answers, is lower than that of Emergency Obstetric Care. It is also interesting to note that CEmOC staff are only slightly more knowledgeable (64% correct) than BEmOC staff (56% correct). Differences between staff groups are also minimal. The biggest gaps in knowledge are management of a baby who does not breathe spontaneously (only 35% answered this correctly) and management of a baby with low Apgar scores at 1 minute: 23% of respondents

gave potentially life-threatening responses, including 8% who said no action was required and 4% who said they did not know what to do.

Only 42% feel that their care is ideal and only 50% of staff indicated that they would always recommend a friend/relative to deliver in their facility. For instance only 27% of respondents indicated that their facility was always clean enough and only 42% indicated that patients get enough information to look after themselves at home. Interestingly staff perceptions seem to be better in BEmOCs (48% ideal on average) than in CEmOCs (28% ideal on average).

We also found a marked lack of correlation how recently a respondent had studied a specific subject and the likelihood that the respondent would get the answer to a question on that subject correct. Also, in both HC and CEmOC staff we found no positive correlation between the number of years of professional training received and the number of correct responses. We also found no correlation between how confident a respondent indicated that they were in a specific subject and how likely they were to get the answers to questions on that subject correct.

Respondents were also asked their year of graduation. There was little correlation between clinical knowledge and year of graduation. Interestingly, older CEmOC staff were found to perceive more ideal staff-patient interactions in their facilities than younger CEmOC staff. It is unclear whether this is due to different attitudes of older staff than younger staff or different perceptions of staff-patient interactions between older and younger staff.

Overall, we found significant gaps in the clinical knowledge of healthcare providers at both health centre and hospital level, with the gaps being greater at health centres. This backdrop is likely to be an important factor influencing outcomes and could have been a barrier to the interventions impacting on maternal and neonatal deaths at the facilities (see sections 4.1, 4.2, and 4.4 for evidence of a lack of effect on facility death rates).

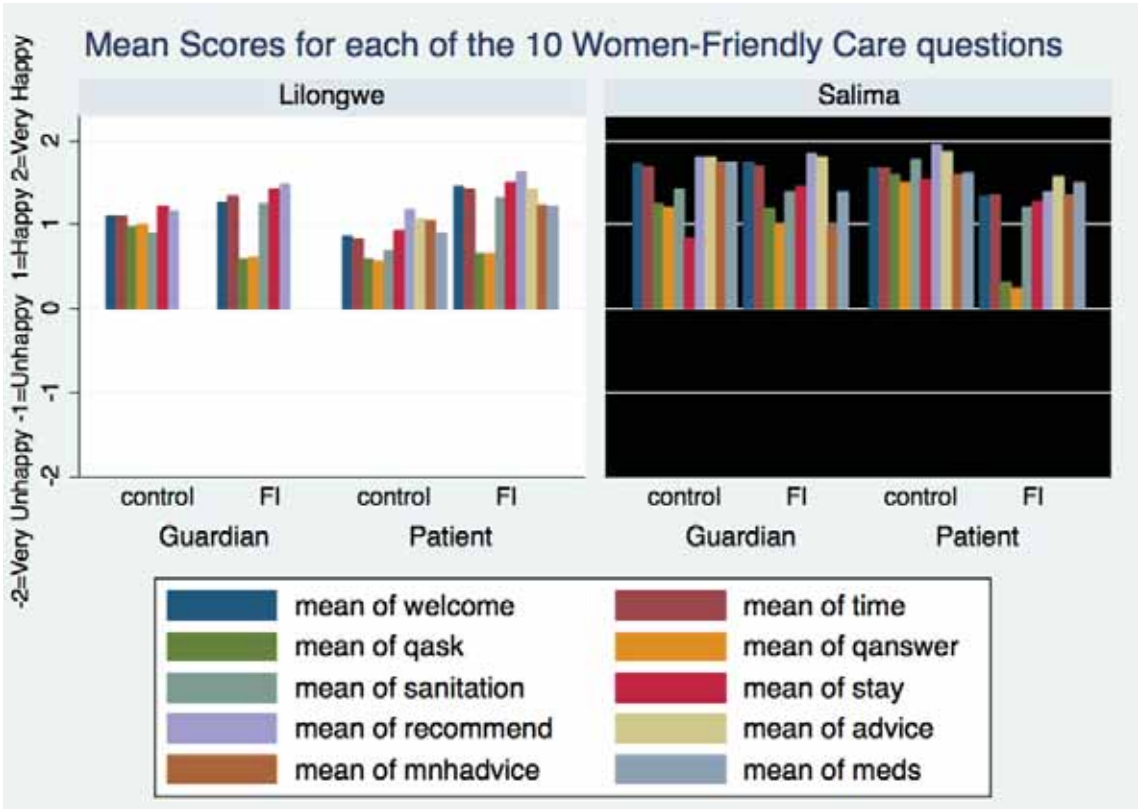
4.2.5.1.4 Perception of patients utilizing healthcare

Analysis of women and guardians accessing care at health centres in Lilongwe and Salima district found women patients at Lilongwe facility intervention health centres to indicate that they were generally happier on the women friendly care questionnaire (see Appendix 15) than women in No FI (control) health centres in Lilongwe. However, in Salima it appears that the No FI (control) health centres score higher on all indicators for patients and most for guardians (Figure 102). Patients scored low on the questions asking about whether they had a chance to ask questions and if they got answers to those questions (questions 3 and 4, Appendix 15).

The differences between patients and guardians are also interesting. Figure 102 shows that there are less difference in the responses of the guardians between FI and No FI (control) health centres. Perhaps the guardians, given that they are not receiving the care (and perhaps don't interact with the health centre staff that much) don't perceive differences/improvements in Women Friendly Care as much as the patients do.

Figure 103 shows the differences in mean score for all ten questions (with data) for each of the health centres in Lilongwe and Salima categorised by FI or No FI (control). It shows that whilst the FI health centres in Lilongwe have a higher mean score on average (1.06; red line) than the non-FI health centres in Lilongwe (0.80; blue line) a significant part of this difference is due to the control HC including Mbabzi and Nsaru which both score negatively on average and can be considered as outliers. In Salima, the situation is reversed with FI health centres having a lower mean score (1.35; red line) than non-FI health centres (mean 1.61; blue line), although it should be noted that the numbers surveyed for each health centre are low. It is also interesting to note that the health centres in Salima appear on average to be more Women-Friendly (mean 1.51) than those in Lilongwe (mean 0.92), but again overall numbers surveyed in Salima are low.

Figure 102: Differences in scores for 10 women-friendly care questions



There was no relationship between age and mean score to all 10 questions (data not shown).

Overall, it is difficult to conclude that the MaiKhanda facilities intervention has had a significant impact on women-friendly care at the health centres. However, in some health centres in Lilongwe there may have been an effect. Given that women-friendly care was one of the initial quality improvement activities in 2008/9 and was not continued intensively throughout (see section 3.2) it is perhaps not surprising that the results of this survey are not more clear-cut.

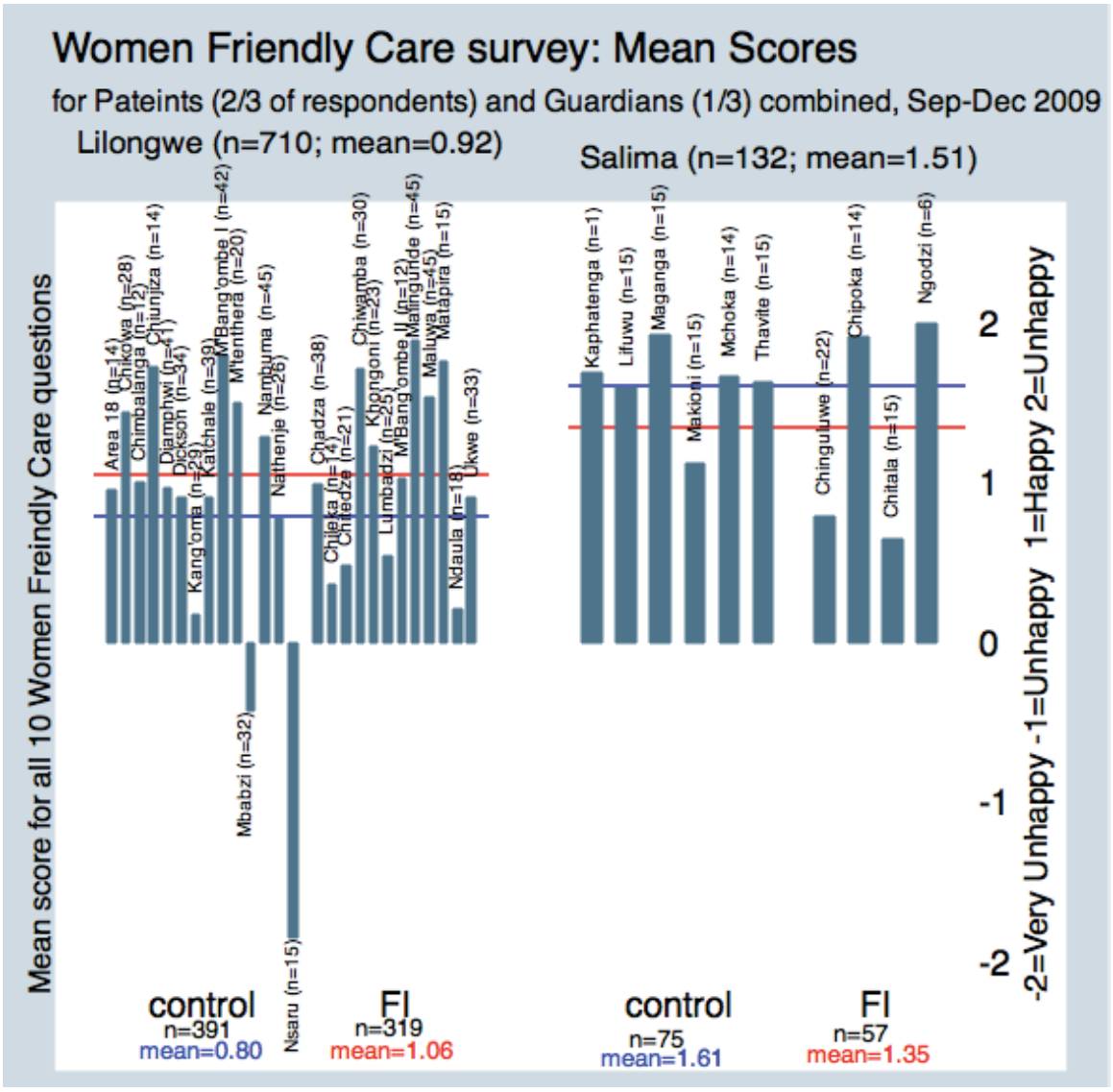
Finally it should be noted that this survey has the following limitations: no data were collected and analysed for Kasungu and not enough data was collected and analysed for Salima; and, there are insufficient months of data (Sep, Oct, Nov, Dec 2009 and some Jan 2010) for an adequate time-trend analysis.

4.2.5.1.5 The macrosystem, health policies and leadership

4.2.5.1.5.1 Macrosystem

Success of quality improvement efforts are known to be affected by leadership by clinicians at facility level, and on building the will of key people within the Health system at district, regional and national level. In terms of building leadership, there was a drive by the facilities intervention team to develop 'super-improvers' during 2008 with 33 people from across the CEmOCs and training institutions (Kamuzu College of Nursing) attending 3 sessions. There was some attrition of these people: of the 23 with data on their whereabouts as of Oct-10, six (26%) have become students elsewhere. This resulted in a vacuum of leadership within certain QI teams which has been further compounded by additional staff turn-over meaning that in effect the composition and leadership of many facility quality improvement (QI) teams was in flux and often not able to reach a critical mass of activity or effect that was sustainable for long enough to have an impact on MCFR of NCFR. Given the

Figure 103 : Mean scores of all 10 Women-Friendly Care questions by HC, intervention and district



context of many QI teams not being self-sufficient or self-starting i.e. needing intense coaching and support from MaiKhanda FI staff (see section 3.2.2).

In terms of building will within the health system, there has been engagement with the District Health Management Team (DHMT)/ Ministry of Health (MoH) since 2007. Such engagement was epitomised by the attendance of the Deputy Director of the Reproductive Health Unit (Fannie Katchale) at MaiKhanda partners meetings in 2008 and 2009, and by the positive engagement of the DHMT in Salima since 2009 and in Kasungu from late 2010 onwards. Engagement of the DHMT/MoH, however, has often been inconsistent due to lack of capacity/interest (it has noticeably been not so good in Lilongwe for example). Given many of the leaders at this level are involved with many other programmes that they are also committed to they may have insufficient time for MaiKhanda. Where other programmes have conflicting methodologies (e.g. adherence to inflexible standards, or 'quality assurance' as opposed to 'quality improvement') work with MaiKhanda and the will for improvement may also be more difficult. Towards the end of 2010 MaiKhanda's engagement with the DHMT/MoH increased; however, as of the close of the evaluation period in December 2010, there was still a heavy reliance on MaiKhanda staff to drive the FI work, highlighting a lack of embedding and sustainability of the intervention to date. The fact that MaiKhanda operated outside of the Sector Wide Approach (SWAp) framework of management and

coordination of interventions may also have affected its ability to embed into the system in a sustainable manner.

On further reflection of building will and leadership it is apparent that a strategy for senior leadership engagement was missing. Such a strategy could have included MaiKhanda showing health system leaders what they could offer them in terms of actual results achieved, setting a timetable for how often they should have engaged health system leaders and formulation of a strategic plan for success. The problem with such a strategy though was its dependence on initial success to spread something, which - if engaged leadership from within the system is a criteria for that initial success – could lead to a Catch 22 situation.

In terms of leadership, the lack of ownership of the programme from within Malawi has also been a factor, as epitomised by the lack of a MaiKhanda board meeting in late 2010 (see section 5.6.1 for a discussion of local vs. foreign ownership). The fact that some of the board were not conversant with maternal and neonatal health was also felt to be an important factor in the sense that they were not spreading MaiKhanda's message to the right people often enough.

4.2.5.1.5.2 External environment

Some of the other factors that will have influenced the intervention and its subsequent evaluation include:

- MoH policy on prohibiting use of Traditional Birth Attendants in 2008 which resulted in additional burden on overstretched facilities, with nothing to replace TBA as an option for safe delivery at home/ in the community.
- Rotation of staff by MoH
- Promotion of staff working on the programme (this is, however, a potential benefit to the wider health system) - dilution of QI team capacity/QI intervention
- Staff turnover, staff leaving, retiring etc. meaning a dilution of QI team capacity
- Vacancy rates for midwives, obstetricians and throughout the health sector – limits health sector ability to meet health needs and deliver quality care and is a tough context for quality improvement to be effective in.
- Lack of staff capacity and system weaknesses in using data for decision making i.e. a weak Health Management Information System (HMIS) – meaning the programme was required to invest more resources (not originally included in budget) in training data personnel and that the data was harder to access.
- Inadequate drug supply (antibiotics, oxytocin) to the health facilities (see Table 39). With bottlenecks and stock-outs the supply system was inadequate to ensuring regular supply to meet the needs of patients. This limited the ability of the health sector to deliver services and the facilities intervention to deliver quality measures i.e. without critical supplies quality improvement work can be redundant.
- A lower baseline maternal mortality ratio as estimated by the baseline community surveillance (see section 4.1) meaning a harder target for programme to reach.

However, these factors were external and therefore beyond the scope of the project to modify or influence.

4.2.5.2 Community level

4.2.5.2.1 Women's Group Facilitator survey results

While the women's group intervention has been successful in places where it has been implemented before, the MaiKhanda model is unique in that it relies on using volunteers as facilitators for the first time. This has implications for programme implementers and policy makers in terms of scaling up and sustainability. We therefore conducted a study to understand the experience of volunteer women's group facilitators. The study uses a mixed method approach to achieve its objectives. A total of 75 (93%) out of the 81 women's group facilitators (WGF), who each supervise 9 of the 729 women's groups, completed the survey questionnaire (Appendix 16) and 9 (11%) WGF, with a range of background characteristics

were selected for interview and interviewed using the interview guidelines we developed (Appendix 17). We only present a summary of the results here.

Most of the volunteers facilitators were in the reproductive age group having had first-hand experiences of pregnancy and childbirth. The average time spent on conducting a group meeting was 2hrs 20 minutes (standard deviation 44 minutes). The vast majority (79%, 57/72) of the WGF thought that the amount of supervision given by MaiKhanda staff was about right, and around half (53%, 40/74) of the facilitators felt that their workload was 'about right', with 39% (29/74) feeling that their workload was too much. Overall, the WGF did not feel that this commitment to voluntary work necessarily affected their current earning capacity/livelihood.

The facilitators also experienced a positive change in their status within society as a result of their engagement with this voluntary activity. More than two-thirds of the 75 facilitators (69%) who completed the questionnaire experienced happiness or enjoyed (84%) the work they were doing.

While monetary incentives[98] were identified as an important motivating factor, opportunities to gain knowledge and learn new skills also emerged as important motivating factors as did the supervision and training the women received from MaiKhanda staff. One of the major challenges the volunteers faced was in reaching out to all their groups given the distance and amount of time this consumed. This was especially true during the rainy season where impassable roads meant that meetings had to be postponed.

An overwhelming majority of the facilitators (96%, 72/75) were confident that their intervention could improve maternal and neonatal health in Malawi; 69 (92%) of the WGF then answered the follow-up question on how the women's groups will improve MNH in Malawi, and the majority (52%, 36/69) indicated that it would be through changes in knowledge with 26% (18/69) indicating it would be through changes in practice, 17% (12/69) that it would be through changes in attitude, and 3 (4%) giving other answers. It is interesting to compare these results to those of the MNH Knowledge, Attitude and Practice survey (section 4.2.1.2.4) which show some agreement in that whilst the knowledge of women in women's group areas was higher than that of women in areas without women's groups, differences in actual practices between women's group members and non-members were generally not observed. Cultural beliefs and practices were identified as important contributory factors to both maternal and neonatal health problems.

In summary, there is some evidence supporting the idea that the volunteer system has been successful, with facilitators generally being happy in their work and motivated by the respect they get from the community as well as opportunities for learning and training. However, perhaps unsurprisingly given widespread poverty in rural areas of Malawi, facilitators are also influenced by financial and material incentives in terms of allowances and bicycles. Any scale-up of the community intervention needs to bear this in mind and budget accordingly in order to ensure the sustainability of the intervention, or look at other ways of sustainably running WGs e.g. with HSAs (as was done in the Perinatal Care Project in Ntcheu, Malawi).

4.2.5.2.2 Women's group self evaluation

Data was available for 190 (78%) of 243 women's groups in Kasungu, but only 84 (26%) of 324 women's groups in Lilongwe and 38 (23%) of 162 women's groups in Salima. On average, the ***WG self evaluation*** scores (see Appendix 18 for questionnaire and section 2.2.5.2.2 for methods) were as follows (scores out of 5 for all districts combined):

- Participation 3.9
- Leadership 4.1
- Organisational structure 3.9

[98] Although these are allowances towards travel and bicycle maintenance, amounting to MK 3950 (about £15) per month, the facilitators consider it as a 'salary'. This may have implications for sustainability of the volunteer-based model.

- Problem assessment 3.9
- Resource mobilisation 3.6
- Asking why 3.4
- Links 3.6
- External agents 4.0
- Programme management 4.0.

These average scores are all fairly high, however they mask considerable variation between the women's groups, an important minority of whom (up to 10% for some indicators) scored themselves as 0 or 1 out of 5. The women's groups in Kasungu were also found to have consistently rated themselves lower on average for all nine indicators than the women's groups in Lilongwe and Salima, whose ratings on the whole were fairly similar. Important exceptions to this being higher ratings for women's groups in Lilongwe on "resource mobilisation" and "asking why". The reasons behind the lower scores in Kasungu require further investigation.

Overall, the results of the self-evaluation of the women's groups indicate that the women generally believe that they have made a success of the groups and executed the action cycle well, with average scores of 4 out of 5 given for most of the indicators of success. These results, and the fact that 90% of the groups (653 / 729) were still running when MaiKhanda last checked towards the end of 2010, therefore indicate that the women have bought into the intervention and that is sustainable from this perspective. What these results do not show, however, given that they are subjective and not linked to tangible outcomes, is whether or not the groups were successful in achieving their aims with regard to improved maternal and neonatal health.

4.2.5.2.3 Women's Groups effect on the availability of resources for MNH

In section 4.2.1.2.3 we presented the available data on the implementation of the strategies chosen by the women to improve maternal and neonatal health in their communities. This information indicates that the groups were able to bring key resources to their community, with 98% (209/213) of the women's groups that chose the strategy of health education (=213/245 surveyed) managing to implement it (this was mainly through MaiKhanda staff giving the health education though); 84% (128/152) of the women's groups that chose the strategy of bed nets (=152/245 surveyed) managing to obtain the bed nets; and, 77% (162/211) of the women's groups that chose the strategy of dimba gardens managing to implement them to mention some of the most successfully implemented strategies (see Table 15 for full list). Some of the strategies to gain resources were less successfully implemented however, such as obtaining a health post for the community, which was only successfully implemented by 30% (13/44) of the women's groups that chose the strategy, which were only 18% (44/245) of the groups surveyed.[99]

Overall there is some evidence that the women's groups were able to increase the availability of resources in for maternal and neonatal health in their communities. However, the extent to which the availability of such resources translates into regular beneficial use of such resources and then again into improved maternal and neonatal health outcomes remains unclear.

4.2.5.2.4 Traditional leadership and government policies

4.2.5.2.4.1 Traditional leaders, community attitudes and the community intervention

The role of traditional leaders and their effect on the community intervention was considered retrospectively as part of the *Data Deep Dive* (see section 2.2.6) as it was recognised that their support is generally required for activities taking place within their communities to be successful. Given that data was not actively collected on the role of traditional leaders and

[99] Perhaps the percentage of groups who chose this strategy was so low because many groups felt that obtaining a health post was an unrealistic goal.

their influence on the community intervention, most of the evidence reported in this section is based on anecdotal accounts from MaiKhanda staff.

Traditional community power structures in rural Malawi generally follow the hierarchy of village headmen (VH) who oversee their own village of around 200-250 people and are overseen by group village headmen (GVH), who typically oversee around 10-20 village headmen (villages) and are overseen in turn by traditional authorities (TA) who then oversee around 30-40 group village headmen areas i.e. a population of around 100,000, a significant proportion of a district. An extensive community entry process involving sequential sensitisation of community leaders from the TA downwards was undertaken before the women's groups were started in 2007 in order to encourage support for the community intervention. In some cases, however, it was found that TA were not interested in the community intervention or its aims but were only interested in what MaiKhanda could give them personally. In these cases GVH under the TA would also sometimes lose interest in the community intervention with the consequence that it was not promoted in their communities. However, other TA were enthusiastic, and there were even instances where such an enthusiastic TA would talk to TA who were not interested to try to persuade them of the value of the community intervention, with some success. The 10 TA in Salima were invited by the Mchinji District Assembly (at the request of MaiKhanda) and went on a learning visit to Mchinji where they learnt about a similar women's group project, MaiMwana.[9, page 15] Following this visit the TA briefed their GVH who briefed their VH in turn to spread MNH messages in their communities by, for example, painting messages on the side of houses as they had seen in Mchinji. The MNH task forces were formed following this visit too, to support the TA in their new quest to reduce maternal mortality in their communities.

Traditional Authorities also introduced bylaws banning delivery in the community. These bylaws support the national ban on traditional birth attendant deliveries (see following subsection). The TA also encouraged TBA to stop delivering babies and instead join the women's groups as a force for improved maternal and neonatal health. TA also showed their enthusiasm by attending MaiKhanda open days[100] (no TA refused an open day invitation) and giving speeches on MNH at them; and by playing a key role in the implementation of strategies requiring the mobilisation of resources (see previous subsection). Local leaders would often give land to the women's groups for their community vegetable gardens for example. There were instances however where a lack of support from local leaders meant that strategies could not be implemented.

For women's group meetings to take place permission is usually required from the VH. The community entry and sensitisation process contributed to permission for meetings being given in the vast majority of cases. In some instances local leaders saw the benefits of MaiKhanda in neighbouring communities and asked for similar assistance in their communities.

One of the key issues in initially getting the buy-in of communities to the women's group intervention (which was generally achieved as evidenced in section 4.2.5.2.2 above) was the fact that the intervention was not based on giving hand-outs to communities (as many other community-based programmes in Malawi are). Communities needed to be convinced of the facilitation role of the intervention implementers and the 'help you to help yourself' concept. In areas with high poverty and illiteracy, with less-educated TA, and with many other projects giving hand-outs, less of the women's groups finished the action-cycle as they felt it was taking too long without tangible benefits. Communities in Kasungu were also interested in cash and what the programme could do for them in relation to their tobacco crops (Kasungu is one of the main tobacco growing districts in Malawi).

Cultural issues are also an important consideration. For example, it is not acceptable for a woman to talk about reproductive health issues in public. Therefore the community intervention had to sensitise communities extensively in order for some of messages of the groups to be disseminated.

[100] Days organized by MaiKhanda to show-case the community intervention to the community. In 2009, nine open days were held and in 2010, 48 were held, across the three districts.

Overall, it seems, albeit with only anecdotal information and no data, that the involvement of traditional leaders is crucial for the success and sustainability of the community intervention. This notion is further supported by the fact that the MaiKhanda community intervention staff attended scheduled TA meetings to push the community intervention and get feedback on the maternal and neonatal health of the communities. Given the outputs of the women's groups in terms of strategy implementation (section 4.2.1.2.3) it appears that the efforts of the community intervention to engage the traditional leaders have been broadly successful, although there have been instances when they were not and the intervention suffered as a result. MaiKhanda staff, however, feel that they have not worked with traditional leaders enough and that more could be done in this area to bring improvements in maternal and neonatal health (personal communication, Cassie Williams, Women and Children First, November 2011).

4.2.5.2.4.2 Government policies

The government of Malawi and it's Ministry of Health (MoH) have shown an overt commitment to maternal and neonatal health since the launch of the road-map in 2005, as described in section 1.1.4. The most significant government policy to affect the MaiKhanda interventions, however, is likely to have been the banning of deliveries by Traditional Birth Attendants (TBA) in March 2008. This seems to have provoked a significant rise in health facility deliveries in all areas of Malawi, as supported by the DHS 2010 results which show an increase from 57% of births being at a facility in 2004 to 73% being at a facility in 2010.[2,page9] Such an increase in facility deliveries may have overburdened some of the facilities and contributed to increased case-fatality rates. For the community intervention, whilst the TBA ban may have strengthened community efforts to encourage women to deliver at a health facility, it appears that such efforts in community intervention areas did not increase the percentage of women delivering at a health facility over an above the rapidly increasing secular trend (see section 4.2.1.2.1).

4.3 Cost-effectiveness

Pending full analysis of the itemised costs, summaries of the costs for each department of MaiKhanda were used to determine overall expenditure on the Facilities Intervention and the Community Intervention for the intervention period (1st October 2008 to 31st December 2010[101]).[102] External costs (e.g. USA expenditure for IHI and UK expenditure for WCF (UK)) were estimated and added to the Malawi costs, the total of which was used as an upper limit of the cost of the interventions in a sensitivity analysis (Table 41).

The estimated effects of the interventions measured in Odds Ratios (see section 4.1) were used, along with the total population under each intervention[103] and the mortality rate in the comparison arm of the RCT, to estimate the number of maternal, neonatal, and perinatal deaths averted as a result of FI, CI and FI+CI (Table 42). Odds Ratios from the unadjusted individual-level logistic regression analysis[104] and the adjusted analysis were used along with their lower and upper 95% Confidence Intervals to determine a range of plausible values for the number of deaths averted (Table 42), which were then used in sensitivity analyses.

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[101] The intervention period is used because this is the period for which the effects are measured (see RCT analysis).

[102] The following assumptions were made in this basic preliminary costing: that the joint costs (all admin, finance, building rent etc.) were shared equally between FI, CI and M&E; that pre-intervention period start-up costs (which need to be adjusted for the useful life and resale value of the capital item) were negligible and not included.

[103] Based on average populations around HC catchment areas (see Table 1: RCT flowchart) and the need to assume equal intervention and comparison group populations for ease of calculation of death averted, a population of 1,200,000 was assumed for FI areas, no FI areas, CI areas and no CI areas and a population of 600,000 was assumed for FI+CI areas and control (neither intervention) areas covered by MaiKhanda.

[104] Two-by-two factorial comparisons of FI vs. no FI, and CI vs. no CI in the presence of the other intervention.

To determine whether the observed costs per death averted are cost-effective, we have used rough cost-effectiveness criteria for health interventions in the developing world developed by WHO (Table 43). These criteria state that an intervention is 'highly cost-effective' if it costs less than the per capita GDP of the country to avert one Disability-Adjusted Life Year (orange shading), that it is 'cost-effective' if it costs between 1 and 3 times the per capita GDP to avert a DALY (yellow shading), and that it is not cost-effective if it costs more than 3 times the per capita GDP to avert a DALY (grey shading). A DALY is a measure of health equating to one year of life free from disability. To determine threshold costs for maternal, neonatal and perinatal deaths we have assumed 30, 20 and 20 DALYs per death averted respectively.[105]

Table 41. Summary costs by intervention during intervention period

From MaiKhanda accounts (costs in US$, Exchange rate 152K per $, xe.com, 13/05/2011)					
01oct08 to 31dec10	**FI**	**CI**	**M&E**	**Admin/Joint**	**FI+CI**
Without Admin/Joint	1,048,444	998,358	761,260	1,009,558	
With Admin/Joint	1,384,964	1,334,877	1,097,779		1,359,921
external costs ($)	1,000,000	162,000	324,000		
external costs (£)		100,000	200,000		
+ external costs	2,384,964	1,496,877	1,421,779		1,940,921

Table 42. Summary of effects of each intervention (deaths averted per year)

Deaths averted per year by Community Intervention				
		Maternal	**Neonatal**	**Perinatal**
Unadjusted	**Estimate**	23	306	933
	lower95%CI	129	789	1609
	upper95%CI	-165	-270	159
Adjusted	**Estimate**	43	222	749
	lower95%CI	140	721	1407
	upper95%CI	-131	-373	1

Deaths averted per year by Facility Intervention				
		Maternal	**Neonatal**	**Perinatal**
Unadjusted	**Estimate**	-41	456	60
	lower95%CI	76	925	788
	upper95%CI	-249	-100	-772
Adjusted	**Estimate**	-59	400	41
	lower95%CI	67	876	705
	upper95%CI	-284	-165	-706

Deaths averted per year by Facility and Community Interventions combined				
		Maternal	**Neonatal**	**Perinatal**
Unadjusted	**Estimate**	-9	384	497
	lower95%CI	60	695	960
	upper95%CI	-172	-14	-63
Adjusted	**Estimate**	-6	318	396
	lower95%CI	61	648	842
	upper95%CI	-164	-103	-136

Table 43. Calculation of cost-effectiveness thresholds for deaths averted

GDP per capita (US$) 270			**Threshold $ per death averted**				
3*GDPpc	810		highly cost effective	1* GDPpc per DALY	cost-effective (1-3 * GDPpc per DALY)	3* GDPpc per capita per DALY	not cost-effective
Maternal Mortality	DALY averted per MD:	30		8100		24300	
Neonatal Mortality	DALY averted per NND:	20		5400		16200	
Perinatal Mortality	DALY averted per PD:	20		5400		16200	

[105] These are rough calculations based on the fact that whilst a mother may have less life remaining to live than a baby, her death will result in the loss of DALYs from her surviving children and family members who will be more prone to sickness without her. Using alternative figures will affect the results as follows: if there are more DALYs per life averted the cost-effectiveness of the interventions will increase, if there are less the cost-effectiveness will decrease. Without discounting future benefits some sources cite the number of DALYs saved from averting an NND as being 33, therefore the figures we are using here may be conservative.

Cost-effectiveness is presented as cost[106] per death averted and was calculated for the two main effects observed from the RCT (section 4.1): the combined facility and community intervention on neonatal mortality (Table 44), and the community intervention on perinatal mortality (Table 45).

The combined Facilities and Community Intervention was found to be 'highly cost-effective' (costing less than $5,400 per neonatal death per averted) in reducing neonatal mortality across all scenarios analysed, except the point estimate of intervention effect when external costs (Table 41) are also included where the cost per death averted is just over the 'highly cost-effective' threshold of $5,400 per neonatal death averted (Table 43) and the upper 95% CI of its unadjusted and adjusted effect estimates which are just above 1 (i.e. no effect).

Table 45 shows that the Community Intervention is 'highly cost-effective' in reducing Perinatal Mortality, except for at the upper 95%CI of its unadjusted effect where it is 'cost-effective', and the upper 95% of it's effect determined by the adjusted analysis (see section 4.1) where it is not cost-effective because the effect estimate is so close to 'no effect' (Odds Ratio 0.9998).

Given the current foreign support to the Malawian health sector, whether such apparently cost-effective interventions can still be sustained is open to debate.

Table 44. Cost-effectiveness results: neonatal mortality reduction

Facilities + Community Intervention combined				
Neonatal: US$ per Neonatal Death averted			**Costs**	
			Malawi only	Malawi + external
Effects	Unadjusted	point estimate	3,544	5,061
		lower95%	1,957	2,795
		upper95%	NO EFFECT	NO EFFECT
	Adjusted	point estimate	4,271	6,099
		lower95%	2,100	2,999
		upper95%	NO EFFECT	NO EFFECT

Table 45. Cost-effectiveness Results: Perinatal Mortality reduction

Community Intervention				
Perinatal: US$ per Perinatal Death averted			**Costs**	
			Malawi only	Malawi + external
Effects	Unadjusted	point estimate	1,431	1,608
		lower95%	830	932
		upper95%	8,420	9,458
	Adjusted	point estimate	1,783	2,003
		lower95%	949	1,065
		upper95%	1,048,229	1,177,384

[106] US$ are used to enable comparison with other studies and for ease of interpretation in relation to thresholds for cost-effectiveness which are based on GDP per capita which is reported in US$.

5 Interpretations, conclusions, learning and recommendations

We conclude our evaluation of the MaiKhanda facility and community interventions in this chapter with further interpretation of the results presented in the previous chapter including reference to their precision and potential sources of bias (limitations of the evaluation), and evidence from the literature on similar interventions. We go through each of the 21 numbered results provided in the summary at the beginning of chapter 4 in turn for the sake of completeness and to ease overall understanding. We then summarise the key findings in relation to the Three Delays and supply and demand side theoretical frameworks underpinning the interventions that were introduced in chapter 1. Following this we discuss the potential of the interventions going forward both in terms of improved implementation and dosage, paying attention to differences in the results over time, and in terms of sustainability, including consideration of integration of the interventions with the Malawian Ministry of Health. We then present additional points of key learning based on experiences of the MaiKhanda programme, and summarise the overall strengths and weakness of the study. Following this we discuss points of debate, including the balance between local ownership and external (foreign) technical assistance and management, and the pros and cons of different methodologies of evaluation. We then finish the report with recommendations, based on the evidence we have gathered, for policy makers, intervention implementers, and researchers.

5.1 Discussion of results: interpretation, precision, bias, and literature comparison

Here we discuss each of the main findings detailed at the beginning of chapter 4 in turn. For each finding, if appropriate, we provide further interpretation, discuss limitations of the evaluation in terms of precision of the finding and potential biases that should be borne in mind during interpretation, and discuss the finding in relation to the literature on similar interventions.

Impact on death rates in the overall population and within health facilities

1. The randomised controlled trial suggests **neonatal mortality decreased by 22% in areas with both the facility intervention at the health centre and the community intervention in surrounding villages compared with control areas**; and, that **perinatal mortality decreased by 16% in areas with the community intervention relative to those without the community intervention** (see section 4.1).

Precision: Both of the observed effects were statistically significant at the 5% level[107] with confidence intervals (see preface) as follows: the effect of the facility and community interventions combined on neonatal mortality: 22% reduction (95%CI: 40% reduction, 1% increase); the effect of the community intervention on perinatal mortality: 16% reduction (95%CI: 28% reduction, 3% reduction). These confidence intervals mean that although we think there were 22% and 16% reductions respectively we can be fairly certain that there was at least some reduction in the total population and that there is also a possibility that there were greater reductions.

Potential bias: Despite the fact that the data from which these finding are based on came from a low-cost community surveillance system with quality control mechanisms that were adequate but not extensive (sections 2.1.4, 2.1.5 and 2.1.7) and despite some loss to follow-up (section 4.1.1) we are confident in the these results of the RCT for four main reasons: observed births were generally in-line with expectations, the steady increases in health facility delivery observed from aggregation of the community surveillance data

[107] The effect of FI+CI on NMR was actually p=0.051 (5.1% significant), but we think it is important not to ignore it because it is just over the 5% threshold, which is an arbitrary cut-off

(section 4.2.1.21) would have been almost impossible for 1800 separate key informants to fake, baseline mortality rates were broadly in-line with expectations considering secular trends (sections 4.1.2.1 and 4.2.2.2.3), and, the individual and combined effects of the two interventions on stillbirth, early and late neonatal deaths - constituent parts of perinatal and neonatal mortality - fit together well (section 4.1.5).

Comparison with the literature: A review of literature by Bhutta and colleagues[108] concluded that strategies enhancing the skills of community health worker cadres have shown demonstrable impact on perinatal mortality especially in combination with health systems strengthening activities. The Warmi Project in Bolivia[6, page 14] first initiated community mobilization through women's groups. Subsequently, randomized trials to test the impact of women's groups on neonatal mortality have been conducted in Nepal[7, page 14], Jharkhand in India,[8, page 14] and Bangladesh.[10, page 14] While the MIRA trial in Nepal[7, page 14] and Ekjut study in Jharkhand and Orissa, India[8, page 14] respectively showed reductions of 30% and 45% in neonatal mortality, the PCP study in Bangladesh did not show any change in mortality rates. [10, page 15] The reasons for the community intervention having more of an effect on perinatal mortality in some situations (on it's own in our study) and neonatal mortality in other situations (in other studies and when combined with the facility intervention in our study, also see finding 3 below regarding timing and changes to the intervention and differences in effects on perinatal and neonatal mortality) requires further investigation.

There have been no other randomised trials testing the effects of facility quality improvement interventions, or both facility and community interventions combined, on neonatal (or perinatal or maternal) mortality as far as we are aware.

Deaths Averted: Assuming an equal total population of 600,000 in each of the four RCT arms (equal to allow calculation of absolute numbers from odds ratios) we estimate that the community intervention averted 933 perinatal deaths (95%CI: 159 perinatal deaths averted, 1609 perinatal deaths averted) and that the combined facility and community intervention averted 384 neonatal deaths (95%CI: 14 neonatal deaths extra, 695 neonatal deaths averted) each year during the 27 month intervention period (Oct-08 to Dec-10). Given the overlap between the community intervention effect and the combined intervention effect given the two-by-two factorial nature of the trial (i.e. CI effect = CI vs. no CI = CI only and FI+CI vs. control and FI only; and FI+CI effect = FI+CI vs. control) and the overlap between perinatal mortality (stillbirths and early neonatal deaths) and neonatal mortality (early neonatal deaths and late neonatal deaths) it is not straight forward to estimate the total number of deaths (stillbirths and neonatal deaths) that were averted by the whole MaiKhanda programme. An estimate taking account of uncertainty can be gained by adding all of the nine constituent effects (FI only on SBR, ENMR, LMNR; CI only on SBR, ENMR, LMNR and FI+CI on SBR, ENMR, LMNR) and then calculating the confidence limits for this sum by summing the 9 confidence limits in quadrature. Following this procedure provides an estimate of 1240 deaths averted per year (95%CI: 379 deaths averted, 2406 deaths averted).

2. **It is likely that the observed effects on mortality of both interventions occurred in the community** (section 4.2.4). This seems likely given the lack of observed effects on deaths at the health centres and hospitals (section 4.2.2), and data on the place of death collected from verbal autopsies. The latter indicate lower neonatal mortality rates in the community, but not in the facility, in areas with both the facility and community interventions compared to control areas; and, lower perinatal mortality rates in the community, but not in the facility, in community intervention areas compared to areas without the community intervention. For the facility intervention this suggests that neonates were leaving facility intervention health centres less likely to die in the community than neonates leaving control health centres, which fits with any facility intervention effect most likely being on late neonatal deaths (section 4.1.5).

[108] Bhutta ZA, Darmstadt GL, Haws RA. Delivering interventions to reduce the global burden of stillbirths: improving service supply and community demand. BMC Pregnancy and Childbirth 2009; 9(Suppl 1): S7

Precision: The precision (and potential bias) surrounding the observations of a lack of effect at the health centres and hospitals is discussed below under findings 5 and 6. Place of death data was available for 78.9% (843/1069) of stillbirths and 91.5% (931/1018) of neonatal deaths. We split total mortality rates (deaths per 1000 births) into fractions occurring in the community, occurring within the facility (and with a missing place of occurrence) using this data. For the CI vs. No CI comparison of place of perinatal mortality there were between 225 and 405 deaths in each comparison group in each time period (see footnote 84 to page 153 and Appendix 23). For the FI+CI vs. control comparison of place of neonatal mortality there were between 69 and 92 deaths in each comparison group in each time period (see footnote 85 to page 156 and Appendix 23). Using these numbers to calculate confidence intervals around the death rate fractions in the community and facility in each time period indicates that the observed reductions in community deaths are not statistically significant at the 5% level for either of the comparisons (data not shown). Therefore finding 2 should only be taken as an indication that the effects of the interventions were more likely to have occurred in the community.

Potential bias: We do not have any reason to suspect bias in the recording of the place of death either from the respondents or the interviewers for the verbal autopsies (see section 2.1.8).

Comparison with the literature: As far as we are aware the other relevant studies (see comparison with the literature for finding 1 above) did not specifically examine the effect of the interventions on place of death. However, both in Jarkhand and Orissa, India, and in Nepal, the vast majority of births (and deaths) happen in the community due to the remoteness and difficulty in accessing health facilities that many rural areas face. It is therefore likely that the observed effects of both studies on neonatal mortality[7,8, page 14] predominantly occurred in the community. In addition to our lack of exploration of the possibility of the facility intervention resulting in neonates leaving health centres less likely to die in the community, there is a lack of literature on changes in place of death resulting from similar facilities interventions.

3. Cause of death data and calendar data (section 4.2.3) suggest **the observed effect of the combined facility and community intervention on neonatal mortality may have been mediated by reductions in mortality due to asphyxia, prematurity and sepsis, in both the early and late neonatal periods, but that the effect was mainly observed in the last, more intensive, 15 months of the intervention period (see section 3.2), when it was larger (a 28% reduction)**; and, that **the effect of the community intervention on perinatal mortality may have been mediated through a reduction of stillbirths during the first 12 months of the intervention period and through a reduction in early neonatal mortality due to sepsis, prematurity and asphyxia in the second, more intensive intervention period** (section 4.2.3; also see section 4.1.5).

Interpretation: The observation that the majority of the effect of the combined intervention on neonatal mortality occurred in the second higher dosage (section 3.2) part of the intervention period, and that during this time period the effect was a 28% reduction in neonatal mortality is important as it clearly indicates the potential of the combined approach going forward. However, looking at the data closer it is apparent that this increase in effect is mainly due to the shift in the community intervention effect from one on stillbirths (not a constituent part of neonatal mortality) in the first intervention period to one on early neonatal deaths (a constituent part of neonatal mortality) in the second intervention period, rather than any increase in effect of the facility intervention which is not apparent (appendix 21). Therefore addition of the task forces to the community intervention and an increase in it's duration, rather than increased dosage and duration of the facilities intervention, is likely to be more responsible for the increase in neonatal mortality effect of the combined facility and community intervention in the second intervention period.

The observation that the effect of the community intervention was primarily on stillbirths during it's first 12 months with women's groups only and that it then had more of an effect on early neonatal deaths during the second intervention period of 15 months when

maternal and neonatal task forces were also included (section 3.1) is also interesting in it's own right. Given an absence of data to elucidate possible specific mechanisms for these different effects (see e.g. sections 4.2.1.2 and 4.2.5.2) further investigation is required in order to determine why they may be apparent, and to what extent task forces and women's groups are separately responsible for reductions in perinatal and neonatal mortality.

Precision: The effect of the combined facility and community intervention on neonatal mortality in the second intervention period (Oct-09 to Dec-10) was a 28% reduction, with a 95%CI of a 50% reduction to a 5% increase (i.e. the effect was just not significant at the 5% level: p=0.084, see preface for explanation). Given this effect was almost statistically significant at the 5% level despite the smaller sample size due to the shorter time period, the implications of the interventions at increased dosage noted above are clearly worth considering.

The effects of the community intervention on stillbirths and early neonatal deaths, the constituent parts of perinatal mortality, during the first and second intervention periods were as follows. CI on stillbirth mortality: during the first intervention period (Oct-08 to Sep-09): 30% reduction (95%CI: 51% reduction, 0% no change, p=0.051), during the second intervention period (Oct-09 to Dec-10): 6% reduction (95%CI: 25% reduction, 18% increase, p=0.621); CI on early neonatal mortality: during the first intervention period: 5% reduction (95%CI: 31% reduction, 29% increase, p=0.727), during the second in intervention period: 21% reduction (95%CI: 40% reduction, 3% increase, p=0.083). The precision of the estimates clearly indicates the predominance of the community intervention effect on perinatal mortality being on stillbirths in the first intervention period and being on early neonatal mortality in the second intervention period.

Potential bias: See above for finding 1.

Comparison with the literature: The Ekjut trial, which showed an effect of community women's groups on neonatal mortality, also observed an increase in intervention effect in the latter part of the intervention period (years 2 and 3).[8, page 14] They found a 45% reduction in NMR in years 2 and 3, but only a 32% reduction in years 1-3 and concluded that this was likely due to the time required for behaviour changes resulting from the intervention to take effect.[8, page 14] The effects of the Ekjut trial were also more on early neonatal mortality (odds ratio: 0.46; 95%CI: 0.37, 0.57; p<0.0005) than on late neonatal mortality (odds ratio: 0.80; 95%CI: 0.56, 1.14; p=0.217); and no effect was observed on stillbirths (odds ratio: 1.01; 95%CI: 0.80; 1.28; p=0.914; figures for year 2 and 3, effects weaker but similar relative to each other for years 1 to 3).[8, page 14] As also stated above for finding 1, the reasons for the differences in community intervention effect remain unclear.

We did not find any RCT or other large studies of facility quality improvement interventions with comparison groups that examined effects of increased dosage or time to intervention effects. However, a time-series study of breakthrough series quality improvement collaboratives in low and middle income countries by Franco and Marquez found the average time to reach 80% compliance with standards or other measures of performance was 9.2 months (standard error 8.5), and to reach 90% was 14.4 months (standard error 12.0).[11, page 15] This study did not examine the effect of dosage of the interventions, however, making a comparison of this time to effect data and the changes in effect observed in the second intervention period of the MaiKhanda facilities intervention relative to the first (i.e. after 12 months) difficult.

4. The randomised trial shows **no impact of either of the interventions on maternal mortality** and **given the observed number of births and deaths in each arm of the randomised trial the probability (calculated using the properties of the binomial distribution) that 30% reductions in maternal mortality really occurred as a result of the MaiKhanda interventions in the total population our sample sought to represent (intervention areas vs. control areas) was: only around 1% for the facility intervention and 28% for the community intervention (section 4.1.4)**.

Precision and interpretation: The observed effects of the interventions on maternal mortality are as follows: FI: 18% increase (95%CI: 34% reduction, 111% increase; p=0.570); CI: 9%

reduction (95%CI: 49% reduction, 63% increase; p=0.754); FI+CI: 8% increase (54% reduction, 157% increase; p=0.854). All of the results have wide confidence intervals, due to the small numbers of maternal deaths. However, using the binomial distribution and the observed births and deaths data it is possible to calculate the probability that there was really a 30% reduction (OR=0.70) in maternal mortality resulting from the facilities intervention, or from the community intervention in the total population that we missed because of our small sample. These probabilities are low at 1.3% and 27.9% respectively. The probabilities of there really being a (still relevant but less than aimed for) 20% reduction in MMR given the observed data for each of the facility and community interventions are 11.0% and 66.9% respectively (please note that these calculations do not take account of clustering, and also don't consider overlap between the probability distributions of observing intervention and control area deaths and are therefore likely to be overestimates – details of calculations available from the authors).

Potential bias: See above for finding 1.

Comparison with the literature: In addition to observing an effect of women's groups on neonatal mortality, the MIRA trial in Nepal also observed a large reduction in maternal mortality, however it was not initially powered for that measurement (there were 2 maternal deaths in women's group areas and 11 maternal deaths in control areas).[7, page 14] The other women's group community intervention studies[7,8,10, page 14], which were also under-powered, did not find any effect on maternal mortality.

5. **Because of low incidence of maternal deaths in health centres it was not possible to determine if maternal case fatality rates were different between intervention and non-intervention health centres.** Maternal death rates were very low compared to those in the hospitals, probably due to most serious cases either being referred to or initially presenting at the hospitals. **Neonatal case fatality rates and fresh stillbirth rates** were also lower at health centres than hospitals and rates in the community, but were high enough to determine differences. **Neonatal case fatality rates were not significantly different between health centres undertaking the quality improvement intervention and those not. Fresh stillbirth rates were lower in facility intervention health centres (7.8 fresh stillbirths per 1000 births) than control health centres (5.5 fresh stillbirths per 1000 births), though given the low rates, the absolute reduction in mortality was small** (section 4.2.2.1)

Interpretation: Of all the deaths the monthly health facility surveillance recorded in the health centres and the hospitals only around 10-15% occurred in the health centres (section 4.2.2); such small numbers making comparisons between facility intervention and control facilities difficult. However, as discovered in the analysis of place of death data from the perinatal verbal autopsies, in the predominantly rural RCT areas, only around 40-45% of stillbirths and neonatal deaths occurred in facilities in each RCT arm and these were split about 45:55 between health centres and hospitals (sections 4.2.4.3 to 4.2.4.5, also see finding 7 below). Given this data, and referral patterns observed using the place of death data in conjunction with cluster of birth data, it is likely that the major bias towards hospital deaths observed by the health facility surveillance was primarily due to the hospitals catering more to urban populations that were not part of the RCT (data for maternal deaths from the RCT population was limited but indicated one third of deaths happened outside a facility). Therefore, although the case fatality rates at the health centres, each of which was the centre of a cluster in the RCT, were low, the RCT was still an important way of measuring the effect of the interventions in the rural communities represented by the RCT sample, and was not significantly overshadowed by the deaths occurring in the non-randomised CEmOCs, which were often likely to be from a separate urban population. The importance of the rural population in Malawi cannot be overstated given that 85% of Malawians live in rural areas.[2, page 12]

Precision: The health centre and hospital death data represent all of the deaths recorded in the health centres and hospitals in each month that data was collected and therefore represent the entire population from which to estimate case-fatality rates and from which to compare intervention and control health centres. Nevertheless, the low numbers of

and control health centres. However, as discussed above, the health centre deaths are only a small subset (around 15-20%) of all of the deaths occurring in the RCT clusters; as such they do not effect the precision of the overall RCT results discussed under finding 1 above.

Potential bias: The data on health centre deaths was collected as part of monthly health facility surveillance by monitoring and evaluation officers who had been trained and had also trained the health facility staff to record the data correctly in the register and in summaries of the register data (see section 2.2.2). In addition, this data was covered as part of the data improvement work of MaiKhanda, which had some success (section 3.3). Therefore, overall the data is likely to be of reasonable quality. We also do not have any reason to suspect the data was of different quality in different comparison groups.

6. **There is no evidence that the MaiKhanda facility intervention had an impact on case fatality rates at the non-randomised hospitals (CEmOCs).** Maternal case fatality rates in the non-randomised hospitals went down in 2009 but increased in 2010 despite an increase in the intensity of the facilities intervention (section 4.2.2.2.1). Similarly, neonatal case fatality rates in 2008 were lower, before rates increased in 2009 and 2010 when the neonatal interventions of the facilities intervention were rolled-out (section 4.2.2.2.2). The worsening of rates after mid-2010 occurred after a rapid increase in rates of health facility delivery, an increase that started in 2008 (sections 4.2.1.2.1 and 4.2.2.1). **It is possible that a threshold for overcrowding was reached in mid-2010, limiting the ability of these poorly resourced facilities to effectively manage the higher volume of patients. All available data on the timing and dosage of the interventions** (section 4.2.1.1) **and cause of death** (section 4.2.2.2.1) **suggest no link between the interventions and changes to the maternal and neonatal case fatality rates at the hospitals.** In the absence of comparison group data for the CEmOCs we analysed secular trends for Malawi using available national data. Analysis of available data shows that **between 2005 and 2010 the secular trend in Malawi was of falling maternal case fatality in hospitals and falling population based maternal mortality** (section 4.2.2.2.1)**; and, slightly declining neonatal mortality** (section 4.2.2.2.2).

Precision: The number of maternal deaths per month in all 9 CEmOCs was fairly low, ranging between 1 and 20 between Jan-06 and Nov-11, making assessment of statistically significant changes difficult. However, as stated above, these deaths are the total population we were seeking to measure and as such are all we have to make our assessment. Using quality improvement control chart techniques (Shewhart charts) a change is significant if it involves 8 consecutive monthly points being below (or above) the mean of all previous points measured; another method, that of run-charts, uses 6-points above/below the median of previous points.[109] The latter corresponds roughly to a 3-10% statistical significance, whereas the former roughly corresponds to a statistical significance of 0.1% to 3% (personal communication, Lloyd Provost). Using the latter run-chart method of 6-points below/above the median results in a third median of maternal case-fatality rates at the 9 CEmOCs that is higher than the second median indicating an increase in maternal case-fatality in the second half of 2010 at the time of increased dosage of the MaiKhanda facilities intervention (see section 4.2.2.2, Figure 75 and Figure 81). That is only however if the first median line begins at months inclusive of Jan-06 to Sep-06, Jan-07-Mar-07 and Dec-07 to Feb-08 (data not shown). Clearly the precision of conclusions regarding trends in time-series data is very dependent on the month we start measuring and the number of points below/above the median used to assess statistical significance. It is for this reason, that whilst control chart methods may be useful for monitoring improvement, we believe they are less useful in evaluation (judgement of success or failure), unless start dates and rules for assessing statistical significance of changes are clearly defined *a priori*. Alternative methods such as lowess regression, capture more nuances in trends in the data, but do not assess the statistical significance of changes.

[109] Perla RJ, Provost LP, Murray SK. The run chart: a simple analytical tool for learning from variation in healthcare processes. BMJ Qual Saf 2011; 20: 46-51

Potential bias: The main limitation of the study on hospital case fatality rates was the lack of a comparison group to control for the effect of secular trends, which were observed in national hospital and population data, and to control for additional activity in the hospitals, which given the complexity of the hospitals and the multitude of other interventions and actors involved could have been more in control of the system producing the case-fatality rates than the MaiKhanda facilities intervention was. In addition, post-hoc analyses of the trends (see above) and post-hoc non-blind annotation of the charts also have significant potential to bias the interpretation of the results of the case-fatality study. Given data improvement work started in 2007 (section 3.3), we do not think the increases in case-fatality rates in 2010 were the result of improved data collection.

Comparison with the literature: A systematic review by Schouten[110] and colleagues on the evidence for quality improvement collaboratives identified 57 studies (from a total of 72 studies) that were based on the breakthrough series collaboratives i.e. the model employed by the MaiKhanda facilities intervention. Of these, 50 had an uncontrolled study design and mainly used self reported measures of improvement. Of the 7 controlled studies, one was a randomized controlled trial evaluating the breakthrough series integrated with the chronic care model. The trial did not show an effect on any of the key processes or intermediate outcomes of care for children with asthma.[111] The USAID sponsored Health Care Improvement (HCI) Project has nearly 15 projects across Africa working mainly on HIV and related problems. The HCI project in Niger[112] focused on institutionalization of quality improvement for essential obstetric and neonatal care and introduced change packages across different levels of the healthcare system. The assessment looked mainly at performance measures but did not report on primary outcomes. A review of 54 collaboratives in 14 low and middle-income countries found 27 collaboratives in 12 countries with useable data, and found evidence supporting the achievement of compliance with standards, and of performance outcomes for 87% of 135 indicators measured in time-series charts.[11, page 15] Like our study of the MaiKhanda facilities intervention, this study was limited by a lack of comparison groups; it was also limited by the outcomes being self-reported and only of process measures rather than mortality. From the literature there is only limited evidence supporting an effect of the breakthrough series collaboratives. Given it's uncontrolled nature and likely negative effect, the study of the MaiKhanda facilities intervention at the CEmOCs has not improved this evidence. The randomised controlled trial of the facilities intervention at the health centres is the first study to be conducted in a developing country, evaluating the effect of quality improvement on maternal and newborn mortality using a RCT design. The evaluation also explored the mechanism by which the interventions could influence the outcome (see findings 8-13 below).

7. Place of death data from the verbal autopsies suggest that the randomised controlled trial population (primarily rural) was distinct from the population served by the non-randomised hospitals (primarily local and urban), with only a 17-22% overlap for stillbirths and neonatal deaths but possibly a 50% overlap for maternal deaths (4.2.4.5). Although the lack of an apparent effect of the MaiKhanda facilities intervention in the non-randomised hospitals precludes this work from biasing the randomised trial results as a consequence of this overlap, this data, especially that for stillbirths and neonatal deaths, provides additional support for the robustness of the randomised trial results with respect to potential dilution from MaiKhanda work in the CEmOCs.

Precision: The number of maternal deaths in the RCT population with place of death data (53) is too small to accurately know the overlap between the RCT population of maternal

[110] Schouten LM, Hulscher ME et al. Evidence for the impact of quality improvement collaboratives: a systematic review. British Medical Journal 2008; 336 (7569): 1491-4

[111] Homer CJ, Forbes P, Horvitz L, Peterson LE, Wypij D, Heinrich P. Impact of a quality improvement program on care and outcomes for children with asthma. Arch Pediatr Adolesc Med 2005; 159(5):464-469.

[112] Boucar M, Franco LM, Sabou D et al. Sustaining better maternal and newborn care and quality improvement in Niger: Challenges and Successes. USAID Health Care Improvement Project-Research and Evaluation Report 2011

deaths and the CEmOC population of maternal deaths. However, as discussed in finding 6 above, we do not have any evidence to support the MaiKhanda facilities intervention having any impact in the CEmOC hospitals that could have diluted the RCT effect on maternal mortality. As stated above under finding 2, place of death data was available for 78.9% (843/1069) of stillbirths and 91.5% (931/1018) of neonatal deaths, fairly large numbers with which to estimate the proportion of the total population of stillbirths and neonatal deaths that the RCT represents that died at a CEmOC hospital. The 95% confidence intervals for these proportions range between 14% and 26% for all four arms of the RCT and are as follows: control clusters: 99/464=21% (95%CI: 18%, 25%); FI only clusters: 85/475=21% (95%CI: 15%, 22%); CI only clusters: 78/441=18% (95%CI: 14%, 22%); FI+CI clusters: 84/394=21% (95%CI: 18%, 26%). Given these fairly narrow confidence intervals, we can be fairly confident of the lack of overlap between the rural RCT and more urban CEmOC stillbirth and neonatal death populations.

Potential bias: see finding 2 above for place of death data and finding 1 above for RCT data.

Facility Intervention

8. **There was no clear evidence for the impact of specific quality improvement activities on clinical practices and intermediate outcomes such as post-partum haemorrhage (PPH) and asphyxia** (section 4.2.1.1).

Interpretation: The lack of clear evidence was mainly to due a lack of enough data or a total lack of data for many of the specific quality improvement activities, as is acknowledged in sections 2.2.1.1 and 4.2.1.1.

Precision: Where data were available they were often for limited months and limited facilities, or of limited completeness as the missed asphyxia deaths, uncovered in our case-study of asphyxia at St. Gabriel's, showed (see section 4.2.1.1). Hence the overall lack of clear evidence stated in finding 8 above.

Potential bias: Most of the data on specific quality improvement efforts was self-reported by quality improvement teams and MaiKhanda facilities intervention staff and therefore has the potential to be biased in that there is an incentive for these staff members to make things look better than they are so that they can show they are achieving something when in reality they haven't been able to achieve it. Subjective interpretation could also lead teams to believe the impact has been greater as they wish this to be true. There is also the potential for front line clinical staff to make things look worse than they are as a cry for help for more assistance. Clinical teams may also not believe they are delivering good quality care or achieving good clinical outcomes in environments where evidence-based medicine and data-driven decision-making are weak. However, given training on the importance of data giving accurate information (see section 3.3.), we hope such biases were not common. As noted above, however, given the lack of data and resulting lack of overall conclusions on specific QI efforts, such potential biases are less of an issue.

Comparison with the literature: see the comparison with the literature section under finding 6 above.

9. Both the health facility surveillance (section 4.2.2) and the health facility resources survey (section 4.2.5.1.1) show that **the health centres were severely under-resourced in terms of emergency obstetric care signal functions (see Box 2) and human resources.** MaiKhanda was not able impact on the availability of such resources.

Interpretation: Although 'effective support systems' was identified as a key driver of health outcomes (section 1.2.4.2) the scope of MaiKhanda to influence the provision of resources in the health system, especially human resources (doctors, clinical officers and nurses), was perhaps limited. The extent to which quality improvement of facility maternal and neonatal care can successfully achieve it's goals in severely resourced-constrained settings, such as those MaiKhanda was tasked to succeed in, remains open to debate. However, it is clear that certain interventions such as adherence to a sepsis treatment protocol are ultimately

completely dependent on such resources (in this case antibiotics), for which MaiKhanda was unable to influence the supply of.

Precision: Monthly data on the availability of BEmOC and CEmOC signal functions (see Box 2) were collected as part of the health facility surveillance (section 2.2.2). Although the facility staff and MaiKhanda staff tasked with ensuring this data were accurate were regularly trained to ensure it's quality it is possible that errors in recording were made. Nevertheless, given the number of facilities and months of data collected, the overall conclusion of scare resources and even the trends in the availability of the signal functions observed across comparison groups comprised of many facilities, are likely to be valid. The health facility resources survey was only undertaken in the first half of 2010 (section 2.2.5.1.1) so only provides a snapshot of the human resources and additional non-signal function resources available in the facilities. It therefore does not give information on any changes to these resources throughout the intervention period we evaluated. It does still provide evidence however of severe shortages in human and material resources which corroborate external reports from the literature (see comparison with the literature below).

Potential bias: There is a potential for front line clinical staff to make things look worse than they are as a cry for help for more assistance (see above for finding 8). However, given training on the importance of data giving accurate information (see sections 3.3 and 2.2.2) we hope such biases were not common.

Comparison with the literature: Other studies have also documented the scarcity of human and material resources for health in Malawi, including those documenting a double burden of HIV and human resource crises,[113] lack of availability of signal functions,[114] and lack of resources for implementation of the essential health package.[115] The literature on the requirement of resources for the success of quality improvement initiatives is more limited. There is anecdotal evidence suggesting QI teams can work around resource shortages,[116] however, we are not aware of studies specifically measuring how quality improvement interventions are affected by resource constraints.

10. The initial 2008 staff psychology survey provided evidence suggesting that **motivation and morale among health staff was poor**. (section 4.2.5.1.2). Given that the follow-up survey was still pending we were unable to assess whether this situation has changed or whether MaiKhanda may have contributed to any improvement in motivation/morale.

Interpretation: Low motivation and low morale are potential barriers to improved productivity. However, in the absence of follow-up data for the staff psychology survey we are unable to establish whether the productivity of the MaiKhanda QI teams improved over time.

Precision: The 2008 staff psychology survey questionnaire results represented 132 clinical staff from all health centres and hospitals included in the MaiKhanda evaluation (124 of whom worked at the randomised health centres, which typically only had 1 to 3 clinical staff members (section 4.2.5.1.1), meaning the response rate was very high) and in addition 15 interviews were conducted with staff from a range of designations. The questions were designed to examine psychological factors, attitudes and actions recognised as being required for success of quality improvement efforts (further details are available from the authors). Overall, the results therefore provide a good representation of how psychological factors affected staff in 2008.

Potential bias: See above for finding 9.

Comparison with the literature: In his seminal meta-analysis of studies examining factors motivating employees, Frederick Herzberg discovered that factors responsible for

[113] McCoy D, McPake B, Mwapasa V. The double burden of human resources and HIV crises: a case study of Malawi. Human Resources for Health 2008; 6:16. doi:10.1186/1478-4491-6-16

[114] Leigh B, Mwale TG, Lazaro D, Lunguzi J. Emergency obstetric care: How do we stand in Malawi? International Journal of Gynecology and Obstetrics (2008) 101, 107—111

[115] Mueller DH, Lungu D, Acharya A, Palmer N (2011). Constraints to implementing the Essential Health Package in Malawi. PLoS ONE 6(6): e20741. doi:10.1371/journal.pone.0020741

[116] Berwick DM. Lessons from developing nations on improving health care. BMJ 2004;328:1124–9.

extreme work satisfaction were predominantly intrinsic motivational factors: achievement, recognition, work itself, responsibility, advancement, and growth; and that factors responsible for extreme work dissatisfaction were found to be more external: company policy and administration, supervision, relationship with supervisor and work conditions.[117] Further work should be undertaken to explore these factors in relation to the implementation of the quality improvement work of the facilities intervention (and also in relation to the operation of the community intervention by the facilitators and MaiKhanda staff).

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11. The provider knowledge survey provides evidence **from 2010 towards the end of the evaluation period that the clinical knowledge of emergency obstetric and neonatal care was lacking** (section 4.2.5.1.3). Unfortunately the names of the facilities were mistakenly not recorded, preventing disaggregation by whether or not the facilities were under the MaiKhanda facilities intervention or not, making it difficult to draw inferences regarding MaiKhanda's impact on this indicator. However, since the termination of LSTM training (2008) clinical skills training has not been part of the facilities intervention (see section 3.1).

Precision: The provider knowledge survey was only completed by 37 health centre and 15 hospital (CEmOC) staff and therefore provides information for only approximately one third of the staff of the facilities included in the evaluation of MaiKhanda. It is possible that the staff who completed the survey were more confident in their knowledge or had more time on their hands to complete the survey, meaning that the sample may not be representative of the population of clinicians as a whole.

Potential bias: The questions included on the questionnaire were devised by a fully qualified medical doctor with inputs from the head of the obstetrics department at Bwaila hospital in Lilongwe, the head of the paediatrics department of KCH and other leading experts, with the intention of assessing knowledge of key basic clinical procedures in obstetrics and neonatal medicine. Therefore the questionnaire should adequately be able to make such an assessment of clinical knowledge. We don't believe there was any incentive for participants to deliberately answer questions wrongly, and given the dissimilarity of answers between respondents, do not have any reason to believe participants copied each others answers, therefore we believe the results are a good reflection of the participants knowledge.

Comparison with the literature: Previous studies in under-resourced settings have also found clinical knowledge of 'skilled birth attendants' to be lacking.[118] Unlike the MaiKhanda facilities intervention, some quality improvement efforts have focused on improving clinical knowledge by providing additional clinical training.[110, 119]

12. The women friendly care survey showed that **the MaiKhanda facilities intervention may have improved the way both patients and guardians felt they were treated at facilities in Lilongwe, but not in Salima** (section 4.2.5.1.4). The survey was not conducted in Kasungu.

Interpretation: Women-friendly care was identified as a key driver to improved quality of care (section 1.2.4.2) and was worked on by most of the MaiKhanda facilities intervention health centres. The results of the women-friendly care survey indicate that there were some successes of MaiKhanda's efforts to improve women-friendly care in Lilongwe, but not in Salima. Further investigations are required to determine why this might have been the case.

Precision: In Lilongwe, completed questionnaires were received from respondents attending 14/19 (74%) control health centres (range 14 to 41 questionnaires per facility) and

[117] Herzberg. One more time: how do you motivate employees. Harvard Business Review. Sep-Oct 1987. (reprint of Jan-Feb 1968 original).

[118] Harvey SA, Blandón YCW, McCaw-Binns A, Sandino I, Urbina L, Rodríguez C, Gómez I, Ayabaca P, Djibrina S, and the Nicaraguan maternal and neonatal health quality improvement group. Are skilled birth attendants really skilled? A measurement method, some disturbing results and a potential way forward. Bulletin of the World Health Organization, October 2007; 85 (10)

[119] Santos C, Diante D Jr, Baptista A, Matediane E, Bique C, Bailey P. Improving emergency obstetric care in Mozambique: The story of Sofala. International Journal of Gynecology and Obstetrics (2006) 94, 190—201

12/15 (80%) facility intervention health centres (range 14 to 45 questionnaires per facility). In Salima, completed questionnaires were received from respondents attending 6/7 (86%) control health centres (range 14 to 15 questionnaires per facility excluding one facility only contributing one questionnaire) and 4/6 (67%) facility intervention health centres (range 6 to 22 questionnaires per facility). Overall, the survey was therefore likely to be fairly representative of the both the control and FI health centres in each of Lilongwe and Salima as a whole (two of the three MaiKhanda districts), but to not have large enough numbers to be representative of individual health centres. The survey was only conducted in the last quarter of 2009; therefore the results are only representative of this limited part of the evaluation period.

Potential bias: Patients and their guardians were asked questions on a range of areas related to the women-friendly care initiatives of the facility intervention including: how they were treated at the facility, whether they were given opportunities to ask questions and whether they received feedback to their questions, whether they felt the facility was clean, and whether they would recommend the facility to others. Therefore it is likely to have been able to determine the success of the women-friendly care initiatives via comparison of the facilities intervention facilities with control facilities. The survey was conducted away from the facility out of ear-shot of clinical staff and the respondents were informed that their responses would be kept confidential, in order to minimise potential bias from being apprehensive about criticising facility staff.

Comparison with the literature: Earlier work by LSTM before they left the programme (see section 3.1) also indicated improvements in women-friendly care as a result of their efforts in 2007 and 2008.[120, 121] A search of Pub Med did not turn up any other empirical studies on women-friendly care in similar settings.[122]

13. Capacity constraints in Ministry of Health (MoH) management structures and competing priorities in the external health system environment mean that **it may be challenging to sustainably embed quality improvement in the health system** (section 4.2.1.5.5). **However, the Malawian government is committed to improving maternal and neonatal health** (section 1.1.4), **and is also committed to supporting quality improvement as detailed in recent strategic documents.**

Interpretation: The Malawian health system is understaffed and also lacks capacity in management structures with many competing demands for priority attention. Our CEmOC survey identified that MaiKhanda was only one of typically 3 other projects being implemented within a hospital in addition to normal duties and as such may have had limited scope to influence overall outcomes (see section 3.2.2.1). Competing priorities can also be characterised by high staff turnover with the most competent QI team members and other key people often being promoted to work elsewhere (see comparison with the literature section below). It remains to be seen whether the Malawian government's written commitment to maternal and neonatal health (see section 1.1.4) and quality improvement can be capitalised on by MaiKhanda going forwards. The recent Ministry of Health strategic documents supporting quality improvement vary in how explicit they are in support of the methods employed by MaiKhanda. From the Road Map, it is unclear what method of quality improvement the MoH is committed to (although there is mention of adherence to standards and maternal and neonatal death reviews there is no mention of PDSA or Criterion-Based Audits).[123] However, the over-arching Malawi Health Sector Strategic plan more clearly supports quality assurance and focuses on adherence to standards, performance management and client and provider satisfaction, although "continuous quality improvement at systems

[120] Kongnyuy EJ, Broek Nvd. Criteria for clinical audit of women friendly care and providers' perception in Malawi. BMC Pregnancy and Childbirth 2008, 8:28

[121] Kongnyuy EJ, Mlava, G, Broek Nvd. Criteria-based audit to improve women-friendly care in maternity units in Malawi. J. Obstet. Gynaecol. Res. Vol. 35, No. 3: 483–489, June 2009.

[122] http://www.ncbi.nlm.nih.gov/pubmed?term=%22women%20friendly%22 (last accessed 18/11/2011)

[123] Republic of Malawi Ministry of Health. Road Map for Accelerating the reduction of Maternal and Neonatal Morbidity and Mortality in Malawi. September 2011.

level" is also mentioned.[124] The German Development Cooperation mission report on supporting the sector-wide approach programme of work on quality of care specifically acknowledges MaiKhanda and it's methods of quality improvement.[125] However, recent work of the MoH in partnership with JHPIEGO suggests alternative approaches to those of MaiKhanda/IHI are being scaled-up already throughout district hospitals in Malawi.[42, page 54]

Precision: Much of the information regarding the lack of capacity of the Malawian government is anecdotal. However, going on health outcomes (section 1.1.2) and lack of availability of human and material resources (finding 9 above) it is apparent that there are serious problems. The commitment, with deeds rather than words, of health workers and health managers to specific health interventions including those of MaiKhanda needs further exploration, as do the mechanisms of getting interventions into policy and practice.

Comparison with the literature: While there is evidence of correlation between retention of quality improvement (QI) team members at the site and perceived competency[112] [126], from the CEmOC evaluation it seems that it is the most prominent and enthusiastic team members, who exhibit some leadership traits that get exported from the QI team (see section 3.2.2.1). Since there is a small resource pool of human capacity to choose from, people exhibiting any kind of leadership or capability are often quickly recruited, away from front-line clinical work, either from within the government or by NGOs/other agencies. This is a constant challenge that implementers will have to address.

Studies in the USA suggest organisational commitment is required to support QI efforts[127] and staff sometimes find research and QI activities difficult due to capacity and time constraints, and those in non-academically focused facilities found such activities more difficult.[128]

Ovretveit and Staines speak about an 'investment threshold' before quality improvement efforts start showing results; such investment taking the form of building awareness, commitment, will, leadership, systems and tools for quality improvement, and possibly taking up to 10 years, but of course being context-dependent.[129] This could perhaps be the case with the MaiKhanda quality improvement interventions, where initial investments in QI do not necessarily show on the operational results but are an important step forward for the institutionalization of QI in the Malawian health care setting. Lessons learned include the need for local leadership and the support and commitment of the Ministry of Health. The Zambian Quality Assurance Program established in 1993, set standards for health services, monitored the indicators of achievement, and included team-based problem solving. It covered the entire nation with a network of QA coaches and trainers. Despite all these measures, the capacity to sustain QA activities remained a challenge.[130] The Niger health care improvement project worked across the entire vertical slice of the health care system involving the DHMTs (District Health Management Teams), the regional HMTs and national HMTs. Despite these efforts the project had limited success in institutionalizing the quality improvement packages for essential obstetric and neonatal care.

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[124] Government of Malawi Ministry of Health. Health Sector Strategic Plan 2011-2016. Moving towards equity and quality. September 2011. Pages 17, 52-54.

[125] Government of Malawi Ministry of Health, GTZ Health Sector Programme. Quality Improvement of Health Care Services in Malawi. Objective, Strategies, and Key Interventions for Building Block 4 of the Health SWAp POW II. Mission Report. October 29th 2010. Page 5.

[126] Wilson B et al. The Leeds University Maternity Audit Project. International Journal for Quality in Health Care 2002; Vol 14,Number 3:175-181

[127] Lin MK, Marsteller JA, Shortell SM, Mendel P, Pearson M, Rosen M, Wu S-Y. Motivation to Change Chronic Illness Care: Results from a National Evaluation of Quality Improvement Collaboratives. Health Care Manage Rev, 2005, 30(2), 139-156

[128] Fox J, Bagley L, Day S, Holleran R, and Handrahan D. Research and quality improvement experience and knowledge: a nursing survey. Journal of Nursing Management, 2011, 19, 623–631.

[129] Ovretveit J, Staines A. Sustained Improvement? Findings from an independent case study of the Jonkoping quality program. Quality Management in Health Care 2007; Vol 16,No.1:pp 68-83

[130] Brouchet B, Francisco M, Ovretveit J. The Zambia Quality Assurance Program: successes and challenges. International Journal for Quality in Health Care 2002; 14,Suppl 1:89-95.

Community Intervention

14. **Community surveillance data on place of delivery showed that the community intervention did not increase health facility deliveries over and above the rapid increase observed in all areas** (section 4.2.1.2.1), which probably occurred due to a 2008 government ban on deliveries by traditional birth attendants (section 4.2.5.2.4.2).

Interpretation: Combined with the suggestion of a decrease in deaths in the community (but not in the facility; finding 2), the lack of additional increases in health facility delivery resulting from the community intervention suggests that women in community intervention areas may have become more confident to deliver at home. Given an absence of data from the knowledge, attitude and practice survey to corroborate this (finding 17), further investigations throughout the MaiKhanda intervention areas are required in order to determine if this may have been the case.

Precision: The community surveillance data on place of birth showed a month on month increase in the percentage of all deliveries that occurred at a health facility from mid-2008 onwards across all three districts (trend data for districts not shown separately) and in all four RCT arms, including the control arm (section 4.2.1.21). Each month's data for each RCT arm typically represented in the region of 200-300 births. Such large sample sizes in conjunction with the random selection of the villages under surveillance means that these trends are highly likely to be representative of those occurring in the whole population.

Potential bias: Given that the data for each RCT arm was collected by hundreds of different key informants in different villages each month, the trends are likely to be robust (also see potential bias for finding 1 above).

Comparison with the literature: The Malawi DHS 2010[2, page 12] also indicates that the percentage of women delivering in health facilities has increased dramatically during a similar time period. In Nepal, the MIRA Makwanpur trial showed a statistically significant increase in health facility deliveries in women's group intervention areas compared to control areas, likely due to the difficult mountainous terrain in the study area. However, this was from a very low base: control areas: 2%, intervention areas 7%.[8, page 14] In Jarkhand and Orrisa, India, the Ekjut trial found no increase in health facility delivery, however, which for years 1 to 3 of the intervention period was 14% in women's group areas and 20% in control areas. The PCP trial in Bangladesh also observed no effect of the women's groups on institutional delivery (15% in intervention areas and 16% in control areas), but unlike the Nepal and Bangladesh trials it also showed no effect on neonatal mortality.[10, page 15]

15. The review of the routine monitoring data from the women's group register revealed that the **number of newly pregnant women who attended women's groups was fairly low at 10% and that the percentage of members who had never had children before was also low at 2%;** we also estimate a **population coverage of approximately 1 women's group to 1200 population** (section 4.2.1.2.2). Given the results of recently published studies[8,10 page 14] **such coverage is likely to be sub-optimal**.

Interpretation – Comparison with the literature: On consideration of the successful trials of community women's groups in India and Nepal, which reduced neonatal mortality and had population densities of approximately 1 group per 500,[7,8, page 14] and the lack of observed effect of community women's groups on neonatal mortality in Bangladesh where women's groups had a population density of approximately 1:1400, it is likely that the MaiKhanda women's groups population density of approximately 1:1200 was sub-optimal (see section 4.2.1.2.2), even despite the fact of the observed reduction in perinatal mortality (finding 1). The Ekjut trial of women's groups in India, which observed a 45% reduction in neonatal mortality during years 2 and 3 of the intervention period (see finding 1) observed successful recruitment of newly pregnant women (a vulnerable group) to the women's groups, with 23% of the attendees of the last women's group meeting being adolescent girls and unmarried women (those who did not already know the 'secrets of child birth'), and observed high coverage of pregnancies with an estimated 38% of all pregnant women in the intervention

areas attending groups in the second year of the intervention period and 55% in the third year, and hypothesised that these factors, in addition to the relatively high total population coverage, were among six factors most likely to have contributed towards the observed reduction in neonatal mortality.[131] It is therefore likely that, in addition to low population coverage, at 10% and 2% respectively, the proportions of pregnancies and new mothers covered by the MaiKhanda women's groups were also likely to have been sub-optimal. The RCT results of the MaiKhanda community intervention on perinatal mortality and on neonatal mortality (in conjunction with the facility intervention; finding 1) need to be considered with regard to this sub-optimal coverage (see section 5.3.2 below).

It is also interesting to note here that the low population coverage observed here, in combination with the minimal overlap between the RCT community surveillance villages (women, births and deaths) and the women's group villages (and members; data not shown), suggests that the observed effects of the community intervention (finding 1) were in some way dependent on a diffusion of ideas from the women's groups and task forces throughout large areas only peppered with women's groups and task forces.

Precision: The number of women's groups (WG) used as the numerator in the total population coverage calculations was taken from MaiKhanda WG monitoring forms and backed up by additional data coming from the women's groups and is likely to be fairly precise. The total population denominator is less precise as it comes from estimates of the size of the catchment areas of the health centres within which the women's groups were set up. Nevertheless these are sufficient to give a rough estimate of the population density of the women's groups accurate to the nearest 100 (i.e. 1:1200). The numerators for the population coverage of new mothers and of pregnancies are taken from the women's group register data from 434 (60%) of the 729 women's groups. The population coverage of pregnancies was then calculated using national crude birth rate data (see section 4.2.1.2.2) and the percentage of women's group members who were aged 15-49 (of child bearing age).

16. A survey of the strategies chose by women's groups and the success with which the groups implemented those strategies showed **the most popular strategies chosen by the women's groups to be bicycle ambulances, health education, vegetable gardens and bed nets** and **the most successfully implemented strategies to be health education, voluntary testing and counselling for HIV/AIDS, village savings and loans, bed nets and vegetable gardens** (section 4.2.1.2.3).

Interpretation: These results give an indication of the activity of the women's groups. We were not, however, able to directly link the implementation of particular strategies to specific changes in health outcomes, such as the observed effect on perinatal mortality in community intervention areas (finding 1). The complete characterisation of such mechanisms and interactions would be a complex task requiring significant investment (see section 4.2.1.2.3.1). It is also likely that some women's group strategies may take some time to yield any effects they may have on health outcomes such as mortality. Therefore, although the community intervention was not observed to impact on maternal mortality, or on neonatal mortality, when not in combination with the facility intervention, the absence of such effects does not preclude the implementation of specific strategies from leading to improved health outcomes in future. Also, considering that we were not able to determine local-level effects on mortality or other health outcomes due to insufficient sample size, or to attempt to map local strategy implementation to such local effects, effects of specific strategies in local areas, and how they vary depending on how successful the implementation of the strategy was, remain unknown. For a discussion of how the community intervention may have impacted on knowledge, attitude and practice of the women's groups see finding 17 below.

Precision: The data on strategy choice and implementation was for only 245/729 (34%) women's groups, but was from all three districts and most women's group areas, so is

[131] Rath S, Nair N, Tripathy PK, Barnett S, Rath S, Mahapatra R, Gope R, Bajpai A, Sinha R, Costello A, Prost A. Explaining the impact of a women's group led community mobilisation intervention on maternal and newborn health outcomes: the Ekjut trial process evaluation. *BMC International Health and Human Rights* 2010, 10:25

still likely to be representative of the MaiKhanda community intervention women's groups as a whole.

Potential bias: We don't believe there was any incentive for women's groups to state that they had chosen strategies that they had not really chosen or not state strategies that they had chosen. It is possible, however, that some women's groups may have stated they successfully implemented a strategy that they didn't really, as they did not want to admit failure. It is also possible that some groups may have stated that they did not successfully implement a strategy that they did really, due to a misconceived idea that they might get more assistance if they were seen to be struggling; however, this is less likely on consideration of the emphasis MaiKhanda put on the fact that they did not give resources to women's groups directly, but rather facilitated the groups acquisition of resources (section 1.2.5.1).

Comparison with the literature: The previously published studies of the effects of women's groups in India (Ekjut), Nepal (MIRA Makwanpur) and Bangladesh (PCP) did not report on the implementation of specific strategies chosen by the women's groups, but instead reported on secondary outcome measures on antenatal, intrapartum and post-partum practices likely to be a consequence of the implementation of specific women's group strategies. For the Ekjut study, although the process evaluation could not conclusively determine the mechanism of action of the women's groups on neonatal mortality, the most effective strategies were possibly those centred around the use of clean delivery kits and improved intrapartum care at home.[7, page 14] In Nepal, the MIRA Makwanpur trial indicated the women's groups to have increased antenatal care, visiting of the health facility in the event of illness, institutional delivery (see finding 14 above), skilled birth attendance, and use of clean delivery kits and other hygienic practices around the time of delivery.[7, page 14] In Bangladesh, the PCP study, which unlike the Ekjut and MIRA studies did not observe an effect of the women's groups on neonatal mortality, did not observe any impact of the women's groups on any of secondary outcome measures of antenatal care, intrapartum and postpartum delivery practices.

17. Evidence from a survey of knowledge, attitude and practices related to maternal and neonatal health among women in women's group (community intervention) areas and women in areas without women's groups suggests **the community intervention did not improve key maternal and neonatal health practices, although knowledge among women in community intervention areas was better for some indicators** (section 4.2.1.2.4).

Interpretation: Our knowledge, attitude and practice survey was conducted in March and April 2011 (i.e. after the RCT evaluation period which ended in Dec-10) and found few differences in maternal and neonatal health knowledge, attitude and practice between women's group members and women in control areas. The survey found slightly lower average knowledge of antenatal care, and danger signs during pregnancy and the postpartum period in women in community intervention areas than women in control areas; similar knowledge and attitudes towards health facility delivery in the two groups, but that women in intervention areas experienced slightly less complications during delivery; a slightly lower rate of exclusive breast-feeding in women in intervention areas; and, that women in intervention areas prepared more, including financially, for their recent births (section 4.2.1.2.4). The survey results may not be representative of the whole of the MaiKhanda women's group intervention, however (see 'potential bias' section below). Further investigations with a more representative sample that go into more detail (for example via the use focus group discussions) on why knowledge attitude and practice are not always correlated, would be useful.

Precision: A total of 345 women in women's group areas and 251 in control areas were interviewed, providing reasonable accuracy of estimates of the levels of maternal and neonatal health knowledge, attitude and practice in the populations the samples represent: although not reported, with these sample sizes, confidence intervals would typically range up to 5 percentage points below and up to 5 percentage points above the point estimates reported in section 4.2.1.2.4 for the 345 intervention area women and up to 6 percentage points either

side of the point estimates for the 251 control area women. Point estimates for each group more than 11% apart for percentages nearer 50% and more than 4% apart for percentages near the extremes of 0% and 100% are therefore likely to show statistically significant differences. Therefore, given most of the differences reported in section 4.2.1.2.4 were not this large, they are likely to not be statistically significant (the confidence intervals for the percentages for each group would overlap).

Potential bias: The study was only conducted in Lilongwe district only and only in 5 community intervention clusters and 4 control clusters (of the RCT, see section 2.1), and therefore may not be representative of the MaiKhanda community women's group intervention as a whole. In addition the study found respondents from the intervention group to be slightly younger on average, have slightly lower literacy and lower average levels of education than women in the control areas (section 4.2.1.2.4.1), which may have affected the results.

Comparison with the literature: See finding 16 above for changes in antenatal, intrapartum and postpartum practices in previous women's group studies. None of these studies specifically report on the effect of women's groups on indicators of maternal and neonatal health knowledge and attitude, however, as far as we are aware.

18. Despite being (unpaid) volunteers, our survey showed that **the women's group facilitators were generally satisfied with their working conditions and were facilitating the groups well**. However allowances and material support were an issue (section 4.2.5.2.1).

Interpretation: The women's group facilitators were given an allowance of 4000K (approx. £13 / US$22) per month towards the costs of bicycle repairs. Although this was not a salary, anecdotal evidence suggests some considered it as such and therefore it is likely this was a motivating factor in their overall level of satisfaction. Given that the small amount of the allowances and other material support was also an issue it is likely that the facilitators would have been more motivated if they were paid employees with monthly salaries. However, as indicated from the survey, the facilitators were on the whole satisfied with their working conditions and motivated to do their work through non-monetary incentives such as status, respect from community members and teaching and learning, as well as the small monthly stipend they received, and adequately performed their duties.

The 'promotors', group members who took over facilitating established groups when the facilitators were tasked with setting up new groups in late 2010/early 2011 (see section 3.2.1) were not paid any allowances or salary at all. Investigation of their motivation and success in facilitation would also be worthwhile.

Precision: 75 (93%) out of the 81 women's group facilitators completed the survey questionnaire, meaning the conclusions are based on the results from an almost complete sample, which is therefore highly representative of the whole population of facilitators.

Potential bias: The survey was anonymous to encourage facilitators to express honest opinions regarding their work and negative opinions were recorded indicating that (at least some of) the facilitators felt free to express their views openly.

Comparison with the literature: The MaiMwana project in Mchinji district Malawi[9, page 15] and the MaiKhanda programme are the first in Africa to test the women's group intervention on maternal and neonatal health. While MaiMwana was a research project, which employed women's group facilitators and aimed to test the effectiveness of the intervention, the MaiKhanda programme was an evaluation of the women's group intervention, where the objective was to see the effectiveness of scaling up the women's group intervention using volunteer women's group facilitators.

19. The self-evaluation of the women's groups by their members in Phase-IV of the action cycle (see Figure 4) was generally positive (section 4.2.5.2.2), providing **subjective evidence that the groups were successful and supported by the community.**

Interpretation: As stated above, given its nature, the self-evaluation was only able to provide subjective evidence indicating the success of the women's groups. The generally positive self-assessments by the groups indicate their viability and along with the data on strategy implementation (see finding 16 above) indicate successful completion of the women's group action cycle (see Figure 4), their main task.

Precision: Less data was available for women's groups in Lilongwe (84 (26%) of 324 groups) and Salima (38 (23%) of 162 groups) than in Kasungu (190 (78%) of 243 groups) meaning that data was not representative of women's groups in all the three districts the MaiKhanda community intervention operated in.

Potential bias: Some groups may not have wanted to criticise their leadership meaning the leadership indicator could have been biased upwards. We believe the other self-evaluation indicators (participation, organisational structure, problem assessment, resource mobilisation, asking why, links, external agents, programme management) were less prone to bias although it is possible that some groups may have not wanted to admit that they were less successful in some areas.

Comparison with the literature: The self-evaluation of the MaiKhanda women's groups was based on a model of evaluating community capacity developed by Glen Laverack.[132] The MaiMwana project used a similar methodology and also found their groups on the whole to have viewed themselves as being successful in identifying maternal and neonatal health problems and executing strategies to deal with these problems.[133, 134, 135]

20. **Traditional leaders in the community are likely to be very important** and in many areas likely to determine the success or failure of the community intervention. **On the whole, MaiKhanda engaged these leaders well** with an extensive community entry process, regular communication with traditional leaders and open days show-casing the community intervention work in the communities, although more could have been done (section 4.2.5.2.4). **In addition the Malawian government is committed to supporting community interventions as detailed in recent strategic documents.**

Precision and potential bias: The evidence in support of the role and importance of traditional leaders in enabling the community intervention in the community was mainly collected in an ad hoc and anecdotal manner and therefore may not be authoritative and may be prone to biases of those who gathered it. Nevertheless, given the reality of the extensive community entry process, it paints a plausible picture of the crucial role of traditional leaders in the success of the community intervention.

Interpretation: In addition to the support of traditional leaders in the community, the support of community, non-governmental and governmental organisations is crucial for the long-term sustainability of the community intervention. Although the Malawian MoH has not specifically endorsed women's groups as part of its Road Map for Accelerating the Reduction of Maternal and Neonatal Mortality and Morbidity in Malawi, it does support community strategies (under strategy 8 of the Road Map) including those involving community core groups, which are perhaps similar to women's groups and task forces.[123, page 200] Community participation is also emphasised in the over-arching HSSP,[124, page 201] and community groups are also mentioned in the strategy plan for improving quality of care as part of the second Sector-Wide Approach (SWAp) programme of work.[125, page 201] Given this

[132] Laverack G. Evaluating community capacity: Visual representation and interpretation. Community Development Journal Vol 41 No 3 July 2006

[133] Rosato M, Mwansambo CW, Kazembe PN, Phiri T, Soko QS, Lewycka S, Kunyenge BE, Vergnano S, Osrin D, Newell M-L, Costello AMdL. Women's groups' perceptions of maternal health issues in rural Malawi. Lancet 2006; 368: 1180–88.

[134] Rosato M, Lewycka S, Mwansambo C, Kazembe P, Costello A. Women's groups' perceptions of neonatal and infant health problems in rural Malawi. Malawi Medical Journal. 2009 Dec;21(4):168-73.

[135] Rosato M, Mwansambo C, Lewycka S, Kazembe P, Phiri T, Malamba F, Newell ML, Osrin D, Costello A. MaiMwana women's groups: a community mobilisation intervention to improve mother and child health and reduce mortality in rural Malawi. Malawi Medical Journal. 2010 Dec;22(4):112-9.

part of the second Sector-Wide Approach (SWAp) programme of work.[125, page 201] Given this support it may be possible to sustain existing women's groups into the future and roll out new women's groups without additional NGO support (for further discussion see section 5.3.2 below).

Comparison with the literature: None of the previous women's group studies specifically examined the role of traditional leaders in the success of the women's group intervention as far as we are aware. However, they all acknowledge the importance of engaging traditional leaders during a community entry process to initially set up the women's groups.[7,8,9,10, page 14]

Cost-Effectiveness Analysis

21. Preliminary results of the cost-effectiveness analysis indicate that **both the effect of the community intervention on perinatal mortality and the effect of the facility and community intervention combined on neonatal mortality are highly cost-effective by WHO criteria** (less than the per capita GDP of Malawi per Disability Adjusted Life Year (DALY) averted, which is **less than US$5,400 per stillbirth or neonatal death averted**; see section 4.3).

Interpretation: The cost-effectiveness analysis here is based on the total costs incurred by MaiKhanda to implement the community and facility interventions as described in chapters 3 and 4. It is therefore from the perspective of any future provider of the interventions. Additional costs, such as those to pay for the necessary human resources (staff time) and material resources at health facilities and in the community, including any additional staff and resources required to ensure that the interventions are implemented more effectively were not included, but could be included as part of a forthcoming sensitivity analysis. In addition, the cost-effectiveness analysis could be extended to capture the costs and benefits of the individual beneficiary, and society as a whole, in addition to those of the provider. Work exploring the effect of the women's groups on quality of life was undertaken as part of the lead author's PhD thesis, which was completed in October 2012 and is available to freely download at: http://discovery.ucl.ac.uk/1366631/.

Precision: A detailed costing of the community and facility interventions still remains to be undertaken. The analyses presented in this report are therefore only approximate. However, they are based on total expenditure so should still allow reasonably accurate conclusions, especially given the use of the WHO criteria, which themselves are broad, to derive conclusions regarding cost-effectiveness. Full analyses including detailed costing of the interventions and sensitivity analyses attempting to look at the cost-effectiveness of different aspects of the interventions will be forthcoming. Such analyses could look at the difference between the women's groups and the task forces in the community intervention and the collaborative learning sessions (perhaps relatively expensive due to the cost of meetings[136]) and other QI activities in the facility intervention.

Potential bias: The costs of the MaiKhanda interventions were determined by the MaiKhanda budget and programme expenditure, including (technical) partner organisations both of which adhere to charity law on internal and external audit requirements. The effects of the MaiKhanda interventions (the other part of the cost-effectiveness equation) were determined from the randomised controlled trial, the potential bias of which is discussed under finding 1 above.

Comparison with the literature: Interventions can be categorised as single interventions (such as taking malaria prophylaxis during pregnancy or exclusive breastfeeding), packages of (single) interventions, and social and system interventions (vehicles to deliver single and packaged interventions).[137] The MaiKhanda facility and community interventions both fall under the latter category of social and system interventions. Evidence of the cost-effectiveness of such interventions for reducing perinatal

[136] J Ovretveit, P Bate, P Cleary et al. Quality collaboratives: lessons from research. Qual Saf Health Care 2002;11:345-351

[137] Osrin D, Prost A. Perinatal interventions and survival in resource-poor settings: which work, which don't, which have the jury out? Arch Dis Child 2010;95:1039–1046.

comparative interventions should be forthcoming.[138] Nevertheless, as social and system interventions for reducing perinatal and neonatal mortality that are highly cost-effective by WHO criteria of less than per capita GDP of Malawi per Disability Adjusted Life Year averted (less than US$5,400 per stillbirth or neonatal death averted), the MaiKhanda facility and community interventions deserve recognition in the national and international policy arenas.

5.2 Relating our findings to the Three Delays framework

Access, coverage, quality and safety are the key intermediate factors necessary for health systems to achieve their overall goal of improved health outcomes.[139] The MaiKhanda programme, through its facility and community interventions, tried to address issues of access and quality using the three delays framework. In the previous section we examined each of our 21 main findings in detail. Here we return to the Three Delays and supply and demand side theoretical frameworks underpinning the interventions that were introduced in chapter 1, by summarising how our findings fit into these frameworks.

Figure 104 attempts to map our key findings to the Three Delays framework developed by Thaddeus and Maine (see section 1.2.2). Overall there is only weak evidence for the interventions reducing each of the three delays. In terms of the socioeconomic and cultural factors influencing the delay in making the decision to seek care (delay 1) there is no specific evidence that either the facility or community interventions affected illness risk factors, or socio-legal factors such as the implementation of by-laws against traditional birth attendant delivery, which happened independently of MaiKhanda (section 4.2.5.2.4.1). We did produce weak evidence however supporting the notion that the community intervention improved women's status, economic status and educational status. The self-evaluation of the women's groups (finding 19) provides weak evidence in support of an improvement in women's status as it shows the women were supported by their communities and indicates that the women were able to implement their strategies effectively which perhaps would not have been possible if women were of low status. Similarly, the support of traditional leaders (finding 20) shows key members of the community value women. It could be possible, however, that the support of the community and traditional leaders would have been apparent without the community intervention. The community intervention may have increased economic status of the community via income generating activities such as *dimba* farming and increased women's education via catalysis of the health education strategy (see finding 16 and sections 4.2.1.2.3 and 4.2.5.2.3). Ultimately, however, the impact of the MaiKhanda community intervention of delay 1 will remain unknown, as we were not able to accurately measure women's status on arrival at health centres or hospitals (which is also partly a function of delay 2) due to no records being kept of the condition of mothers from when they actually arrived at the facility to when they were seen (often hours later). We also did not measure household decision-making with regard to seeking care for women and babies and how it relates to the socio-economic and cultural factors outlined in Figure 104 and discussed above.

In terms of accessibility of facilities, the main driver of the delay in getting transport and reaching the medical facility (delay 2; Figure 104), the MaiKhanda interventions did not decrease the distance to facilities (e.g. by building new facilities) or improve the road condition or decrease the cost of transport, as these were all clearly beyond their remit. There is weak evidence, however, in the form of the bicycle ambulance strategy (see finding 16 and sections 4.2.1.2.3 and 4.2.5.2.3) that the community intervention contributed to improved availability of transport. The evidence is weak because we do not have data detailing the effect the bicycle ambulances may have had on timely access to facilities.

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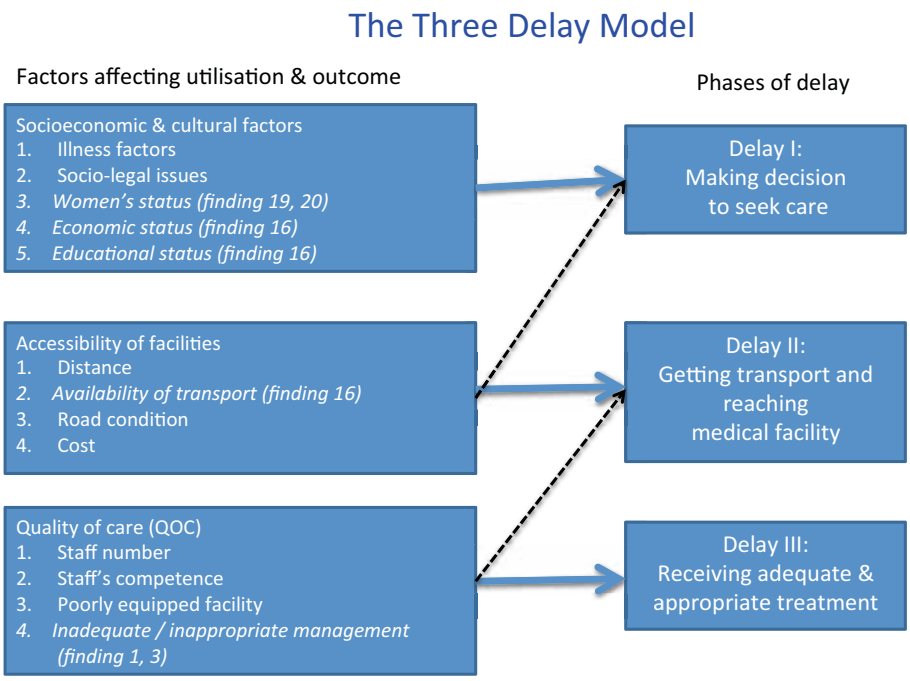
[138] Barros FC, Bhutta ZA, Batra M, Hansen TN, Victora CG, Rubens CE, GAPPS Review Group. Global report on preterm birth and stillbirth (3 of 7): evidence for effectiveness of interventions. BMC Pregnancy and Childbirth 2010, 10(Suppl 1):S3.

[139] WHO. Everybody business: strengthening health systems to improve health outcomes: WHO's framework for action. 2007.

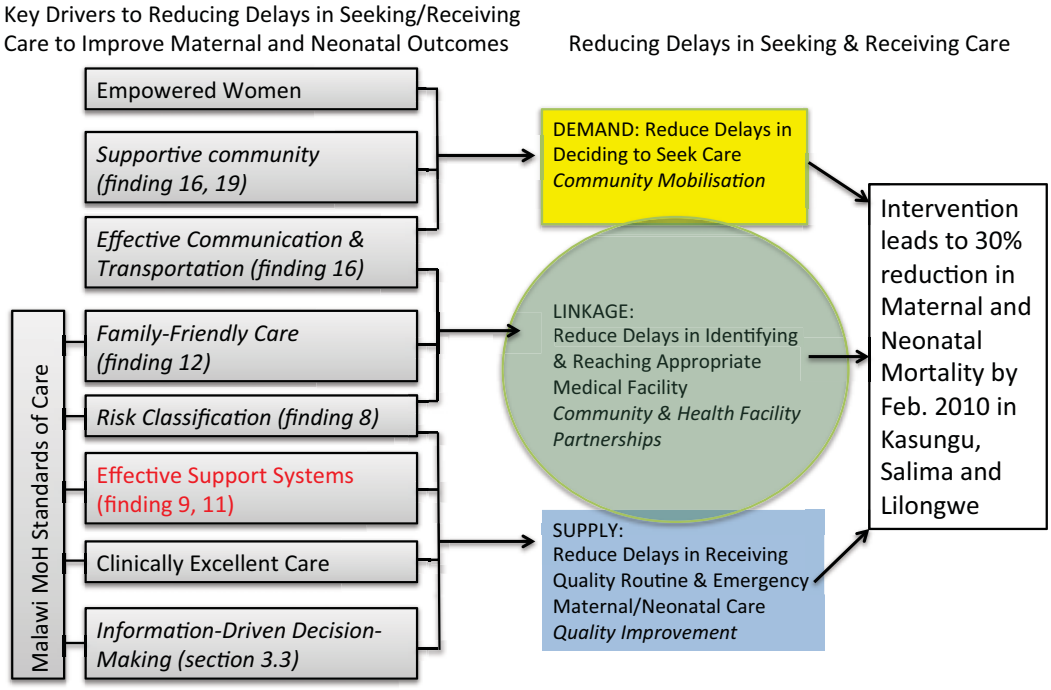
Figure 104: How might MaiKhanda have affected the Three Delays?



Source: Thaddeus S, Maine D. 1994

Italic text denotes weak evidence of effects of MaiKhanda interventions

Figure 105: How far might MaiKhanda have achieved its aims as set out in the conceptual model?



Adapted from "Three Delays Framework" on www.unfpa.org/mothers/obstetric.htm

weak evidence of effects of MaiKhanda interventions

Evidence of external problems in this area not addressed by MaiKhanda

Finally, with regard to quality of care - the main driver of the delay in receiving adequate & appropriate treatment at the facility (delay 3), as Figure 104 indicates, the MaiKhanda interventions did not affect the number of staff or improve the fact that the facilities were poorly equipped. The results of our provider knowledge survey were not able to determine whether or not the MaiKhanda facilities intervention improved staff's competence, but did suggest that staff competence was sub-optimal. It is possible that the effects of both the combined facility and community intervention on neonatal mortality and the community intervention on perinatal mortality were mediated by improvements to inadequate/inappropriate management (findings 1 and 3, section 4.2.3). The finding of reduced deaths in the community (finding 2) also suggests improved care seeking (delay 1) and treatment (delay 3) could have also occurred within the community as a result of the MaiKhanda interventions.

Figure 105 details how far our findings support the achievement of the objectives of the MaiKhanda interventions as they were set out originally in the conceptual model, the theoretical underpinning of the interventions (see section 1.2.2). Empowerment of women is hard to measure and we did not attempt to measure it in our evaluation, we therefore do not have any evidence to determine whether or not the community intervention resulted in empowered women. We do have weak evidence supporting the notion that the community intervention strengthened community support for and demand for improved maternal and neonatal health. Communities implemented strategies collectively (finding 16, section 4.2.1.2.3) and the self-evaluations of the women's groups often indicated community support (section 4.2.5.2.2, finding 19).

At the facility we found weak evidence supporting an effect on women-friendly care in some areas (finding 12) but data on how such efforts might have lead to increased linkages between communities and facilities, an area that was relatively neglected by MaiKhanda as a whole and was to be more of a focus for the organisation going forwards, was lacking. We found limited evidence in support of efforts to classify women as high-risk and follow them up, but ultimately did not have enough data (see section 4.2.1.1.2, finding 8). In terms of effective support systems, our findings clearly show that the facilities, and especially the health centres, were under-resourced in staff, drugs and supplies (finding 9) and that clinical knowledge was lacking (finding 11) and that MaiKhanda was not able to remedy these problems. In terms of clinically excellent care we did not specifically measure clinical practices. Finally, in terms of information-driven decision-making, we did document improvements following MaiKhanda data improvement work (section 3.3).

Overall, we only have limited evidence in support of MaiKhanda achieving some of the aims it set out to achieve in minimising the three delays, as set out in its conceptual framework. Nevertheless, we do have robust evidence of the impact of the combined facility and community intervention on neonatal mortality and the community intervention on perinatal mortality, and data detailing a number of other interesting findings, as discussed in the previous section. We also have evidence suggesting the effects of the interventions could be greater going forwards. However, we also have concerns over the sustainability of the interventions. Both of these issues are discussed in the following section.

5.3 Future potential of the interventions: implementation, dosage and sustainability

Given an increased effect of the combined facility and community intervention on neonatal mortality in the second increased dosage and longer lead-time intervention period (finding 3) and evidence suggesting sub-optimal implementation of the interventions (chapter 3), it is possible that properly implemented and at sufficient dose both interventions could achieve better results than those observed from the randomised controlled trial (finding 1). There are also concerns regarding the sustainability of both of the interventions with regard to their integration with Ministry of Health work and reliance on external (foreign) technical assistance and financial support. In this section we discuss the future of each of the interventions, separately and in combination, with reference to these, and other, issues.

5.3.1 Facility Intervention

We only found evidence suggesting an effect of the facility intervention on it's own on late neonatal mortality (section 4.1.5), perhaps mediated by neonates leaving health centres less likely to die in the community (finding 2). The lack of additional effects, including on maternal mortality and of the work at the hospitals on maternal and neonatal fatalities, is perhaps due to sub-optimal implementation. Although initial poor dosage of the facilities intervention was remedied (section 3.2) it did not appear to result in reduced case-fatality rates at the hospitals (section 4.2.2.2) or a change in the effects of the facility intervention alone observed from the randomised controlled trial (Appendix 21, comparison of first intervention period with second higher dose intervention period). It is therefore likely that dosage was not the main thing holding the facility intervention back. Fidelity of implementation may have been an issue, however, we lack enough process data to determine what exactly happened and what didn't due to poor documentation by QI teams (section 4.2.1.1). Following from this, we are not able to make an assessment of the feasibility of high-fidelity implementation of quality improvement in Malawi on which to base any recommendations. The other alternative is, of course, that the intervention is not very effective in reducing maternal, neonatal and perinatal mortality in the Malawian setting, perhaps due to the severe lack of material and human resources (finding 9), lack of clinical skills (finding 11), lack of motivation and morale, lack of interest or ability to use quality improvement methods (anecdotal evidence suggests that many QI teams in Malawi were still not using PDSA and other main tools in 2011, also see section 3.2.2.1), or any combination of these factors.

According to Perla *et al*[140], there are four main drivers of large-scale improvement (which is one of the objectives that MaiKhanda was to achieve). These are: planning and infrastructure; individual and group organization and system factors; the process of change; and, performance measurement and evaluation. There should also be an emphasis on training and development for capacity and capability building as well as the need to understand the cognitive dimension of spread.

Establishing standards followed by incorporating improvement methods has been associated with successful interventions.[11, page 15] The initial design of MaiKhanda interventions was to establish Criterion Based Audits and Maternal Death Audits followed by QI methods. But this design was modified midway through the intervention to adopt a more focused QI approach characterized by the quality improvement collaborative breakthrough series and action periods (see section 3.1).

While there were QI experts (MaiKhanda programme team members), there were usually no senior clinical staff available to attend the MaiKhanda collaboratives. This could have affected buy-in to the QI model from the local clinical QI teams. MaiKhanda has struggled throughout the programme to establish a good threshold of QI and clinical expertise within the programme. Clinical experts were identified from within the existing health system but complete engagement of the experts never took off as a result of severe resource constraints within the system, and possibly, competing training demands. The QI expertise within the organization was thinly spread out across the intervention areas and in addition was also responsible for managing the programme/programme implementation. As quality improvement was a newly introduced concept to Malawi, the diffusion of the methods needed to be more intense making the job of the QI expert very demanding; as such engaging QI teams in the facilities proved to be a very human resource intense process. So it remains unclear if the level of support received by the QI teams was adequate or not. We found no evidence in the literature on the level of support required by QI teams.

In the MaiKhanda programme, initial collaboratives gave participants the option to decide on their choice of topics, but later on MaiKhanda initiated these as the need for an agreed change package that focussed on the key drivers for MNH linked to the three delays model became clear. Both approaches have their limitations and it is difficult for implementers to strike a balance. Giving teams the opportunity to decide can make them more engaged in the collaborative, but the collaborative itself could become difficult to

[140] Perla RJ, Bradbury E, Gunther-Murphy C. Large-Scale Improvement initiatives in healthcare: A scan of literature. Journal of Healthcare Quality 2011; pp 1-11.

manage. On the other hand, having collaboratives on specific pre-determined topics may not generate necessary buy-in from all the participating teams. [141]

The MaiKhanda facility intervention underwent a series of changes within the life of the project. The initial design of the facilities intervention was focused on implementation of change packages at the micro/clinical-ward level. The program evolved over time to adopt a more system wide approach to QI in the latter part of the intervention. This included engagement with the DHMTs and the Zonal[142] teams. The focus in 2011 (post-evaluation period), was to embed the MaiKhanda interventions within the Ministry of Health.

Given the Malawian Ministry of Health's endorsement of quality improvement in their Road Map for Accelerating the Reduction of Maternal and Neonatal Mortality and Morbidity in Malawi, it is possible that the MaiKhanda facilities intervention may be sustained in Malawi without the need for external financial resources going forward. However, from the Road Map, it is also unclear what method of quality improvement the MoH is committed to (although there is mention of adherence to standards and maternal and neonatal death reviews there is no mention of PDSA or Criterion-Based Audits).[123, page 200] Recent work of the MoH in partnership with JHPIEGO suggests alternative approaches to those of MaiKhanda/IHI are being scaled-up already throughout district hospitals in Malawi.[42, page 54] A further issue is the future need for external (foreign) technical assistance, given the heavy reliance of the facility intervention on foreign expertise provided by IHI. This issue discussed in section 5.6.1 below.

5.3.2 Community Intervention

The community intervention was observed to reduce perinatal mortality by 16% on it's own, and neonatal mortality by 23% when in combination with the facility intervention (finding 1, section 4.1.4). This was despite the overall low coverage of the intervention (finding 15). With increased population coverage resulting from the formation of additional women's groups and task forces in-progress throughout 2011 and 2012, it is therefore possible that the effects of the community intervention on perinatal and neonatal mortality (stillbirths and early neonatal deaths, finding 3) could increase. The effects of increased dosage of women's groups is being tested by a follow-up randomised trial in the same area of Bangladesh that originally observed no effect of the women's groups at low dosage.[143] The effects of the community intervention could also increase over time given that behaviour change interventions often take years to reach their full-effects due to the often-slow pace of change of socio-cultural practices. However, we did not observe any increase in effect of the community intervention on it's own in the second intervention period relative to the first, but rather observed a shift in effect from one on stillbirths to one on early neonatal mortality (finding 3, section 4.1.5, Appendix 21). The implications of this going forward, and with regard to possible differences in the effects and mechanisms of women's groups and task forces (and alternative explanations), requires further investigation.

The available process data for the community intervention suggested the women's group action cycle (see section 1.2.5.1) was executed adequately by most women's groups with the help of their facilitators (sections, 4.2.1.2.3, 4.2.5.2.1 and 4.2.5.2.2), therefore concerns over the fidelity with which the community intervention was implemented are low. Nevertheless, the intervention could perhaps have paid more attention to factors identified to be important for the success of women's groups in other studies, such as: ensuring the acceptability of the intervention to women and the community in general, encouraging more community involvement beyond the groups, focusing more on marginalized communities, and, in particular the active recruitment of newly pregnant women into groups.[131, page 203] If

[141] J Ovretveit, P Bate, P Cleary et al. Quality collaboratives: lessons from research. Qual Saf Health Care 2002;11:345-351

[142] Zones are made up of several districts.

[143] Houweling TAJ, Azad K, Younes L, Kuddus A, Shaha S, Haq B, Nahar T, Beard J, Fottrell EF, Prost A and Costello A, for the PCP study team. The effect of participatory women's groups on birth outcomes in Bangladesh: does coverage matter? Study protocol for a randomized controlled trial. Trials 2011, 12:208

made, such improvements to the MaiKhanda community intervention could also result in greater effects in future. The effect of shortening the women's group action cycle from 12 meetings as done in MaiMwana[9, page 15] to the eight meetings used by MaiKhanda in their first cycle, is also unknown.

Although the community intervention appears to have enjoyed the support of traditional community leaders and is likely to going forwards (finding 20, section 4.2.5.2.4) this critical factor may not be enough to sustain it. Financial support may also be required for programme staff, such as the MaiKhanda community mobilisation officers, to oversee the intervention and supervise the women's group facilitators and task force committees. Alternatively government HSA would need to be engaged in a supervisory role (as was done in Ntcheu – see following paragraph). However it is also important to note that women's groups in Nepal continued to meet despite being cut-off during the civil war, and therefore financial or supervisory support may not be needed. Although the Malawian MoH has not endorsed women's groups as part of its Road Map for Accelerating the Reduction of Maternal and Neonatal Mortality and Morbidity in Malawi, it does support community strategies (under strategy 8 of the Road Map) including those involving community core groups, which are perhaps similar to women's groups and task forces. Given this support it may be possible to sustain existing women's groups into the future and roll out new women's groups without additional NGO support. However, additional NGO support may also not be that difficult for MaiKhanda to obtain, given the evident interest in the MaiMwana women's group model - which is similar to MaiKhanda[9,page 10] - to date. MaiMwana has recently established itself as a training organisation and is assisting other NGOs to set up their own women's groups in several other districts of Malawi (personal communication, Tambosi Phiri, MaiMwana project manager, November 2011).

There needs to be further discussion regarding the sustainability of the women's group intervention. Malawi has had three different models of women's group intervention. The MaiMwana model which uses paid facilitators to facilitate the women's groups. The MaiKhanda model, which uses volunteers from within the local community to facilitate the women's groups; and, the Ntcheu-PCP (Perinatal Care Project) model, which uses HSAs from within the health care system to facilitate the women's group intervention. There were further modifications to the MaiKhanda model with the introduction of a shorter action cycle and the formation of MNH task forces in some of the women groups. While the MaiMwana and MaiKhanda projects were cluster RCT, evaluation of the Ntcheu project used a before-after study design. More detailed analysis of these three different models including their cost-effectiveness and feasibility need to be undertaken.

5.3.3 Combined facility and community intervention

The facility and community interventions in combination with each other were found to reduce neonatal mortality by 22% (finding 1). Intriguingly, this effect was found to be almost completely concentrated, and therefore obviously higher (28% reduction, p=0.084) in the second intervention period (finding 3, section 4.1.5), when the dosage of the facilities intervention was increased and the community intervention included 365 task forces as well as 729 women's groups (chapter 3). As stated in the interpretation of finding 3 above, it is apparent that this increase in effect is mainly due to the shift in the community intervention effect from one on stillbirths in the first intervention period to one on early neonatal deaths in the second intervention period (appendix 21). Therefore changes to the community intervention and an increase in its duration, rather than increased dosage or duration of the facilities intervention, may be mainly responsible for the increase in neonatal mortality effect. Nevertheless, if improvements, such as those suggested above for each individual intervention, were made, the potential of the combined approach in reducing neonatal and perinatal mortality is clearly large. Although we lack any evidence suggesting an effect of either or both of the interventions on maternal mortality, it is of course possible that such improvements could also eventually result in an effect on maternal mortality too. Given the recent shift in the community vs. facility debate in academic and policy circles to more reasoned views accepting the need to focus on both community and facility approaches to

reducing maternal, neonatal and perinatal mortality, the time is also ripe for the adoption of a combined approach in Malawi and other low-income settings throughout the world. The Partnership for Maternal, Newborn and Child Health (http://www.who.int/pmnch/en/) has a knowledge portal for resources from more than 400 PMNCH partner organizations which provides: 1) PMNCH knowledge summaries and 2) an integrated, customised search function of all partner organizations and other key MNCH knowledge resources, including journals. Continuous care across life stages, and from home to hospital, is crucial for health - for complete physical, mental and social well-being. The PMNCH recognise that good quality health services, and demand side interventions like community mobilisation and cash incentives, play complementary roles in ensuring poor women and their families enjoy better health. The MaiKhanda programme brings unique field experience of a combined supply and demand intervention in Africa.

5.4 Additional considerations and key learning

The following points of learning, additional to those reported in chapter 4, and discussed in section 5.1, were captured as part of the *Data Deep Dive* process (section 2.6) and additional discussions with MaiKhanda staff and staff of partner organisations.

- The programme could have benefited from a start up phase for planning and coordination and better senior leadership within the programme from the start.
- Implementation design and dosage: the facilities intervention should have used a clear phased design for scale-up (intensive learning phase, development of a clear change package, building of will, building of capacity, engagement of the Ministry of Health, then scale up), with each phase of the project being fully dosed and completed before the next phase was moved on to.
- Earlier investment in QI training should have been done e.g. more staff sent to the IHI Improvement Advisor course earlier.
- There was an initial lack of a recognisable local identity to the organisation before MaiKhanda was established as an independent NGO.
- Linkages between the facility and community interventions were under conceptualised and underdeveloped.
- Leadership: strong, well capacitated local leadership is required
- Earlier and ongoing engagement of Ministry of Health and their leadership in project execution is important.
- External partner leadership: the programme would have benefited from clear authority of the lead partner, clear boundaries of the funder, a better sense of partnership and cohesion of inputs.
- Stronger focus on data training and improvement of government data systems is required.
- More data should have been collected to enable monitoring and evaluation of the intensity, quality, and thoroughness of testing of quality improvement change ideas and to better determine mechanisms of action of the facilities intervention.
- More data should have been collected to determine the mechanisms of action of the community intervention, especially with regard to differences in the effects of women's groups and task forces and impacts of specific women's group strategies on specific causes of death.
- Better coordination with other NGOs would have helped.
- RCT design: there should have been better collaboration with district managers and a firm commitment to scale up to all areas after the RCT (due to the trial taking longer than originally planned and resulting resource constraints, this was not done). Using a stepped wedge design could have decreased the risk of contamination i.e. if district managers knew all areas of the district would get the intervention soon. Such a design is well suited to phased scale-up.
- Despite being included as an aim, advocacy was largely missing from the whole programme at national, district and grassroots levels.

5.5 Overall strengths and weakness of the study

A systematic review of literature looking at evidence of large scale interventions identified 72 articles, of which 50 were based on the IHI Breakthrough series model. Most of these were before and after studies, unable to account for secular trends, and most used self-reported measures rather than medical records or other more objective means of measuring outcomes.[110, page 196] The evaluation of MaiKhanda involved a cluster randomized controlled design using an objective outcome measure (mortality) measured by means of a continuous surveillance of births and deaths (at the community and facility level) throughout the length of the study. As such, as far as we are aware, it is the only study of robust methodological quality ever undertaken to evaluate a quality improvement intervention in a low-income setting.

The evaluation has adapted a mixed methods approach in an attempt to understand the causal linkages between the processes and mechanisms of the interventions and outcomes. The mixed method approach includes a combination of different end points measured across the causal chain as well as qualitative and quantitative observations.[144]

The evaluation was conducted in a real world setting, thereby increasing the generalizability of the study.

It is important to consider context when trying to understand the black box of how and why interventions work.[145] Furthermore, understanding the contexts within which interventions operate is necessary in order to generalizing the findings to larger populations of interest, which may only share certain facets of the original context within which the interventions were evaluated. Whilst we examined some of the important contextual factors surrounding the MaiKhanda community and facility interventions, and as such were able to go some way towards explaining how the interventions interact with and depend on the contexts within which they operate, we were unable to fully reveal the black boxes of the mechanisms of action of the interventions.

From an evaluation perspective, the timing of the intervention is crucial, and especially for large-scale improvement activities. This includes not just the time of introduction of the intervention but also the duration of the intervention. Although Franco and Marquez show that 80% adherence to standards can be achieved in 9 months (see finding 3, *comparison of the literature* above), it is not clear from the literature how long a quality improvement initiative or collaborative should run before it should start reducing mortality. Therefore we cannot be sure whether our evaluation period was sufficient to allow the full effects of the facility intervention to be revealed. Similarly, given that the MaiKhanda community intervention is also based around behaviour change (but of women in rural communities rather than health workers in health facilities), and that such changes can take a long time, we also cannot be sure whether the evaluation period allowed sufficient time for the community intervention to realise it's full potential in terms of effects on perinatal, neonatal and maternal mortality, particularly given the low population coverage. Inter-generational learning effects were also obviously beyond the scope of our study.

5.6 Points of debate

From our experience of evaluating MaiKhanda over the past 5 years and through discussions with staff from MaiKhanda and partner organisations, including those of the *Data Deep Dive* (section 2.2.6) the following points of debate arose: the balance between local ownership and external (foreign(technical assistance and management; whether the interventions were designed to increase health facility delivery; the optimum time for running a quality improvement project; and how best to evaluate quality improvement interventions. Each of these are briefly discussed below.

[144] C Brown, T Hofer, A Johal, et al. An epistemiology of patient research: a framework for study design and interpretation. Part 4.Onse size does not fit all. Qual Saf Health Care 2008;17:178-181.
[145] C Brown, T Hofer, A Johal, et al. An epistemiology of patient research: a framework for study design and interpretation. Part 2.Study design. Qual Saf Health Care 2008;17:163-169.

5.6.1 Balance between local ownership and external (foreign) technical assistance and management

In terms of the MaiKhanda facilities intervention, at the beginning there was strong technical input from IHI staff on the ground with one IHI staff member leading the quality improvement programme from early 2006 till February 2007 and frequent visits from a number of other IHI staff (as well as those from LSTM and LATH – see section 3.1). As the programme progressed more local MaiKhanda staff were trained in quality improvement methods (for example by attending IHI's Improvement Advisor course). However design of the interventions was still dominated by IHI, who led the design of new maternal and neonatal change packages in late-2010/early-2011. And numerous phone calls and visits from external (foreign) experts from IHI still underline the dependence of MaiKhanda on this technical assistance.

In terms of the community intervention, external (foreign) technical assistance from WCF was also significant. However, once set up in 2007 the community intervention was run by a local team with indirect technical support only. The design of the new women's group manual in 2010 was also largely done by local staff without much input from WCF. However, regular phone calls, email and visits to Malawi by WCF staff continued throughout the project.

The debate surrounding the dependence of MaiKhanda on external (foreign) technical assistance can be encapsulated by the question: 'To what extent is local ownership desirable at an early stage of a new NGOs existence?' On the one hand it can be argued that an organisation is only able to perform highly when it is able to exert itself without being completely controlled by outsiders. On the other hand it could be that a premature focus on local ownership when the organisation does not have the required technical capacity could lead to poor results. To shed light on these alternative possibilities we require a better understanding of the evolution and development of decision rights and how they affect performance. A further question along these lines is 'how long might it take to develop a local organisation that can independently solicit technical support, as opposed to a developmental process that precludes immediate local ownership?' Being clear about roles and responsibilities in the planning phase of a programme is clearly crucial for determining the goals and subsequent outcomes with respect to local ownership and external (foreign) technical assistance.

5.6.2 Were the MaiKhanda interventions designed to increase health facility delivery?

It is unclear as to whether the MaiKhanda interventions were designed to increase health facility deliveries and the appropriateness of health facility delivery as an outcome indicator consequent to this. In addition, health facility delivery may not be a good outcome indicator of success leading to reduced mortality as, due to shortages of resources (finding 9) and in some cases, even basic clinical knowledge (finding 11), health facility delivery may not always equate to skilled attendance. Some facilities also became overburdened by increases in deliveries and there are other options for skilled delivery, e.g. government plans to train a cadre of community-based midwives. As well as being important due to facility overburdening, such alternatives are important because they increase choice of a significant proportion of women who are still not willing/able to access facilities to deliver, and consequently still deliver in the community.

5.6.3 What is the optimum time period for running a quality improvement project?

Traditional quality improvement projects have reported an average length of 17 months from identification of problem to completion of first pilot improvement.[146] While evidence for QI collaboratives is sparse, the average length for a collaborative to show effect has been identified as ranging from 12 months to 24 months.[136] The breakthrough series collaborative meetings of MaiKhanda were held at 90-day intervals; the rationale and evidence for this spacing remains unclear. It was perhaps influenced by the project time frame, but whether such short cycles are able to effect performance and outputs remains debatable.

[146] Alemi F, Safaie, F Neuhauser, D. A survey of 92 quality improvement projects. Jt Comm J Qual Improve 2001;27:619–32.

5.6.4 Evaluation methodologies

Quality improvement, as practiced by the MaiKhanda facilities intervention, has adapted methods from industry to analyse changes in healthcare and this is an intermediary between complete absence of use of data for decision-making and a rigorous research method. Such statistical process control methods provide vital tools for analysing variance and monitoring progress[109, page 195] but additional methods are still useful to measure effectiveness of interventions.[147] Methods accounting for differences in case-mix at different times and different facilities can be employed, such as the CUSUM chart which adjusts expected outcomes based on observed risks.[148][149][150] Such analyses require a lot of data on the risk of the outcome in each patient and are complicated to undertake, however, and were beyond the scope of the MaiKhanda facilities intervention. An alternative, and perhaps easier way of accounting for secular trends and attribution is the use of a control group. If intervention and control groups are randomly allocated and there are enough facilities in each group it is also more likely that any known and unknown confounding factors that could also be responsible for changes in outcomes will be roughly balanced therefore allowing a fairly accurate estimation of the net effect of the intervention. It can be argued therefore that in order to measure effectiveness of the facility interventions the use of established research methods such as the randomised controlled trial are best, where resources permit.

As this evaluation has shown, the use of additional methods such as specially designed surveys, focus group discussions and interviews, in a parallel process evaluation are also critical in order to determine the active ingredients and mechanisms of interventions and the contexts within which they are most successful. Furthermore, detailed costing and cost-effectiveness analyses are required in order to determine whether the interventions, or specific aspects of them, are good value for money.

5.7 Recommendations

We finish this report with recommendations, based on the evidence we have gathered, for policy makers, intervention implementers, and researchers.

5.7.1 For policy makers

Work must continue to find the most effective quality improvement methods, combined with close attention to the maintenance of drug and equipment supplies, health worker training and supervision.

Community mobilization using women's group interventions and with addition of maternal and neonatal health task forces has been demonstrated to show an effect on perinatal mortality.

A combined facilities and communities intervention is considered a better model to reduce maternal and neonatal mortality at the population level, thereby addressing both supply and demand issues outlined in the three delays model[151], and has been demonstrated to show an effect on neonatal mortality.

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[147] Provost LP, Murray S. The Health Care Data Guide: Learning from Data for Improvement. San Francisco: Jossey-Bass; 2011.

[148] Grunkemeier GL, Wu YX, Furnary AP. Cumulative Sum Techniques for Assessing Surgical Results. Ann Thorac Surg 2003; 76: 663–7

[149] Biau DJ, Resche-Rigon M, Godiris-Petit G, Nizard RS, Porcher R. Quality control of surgical and interventional procedures: a review of the CUSUM. Qual. Saf. Health Care 2007;16; 203-207

[150] Grunkemeier GL, Jin R, Wu YX. Cumulative Sum Curves and Their Prediction Limits. Ann Thorac Surg 2009; 87: 361–4

[151] It's worth noting here that demand doesn't always have to be the focus of the community e.g. better care – supply- could be given in the community; and supply doesn't always have to be the focus of the facility e.g. women-friendly care or improved quality of care at the facility can generate demand: Kruk ME, Rockers PC, Mbaruku G, Paczkowski MM, Galea S. Community and health system factors associated with facility delivery in rural Tanzania: A multilevel analysis. Health policy (Amsterdam, Netherlands). 2010; 97(2): 209-16

Low cost surveillance systems can give invaluable up-to-date information from sentinel sites about maternal and newborn death rates and stillbirths in the whole population (including the community), which are much more representative than historical estimates by retrospective surveys using the sisterhood method and than health facility statistics.

5.7.2 For implementers

Improvement efforts will be enhanced by the presence of consistent quality improvement teams in each of the intervention sites.

Understanding of the context within which the interventions operate is very important.

Investment of time is equally important as investment of funds, for two reasons: Data systems are still in an evolving phase to provide all of our information requirements - so significant investments/inputs to organizational data systems are required. Secondly, given the relatively new concepts that quality improvement and community mobilisation bring in which challenge traditional/conventional approaches, it takes a while for people to assimilate these concepts, and for subsequent behaviour change to occur.

Paucity of good quality data is a big challenge for work in developing country settings. A dual approach with a long-term strategic plan of investing in country information systems, through data quality forums, human resource capacity building, and database creation and maintenance, in addition to a programme specific strategic plan is required.

5.7.3 For researchers

Considering the gaps in the literature that we've identified in sections 5.1 and 5.2 above, the following specific research areas and questions need focusing on:

- Randomised controlled trials of quality improvement interventions
- Place of death effects of facility and community maternal and neonatal health interventions
- Effects of increased dosage on facility and community interventions
- Mechanisms of facility and community interventions with respect to their effects on specific causes of death, and key drivers of death including those associated with the Three Delays.
- Specific effects of resource constraints on quality improvement initiatives
- Staff psychology
- Dependence of quality improvement on provider knowledge (how much should quality improvement focus on clinical knowledge?)
- Specific effects of women-friendly care initiatives including possible linkages to mortality?
- Interaction of facility and community interventions with interventions using different methods
- Does the women's group methodology actually empower women and communities to address issues that impact on maternal and neonatal health and mortality?

Additional research remaining from this evaluation at the time of publication includes, further analysis of available data on the effect of women's groups and task forces on maternal and neonatal health knowledge attitude and practice, the follow-up staff psychology survey; mapping of signal function availability (Box 2) to health centre and hospital case-fatality rate time-lines; mapping of CEmOC mortality to population level mortality; and, a more detailed cost-effectiveness analysis, including sensitivity analyses.

Appendix 1: Power Calculations for the RCT

The total sample size (number of livebirths – the denominator for calculation of maternal and neonatal mortality rates) was 20,576 after data collection 27 months for the both QI and WG trials (Oct-08 to Dec-10). Using the formula for the sample size for comparing two rates,[1] adjusted for the fact observations are clustered[2] we can estimate the minimum statistically significant (5% level) reductions in mortality that we will have a certain power (probability) of detecting given total sample size. This is illustrated in Figure 44 for maternal mortality reduction from the QI intervention and the WG intervention (61 clusters) and the QI+WG intervention (31 clusters).

Measurement of maternal mortality reduction

Baseline maternal mortality was measured at 415 maternal deaths per 100,000 livebirths, much lower than the figure of 984 that the original proposal sought to address. The Intraclass Correlation Coefficient, *ICC* for maternal mortality was determined to be 0.00118 for control clusters in the intervention period. Figure 44 shows that we only had the recommended 80% power to detect a 50% reduction in maternal mortality from the QI intervention and the WG intervention and a 58% reduction from the QI+WG intervention. Given this low power, it is therefore possible that we may not have detected reductions in maternal mortality resulting from the interventions. However, given the observed odds ratios estimating the possible effect of each intervention on maternal mortality (for quality improvement: OR: 1.18 (95%CI: 0.66, 2.11); for women's groups: OR: 0.91 (95%CI: 0.51, 1.63) it is less likely that we have missed significant effects that may have occurred (see section 4.1.4)

Measurement of neonatal mortality reduction

If we desire an 80% power (as is standard) to detect a statistically significant ($p<0.05$) reduction in neonatal mortality and use the revised baseline mortality figure of 30.7 neonatal deaths per 1000 livebirths and the *ICC* for neonatal mortality in control clusters during the intervention period $(0.00213)^2$, we have the power to detect a 22% reduction in neonatal mortality from the QI intervention and the WG intervention and a 31% reduction from the combined QI+WG intervention. Given that it was hypothesised that the interventions could reduce neonatal mortality by 30% it is therefore highly likely that we will have detected such reductions if they have occurred. The power to detect reductions in Perinatal Mortality is similar.

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[1] From Kirkwood & Sterne, *Essential Medical Statistics* 2nd Edition, Blackwell, Oxford, page 420:

$s = \frac{(u+v)^2(\mu_1+\mu_0)}{(\mu_1-\mu_0)^2}$; where *s* is the sample size in births (the denominator of the mortality rates) *u* is the one-sided percentage point of the normal distribution corresponding to 100% minus the power; *v* is the percentage point corresponding to the two-sided significance level; μ_1 is the rate in the intervention period and μ_0 the baseline rate

[2] The total sample size required is increased by the design effect, $d: = 1 + (m-1)ICC$; where *m* is the average cluster size in number of births and *ICC* is the intra-cluster correlation coefficient which is a measure of how much more alike individuals are within a given cluster than they are to those from a different cluster. The *ICC* ranges from 0 (individuals within a cluster are no more alike thank those from different clusters) to 1 (individuals within a cluster have identical outcomes). To determine study power *post-hoc* we used the *ICC* for maternal mortality and neonatal mortality using the observed data in control clusters during the intervention period, with the rationale that it is the same time period used for analysis and the ICC in control clusters will not have been effected by the interventions. The *ICC* for MMR was 0.00118 (95%CI: 0 – 0.00316) and for NMR was 0.00213 (95%CI: 0-0.00446)

Figure 1: Detection of maternal mortality reduction from the QI, WG and QI+WG trials

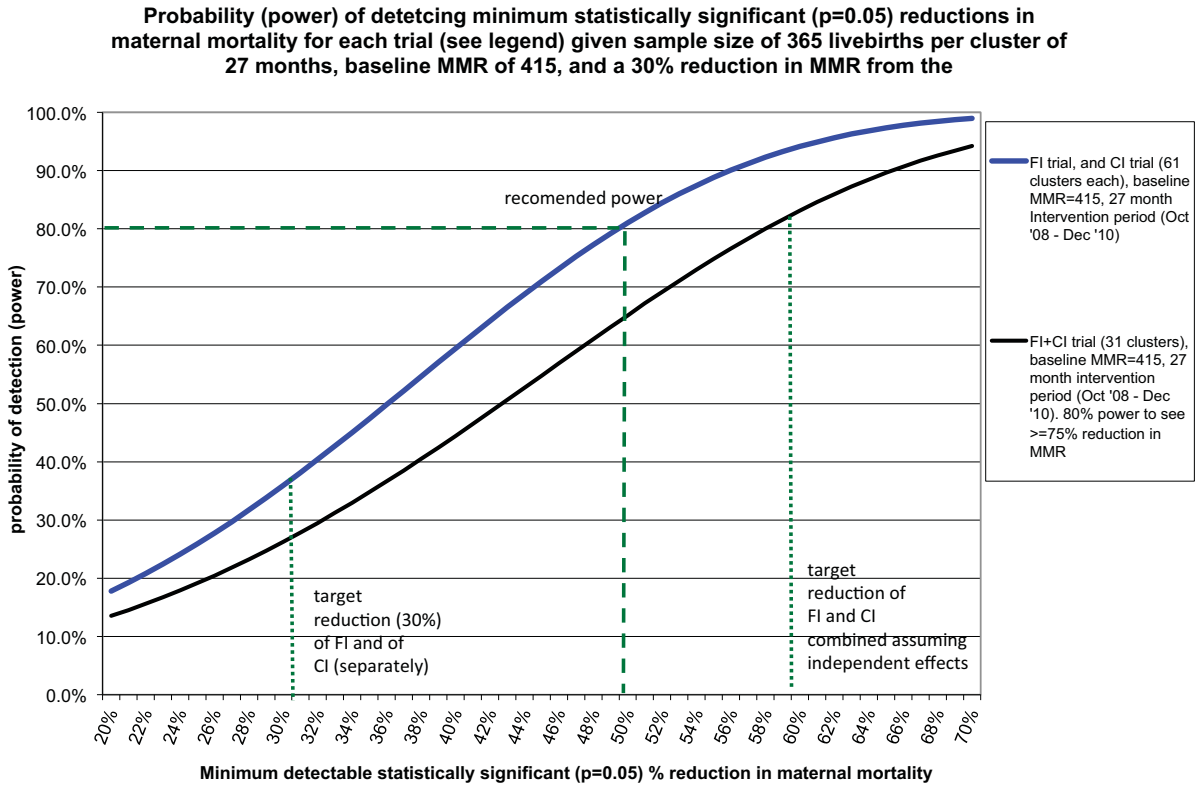
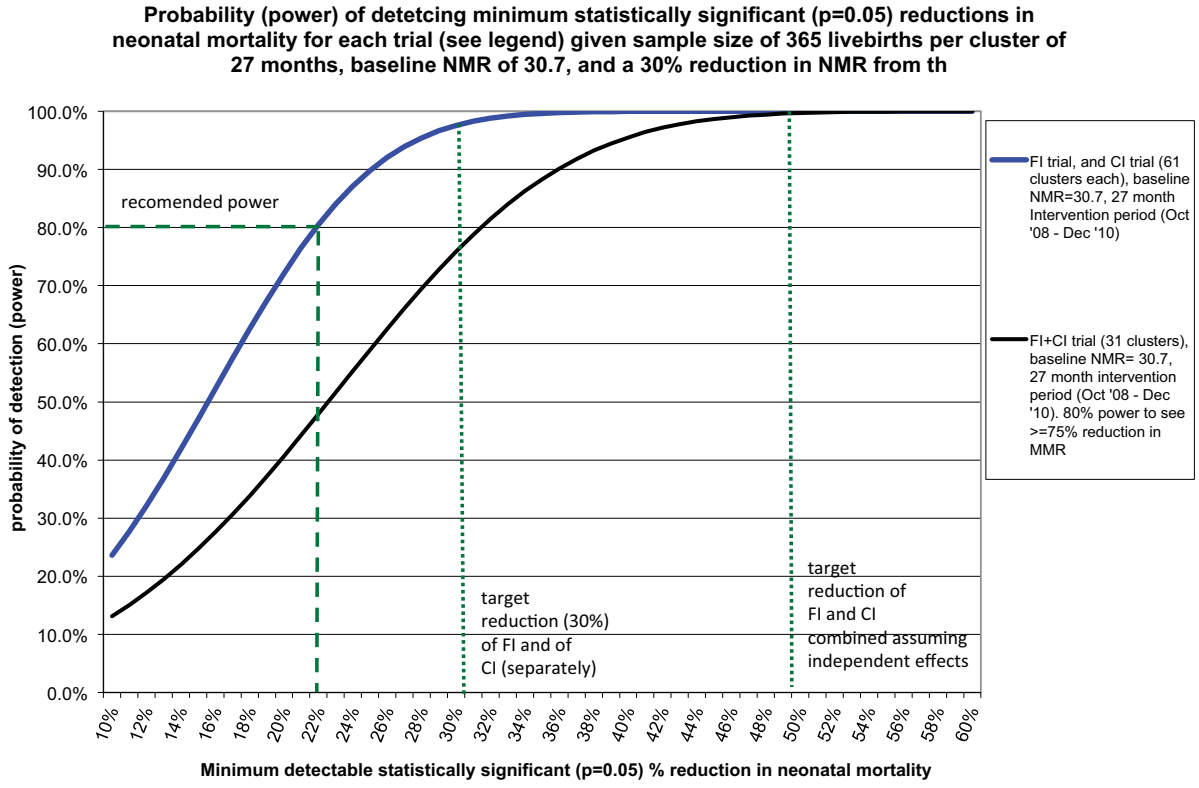


Figure 2. Detection of neonatal mortality reduction from the QI, WG and QI+WG trials



Appendix 2: Population selected for community surveillance

During March 2007 all of the Health Surveillance Assistants (HSA) in all of the Health Centres in Lilongwe, Kasungu and Salima (the RCT area) were surveyed. The following information was collected: whether they kept their Village Health Register up to date and how frequently; whether they collected information on maternal deaths, neonatal deaths and livebriths and how frequently they collected such information; the extra work with other NGOs they were engaged in; the names, populations and distances to the nearest health facility of all the villages in their catchment areas; the names and training status of the Traditional Birth Attendants in their catchment area villages; and the names of all the active Village Health Volunteers in their villages catchment area villages.

Because the majority of HSA did not collect maternal and neonatal mortality data it was necessary to set up our community surveillance system. Using the population per village data we were able to determine the catchment population size each HSA covered (data for all 628 HSA surveyed are available from the authors). From this data using the Complex Samples procedure in SPSS we randomly selected HSA for each Health Centre/dispensary (RCT cluster) until the total population for all HSA for the Health Centre/dispensary was as close as possible to 4000. This typically meant selecting 2 to 4 HSA per cluster. Details of the randomly selected HSA are provided in Table 1.

As stated in the main text, following a successful government drive, sponsored by the Global Fund to fight AIDS, TB and Malaria, to reduce HSA catchment areas to an average of 1000 population the number of HSAs increased two to three fold. We maintained the same surveillance population by working with the new HSAs who were each assigned to parts of the existing HSAs catchment areas.

Other characteristics of the catchment areas randomly selected for surveillance that are relevant for the RCT are: the % of villages with active village health committees, the % of Traditional Birth Attendants (TBA) that are trained and the average distance of the surveillance villages to the Health Centre. As such variables could affect maternal and neonatal mortality it is important to be sure that the randomisation resulted in roughly even values for such statistics between each of the arms of the study. Details of such an analysis along with other analyses to ensure the results of the RCT are unbiased are given in the RCT Results section.

Table 1. Randomly selected HSA areas for RCT Community Surveillance

District:	Health Facility:	HSA:	No. of Villages	Total population
Kasungu	BUA	ISAAC KACHINGWE	25	3285
Kasungu	CHAMWABVI	G.C. PHIRI	22	2173
Kasungu	CHULU	C. Chunda	31	2884
Kasungu	DWANGWA	S.W. BANDA	15	3271
Kasungu	GOGODE	VDH CHIRWA	12	3185
Kasungu	KALULUMA	IAN BANDA	25	3545
Kasungu	KALULUMA	JUSTICE MAWANGO	28	3412
Kasungu	KAMBONI	LISNET NJATANI	9	1490
Kasungu	KAMBONI	JAPHET PHIRI	12	1597
Kasungu	KAPELULA	CHRISPINE CHAPO	19	2348
Kasungu	KAPELULA	D.J. Malala	14	3513
Kasungu	KASUNGU	W. Maseko	3	5670
Kasungu	KAWAMBA	L.C. Simbeye	16	2094
Kasungu	KAWAMBA	O Satheka	16	2168
Kasungu	KHOLA	G.W. CHANANZA	14	5705
Kasungu	LINYANGWA	T. Vinjenje	9	3310
Kasungu	LINYANGWA	WILSON D. MASEBO	6	2548
Kasungu	LODJWA	K. MOYO	7	1428
Kasungu	LODJWA	W. NHLEMA	20	2512

District:	Health Facility:	HSA:	No. of Villages	Total population
Kasungu	MKHOTA	KESTON BANDA	8	3705
Kasungu	MPASADZI	ADALAKWANJI KAKWESA	16	2082
Kasungu	MPASADZI	WILLIAM KASAMBARA	14	1573
Kasungu	MPEPA	FLORENCE MUGHOGHO	5	2050
Kasungu	MPEPA	M.M. NKHOMA	10	2703
Kasungu	MTUNTHAMA	BENSON S.M. MWALE	19	2462
Kasungu	MTUNTHAMA	Judith Chipeni	19	5621
Kasungu	MZIZA	ELIZA M. ZIMBA	4	915
Kasungu	MZIZA	PATRICIA CHALUNGAMA	9	1331
Kasungu	NKHAMENYA	J. KUYOKWA	19	1554
Kasungu	NKHAMENYA	MC BOSCO CHINGUWO	31	4395
Kasungu	OFESI	J.S. DODOZI	19	2133
Kasungu	SANTHE	CLEMENT JAMBO	14	5654
Kasungu	SIMULEMBA	H. Chipa Chunga	18	4612
Kasungu	WIMBE	H.C. MHANGO	15	1902
Kasungu	WIMBE	J. Kalua	20	6656
Lilongwe	Area 18	Mrs Temani	13	6021
Lilongwe	Area 25	G. Kambizi	5	1255
Lilongwe	Area 25	A. Silungwe	10	3067
Lilongwe	Chadza	S. Kapakasa	20	2294
Lilongwe	Chikowa	O.J.P Chilombo	14	3128
Lilongwe	Chileka	G.T Kachali	8	2000
Lilongwe	Chileka	L. Zungu	9	2219
Lilongwe	Chilobwe	N. Chimbalanga	10	2605
Lilongwe	Chilobwe	E.D. Mandaachepa	16	2075
Lilongwe	Chimbalanga	R.W. Dudu	21	3230
Lilongwe	Chitedze	S. Malamba	18	2331
Lilongwe	Chiunjiza	M.G Mtenga	14	2287
Lilongwe	Chiunjiza	J. Saka	20	2530
Lilongwe	Chiwamba	Clara Chisambo	11	2232
Lilongwe	Chiwamba	B.K Mweso	20	3089
Lilongwe	Chiwe	Clifford Munthali	5	2241
Lilongwe	Diamphwe	M.M Pezemmawa	13	1023
Lilongwe	Diamphwe	A.M Kadya	11	1098
Lilongwe	Diamphwe	E. Katandika	8	1113
Lilongwe	Diamphwe	R.M Kansinjiro	12	1399
Lilongwe	Dickson	Mtsosolo	21	6042
Lilongwe	Dzenza	G.H Chimangire	5	2121
Lilongwe	Kang'oma	Susani Kalua	10	910
Lilongwe	Kang'oma	Rabecca Mdulamizu	6	1147
Lilongwe	Kang'oma	L.S Sikaja	12	1802
Lilongwe	Katchale	F.S Masina	9	1733
Lilongwe	Katchale	Samuel Malonjezano	10	2284
Lilongwe	Kawale	Chimungu	4	4328
Lilongwe	Khongoni	E.L Muona	11	2028
Lilongwe	Khongoni	M. Chimsalazo	11	2371
Lilongwe	Lemwe	C. Mozes	7	0
Lilongwe	Lemwe	P.K Kotasi	8	2364
Lilongwe	Lumbadzi	E.H Kadzakalowa	25	5103
Lilongwe	Malembo	J. Kampangire	20	4913
Lilongwe	Malingunde	M.G Femvu	16	4521
Lilongwe	Maluwa	Grandford Maloni	25	4673
Lilongwe	Matapila	N.C Mwale	13	4811
Lilongwe	Mbabzi	B. Mkandawire	3	1989
Lilongwe	Mbabzi	G. Khaya	2	2875
Lilongwe	Mbang'ombe I	Charles Chandale	15	1764
Lilongwe	Mbang'ombe I	R.M Chimodzi	13	2163
Lilongwe	Mbang'ombe II	B.W Tchete	9	3253
Lilongwe	Mbwatalika	K. Msunje	9	2203
Lilongwe	Ming'ongo	C. Mikwamba	20	1173
Lilongwe	Ming'ongo	M. Mambala	18	2279
Lilongwe	Mtenthera	M.C Chimphamba	18	5556
Lilongwe	Nambuna	Geofrey M. Mchirawagaru	7	1578
Lilongwe	Nambuna	C.B.F Kafwafwa	8	2332
Lilongwe	Nathenje	W.N. Mwanyambo	10	1884
Lilongwe	Nathenje	A. Chadzabwanji	6	2846
Lilongwe	Ndaula	P. Mtanga	11	2099
Lilongwe	Ndaula	J.V Kanyenda	16	2626
Lilongwe	Ngoni	C. Chisale	13	3317
Lilongwe	Nsaru	F.M Benson	14	2790

District:	Health Facility:	HSA:	No. of Villages	Total population
Lilongwe	Nthondo	McLucky Lamulani	8	1630
Lilongwe	Nthondo	A. Tumeyo	10	2247
Lilongwe	Ukwe	Z. Zimba	10	2173
Lilongwe	Ukwe	V. Chirwa	11	2283
Salima	ADMARC	Mrs. P. Sankhani	5	
Salima	ADMARC	O. CHIPALA	8	1430
Salima	CHAGUNDA	K.V. MOYO	16	1337
Salima	CHAGUNDA	W.S.PHIRI	16	1768
Salima	CHINGULUWE	H.N. KENANI	10	2423
Salima	CHINGULUWE	A. MWALE	11	873
Salima	CHINGULUWE	J.B.GEDION	11	1423
Salima	CHIPOKA	R.MANGWERE	3	3007
Salima	CHIPOKA	A.MAGOMBO	3	1697
Salima	CHITALA	C.NYAMAYAZIZI	4	627
Salima	CHITALA	M.A. FISI	11	1229
Salima	CHITALA	R.T.NGOZA	19	1154
Salima	KAPHATENGA	E.M.CHILOMBE	9	1558
Salima	KAPHATENGA	C.H.L.MWALE	42	4409
Salima	KHOMBEDZA	H. MBADZA	22	2751
Salima	LIFELINE	E.PEREKAMOYO	8	3656
Salima	LIFUWU	D.KASO	9	1979
Salima	LIFUWU	R.JANA	4	2176
Salima	MAFCO	L.Z. CHANGATA	3	2565
Salima	MAFCO	M.KAKWALE	1	995
Salima	MAGANGA	A.K.S.BOTOMANI	25	2853
Salima	MAGANGA	RUTH PHIRI	17	2537
Salima	MAKION	J.MBONONGO	46	5338
Salima	MCHOKA	IREEN MWAWANJI	13	4835
Salima	NGODZI	E. CHIKUSE	5	1768
Salima	NGODZI	L.K.PAULO	4	1864
Salima	NGODZI	L.KATSICHI	4	1140
Salima	SDH	A.T.BWANALI	16	3047
Salima	SENGA BAY	MRS MSOWOYA	3	3270
Salima	SENGA BAY	R. NGOMA	3	494
Salima	THAVITE	SIMEON R. NKHOMA	14	1396
Salima	THAVITE	N.MATEWERE	12	1245

Appendix 3: Community Surveillance form: English and Chichewa

Monthly Surveillance of all Pregnancies, Births and maternal and neonatal deaths in the community

Record every woman from the time of pregancy identification until 2 months after birth (or the end of the pregnancy)
The data collection date for each woman / baby (last column) should be the actual date that the information was collected for this person
If twins, record each twin on a separate row

Month _____

District _____ Village name _____
TA _____ HSA Name _____
Nearest Health facility _____ Volunteer Name _____

No.	Name-Head of household	Pregnant woman / new mother			Pregnancy outcome						Maternal status			Delivery place (please tick)				Status of baby at 1 month			Date of data collection (DD/MM/YY)
		First name	Last name	Alternate name	Expecting	Live Birth (Date: DD/MM/YY)	Still Birth (Date)	miscarriage (Date)	abortion (Date)	not in village this month (tick)	Alive (tick)	Dead (date)	Unknown (tick)	Home	TBA	health facility	on the road	Alive (tick)	Dead (date)	Unknown (tick)	
1						/ /	/ /	/ /	/ /			/ /							/ /		/ /
2						/ /	/ /	/ /	/ /			/ /							/ /		/ /
3						/ /	/ /	/ /	/ /			/ /							/ /		/ /
4						/ /	/ /	/ /	/ /			/ /							/ /		/ /
5						/ /	/ /	/ /	/ /			/ /							/ /		/ /
6						/ /	/ /	/ /	/ /			/ /							/ /		/ /
7						/ /	/ /	/ /	/ /			/ /							/ /		/ /
8						/ /	/ /	/ /	/ /			/ /							/ /		/ /
9						/ /	/ /	/ /	/ /			/ /							/ /		/ /
10						/ /	/ /	/ /	/ /			/ /							/ /		/ /
11						/ /	/ /	/ /	/ /			/ /							/ /		/ /
12						/ /	/ /	/ /	/ /			/ /							/ /		/ /
13						/ /	/ /	/ /	/ /			/ /							/ /		/ /
14						/ /	/ /	/ /	/ /			/ /							/ /		/ /
15						/ /	/ /	/ /	/ /			/ /							/ /		/ /
16						/ /	/ /	/ /	/ /			/ /							/ /		/ /
17						/ /	/ /	/ /	/ /			/ /							/ /		/ /
18						/ /	/ /	/ /	/ /			/ /							/ /		/ /
19						/ /	/ /	/ /	/ /			/ /							/ /		/ /
20						/ /	/ /	/ /	/ /			/ /							/ /		/ /

Data collection sheet submitted by HSA/Volunteer (name) _____ Received by MEO (Name, date & sign) _____

KAWUNDULA WA A MAI APAKATI, ANA OBADWA NDI IMFA ZA UCHEMBERE NDI ANA AMAKANDA

Mzimayi akuyenera kulembedwa kuyambira nthawi imene wayima kufikira miyezi iwiri atachira.

Tsiku Lakaundula wa mai / mwana (kolamu yumalizira) iyenera kukhala tsiku limene kafukufuku anachitika Mwezi: _____

Ngati ana ndi amapasa, anawo alembedwe aliyese payekha payekha

Boma _____ Dzina la mudzi _____

TA _____ Dzina la mlangizi _____

Chipatala cha pafupi _____ Dzina la volunteer _____

No.	Dzina la mutu wa banja	Mzimayi woyembekezela/wochila kumene			Zotsatira Za Mimba						Zotsatira Zauchembere			Malo Ochilira				Zotsatira za mwana patatha mwezi umodzi atabadwa			Tsiku Lakaundula
		Dzina Lopatsidwa	Mfunda	Dzina Lina	Woyembekezela (miyezi)	Mwana Wamoyo (Tsiku: DD/MM/YY)	Mwana wakufa(nthayo) (Tsiku amwalira)	Kupita padera (Tsiku)	Kuchotsa Mimba (Tsiku)	Anachoka Mmudzi (chongani)	Mayi Wamoyo (chongani)	Mayi anamwalira (Tsiku)	Sizikudziwika (chongani)	Kunyumba (chongani)	Kwa Azamba (chongani)	Kuchipatala (chongani)	Munjira (chongani)	Wamoyo (chongani)	Anamwalira (Tsiku)	Sizikudziwika (chongani)	
1						/ /	/ /	/ /	/ /			/ /							/ /		/ /
2						/ /	/ /	/ /	/ /			/ /							/ /		/ /
3						/ /	/ /	/ /	/ /			/ /							/ /		/ /
4						/ /	/ /	/ /	/ /			/ /							/ /		/ /
5						/ /	/ /	/ /	/ /			/ /							/ /		/ /
6						/ /	/ /	/ /	/ /			/ /							/ /		/ /
7						/ /	/ /	/ /	/ /			/ /							/ /		/ /
8						/ /	/ /	/ /	/ /			/ /							/ /		/ /
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11						/ /	/ /	/ /	/ /			/ /							/ /		/ /
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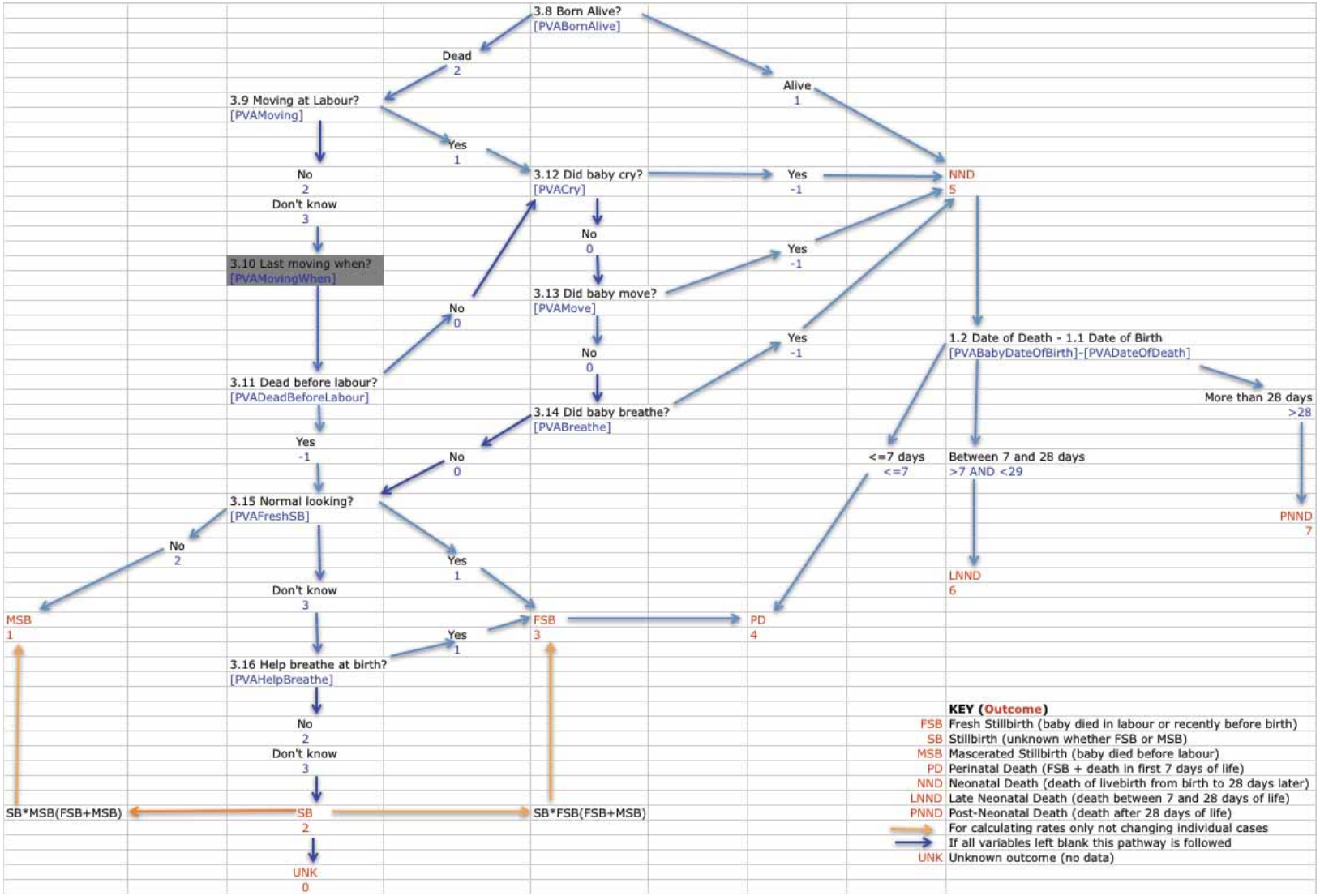
16						/ /	/ /	/ /	/ /			/ /							/ /		/ /
17						/ /	/ /	/ /	/ /			/ /							/ /		/ /
18						/ /	/ /	/ /	/ /			/ /							/ /		/ /
19						/ /	/ /	/ /	/ /			/ /							/ /		/ /
20						/ /	/ /	/ /	/ /			/ /							/ /		/ /

Data collection sheet submitted by HSA/Volunteer (name) _____ Received by MEO (Name, date & sign) _____

Appendix 4: SB or NND algorithm for PVA data



Appendix 5: Maternal Verbal Autopsy form

On arriving at the respondent's house – GREET THE RESPONDENT AND OFFER CONDOLENCES. ASK FOR A PRIVATE PLACE TO SIT AND CHAT, AWAY FROM OTHER PEOPLE. ASK THE RESPONDENT TO BRING THE HEALTH PASSPORT AND TTV CARD OF THE WOMAN WHO HAS JUST DIED, IF SHE HAS ONE. CHAT A LITTLE BIT, TO HELP THE RESPONDENT TO FEEL RELAXED.

Consent – My name is _____. I am working with The Health Foundation project. Our project is trying to improve the health status of mothers and babies in Kasungu, Lilongwe and Salima. We are doing a survey of women who have recently given birth, in order to learn about their experiences. The purpose of this interview is to try and understand why (NAME) died, so that we can help to prevent other women from dying of pregnancy-related causes in future. I'm sorry that I will be bringing back the memories of the late (NAME). I hope that is okay with you.

We assure you that everything you tell us will be kept confidential, and will only be used for study purposes. You do not have to take part in this research if you do not want to. If you do not wish to take part, this will not affect your right to take part in other Health Foundation activities in the future. If there are any questions that you do not want to answer, you do not have to answer them. There are no wrong answers to these questions. We just want to know about the experiences of pregnant women. If you do not understand a question, please ask me to explain it again.

This interview will take about one hour. Do you agree to take part?

Yes |__|

No |__|

Name of woman that died: first/second/alternative	
Name of head of household:	
Village name:	
TA name:	
Nearest Health Facility:	
Name of Interviewer	

Date of interview: |__|__|/|__|__|/|__|__|	Date received in office: |__|__|/|__|__|/|__|__|
	District Co-ordinator's signature:
Name of main respondent: first/second/alternative	
What is the relationship of the main respondent to the woman who has died?	1 = Husband 2 = Mother 3 = Mother-in-law 4 = Sister 5 = Woman's family member 6 = Husband's family member 7 = Friend/neighbour 8 = TBA 9 = Other (specify _____)
When did (NAME) die?	Day/Month/Year |__|__|/|__|__|/|__|__|
Where did she die?	1 = Home 2 = On the way to treatment 3 = Hospital(specify _____) 4 = Other health facility in the district (specify _____) 5 = Other health facility outside the district (specify _____) 6 = Other (specify _____)
Is the baby still alive?	1 = Yes 2 = No

Part A: Personal Details of Mother and Father

First I would like you to tell me about the mother and the father of the baby			
Mother			
1.1	How old was (NAME) when she died?	Age (years) |__|__| Day/Month/Year |__|__|/|__|__|/|__|__|	
1.2	What is the highest level of school she attended? FOR PRIMARY AND SECONDARY ALSO PUT HIGHEST STANDARD OR FORM REACHED	1 = None 2 = Primary |__| 3 = Secondary |__| → 4 = Tertiary	 Q1.4
1.3	Did she ever participate in a literacy programme or any other programme that involves learning to read or write (not including primary school)?	1 = Yes 2 = No	
Father			
1.4	What is the age of the man who fathered this pregnancy? IF THE RESPONDENT DOESN'T KNOW THE EXACT AGE, CIRCLE THE CORRECT AGE GROUP	Age (years) |__|__| 1 = <20 years 2 = 20-29 years 3 = 30-39 years 4 = 40-49 years 5 = >49 years	
1.5	What was (NAME'S) relationship to him?	1 = Married 2 = Boyfriend/fiancé 3 = Casual acquaintance → 4 = Relative 5 = Divorced/separated → 6 = Widowed → 7 = Other (specify)	 Q2.1 Q2.1 Q2.1
1.6	Which of the following best described (NAME'S) living arrangements with this man? READ OUT THE LIST OF STATEMENTS	1 = Lived together all of the time 2 = Live together but occasionally apart for work reasons 3 = Lived together but separated for a period every year for work reasons (i.e. seasonal/ganyu work) 4 = Lived apart but regular/frequent cohabitation (i.e. return visits) 5 = Lived apart, infrequent cohabitation 6 = Never lived together	
1.7	What is the highest level of school he attended? FOR PRIMARY AND SECONDARY ALSO PUT HIGHEST STANDARD OR FORM REACHED	1 = None 2 = Primary |__| 3 = Secondary |__| → 4 = Tertiary	 Q1.9
1.8	Has he ever participated in a literacy programme or any other programme that involves learning to read or write (not including primary school)?	1 = Yes 2 = No	
1.9	What is his main occupation? PROBE FOR THE ONE WHICH HE SPENDS MOST TIME DOING	1 = Farming 2 = Casual worker/ganyu 3 = Salaried worker 4 = Small business/artisan 5 = Student 6 = No work 7 = Other (specify _____)	
1.10	Does he do any other type of work? If yes, what type?	1 = No other work 2 = Farming 3 = Casual worker/ganyu 4 = Salaried worker 5 = Small business/artisan 6 = Student 7 = Other (specify _____)	

Part B: Birth History

2.1	Has (NAME) ever had a pregnancy before this child, even if it ended early or the baby was a stillbirth?					1 = Yes 2 = No ---------- (→ Q3.1)	
	Now I am going to ask you some questions about all of the pregnancies (NAME) had during her life before this one. Starting from her first pregnancy, can you tell me about ALL her pregnancies, even if the pregnancy only lasted a few months, if the baby was born dead, or if it died soon after birth?						
	2.2 On what day, month and year was the baby born? PROBE: "What is his/her birthday?" CHECK HEALTH PASSPORT IF AVAILABLE	2.3 Was this pregnancy single or multiple? *RECORD TWINS AND TRIPLETS ON SEPARATE LINES*	2.4 Did this pregnancy end in a miscarriage, a stillbirth or a live birth? FOR STILLBIRTHS, PROBE FOR SIGNS OF LIFE AT BIRTH IF MISCARRIAGE OR STILLBIRTH, GO TO NEXT PREGNANCY	2.5 Is (NAME) a boy or a girl?	2.6 Is (NAME) still alive?	2.7 How old was (NAME) at his/her last birthday? RECORD AGE IN COMPLETED YEARS GO TO NEXT PREGNANCY	2.8 How old was (NAME) when he/she died? PROBE TO MAKE SURE YOU GET THE RIGHT AGE CATEGORY
01	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
02	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
03	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
04	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
05	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
06	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
07	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
08	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
09	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
10	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
11	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
12	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
		1 = Single 2 = Multiple	1 = Live birth 2 = Stillbirth 3 = Miscarriage	1 = Girl 2 = Boy			1 = 0-7 days 2 = 8-28 days 3 = 29 days -1yr 4 = >1yr 5 = >2yrs 6 = >3yrs 7 = >4yrs 8 = >5yrs

REMEMBER:

- A **MISCARRIAGE** IS A PREGNANCY THAT ENDS BEFORE 7 COMPLETED MONTHS
- A **STILLBIRTH** IS A PREGNANCY THAT ENDS AFTER 7 COMPLETED MONTHS, BUT THE BABY IS BORN DEAD
- A **LIVE BIRTH** IS A PREGNANCY THAT ENDS WITH A LIVE BABY, EVEN IF THAT BABY ONLY SURVIVES FOR A FEW MOMENTS

- PROBE BY ASKING "APART FROM THE PREGNANCIES YOU HAVE MENTIONED, HAVE YOU HAD ANY OTHERS THAT ENDED BEFORE 7 MONTHS, OR THAT ENDED AFTER 7 MONTHS BUT WERE BORN DEAD?"
- FOR ANY STILLBIRTHS REPORTED, MAKE SURE YOU ASK "DID THE BABY CRY OR SHOW SIGNS OF LIFE? DID IT MOVE AN ARM OR A LEG, OR BREATHE FOR A MOMENT?"

2.9	Did (NAME) ever have a pregnancy that ended before 7 completed months? IF YES, MAKE SURE THESE DETAILS ARE RECORDED IN TABLE 2	1 = Yes 2 = No	
2.10	Did (NAME) ever have a pregnancy that ended with a dead baby?	1 = Yes 2 = No →	Q2.12
2.11	Did the baby show any signs of life after it was born? Did it cry or breathe or move an arm or a leg? IF YES, RECORD THE BABY AS A LIVEBIRTH IN TABLE 2 IF NO, RECORD THE BABY AS A STILLBIRTH IN TABLE 2	1 = Yes 2 = No	
2.12	Did (NAME) ever have any children that died at any time after being born? IF YES, MAKE SURE THESE CHILDREN ARE RECORDED IN TABLE 2	1 = Yes 2 = No	

Pre-existing illness			
3.1	Before (NAME) was pregnant this time, do you know if she had any sort of illness?	1 = Yes 2 = No → 3 = Don't know →	 Q3.3 Q3.3
3.2	What sort of illness? DESCRIBE ILLNESS		
3.3	Did she ever have to go to the hospital for any illness before she was pregnant?	1 = Yes 2 = No → 3 = Don't know →	 Q3.5 Q3.5
3.4	For what reason?		
3.5	Did she ever have an operation? NOT INCLUDED HERE ARE ANY OPERATIONS DONE DURING THE DELIVERY OF A BABY	1 = Yes 2 = No → 3 = Don't know →	 Q3.7 Q3.7
3.6	For what reason?		
3.7	Before she was pregnant, did she ever have epilepsy (convulsions)?	1 = Yes 2 = No 3 = Don't know	
3.8	Did she ever need an operation to deliver a baby?	1 = Yes 2 = No 3 = Don't know	

Part C: Details About the Recent Pregnancy

Now I would like to ask you about the details of (NAME'S) recent pregnancy			
ANC			
4.1	Did (NAME) go for an antenatal check-up during this pregnancy?	1 = Yes 2 = No → 3 = Don't know →	 Q4.9 Q4.9
4.2	Where did she go? PROBE FOR MORE CIRCLE ALL THAT APPLY FOR OUTREACH SPECIFY WHERE THE OUTREACH WAS, NOT THE HEALTH FACILITY THAT IT CAME FROM CHECK HEALTH PASSPORT IF AVAILABLE TO HELP FILL IN GAPS WHERE THE RESPONDENT IS NOT SURE	1 = District Hospital 2 = 3 = 4 = 5 = 6 = 7 = 8 = 9 = 10 = 11 = 12 = 13 = 14 = 15 = TBA 16 = Outreach (specify _____) 17 = Other (specify _____) 18 = Don't know	
4.3	How many months pregnant was she when she first went?	1 = |__| months 2 = Don't know	
4.4	How many times did she go altogether during this pregnancy?	1 = |__|__| times 2 = Don't know	
4.5	Did (NAME have a Tetanus Toxoid Vaccine (TTV) injection in the arm during this pregnancy? CHECK HEALTH PASSPORT	1 = Yes 2 = No → 3 = Don't know →	 Q4.8 Q4.8
4.6	During this pregnancy, how many times did she get this injection? CHECK HEALTH PASSPORT	1 = |__| times 2 = Don't know	
4.7	Has (NAME) received all the five injections? CHECK TTV CARD OR HEALTH PASSPORT	1 = Yes 2 = No 3 = Don't know	
4.8	During this pregnancy was (NAME) given, or did she buy any iron tablets or iron syrup? CHECK HEALTH PASSPORT	1 = Yes 2 = No → 3 = Don't know →	 Q4.13 Q4.13
4.9	Why did she not go to ANC?		
4.10	Did she go to anyone else for advice during her pregnancy?	1 = Yes 2 = No → 3 = Don't know →	 Q4.12 Q4.12
4.11	Who did she go to?	1 = TBA 2 = Sing'anga 3 = Grandmother 4 = Other (specify _____)	
4.12	During this pregnancy, did (NAME) take any drugs in order to prevent her from getting malaria? NOT CONSIDERED HERE ARE INSTANCES WHEN SHE TOOK THE DRUG BECAUSE SHE HAD MALARIA	1 = Yes 2 = No → 3 = Don't know →	 Q4.15 Q4.15
4.13	Which medicines did she take to prevent malaria? RECORD ALL MENTIONED. AND ASK FOR EACH DRUG CIRCLED HOW MANY TIMES IT WAS TAKEN DURING THE PREGNANCY	1 = SP/Fansidar/Novidar |__|__| 2 = Other (specify _____) |__|__| 3 = Don't know	
4.14	Did she get the medicine during an antenatal visit, during another visit to a health facility or from some other source?	1 = Antenatal visit 2 = Another facility visit 3 = Other source (specify _____) 4 = Don't know	

4.15	Does her household have any mosquito nets that can be used while sleeping?	1 = Yes 2 = No → 3 = Don't know →	 Q4.23 Q4.23
4.16	How many mosquito nets does her household have?	1 = |__| nets 2 = Don't know	
4.17	Since she got the mosquito net, was it ever soaked or dipped in chemicals to repel mosquitoes or insects?	1 = Yes 2 = No → 3 = Not sure →	 Q4.19 Q4.19
4.18	When was the last time the net was soaked or dipped in these chemicals?	1 = |__|__| months ago 2 = Don't know	
4.19	Did anyone sleep under a mosquito net last night? If yes, who? CIRCLE ALL THAT APPLY	1 = Nobody 2 = Self 3 = Husband 4 = New baby 5 = All other children 6 = Some other children 7 = Other (specify _____) 8 = Don't know	
4.20	During this pregnancy, how often did she sleep under the mosquito net?	1 = Every night → 2 = Some nights 3 = Never 4 = Don't know	Q4.23
4.21	Why did she not sleep under the mosquito net every night?		Q4.23
4.22	Why does she not have any mosquito nets?		
4.23	IF THE HUSBAND IS NOT THE RESPONDENT, GO TO Q4.29 Did you ever talk with (NAME) about ways to prevent HIV?	1 = Yes 2 = No	
4.24	What methods did you ever try to prevent HIV? LIST ALL MENTIONED		
4.25	I do not want to know the result, but did (NAME) ever go for VCT?	1 = Yes 2 = No → 3 = Don't know →	 Q5.1 Q5.1
4.26	When did she go for VCT? READ OUT THE LIST OF RESPONSES	1 = During ANC visit 2 = A separate visit during this pregnancy 3 = Before she was pregnant 4 = After this pregnancy 5 = Don't know	
4.27	Where did she go?	1 = 2 = 3 = 4 = 5 = Other (specify _____) 6 = Don't know	
4.28	Did she go for testing together with her partner?	1 = Yes 2 = No 3 = Don't know	
4.29	Did she collect her results?	1 = Yes 2 = No 3 = Don't know	

1.1.1.1.1.1.1 Verbal autopsy	
5.1	We need to understand how and why (NAME) died. So please tell me the story of how the death came about, including all of the problems she had, from the beginning to the end. PROBE UNTIL THEY HAVE TOLD YOU EVERYTHING THEY CAN REMEMBER

Time of death and stage of pregnancy			
5.2	When did her death occur? AS WELL AS CIRCLING THE CORRECT CODE, ALSO WRITE THE CORRESPONDING NUMBER OF MONTHS OF PREGNANCY, OR WEEKS/DAYS AFTER BIRTH IF THE MOTHER DIED WITHIN 12 HOURS OF THE BABY'S BIRTH, WRITE "0" DAYS, IF FROM 13 HOURS TO ONE DAY WRITE "1" DAY	1 = Before 7 months (|__| months of pregnancy) →	Q6.1
		2 = After 7 months, but before labour started (|__|__| months of pregnancy) →	Q7.1
		3 = During labour, during the birth of the baby or after the baby was born (|__|__| days or |__| weeks after the delivery) →	Q8.1

Death before 7 months			
6.1	Did (NAME) die as the result of a miscarriage?	1 = Yes 2 = No →	Q6.4
6.2	How many months pregnant was she when the miscarriage happened?	|__| months	
6.3	What was the reason for the miscarriage?		
Illness in early pregnancy			
6.4	Did she have any vaginal bleeding?	1 = Yes 2 = No →	Q6.7
6.5	Did the bleeding soak her clothes, the mattress or the floor?	1 = Yes 2 = No	
6.6	Did she have stomach pain during the bleeding?	1 = Yes 2 = No	
6.7	Did she have a fever continuously for more than 24 hours?	1 = Yes 2 = No →	Q6.9
6.8	How many days did the fever last?	|__|__| days *or* |__|__| months	
6.9	Did she have a foul vaginal discharge?	1 = Yes 2 = No → 3 = Don't know →	Q6.11 Q6.11
6.10	How many days did the discharge last?	|__|__| days *or* |__|__| months	
6.11	Did she have any other problem or accident?	1 = Yes 2 = No →	Q9.1
6.12	If yes, explain…		

Death after 7 months, but before the start of labour			
7.1	Did she have vaginal bleeding before she died?	1 = Yes 2 = No →	 Q7.4
7.2	Did the blood soak her clothes, the mattress or the floor?	1 = Yes 2 = No	
7.3	Did she have stomach pain during the bleeding?	1 = Yes 2 = No	
7.4	Did she have any convulsions before she died?	1 = Yes 2 = No	
7.5	Did she have a headache for more than half a day?	1 = Yes 2 = No	
7.6	Was her face swollen during the pregnancy?	1 = Yes 2 = No	
7.7	Were her legs/feet swollen during the pregnancy?	1 = Yes 2 = No	
7.8	Was her vision blurred during the pregnancy?	1 = Yes 2 = No	
7.9	Was her blood pressure measured during the pregnancy?	1 = Yes 2 = No → 3 = Don't know →	 Q7.11 Q7.11
7.10	Do you know how her blood pressure was?	1 = Low 2 = Normal 3 = High 4 = Don't know	
7.11	Did she have a fever continuously for more than 24 hours during the pregnancy?	1 = Yes 2 = No 3 = Don't know	
7.12	Did she have burning when passing urine?	1 = Yes 2 = No 3 = Don't know	
7.13	Did she have a foul vaginal discharge for more than 24 hours?	1 = Yes 2 = No 3 = Don't know	
7.14	Was she breathless when doing the housework?	1 = Yes 2 = No 3 = Don't know	
7.15	Did she look pale?	1 = Yes 2 = No 3 = Don't know	
7.16	Did she have any other severe illness or accident in the 7 days before her death?	1 = Yes 2 = No →	 Q9.1
7.17	If yes, explain…		

Death during labour, during the birth of the baby, or after the baby was born			
8.1	Was her face swollen during the pregnancy?	1 = Yes 2 = No	
8.2	Were her legs/feet swollen during the pregnancy?	1 = Yes 2 = No	
8.3	Was her vision blurred during the pregnancy?	1 = Yes 2 = No	
8.4	Was her blood pressure measured during the pregnancy?	1 = Yes 2 = No → 3 = Don't know →	 Q8.6 Q8.6
8.5	Do you know how her blood pressure was?	1 = Low 2 = Normal 3 = High 4 = Don't know	
8.6	How long did the labour last?	|__|__| hours *or* |__|__| days	
8.7	Did the waters break more than 24 hours before the baby was born?	1 = Yes 2 = No 3 = Don't know	
8.8	Were the waters foul?	1 = Yes 2 = No 3 = Don't know	
8.9	What colour were the waters?	1 = Clear 2 = Brown 3 = Other (specify _____) 4 = Don't know	
8.10	Did (NAME) have vaginal bleeding during the labour?	1 = Yes 2 = No →	 Q8.16
8.11	Did the blood soak her clothes, the mattress or the floor?	1 = Yes 2 = No	
8.12	When did the bleeding occur?	1 = Before the baby was born 2 = After the baby was born	
8.13	Did she have stomach pain during the bleeding?	1 = Yes 2 = No	
8.14	Did she have a vaginal examination when she was ill?	1 = Yes 2 = No →	 Q8.16
8.15	Did the bleeding increase after the vaginal examination?	1 = Yes 2 = No	
8.16	Did she have any convulsions before she died?	1 = Yes 2 = No	
8.17	Did she have a fever in the 3 days before the labour?	1 = Yes 2 = No 3 = Don't know	
8.18	Did she have a foul vaginal discharge in the 3 days before the labour?	1 = Yes 2 = No 3 = Don't know	
8.19	Did she take any sort of pharmaceutical medicine before or after the labour?	1 = Yes 2 = No	
8.20	Did (NAME) drink 'mwana mphepo' medicine to assist labour?	1 = Yes 2 = No →	
8.21	How many spoonfuls did she drink?	|__| spoonfuls	
8.22	Did she take any other sort of traditional medicine before or after the labour?	1 = Yes 2 = No	
8.23	Which part of the baby came out first?	1 = Head 2 = Buttock 3 = Hand/foot 4 = Cord 5 = Don't know	
8.24	How did the baby come out?	1 = Normal 2 = Breech 3 = Forceps/vacuum	

		4 = Operation	
8.25	Did (NAME) die before the baby was born?	1 = Yes 2 = No →	Q8.28
8.26	Did she have any other sort of problem during labour?	1 = Yes 2 = No →	Q9.1
8.27	If yes, explain… NOW GO TO Q9.1		Q9.1
8.28	How long after the baby's birth did the placenta come out? IF THE BABY WAS BORN BY C-SECTION, CIRCLE "Within 30 minutes"	1 = Within 30 minutes 2 = Between 30 minutes and 1 hour 3 = Between 1 and 3 hours 4 = Between 3 and 12 hours 5 = Between 12 and 24 hours later 6 = She died before the placenta came out →	Q8.30
8.29	Did the placenta come out whole or in pieces?	1 = Whole 2 = In pieces 3 = Don't know	
8.30	After the delivery, did (NAME) have vaginal bleeding?	1 = Yes 2 = No →	Q8.32
8.31	Did the blood soak her clothes, the mattress or the floor?	1 = Yes 2 = No	
8.32	Did she have fever in the 3 days before she died?	1 = Yes 2 = No 3 = Don't know	
8.33	Did she have foul vaginal discharge in the 3 days before she died?	1 = Yes 2 = No 3 = Don't know	
8.34	Was she breathless when doing the housework?	1 = Yes 2 = No 3 = Don't know	
8.35	Did she look pale?	1 = Yes 2 = No 3 = Don't know	
8.36	Did she have trouble seeing at night?	1 = Yes 2 = No 3 = Don't know	
8.37	In the 7 days before she died, did she have any other illness or accident?	1 = Yes 2 = No →	Q9.1
8.38	If yes, explain…		

Part D: Problems, Healthcare-seeking and Treatment

Antenatal problems									
9.1 Did (NAME) have any serious problems while she was pregnant this time?							1 = Yes 2 = No ---------- (→ Q10.1)		
Now I would like to ask you about what (NAME) did when she had these problems									
9.2 What was the first/next problem (NAME) had? PROBE TO CAPTURE ALL PROBLEMS FROM PARTS 6 OR 7, AND ANY OTHERS	9.3 Did she consult anybody?	9.4 If not, why not? SKIP TO NEXT PROBLEM	9.5 If yes, who was the first/next person she consulted? WRITE ALL THAT APPLY	9.6 What did the person she consulted do?	9.7 Did she have to ask permission from anyone before she could go there? If yes, who?	9.8 How long was it from the start of her illness until she received treatment?	9.9 Did she go to anyone else for help? If yes, was she referred or did she go of her own accord?	9.10 Did she go?	9.11 If not, why not?
1	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
2	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
3	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
4	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
5	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
6	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
	1 = Yes → 9.5 2 = No → 9.2 (SKIP TO NEXT PROBLEM)		1 = Sing'anga 2 = TBA 3 = HSA 4 = Health worker in Lilongwe 5 = Health worker outside Lilongwe 6 = Grandmother 7 = Other relative 8 = Other (specify)		1 = No 2 = Husband 3 = Mother 4 = Father 5 = Mother-in-law 6 = Other relative 7 = Other (specify)		1 = Didn't go → Q9.2 (SKIP TO NEXT PROBLEM) 2 = Went without referral → Q9.5 (START A NEW LINE) 3 = Was referred → Q9.10	1 = Yes 2 = No IF YES, START AT Q9.5 WITH A NEW LINE	

Delivery Problems									
10.1 Did (NAME) have any serious problems during this delivery?							1 = Yes 2 = No ---------- (→ Q11.1)		
Now I would like to ask you about what (NAME) did when she had these problems									
10.2 What was the first/next problem (NAME) had? PROBE TO CAPTURE ALL PROBLEMS FROM PART 8, AND ANY OTHERS	10.3 Did she consult anybody?	10.4 If not, why not? SKIP TO NEXT PROBLEM	10.5 If yes, who was the first/next person she consulted?	10.6 What did the person she consulted do? WRITE ALL THAT APPLY	10.7 Did she have to ask permission from anyone before she could go there? If yes, who?	10.8 How long was it from the start of her illness until she received treatment?	10.9 Did she go to anyone else for help? If yes, was she referred or did she go of her own accord?	10.10 Did she go?	10.11 If not, why not?
1	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
2	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
3	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
4	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
5	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
6	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
	1 = Yes → 10.5 2 = No → 10.2 (SKIP TO NEXT PROBLEM)		1 = Sing'anga 2 = TBA 3 = HSA 4 = Health worker in Lilongwe 5 = Health worker outside Lilongwe 6 = Grandmother 7 = Other relative 8 = Other (specify)		1 = No 2 = Husband 3 = Mother 4 = Father 5 = Mother-in-law 6 = Other relative 7 = Other (specify)		1 = Didn't go → Q10.2 (SKIP TO NEXT PROBLEM) 2 = Went without referral → Q10.5 (START A NEW LINE) 3 = Was referred → Q10.10	1 = Yes 2 = No IF YES, START AT Q10.5 WITH A NEW LINE	

Post-natal Problems									
11.1 Did (NAME) have any serious problems after this delivery, including problems related to breastfeeding?							1 = Yes 2 = No ---------- (→ Q12.1)		
Now I would like to ask you about what (NAME) did when she had these problems									
11.2 What was the first/next problem (NAME) had? PROBE TO CAPTURE ALL PROBLEMS FROM PART 8, AND ANY OTHERS	11.3 Did she consult anybody?	11.4 If not, why not? SKIP TO NEXT PROBLEM	11.5 If yes, who was the first/next person she consulted?	11.6 What did the person she consulted do? WRITE ALL THAT APPLY	11.7 Did she have to ask permission from anyone before she could go there? If yes, who?	11.8 How long was it from the start of her illness until she received treatment?	11.9 Did she go to anyone else for help? If yes, was she referred or did she go of her own accord?	11.10 Did she go?	11.11 If not, why not?
1	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
2	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
3	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
4	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
5	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
6	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
	1 = Yes → 11.5 2 = No → 11.2 (SKIP TO NEXT PROBLEM)		1 = Sing'anga 2 = TBA 3 = HSA 4 = Health worker in Lilongwe 5 = Health worker outside Lilongwe 6 = Grandmother 7 = Other relative 8 = Other (specify)		1 = No 2 = Husband 3 = Mother 4 = Father 5 = Mother-in-law 6 = Other relative 7 = Other (specify)		1 = Didn't go → Q11.2 (SKIP TO NEXT PROBLEM) 2 = Went without referral → Q11.5 (START A NEW LINE) 3 = Was referred → Q11.10	1 = Yes 2 = No IF YES, START AT Q11.5 WITH A NEW LINE	

Part E: Family Planning and Relationships

IF THE HUSBAND IS NOT THE RESPONDENT, GO TO Q13.1 Now I would like to ask you some questions about family planning and sexual relationships in your family. I know that many people feel shy talking about these sorts of things, but I would like to assure you that everything you tell me will be kept in confidence.			
Family Planning			
12.1	Have you and (NAME) ever used family planning in the past? If yes, which methods? DO NOT READ THE LIST CIRCLE ALL METHODS MENTIONED PROBE FOR MORE ANSWERS	1 = Lactational amenorrhea 2 = Pill 3 = Norplant 4 = Depo (Injection) 5 = Condom 6 = Loop 7 = Chingwe 8 = Traditional medicine 9 = Following cycles 10 = Withdrawal 11 = Abstinence 12 = Others (specify_____) 13 = No	Q12.3 “ “ “ “ “ “ “ “ “ “ “ Q12.2
12.2	If not, why not?		
12.3	IF WOMAN DIED BEFORE 7 MONTHS OF PREGNANCY, GO TO Q12.4 How many months pregnant was (NAME) the last time you had sex before the delivery?	|__| months	
12.4	How many months after the birth were you planning to resume sex?	|__| months	
12.5	Did you use condoms during pregnancy or since the baby was born?	1 = During pregnancy 2 = After the birth 3 = Both during the pregnancy and after birth 4 = No →	Q13.1
12.6	How many times?	|__|__| times during pregnancy |__|__| times after the baby was born	
Relationships			
13.1	How many times has (NAME) ever been married or in a long-term relationship (lasting more than 12 months)? INCLUDE CURRENT RELATIONSHIP IF SHE WAS MARRIED	1 = |__|__| times 2 = Don’t know	
13.2	How old was she when she first entered such a relationship?	1 = |__|__| years 2 = Don’t know	
13.3	What was her marital status when she died?	1 = Married 2 = Single/never married → 3 = Divorced/separated → 4 = Widowed → 5 = Other (specify)	 Q13.12 Q13.12 Q13.12
13.4	How long was she in this relationship?	1 = |__|__| years |__|__| months 2 = Don’t know	
13.5	Did this man have any wives apart from her? If yes, how many?	1 = Yes |__| wives 2 = No	
13.6	Was she the first, second, third… wife?	|__|__| rank	
13.7	IF HUSBAND IS NOT THE RESPONDENT, GO TO Q13.10 How many nights did you sleep in the same room together in the month before she died?	|__|__| If 30 nights →	 Q13.9
13.8	How many nights did you stay in other places apart from her house in the month before she died? PROBE TO FIND OUT IF THE PLACE WAS OUTSIDE THE VDC, OUTSIDE THE TA, OUTSIDE DISTRICT, OR OUTSIDE MALAWI. FIND OUT WHETHER THE PLACE WAS A VILLAGE, A TRADING CENTRE OR A TOWN.	Place 1: _____ Reason: _____ _____ |__|__| nights	

	IF NO NIGHTS WERE SPENT IN OTHER PLACES, GO TO 9.8	Place 2: Reason: _____ _____ |__|__| nights Place 3: Reason: _____ _____ |__|__| nights Place 4: Reason: _____ _____ |__|__| nights	
13.9	How many times has this man ever been married before (not including (NAME) or co-wives)?	|__|__| times	
13.10	Taken altogether, how many children has this man ever fathered with other women (not including (NAME), but including co-wives)?	|__|__| children	

Part F: Exposure to Interventions

Now I would like to ask you some questions about community activities that (NAME) was involved with in your village			
14.1	Did (NAME) ever attend a Health Foundation women's group meeting?	1 = Yes 2 = No → 3 = Don't know →	 Q14.3 Q14.4
14.2	How many times did she go?	|__|__| times →	Q14.4
14.3	If no, why not?		
14.4	Who did she talk to about issues relating to pregnancy and newborn care in the last 4 months?	1 = Other women's group members 2 = Other female friends from the village 3 = Other female friends from another village 4 = Female relatives 5 = Husband 6 = Nobody 7 = Other (specify _____)	
14.5	Was she involved in any other community activities, groups or committees in the last year? If yes, what were they?		
14.6	Did she or her husband hold any of the following positions?	1 = Village headman 2 = Group village headman 3 = TBA 4 = Sing'anga 5 = HSA 6 = Member of village health committee 7 = Member of other community group (specify _____)	

This is the end of the interview…

This is the end of the interview. Thank you for sharing with us the details of the recent death of (NAME). We hope that we will be able to learn from her experiences and help other mothers and babies in Malawi in the future.

Feedback from the interviewer…	
Apart from the main respondent, did any other people provide information to help complete the interview?	1 = Husband 2 = Mother 3 = Mother-in-law 4 = Sister 5 = Woman's family member 6 = Husband's family member 7 = Friend/neighbour 8 = TBA 9 = Other (specify _____)
Was the interview interrupted at all? (Explain)	
Were there any other people around during the interview? (Specify who)	
Were there any questions that the respondent had problems answering? (Explain)	
Were there any questions that the respondent seemed to be holding back information on? (Explain why if possible)	
Any other comments	

Appendix 6: Perinatal Verbal Autopsy form

On arriving at the respondent's house – GREET THE RESPONDENT AND OFFER CONDOLENCES. ASK FOR A PRIVATE PLACE TO SIT AND CHAT, AWAY FROM OTHER PEOPLE. ASK THE RESPONDENT TO BRING HER HEALTH PASSPORT, IF SHE HAS ONE. CHAT A LITTLE BIT, TO HELP THE RESPONDENT TO FEEL RELAXED.

Consent – My name is _____. I am working with The Health Foundation Project. Our project is trying to improve the health of mothers and babies in Kasungu, Lilongwe and Salima. We are doing a survey of women who have recently given birth, in order to learn about their experiences. The purpose of this interview is to try and understand why your baby died, so that we can help to prevent other babies from dying in future. I am sorry that I am going to remind you about the death of your baby. I hope you will allow me to talk about it.

We assure you that everything you tell us will be kept confidential, and will only be used for study purposes. You do not have to take part in this research if you do not want to. If you do not wish to take part, this will not affect your right to take part in other Health Foundation activities in the future. If there are any questions that you do not want to answer, you do not have to answer them. There are no wrong answers to these questions. We just want to know about the experiences of pregnant women. If you do not understand a question, please ask me to explain it again.

This interview will take about one hour. Do you agree to take part?

Yes |__|

No |__|

Name of woman that died: first/second/alternative	
Name of head of household:	
Village name:	
TA name:	
Nearest Health Facility:	
Name of Interviewer	

Date of interview: |__|__|/|__|__|/|__|__|	Date received in office: |__|__|/|__|__|/|__|__|
	District Co-ordinator's signature:
Is the mother still alive?	1 = Yes 2 = No
What is the relationship of the respondent to the infant?	1 = Mother 2 = Father 3 = Mother's relative 4 = Father's relative 5 = Neighbour 6 = TBA 7 = Other (specify _____)

RECORD TIME STARTED INTERVIEW: __ __ : __ __

Part A: Details of the Birth

First I would like you to tell me the details about the birth of this baby			
Details of the birth			
1.1	What date was the baby born on?	Day/ Month/ Year __ __/__ __/__ __	
1.2	What date did the baby die on?	Day/ Month/ Year __ __/__ __/__ __	
1.3	Where did your baby die?	1 = At home 2 = On the way to treatment 3 = At a health facility (specify _____) 4 = At TBA's house 5 = At sing'anga's 6 = Other (specify _____)	
1.4	Was your baby a girl or a boy?	1 = Girl 2 = Boy 3 = Don't know	
1.5	What was the name of your baby? IF NOT GIVEN WRITE 'NO NAME' AND GO TO Q1.6		
1.6	Was the baby born at the expected time?	1 = Early 2 = On time 3 = Late	
1.7	After how many completed months of pregnancy was the baby born?	|__|__| months	
1.8	Was the baby one of twins?	1 = Yes 2 = No →	Q1.10
1.9	Was the baby the first or second born twin?	1 = First 2 = Second	
1.10	How big was the baby?	1 = Very large 2 = Average 3 = Very small 4 = Don't know	
1.11	Was the baby weighed at birth? CHECK HEALTH PASSPORT	1 = Yes 2 = No →	Q1.13
1.12	How much did the baby weigh? CHECK HEALTH PASSPORT	|__|•|__| kg	
1.13	Where was the baby born?	15 = TBA 16 = At home 17 = On the way to health facility 18 = Other (specify _____)	
1.14	Was there a fire, stove or any form of heating in the room?	1 = Yes 2 = No 3 = Don't know	
1.15	Who helped with the delivery?	1 = Doctor/Nurse/Clinical Officer/Midwife 2 = Other health worker 3 = TBA 4 = Relative/friend 5 = Nobody →	Q1.18
1.16	Did the person who helped wash his/her hands with soap before the	1 = Yes	

	delivery?	2 = No 3 = Don't know	
1.17	1.1.1.2 Did the person who helped wear gloves during the delivery?	1 = Yes 2 = No 3 = Don't know	
1.18	How was the baby delivered?	1 = Normal 2 = TBA/relative/friend pulled the baby or pushed on the belly 3 = Health worker used forceps 4 = Health worker did a caesarean section 5 = Health worker did a Vacuum Extraction	
1.19	Which part of the baby came out first?	1 = Head 2 = Buttock 3 = Hand/foot 4 = Cord 5 = Don't know	

Part B: Open History

Verbal autopsy	
2.1	We need to understand how and why your baby died. So please tell me the story of how the death came about, including all of the problems he/she had, from the beginning to the end. PROBE UNTIL THEY HAVE TOLD YOU EVERYTHING THEY CAN REMEMBER

Part C: Details of Illnesses Leading to the Death of the Baby

Congenital abnormalities			
3.1	Did the baby have any obvious deformity?	1 = Yes 2 = No →	Q3.7
3.2	Can you describe it for me?		
3.3	Did the baby have a very small head?	1 = Yes 2 = No	
3.4	Did the baby have a mass or defect on the back of the head or spine	1 = Yes 2 = No	
3.5	Did the baby have a cleft lip or palate?	1 = Yes 2 = No	
3.6	Did the baby have abnormal arms or legs	1 = Yes 2 = No	

Stillbirth or live birth			
3.7	Did the baby have bruises or signs of injury?	1 = Yes 2 = No 3 = Don't know	
3.8	Was the baby born alive or dead?	1 = Alive → 2 = Dead	Q4.1
3.9	Was the baby still moving when labour started?	1 = Yes → 2 = No 3 = Don't know	Q3.12
3.10	When did you last feel the baby moving?	|__|__| Days before labour started |__|__| Hours before labour started	
3.11	Do you think that the baby had died before you went into labour?	1 = Yes → 2 = No	Q3.15
3.12	Did the baby ever cry, even a little?	1 = Yes → 2 = No	Q4.1
3.13	Did the baby ever move, even a little?	1 = Yes → 2 = No	Q4.1
3.14	Did the baby ever breathe, even a little?	1 = Yes → 2 = No	Q4.1
3.15	Did the baby look like a normal baby, or had the skin and body changed and become pulpy/puffy/mushy/swollen?	1 = Yes 2 = No 3 = Don't know	
3.16	Was anything done to try to help the baby to breathe at birth?	1 = Yes 2 = No → 3 = Don't know →	 STOP STOP
3.17	What was done to try to help the baby to breathe?	1 = Stimulation 2 = Mouth to mouth 3 = Mouth to tube or mask 4 = Bag and mask	STOP STOP STOP STOP
THIS IS THE END OF THE INTERVIEW IF THE BABY WAS A STILLBIRTH. IF YOU HAVE NOT SKIPPED TO Q4.1, STOP THE INTERVIEW HERE AND THANK THE RESPONDENT			

Now I would like to ask you some more questions about the illness of the baby before he/she died			
Breathing difficulties			
4.1	Did the baby cry at birth?	1 = Yes → 2 = No	Q4.3
4.2	How long after birth did the baby first cry?	1 = Within 5 minutes 2 = Within 5-30 minutes 3 = More than 30 minutes 4 = Never	
4.3	Was anything done to try to help the baby to breathe at birth?	1 = Yes 2 = No →	 Q4.5
4.4	What was done to try to help the baby to breathe?	1 = Stimulation 2 = Mouth to mouth 3 = Mouth to tube or mask 4 = Bag and mask	
4.5	Was the baby sleepy and floppy at the time of birth?	1 = Yes 2 = No	
4.6	Did the baby ever have difficulty breathing?	1 = Yes 2 = No →	 Q4.15
4.7	What was the difficulty?	1 = Intermittent breathing 2 = Fast breathing	

4.8	When did the difficulty start?	1 = Immediately at birth 2 = Not immediately but within 6 hours 3 = More than 6 hours after birth	
4.9	How long did the difficulty continue?	|__|__| days	
4.10	Did the difficulty continue until the baby died?	1 = Yes 2 = No	
4.11	Was there chest indrawing?	1 = Yes 2 = No	
4.12	Was there grunting (demonstrate)?	1 = Yes 2 = No	
4.13	Was there nostril flaring (demonstrate)?	1 = Yes 2 = No	
4.14	Did the baby have pneumonia?	1 = Yes 2 = No	
Difficulty feeding			
4.15	Did the baby ever suckle normally?	1 = Yes 2 = No →	Q4.20
4.16	Did the baby always suckle normally?	1 = Yes → 2 = No	Q4.20
4.17	When did the problem start?	1 = On the day he/she was born 2 = After the day of birth but in the first 3 days 3 = After the first 3 days	
4.18	How long did the problem continue?	|__|__| days	
4.19	Did the feeding problem continue until the baby died?	1 = Yes 2 = No	
Tetanus			
4.20	Could the baby open her mouth?	1 = Yes 2 = No	
4.21	Did the baby arch her back and have spasms? SHOW PHOTO	1 = Yes 2 = No	
4.22	Did the baby have tetanus?	1 = Yes 2 = No	
Diarrhoea			
4.23	Did the baby have more frequent liquid stools than usual?	1 = Yes 2 = No	
4.24	Did the baby have diarrhoea?	1 = Yes 2 = No →	Q4.27
4.25	Was there blood in the stool?	1 = Yes 2 = No	
4.26	How long did the diarrhoea continue?	|__|__| days	
4.27	Did the baby vomit everything?	1 = Yes 2 = No	
Other illness			
4.28	Did the baby have a fever?	1 = Yes 2 = No →	Q4.31
4.29	When did the fever start	|__|__| days after birth	
4.30	How long did the fever continue?	|__|__| days	
4.31	Were the baby's skin and eyes very yellow?	1 = Yes 2 = No	
4.32	Did the baby have any fits/convulsions/seizures?	1 = Yes 2 = No →	Q4.34
4.33	On which day of life?	1 = First day 2 = After first day	
4.34	Did the baby feel cold?	1 = Yes 2 = No →	Q4.37

4.35	When did the baby start feeling cold?	|__| days	
4.36	How long did the baby feel cold?	|__|__| days |__|__| hours	
4.37	Did the baby have pustules on the skin?	1 = Yes 2 = No	
4.38	Did the baby have ear discharge?	1 = Yes 2 = No	
4.39	Did the baby have red eyes with pus in them?	1 = Yes 2 = No	
4.40	Did the baby have a bright red ring on the skin around the umbilical cord stump?	1 = Yes 2 = No	
4.41	Did the baby bleed?	1 = Yes 2 = No →	Q4.43
4.42	Where did the baby bleed from?		
4.43	What did the baby's fontanelle look like?	1 = Sunken down 2 = Normal 3 = Bulging up	
4.44	Did the baby become drowsy and unconscious when he/she had been normal before?	1 = Yes 2 = No	
4.45	How long was the baby ill before he/she died?	|__|__| days	
4.46	Did the baby die suddenly without any sign of illness?	1 = Yes 2 = No	
4.47	Did the baby have some other problem that we haven't discussed?	1 = Yes 2 = No →	Q5.1
4.48	What was the problem?		

Part C: The Newborn Baby

Now I would like to ask you some details about how you looked after the baby after he/she was born			
Newborn care			
5.1	What was the cord cut with?		
5.2	What was the cord tied with?		
5.3	What substances were put on the cord stump after it was cut?		
5.4	How long after birth was (NAME) wrapped up?	|__|__| hours |__|__| minutes	
5.5	How long after the birth was (NAME) bathed?	|__|__| hours |__|__| minutes	
5.6	What was the first thing the baby swallowed after he/she was born?		
5.7	Did (NAME) have a BCG immunisation? CHECK HEALTH PASSPORT IF AVAILABLE	1 = Yes 2 = No	
5.8	Did (NAME) have oral polio vaccine? CHECK HEALTH PASSPORT IF AVAILABLE	1 = Yes 2 = No	
Post-natal Check-up			
6.1	After the baby was born, did a health professional or a traditional birth attendant check on your or your baby's health? THIS DOES NOT INCLUDE CHECKS MADE BY HEALTH WORKERS IMMEDIATELY AFTER A DELIVERY AT A HEALTH FACILITY	1 = Yes 2 = No →	Q6.6
6.2	How many days after delivery did the first check take place?	|__|__| days	
6.3	Why did you go?	1 = Normal check-up 2 = Problem for mother 3 = Problem for baby	

6.4	Where did this first check take place? FOR OUTREACH SPECIFY WHERE THE OUTREACH WAS, NOT THE HEALTH FACILITY THAT IT CAME FROM	15 = TBA 16 = Outreach (specify _____) 17 = Other (specify _____)	
6.5	Since the delivery, have you received a dose of Vitamin A? SHOW VITAMIN A TABLET	1 = Yes → 2 = No →	Q7.1 Q7.1
6.6	Why was there not a check?		
Now I would like you to tell me about how you fed your baby			
Breastfeeding			
7.1	Did you ever breastfeed (NAME)?	1 = Yes 2 = No → 3 = Baby died immediately, before it could be given anything →	 Q7.3 Q9.1
7.2	How long after birth did you first breastfeed the baby/put (NAME) to the breast?	|__|__| hours |__|__| minutes	
7.3	What did you give (NAME) to drink in the first three days after delivery, before your milk began flowing regularly? PROBE 'Anything else?' RECORD ALL FOODS/DRINKS MENTIONED IF BREAST MILK ONLY, GO TO Q7.5		
7.4	Why did you give these things?		
7.5	Did (NAME) drink any pharmaceutical medicine after he/she was born? INCLUDE LIQUID MEDICINES AND LIQUID VITAMINS OR MINERALS AND COMMERCIAL GRIPE WATER	1 = Yes (specify _____) 2 = No →	 Q7.8
7.6	What was the medicine for?		
7.7	How many times did (NAME) drink pharmaceutical medicine?	|__|__| times	
7.8	Did (NAME) drink any traditional medicine after he/she was born?	1 = Yes (specify _____) 2 = No →	 Q7.11
7.9	What was the medicine for?		
7.10	How many times did (NAME) drink traditional medicine?	|__|__| times	
7.11	Did (NAME) drink any water after he/she was born?	1 = Yes 2 = No →	 Q7.13
7.12	How many times did (NAME) drink water?	1 = Only on the first day 2 = On some days 3 = Every day 4 = Other (specify) _____	
7.13	Were you still breastfeeding (NAME), until the day he/she died?	1 = Yes →	Q7.15

		2 = No	
7.14	Why did you stop breastfeeding?		
7.15	Did you have any problems with breastfeeding?	1 = Yes 2 = No →	Q7.20
7.16	What were they?		
7.17	Did you go, or were you referred to a health facility because of these problems?	1 = Went without referral 2 = Was referred 3 = Didn't go	
7.18	Did you change the way you fed your baby during the time you had breast problems?	1 = Yes 2 = No →	Q7.20
7.19	What did you do differently? WRITE ALL CHANGES MENTIONED		
7.20	Did you change the way you fed your baby at any time the time when you or your baby were sick after the delivery?	1 = No → 2 = Yes, when I was sick 3 = Yes, when the baby was sick 4 = Yes, for another reason (specify _____)	Q7.22
7.21	What did you do differently? WRITE ALL CHANGES MENTIONED		
7.22	Did anyone else (beside yourself) ever breastfed (NAME)?	1 = Yes 2 = No → 3 = Don't know →	Q7.24 Q7.24
7.23	Why did the other person breastfeed (NAME)?		
7.24	Did you ever express your breast milk after (NAME) was born?	1 = Yes 2 = No →	Q8.1
7.25	Did you give the expressed breast milk to (NAME)?	1 = Yes 2 = No →	Q7.27
7.26	How did you give the milk to (NAME)?	1 = Cup 2 = Bottle 3 = Other (specify _____)	
7.27	Did you heat-treat your breast milk?	1 = Yes 2 = No	
7.28	Why did you express milk?		
7.29	Who explained to you how to express the milk?	1 = Health worker 2 = Sister 3 = Mother 4 = Other family member 5 = Neighbour 6 = MaiMwana IF counsellor 7 = Other (specify _____)	

Feeding recall					
Now I would like you to tell me the details about how you fed (NAME)					
	First I'm going to ask you about all the things (NAME) drank during the first week after birth			IF THE BABY DIED WITHIN 7 DAYS AFTER BIRTH, GO TO Q9.1 Now I want to ask you about all the things (NAME) drank in the last 7 days before he/she died	
	8.1	8.2	8.3	8.4	8.5

		Before you gave any breast milk, was (NAME) given…	On the day he/she was born, was (NAME) given…	Between day 2 and day 7 after (NAME) was born, was he/she given…	On the day before (NAME) died, was he/she given…	Apart from the day before (NAME) died, in the last week, was he/she given…
01	Breast milk?					
02	Other milks?					
03	Water/dawale?					
04	Home-made gripe water/rice water/mzuwa?					
05	Phala?					
06	Other foods or drinks (specify)?					
07	Traditional medicines					
08	Pharmaceutical medicines					
09	Unsure of other foods or drinks given					
		1= Yes 2 = No 3 = Baby died 4 = Don't know	1= Yes 2 = No 3 = Baby died 4 = Don't know	1= Yes 2 = No 3 = Baby died 4 = Don't know	1= Yes 2 = No 3 = Baby died 4 = Don't know	1= Yes 2 = No 3 = Baby died 4 = Don't know

REMEMBER: **OTHER MILKS** INCLUDE COMMERCIAL FORMULA MILK, FRESH ANIMAL MILK, TINNED OR POWDERED MILK, FERMENTED OR SOUR MILK, YOGHURT, CHEESE, AND ALL OTHER MILK FROM A COW OR OTHER ANIMAL

Part H: Problems, Healthcare-seeking and Treatment – Baby

Now I would like to ask you about any help you sought for the problems (NAME) had, that we talked about earlier									
9.1 What was the first/next problem (NAME) had? CONTINUE UNTIL YOU HAVE COVERED ALL OF THE PROBLEMS MENTIONED IN PART 4	9.2 Did you consult anybody?	9.3 If NO, why not? SKIP TO NEXT PROBLEM AT Q9.1	9.4 If YES, who was the first/next person you consulted?	9.5 What did the person you consulted do? WRITE ALL THAT APPLY	9.6 Did you have to ask permission from anyone before you could go there? If YES, who?	9.7 How long was it from the start of the illness until (NAME) received treatment?	9.8 Did you go to anyone else for help for (NAME)? If YES, were you referred or did you go of your own accord?	9.9 Did you go?	9.10 If NO, why not?
1	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
2	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
3	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
4	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
5	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
6	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
	1 = Yes → 9.4 2 = No		1 = Sing'anga 2 = TBA 3 = HSA 4 = Health worker in Lilongwe 5 = Health worker outside Lilongwe 6 = Grandmother 7 = Other relative 8 = Other (specify)		1 = No 2 = Husband 3 = Mother 4 = Father 5 = Mother-in-law 6 = Other relative 7 = Other (specify)		1 = Didn't go → Q9.1 (SKIP TO NEXT PROBLEM) 2 = Went without referral → Q9.4 (START A NEW LINE) 3 = Was referred → Q9.9	1 = Yes 2 = No IF YES, START AT Q9.4 WITH A NEW LINE	

RECORD TIME FNISHED INTERVIEW: __ __ : __ __

This is the end of the interview…

This is the end of the interview. Thank you for sharing with us the details of the recent death of your baby. We hope that we will be able to learn from your experiences and help other mothers and babies in Lilongwe in the future.

Feedback from the interviewer…	
Apart from the respondent, did anyone else help to answer the questions in the interview?	1 = Father of the baby 2 = Grandmother of the baby 3 = Relative of the mother of the baby 4 = Relative of the father of the baby 5 = Friend/neighbour of the mother of the baby 6 = TBA 7 = Other (specify _____)
Was the interview interrupted at all? (Explain what happened)	
Were there any other people around during the interview? (Specify who)	
Were there any questions that the respondent had problems answering? (Explain)	
Were there any questions that the respondent seemed to be holding back information on? (Explain why if possible)	
Any other comments	

Appendix 7: Perinatal Verbal Autopsy short form

On arriving at the respondent's house – GREET THE RESPONDENT AND OFFER CONDOLENCES. ASK FOR A PRIVATE PLACE TO SIT AND CHAT, AWAY FROM OTHER PEOPLE. ASK THE RESPONDENT TO BRING HER HEALTH PASSPORT, IF SHE HAS ONE. CHAT A LITTLE BIT, TO HELP THE RESPONDENT TO FEEL RELAXED.

Consent – My name is _____. I am working with MaiKhanda. Our project is trying to improve the health of mothers and babies in Kasungu, Lilongwe and Salima. We are doing a survey of women who have recently given birth, in order to learn about their experiences. The purpose of this interview is to try and understand why your baby died, so that we can help to prevent other babies from dying in future. I am sorry that I am going to remind you about the death of your baby. I hope you will allow me to talk about it.

We assure you that everything you tell us will be kept confidential, and will only be used for study purposes. You do not have to take part in this research if you do not want to. If you do not wish to take part, this will not affect your right to take part in other MaiKhanda activities in the future. If there are any questions that you do not want to answer, you do not have to answer them. There are no wrong answers to these questions. We just want to know about the experiences of pregnant women. If you do not understand a question, please ask me to explain it again.

This interview will take about 20 minutes. Do you agree to take part?

Yes |__|

No |__|

Name of woman of baby that died: first/second/alternative	
Name of head of household:	
Village name:	
TA name:	
Nearest Health Facility:	
Name of Interviewer	
Date of interview: |__|__|/|__|__|/|__|__|	Date received in office: |__|__|/|__|__|/|__|__|
	District Co-ordinator's signature:
Is the mother still alive?	1 = Yes 2 = No
What is the relationship of the respondent to the infant?	1 = Mother 2 = Father 3 = Mother's relative 4 = Father's relative 5 = Neighbour 6 = TBA 7 = Other (specify _____)

RECORD TIME STARTED INTERVIEW: __ __ : __ __

Part A: Details of the Birth

First I would like you to tell me the details about the birth of this baby			
Details of the birth			
1.1	What date was the baby born on?	Day/ Month/ Year __ __/__ __/__ __	
1.2	What date did the baby die on?	Day/ Month/ Year __ __/__ __/__ __	
1.3	Where did your baby die?	1 = At home 2 = On the way to treatment 3 = At a health facility (specify _____) 4 = At TBA's house 5 = At sing'anga's 6 = Other (specify _____)	
1.4	Was your baby a girl or a boy?	1 = Girl 2 = Boy 3 = Don't know	
1.6	Was the baby born at the expected time?	1 = Early 2 = On time 3 = Late	
1.7	After how many completed months of pregnancy was the baby born?	|__|__| months	
1.8	Was the baby one of twins?	1 = Yes 2 = No →	Q1.10
1.10	How big was the baby?	1 = Very large 2 = Average 3 = Very small 4 = Don't know	
1.18	How was the baby delivered?	1 = Normal 2 = TBA/relative/friend pulled the baby or pushed on the belly 3 = Health worker used forceps 4 = Health worker did a caesarean section 5 = Health worker did a Vacuum Extraction	
1.19	Which part of the baby came out first?	1 = Head 2 = Buttock 3 = Hand/foot 4 = Cord 5 = Don't know	

Part B: Details of Illnesses Leading to the Death of the Baby

Congenital abnormalities			
3.1	Did the baby have any obvious deformity?	1 = Yes 2 = No →	Q3.8
3.3	Did the baby have a very small head?	1 = Yes 2 = No	
3.4	Did the baby have a mass or defect on the back of the head or spine	1 = Yes 2 = No	
3.5	Did the baby have a cleft lip or palate?	1 = Yes 2 = No	
3.6	Did the baby have abnormal arms or legs	1 = Yes 2 = No	

Stillbirth or live birth			
3.8	Was the baby born alive or dead?	1 = Alive → 2 = Dead	Q4.6
3.9	Was the baby still moving when labour started?	1 = Yes → 2 = No 3 = Don't know	Q3.12
3.11	Do you think that the baby had died before you went into labour?	1 = Yes → 2 = No	Q3.15
3.12	Did the baby ever cry, even a little?	1 = Yes → 2 = No	Q4.6
3.13	Did the baby ever move, even a little?	1 = Yes → 2 = No	Q4.6
3.14	Did the baby ever breathe, even a little?	1 = Yes → 2 = No	Q4.6
3.15	Did the baby look like a normal baby, or had the skin and body changed and become pulpy/puffy/mushy/swollen?	1 = Yes 2 = No 3 = Don't know	
3.16	Was anything done to try to help the baby to breathe at birth?	1 = Yes 2 = No → 3 = Don't know →	 STOP STOP
THIS IS THE END OF THE INTERVIEW IF THE BABY WAS A STILLBIRTH. IF YOU HAVE NOT SKIPPED TO Q4.6, STOP THE INTERVIEW HERE AND THANK THE RESPONDENT			

Now I would like to ask you some more questions about the illness of the baby before he/she died			
Breathing difficulties			
4.6	Did the baby ever have difficulty breathing?	1 = Yes 2 = No →	 Q4.16
4.7	What was the difficulty?	1 = Intermittent breathing 2 = Fast breathing	
4.11	Was there chest indrawing?	1 = Yes 2 = No	
4.12	Was there grunting (demonstrate)?	1 = Yes 2 = No	
4.13	Was there nostril flaring (demonstrate)?	1 = Yes 2 = No	
Difficulty feeding			
4.16	Did the baby always suckle normally?	1 = Yes → 2 = No	Q4.20
4.17	When did the problem start?	1 = On the day he/she was born 2 = After the day of birth but in the first 3 days 3 = After the first 3 days	
Tetanus			
4.20	Could the baby open her mouth?	1 = Yes 2 = No	
4.21	Did the baby arch her back and have spasms? SHOW PHOTO	1 = Yes 2 = No	
Diarrhoea			
4.24	Did the baby have diarrhoea?	1 = Yes 2 = No →	 Q4.27
4.25	Was there blood in the stool?	1 = Yes 2 = No	
4.26	How long did the diarrhoea continue?	|__|__| days	
4.27	Did the baby vomit everything?	1 = Yes 2 = No	

Other illness			
4.28	Did the baby have a fever?	1 = Yes 2 = No →	Q4.31
4.30	How long did the fever continue?	|__|__| days	
4.31	Were the baby's skin and eyes very yellow?	1 = Yes 2 = No	
4.32	Did the baby have any fits/convulsions/seizures?	1 = Yes 2 = No →	Q4.37
4.33	On which day of life?	1 = First day 2 = After first day	
4.37	Did the baby have pustules on the skin?	1 = Yes 2 = No	
4.40	Did the baby have a bright red ring on the skin around the umbilical cord stump?	1 = Yes 2 = No	
4.43	What did the baby's fontanelle look like?	1 = Sunken down 2 = Normal 3 = Bulging up	
4.44	Did the baby become drowsy and unconscious when he/she had been normal before?	1 = Yes 2 = No	

Part C: The Newborn Baby

Now I would like to ask you some details about how you looked after the baby after he/she was born			
Newborn care			
5.7	Did (NAME) have a BCG immunisation? CHECK HEALTH PASSPORT IF AVAILABLE	1 = Yes 2 = No	
5.8	Did (NAME) have oral polio vaccine? CHECK HEALTH PASSPORT IF AVAILABLE	1 = Yes 2 = No	

This is the end of the interview…

This is the end of the interview. Thank you for sharing with us the details of the recent death of your baby. We hope that we will be able to learn from your experiences and help other mothers and babies in Lilongwe/Kasungu/Salima in the future.

Appendix 8: Women's Group Register

WOMEN GROUP MEMBERS REGISTER (Should be compiled after every meeting) ***N*** = not pregnant; ***P*** = pregnant; ***M*** = mother													
	Women Group Facilitator					Village:				Women Group Name:			
	Woman's names	Village in which the woman lives	Age	**# of Children**	**Delivery Place**	**Meeting1**	Meeting 2	Meeting 3	Meeting 4	Meeting 5	Meeting 6	Meeting 7	Meeting 8
						Date	Date	Date	Date	Date	Date	Date	Date
						Location	Location	Location	Location	Location	Location	Location	Location
1						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
2						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
3						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
4						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
5						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
6						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
7						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
8						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
9						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
10						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
11						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
12						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
13						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
14						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
15						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
16						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**
17						**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**	**N P M**

Appendix 9: MNH Knowledge, Attitude and Practice Survey Questionnaire

STRICTLY CONFIDENTIAL

MAIKHANDA'S MATERNAL AND NEONATAL HEALTH PROGRAM IN RURAL COMMUNITIES OF MALAWI

Time Interview Started: Hour: _____ Minute: _____

A) District:	**……**	
B) Cluster No.:	**……**	
E) Village name:	**……**	
F) Respondent & Name No:	**……**	

	INTERVIEWER VISITS		
	1	**2**	**3**
DATE			
INTERVIEWER'S NAME:			
RESULT*			
NEXT VISIT : DATE			
TIME			

Verbal Consent Form

Hallo!

I am…….. I am from MaiKhanda. We have come here to find out about the health of mothers and babies to help you and your community keep mothers and babies healthy.We are asking many people in many communities the same questions because it helps leaders in the communities, in the district and in Government to see what are the common concerns of many people. It also helps everyone to see what new services are needed in the community to support mothers and babies and later on to see if they really make a difference.

Some of the questions I will ask you may seem very personal and if you don't feel comfortable with them you don't need to respond. But I assure you that your name will not be written on this paper, only your initials and a number. Your name will not be shared with anyone else and your answers to my questions will be combined with answers from many other people so that no one will know that the answers you give me today belong to you. Your privacy is protected and I assure that your answers are confidential. If you don't wish to participate or want to stop at any time, please feel free to do so.

May I proceed with the questions? Yes/No

"I have read the consent form completely before the respondent and the respondent voluntarily agreed to

participate in the study".

Name of interviewer: _____

Date _____

SECTION A: RESPONDENT'S BACKGROUND

No	Question	Codes	Skip rule
1.1	**How old are you?**	**Age……** **Don't Know……98**	
1.2	**Do you know how to read and write**	**No……0** **Yes……1**	
1.3	**Have you ever attended school?**	**No……0** **Yes……1**	**→ 1.5**
1.4	**What is the highest class you completed?**	**Standard 1……1** **Standard 2……2** **Standard 3……3** **Standard 4……4** **Standard 5……5** **Standard 6……6** **Standard 7……7** **Standard 8……8** **Form 1……9** **Form 2……10** **Form 3……11** **Form 4……12** **Post secondary……..13**	
1.5	**What is your occupation?**	**Labour …… 1** **Agriculture…… 2** **Private office employee…… 3** **Govt. office employee …… 4** **Small business – sewing, carpentry.. 5** **Shopkeeper …… 6** **Unemployed …… 7** **Student …… 8** **Incapacitated …… 9** **Others (Specify) _____ 10**	
1.6	**Are you married?**	**No……0** **Yes……1**	**→1.10**

1.7	**Did your husband ever attended school?**	**No…….0** **Yes……1**	
1.8	**What was the highest class he completed?**	**Standard 1……1** **Standard 2……2** **Standard 3……3** **Standard 4……4** **Standard 5……5** **Standard 6……6** **Standard 7……7** **Standard 8……8** **Form 1……9** **Form 2……10** **Form 3……11** **Form 4……12** **Post secondary……..13** **Don't know……98**	
1.9	**What is your husband's occupation?**	**Labour …… 1** **Agriculture…… 2** **Private office employee…… 3** **Govt. office employee …… 4** **Small business – sewing, carpentry.. 5** **Shopkeeper …… 6** **Unemployed …… 7** **Student …… 8** **Incapacitated …… 9** **Others (Specify) _____ 10**	
1.10	**What form of transport do you normally use to go to the health facility where you go for most of your health care needs?**	**Walking ……1** **Bus ……2** **Bicycles ……3** **Bicycle Ambulance……4** **Other (specify) _____ 9**	
1.11	**How far is your village to the health facility?**	**In Kilometres:……** **Don't know……98**	
1.12	**How much does it cost to use this transportation to go from your home to the facility and then return home?**	**MK ……** **No cost (walking) ……97** **Don't know…… 98**	
1.13	**In the past 12 months, have you ever been unable to access health services because service delivery point was not staffed?**	**No ……0** **Yes……1** **Don't know …… 8**	

1.14	**In the past 12 months, have you ever been unable to access health services because travel between home and service delivery point was unsafe?**	**No ……..0** **Yes……..1** **Don't know …….. 8**	

SECTION B: FERTILITY

Interviewer: "*Now I would like to ask you about pregnancy and child bearing"*

No	Question	Codes	Skip rule
2.1	**How old were you when you (first) got married?**	**Age …….** **Don't Know……98**	
2.2	**How old were you when you first became pregnant?**	**Age …….** **Don't Know……98**	
2.3	**How many times have you been pregnant?**	**# of times……** **Don't know……98**	
2.4	**What was the outcome of your most recent delivery?**	**Live birth……1** **Still birth……..2** **Abortion……...3** **Don't know……..4**	
2.5	**Are you pregnant now?**	**No……..0** **Yes……1** **Unsure……8**	
2.6	**At the time you last became pregnant did you want to become pregnant** then, later **or** not want at all**?**	**Then …….. 1** **Later …….. 2** **Not at all …….. 3**	
2.7	**How many sons and daughters have been ever born to you (including those who might currently be away from home)?** (IF NONE ENTER "00".)	**Total sons:……..** **Total daughters……..**	
2.8	**How many children were delivered at ……..** (IF NONE ENTER "00".)	**Health Facility……..** **TBA……** **Home……..** **On the way……..**	
2.9	**Of all the children born to you, how many sons and daughters are alive now?** (IF NONE ENTER "00".)	**Total sons:……..** **Total daughters……..**	
2.10	**How many of your children who were born alive died in the first month of life?**	**# of Children……..**	
2.11	**Have you ever delivered a child who was (**gestation period 28 weeks or more**) stillborn?**	**No……..0** **Yes……1**	
2.12	**How many times have you delivered a stillborn child?**	**# of times……..**	
2.13	**Is your youngest child alive or dead?**	**Alive……..1**	**→ 3.1**

		Dead……..2	
2.14	**Where did the child die?**	**Health facility……1** **Home……...2** **TBA……3** **On the Road……4** **Others……..5**	

SECTION 3: ANTENATAL CARE

Interviewer*: "Now, I would like to ask you some questions about when you were pregnant prior to your most recent delivery."*

No	Question	Codes				Skip rule
3.1	**Did you see anyone for antenatal care for the pregnancy prior to your most recent delivery?**	**No……0** **Yes……...1**				**→ 3.3**
3.2	**Whom did you see?**	**Doctor……..1** **Nurse……2** **HSA……3** **Ward Attendant……4** **TBA……5** **Others……..6**				
3.3	**How many times did you receive antenatal care during the pregnancy prior to your most recent delivery?**	**# of times……..** **Don't know……98**				
3.4	**How many months pregnant were you when you first received antenatal care for the pregnancy prior to your most recent delivery?**	**# of months……..** **Don't know……98**				
3.5	**As part of your antenatal care during the pregnancy prior to your most recent delivery, were any of the following done at least once?** Read each service, circle appropriate response		**Yes**	**No**	**DK**	
	1. Was your abdomen examined?		**1**	**0**	**8**	
	2. Did you receive iron tablets?		**1**	**0**	**8**	
	3. Did you receive deworming tablets?		**1**	**0**	**8**	
	4. Did you receive TT vaccination?		**1**	**0**	**8**	
	5. Was your weight measured?		**1**	**0**	**8**	
	6. Was your height measured?		**1**	**0**	**8**	
	7. Was your blood pressure measured?		**1**	**0**	**8**	
	8. Did you give a urine sample?		**1**	**0**	**8**	
	9. Did you give a blood sample?		**1**	**0**	**8**	
3.6	**Where did you receive antenatal care for your most recent antenatal care visit?** Multiple choice	**Hospital……1** **Health centre……2** **TBA……3** **Health Post……4**				

		Mobile clinic……..5 **Others……6** **Don't Know……..98**			
3.7	**During any of your antenatal care visits with health workers during your pregnancy prior to your most recent delivery, were you counseled on:** (READ ALL RESPONSES)	**Yes**	**No**	**DK**	
	1. Financial preparation for your delivery?	**1**	**0**	**8**	
	2. Breastfeeding immediately after birth?	**1**	**0**	**8**	
	3. Danger signs during pregnancy?	**1**	**0**	**8**	
	4. Tetanus toxoid vaccination?	**1**	**0**	**8**	
	5. Wrapping the newborn?	**1**	**0**	**8**	
	6. Using a skilled birth attendant?	**1**	**0**	**8**	
	7. Family planning?	**1**	**0**	**8**	
	8. Identifying emergency transport options?	**1**	**0**	**8**	
	9. Arranging for blood in case of emergency?	**1**	**0**	**8**	
3.8	**Did you discuss planning for your delivery with your husband while you were pregnant?**	**No……0** **Yes……..1**			
3.9	**Who are the people who accompanied you at least one time to your antenatal care?** (Circle all responses.)	**Husband……1** **Mother-in-law . . . ……2** **Father-in-law……3** **Mother…… ……4** **Other family member…… 5** **Friend / Neighbor ……6** **Other (specify)_____7** **Nobody (went alone) ……8** **Don't know……98**			
3.10	**In total, how many injections for TT have you had in your lifetime?**	**Number of shots……** **Don't know……98**			
3.11	**During the whole pregnancy, for how many days did you take the iron tablets?**	**Number of days……** **Don't know……98**			
3.12	**When you were pregnant, did you eat less than usual, about the same amount as usual, or more than usual?**	**Less than usual……1** **Same as usual……2** **More than as usual ……3** **Don't know…… .98**			
3.13	**When you were pregnant, did you receive less care and support than usual, about the same care and support as usual, or more care and support than usual from your family members?**	**Less than usual……1** **Same as usual……2** **More than as usual ……3** **Don't know…… .98**			
3.14	**Please tell me where you can go for health services if you have danger signs while you are pregnant.**	**Hospital……1** **Health centre……2**			

		TBA……3 **At home……..4** **Others……5** **Don't Know……..98**	
3.15	**How many check-ups should a woman have with a trained health worker while she is pregnant?**	**# of checkups _____** **Don't know 98**	
3.16	**What are the symptoms during pregnancy indicating the need to seek immediate care?** (CIRCLE ALL RESPONSES GIVEN)	**Vaginal bleeding (any amount) ..... 1** **Severe lower abdominal pain.....2** **Severe headache.....3** **Convulsion.....4** **Blurred vision / swelling of hands/ face.....5** **Other (specify).....6** **Don't know.....98**	

3.17	**When you were pregnant, did you experience any of the following problems at anytime?** Read out all responses one after another	**Yes**	**No**	
	1 Blurred vision?	**1**	**0**	
	2 Severe lower abdominal pain?	**1**	**0**	
	3 Severe headache?	**1**	**0**	
	4 Convulsion?	**1**	**0**	
	5 Swelling of the hands, body or face?	**1**	**0**	
	6 Any vaginal spotting or bleeding?	**1**	**0**	
	7 None of the above	**1**	**0**	

3.18	**What did you do for the problems that you stated above?** Circle all answers	**Go to traditional healers…… .... 1** **Go to Hospital …….. 2** **Go to Health Centre…….. 3** **Go to Health Post……4** **Bought medicine from pharmacy ... 5** **Go to TBA …….. ....6** **Others……7** **Nothing ……8**	→

SECTION D: DELIVERY CARE

Interviewer*: "Now, I would like to ask you some questions about your most recent delivery."*

No	Question	Codes	Skip rule
4.1	**Where did you give birth in your most recent delivery?**	**Health facility ……1** **TBA……2** **At home……..3** **Others……4**	**→ 4.3**
4.2	**Why didn't you deliver in a health facility?** Circle all responses.	**Cost too much …… 1** **Facility not open …… 2** **Too far / no transportation ……. 3** **Don't trust facility / poor quality service ……4** **No female provider at facility …… 5** **Husband / family did not allow ….. 6** **Not necessary …… 7** **Not customary …… 8** **Other (specify) _____ 9**	
4.3	**Who assisted with your most recent delivery?**	**Doctor……1** **Staff Nurse . . . ……2** **Patient Attendant……3** **TBA……4** **Relative/Friend ……5** **Other (specify)_____6** **Nobody …… …..7**	
4.4	**Do you think it is important for pregnant women to deliver at health facility?**	**No……0** **Yes……1**	**→ 4.6**
4.5	**Why do you think it is important for pregnant women to delivery at health facility?** (Circle all responses.)	**To examine the condition of mother and child……1** **To confirm the position of the fetus….2** **For infection free delivery……3** **For the safety of mother ……4** **For the safety of child……5** **To manage complications easily……6** **To identify danger signs ……7** **To receive adequate care in case of serious problem with the delivery …… 8** **In order to have a normal delivery ….. 9** **Other (specify)…… 10** **Don't know ……98**	
4.6	**In your opinion, what things need to be kept clean during childbirth?**	**Birth attendant's nails …… 1** **Birth attendant's hands …… 2**	

	(Circle all responses.)	**Blade ..... 3** **Surface ..... 4** **Thread ..... 5** **Mother's perineum..... 6** **Baby's clothes ..... 7** **Other (specify) _____ 8** **Don't know..... 98**	
4.7	**What are the signs/symptoms during labor indicating the need to seek immediate care?** (Circle all responses.)	**Labor longer than 8 hours ..... 1** **Appearance first of any part of the baby that is not the head ..... 2** **Excessive bleeding before or after delivery ..... 3** **Convulsion ..... 4** **Other (specify) _____ 5** **Don't know..... 98**	

4.8	**During your delivery, did you experience any of the following problems at anytime?** (Read out all responses one after another.)	**Yes**	**No**	**For any Response SKIP 4.9**
	1 So much bleeding that you feared it was life threatening?	**1**	**0**	
	2 Convulsions?	**1**	**0**	
	3 Prolonged labor (>8 hours)?	**1**	**0**	
	4 The baby's hand, leg or cord came out first ?	**1**	**0**	
	5 None of the above	**1**	**0**	

4.9	**Did a health worker refer you or advise you to go to a health facility for delivery during your recent pregnancy?**	**No……0** **Yes……1** **Don't know……..98**	**→ 4.12**
4.10	**After you were advised to deliver at the health facility, did you go to any health facility?**	**No……0** **Yes……1**	
4.11	**Where did you go for delivery?**	**Hospital……..1** **Health Centre……2** **Others……3**	
4.12	**In the past three months, have you seen, heard, or read anything about health facility delivery?**	**No……0** **Yes……2**	**→ 4.14**

4.13	**Please tell me where you saw or heard a message about health facility delivery.**		Yes	No	
	1.	**On walls of the houses**	**1**	**0**	
	2.	**MNH Taskforce members**	**1**	**0**	
	3.	**From TBA**	**1**	**0**	

	4.	**From a health worker at the health facility**	**1**	**0**	
	5.	**Women group members**	**1**	**0**	
	6.	**Posters, pamphlets, leaflets**	**1**	**0**	
	7.	**Newspapers**	**1**	**0**	
	8.	**Radio**	**1**	**0**	
	9.	**TV**	**1**	**0**	
	10.	**Women Group Facilitators**	**1**	**0**	
	11.	**Public meetings**	**1**	**0**	
	12.	**Others**	**1**	**0**	
4.14	**Have any friends, family members or other acquaintances spoken with you informally during the past two months about going to health facility for delivery?**		**No……0** **Yes……1**		
4.15	**"Some people say it is not necessary to deliver a baby at a health facility." Do you agree?**		**Strongly disagree ……1** **Disagree …… 2** **Agree …… 3** **Strongly agree …… 4**		
4.16	**"If you have another delivery, you will not deliver at any health facility." Do you agree?**		**Strongly disagree …… 1** **Disagree …… 2** **Agree …… 3** **Strongly agree …… 4**		
4.17	**"All the pregnant mothers in your community should deliver their babies at the health facility." Do you agree?**		**Strongly disagree …… 1** **Disagree …… 2** **Agree …… 3** **Strongly agree …… 4**		

SECTION E: POSTNATAL CARE

Interviewer**: *"Now I am going to ask you some more detailed questions about the postnatal care that you received."***

No	Question	Codes	Skip rule
5.1	**Did a health professional check on your health during the** first three days **after birth?**	**No……0** **Yes……1**	
5.2	**Did a health professional check on your health at day** seven **after birth?**	**No……0** **Yes……1**	**→ 5.5**
5.3	**Who checked on your health at the health facility during the** first Seven days **after birth?** Circle all responses.	**Doctor …… 1** **Nurse ….. …… 2** **Patient Attendant…… 3** **HSA ……4** **Other (specify) _____ 5** **Don't know/ don't remember……98**	

5.4	**Where did these checks take place?** Circle all responses	**Hospital……1** **Health Centre……2** **Health Post……3** **During mobile clinics……4** **At Home …… 5** **Other (specify) _____ 9**	For any answer SKIP to 5.6
5.5	**Why didn't you go to a health facility at day seven after delivery?** Circle all responses.	**Do not think it is necessary……1** **Do not know who to ask ……2** **No service available nearby……3** **No practice in the community……4** **Family members do not allow….5** **Will cost too much ……6** **Received treatment from traditional healer ……7** **Didn't know I should get a checkup…. 8** **Felt unsafe to go …… 9** **The facility is too far from here……10** **Other (specify) _____ 11**	
5.6	**Did a health professional check on your health between** eight days and six weeks **after birth?**	**No……0** **Yes……1**	**→ 5.10**
5.7	**How many times did a health professional check on your health** between eight days and six weeks **after birth?**	**# times: _____** **Don't Know …… 98**	
5.8	**Where did these checks take place?** Circle all responses	**Hospital……1** **Health Centre……2** **Health Post……3** **During mobile clinics……4** **At Home …… 5** **Other (specify) _____ 9**	
5.9	**Did you go to a health facility approximately 6 weeks after your most recent delivery for a checkup?**	**No……0.** **Yes……1**	**→ 5.14**
5.10	**Why didn't you go to a health facility?** (Circle all responses.)	**Do not think it is necessary……1** **Do not know who to ask ……2** **No service available nearby……3** **No practice in the community……4** **Family members do not allow….5** **Will cost too much ……6** **Received treatment from**	

		traditional healer ……7 **Didn't know I should get a checkup…. 8** **Felt unsafe to go …… 9** **The facility is too far from here……..10** **Other (specify) _____ 11**	

5.11	**Which of the following activities were conducted by the health worker during your postnatal checkup?** (READ ALL)	**Yes**	**No**	**DK**	
	1 Examination of abdomen?	**1**	**0**	**8**	
	2 Asked if you had excessive bleeding / severe abdominal pain?	**1**	**0**	**8**	
	3 Counseled you about Family Planning?	**1**	**0**	**8**	
	4 Counseled you about breastfeeding?	**1**	**0**	**8**	
	5 Counseled you about immunization?	**1**	**0**	**8**	
	6 Provided advice on newborn care?	**1**	**0**	**8**	

5.12	**Did you take your baby when you visited the health facility approximately six weeks postdelivery?**	**No……..0** **Yes……1**	→ **5.16**
5.13	**Why not?** (Circle all responses.)	**Do not think it is necessary……1** **Do not know who to ask ……2** **No service available nearby……3** **No practice in the community…….4** **Family members do not allow…….5** **Will cost too much ……6** **Received treatment from traditional healer ……7** **Didn't know newborn needs checkup .. ……8** **Felt unsafe to take my child ……. 9** **Other (specify) _____10**	

5.14	**Which of the following activities were conducted by the health worker during your baby's checkup? (**READ ALL)	**Yes**	**No**	**DK**	
	1 Health worker asked questions about baby's feeding habits?	**1**	**0**	**8**	
	2 Baby was weighed	**1**	**0**	**8**	
	3 Baby was given vaccination?	**1**	**0**	**8**	

	4 Baby received physical examination?	**1**	**0**	**8**	
5.15	**After your most recent delivery, for about how many days did you take iron or folic tablets?** (If not taken at all enter '000')	**Number of days……..** **Don't know……98**			
5.16	**In the first 42 days after delivery, did you receive a Vitamin A dose?**	**No……0** **Yes……1**			
5.17	**What are the symptoms of the mother indicating the need for her to seek immediate health care during the first six weeks after delivery?** (Circle all responses.)	**High fever…… 1** **Pain in lower abdomen or smelling/ vaginal discharge…… 2** **Excessive bleeding…… 3** **Severe headache…… 4** **Convulsion and fit…… 5** **Others (Specify)_____ 6** **Do not know…… 98**			
5.18	**Following your delivery, did a health worker counsel you on the following maternal danger signs or issues?** (READ ALL)		**Yes**	**No**	
	1 High fever?		**1**	**0**	
	2 Severe lower abdominal pain?		**1**	**0**	
	3 Smelly discharge?		**1**	**0**	
	4 Excessive bleeding?		**1**	**0**	
	5 Severe headache?		**1**	**0**	
	7 Breast problems?		**1**	**0**	
	8 Where to go for services?		**1**	**0**	
5.19	**Within how many days after birth should mothers and newborns have their health checked by a health worker ?**	**Days: ……..** **Don't know……98**			
5.20	**During the six weeks following your most recent delivery, did you experience any of the following problems at anytime?** (Read out all responses one after another)		**Yes**	**No**	
	1 So much bleeding that you feared it was life threatening?		**1**	**0**	
	2 High fever?		**1**	**0**	
	3 Severe lower abdominal pain?		**1**	**0**	
	4 Convulsions?		**1**	**0**	
	5 None of the above			**7**	
5.21	**What did you do for the problems that you stated above?**	**Go to traditional healers…… …. 1** **Go to Hospital …… 2** **Go to Health Centre…… 3**			→

	Circle all answers	**Go to Health Post……4** **Bought medicine from pharmacy … 5** **Go to TBA …… ….6** **Bought medicine from grocery……7** **Others……8** **Nothing ……9**	

SECTION F: IMMEDIATE NEWBORN CARE

Interviewer*: "Now, I would like to ask you some questions about the care of your child after delivery."*

No	Question	Codes	Skip rule
6.1	**What instrument was used to cut the cord?**	**Razor Blade……1** **Knife……2** **Scissor……7** **Other (specify) _____8** **Don't know ……98**	
6.2	**What was used to tie the cord?**	**New ties …… 1** **String or thread …… 2** **Twine…… 3** **Other (specify) _____4** **Don't know ……8**	
6.3	**Did anybody apply anything on the stump after the baby's cord was cut?**	**No ……0** **Yes……1** **Don't know ……8**	**→ 6.5** **→ 6.5**
6.4	**What did they apply?** (Circle all responses)	**Oil……1** **Ash……2** **Animal dung……3** **Powder……4** **Spilit ……5** **Other (specify) _____ 6** **Don't know……98**	
6.5	**How long after birth was your baby bathed for the first time?**	**Within 1 hour …… 1** **2-24 hours …… 2** **After 24 hours …… 3** **Don't know……8**	
6.6	**Did you ever breastfeed (NAME)?**	**No……0** **Yes……1**	**→ 6.8**

6.7	**How long after birth did you first put (NAME) to the breast?**	**During the first hour after delivery….1** **More than 1 hour. ……..2** **Don't know……..8**	
6.8	**Did you give (NAME) the first liquid that came from your breasts?**	**No……0** **Yes……1**	
6.9	**In the first three days after birth was (NAME) given anything to drink other than breast milk?**	**No……0** **Yes……1**	
6.10	**Are you still breastfeeding (NAME)?**	**No……0** **Yes……1**	
6.11	**At how many completed months of age did you first start giving food or drink other than breastmilk to your baby?**	**# months: ___ ___** **Baby exclusively breastfed until now 95** **Don't know …….. 98**	
6.12	**Please tell me when should a newborn child be bathed after the birth?**	**Immediately after the birth……..1** **Within 24 hours after birth……..2** **After 24 hours after birth……..3** **Should not be bathed……..4** **Other (specify) _____ 5** **Don't know……..8**	
6.13	**Please tell me when should a newborn child be breast fed for the first time after the birth?**	**Immediately after the birth……..1** **After the placenta is out……2** **After bathing the new born……..3** **After 24 hours after birth……4** **Other (specify) _____ 5** **Don't know……..8**	

SECTION G: NEWBORN CARE DURING FIRST MONTH

Interviewer*: "Now, I would like to ask you some questions about the health of your child during the month after your most recent delivery."*

No	Question	Codes	Skip rule
7.1	**What are the symptoms of *the infant within 7 days after delivery* indicating the need to seek immediate health care?** Circle all responses	**Poor sucking or feeding……. 1** **Fast or difficult breathing ….. 2** **Feels cold or too hot…… .3** **Difficult to wake/ lethargic/**	

		unconscious……4 **Pustules on skin 1 large or more than 10 small ones……5** **Severe umbilical infection redness of skin around the cord/ foul smelling discharge ……6** **Other (specify) _____ 7** **Don't know……98**	
7.2	Interviewer: - Observation-Which of the following conditions is true: **Baby still alive……1** **Baby born alive, then died at 2+ months……2** **Baby born alive, then died at 0-1 months……3** **Baby stillborn……4**		**→7.11**
7.3	**During the first four weeks after your most recent delivery, did a health professional check on your newborn's health?**	**No……0** **Yes……..1**	**→7.7**
7.4	**During the** first three days **after your most recent delivery, did a health professional check on your newborn's health?**	**No……0** **Yes……..1**	
7.5	**At** day Seven **after your most recent delivery, did a health professional check on your newborn's health?**	**No……0** **Yes……..1**	
7.6	**Who checked on your newborn's health between** four days and four weeks **after birth?** (Circle all responses.)	**Doctor ..... 1** **Nurse .... 2** **Patient Attendant..... 3** **HSA ……4** **Other (specify) _____ 5** **Don't know/ don't remember...98**	

7.7 Prior to or following your delivery, did a health worker counsel you at any time on the following newborn issues? (READ ALL)

	Yes	No	DK
1 Keeping the baby warm?	**1**	**0**	**8**
2 Immunization?	**1**	**0**	**8**
3 Newborn Danger signs (e.g. fast breathing, poor feeding,	**1**	**0**	**8**
4 Cord care?	**1**	**0**	**8**
5 Special care of small baby?	**1**	**0**	**8**
6 Breastfeeding ?	**1**	**0**	**8**

7.8	**During the first four weeks of your newborn's life, did you or any of your family members ever put the baby directly on your skin and keep her there for some time to help keep her warm?**	**No……..0** **Yes……1**	

7.9	**Did your newborn experience any of the following health problems at anytime in the first four weeks following delivery?** (Record all responses accordingly.)		**Yes**	**No**
	1. Fever?		**1**	**0**
	2. Feeding problem?		**1**	**0**
	3. Fast and difficult breathing?		**1**	**0**
	4. Chest-in-drawing?		**1**	**0**
	5 Drowsy/unconscious?		**1**	**0**
	6 Convulsions?		**1**	**0**
	7 Skin pustules?		**1**	**0**
	8 Skin around cord red?		**1**	**0**
	9 Felt cold?		**1**	**0**
	10 None of the above			**7**
7.10	**What did you do for the problems that you stated above?** (Circle all answers)	**Go to traditional healers…… …. 1** **Go to Hospital …… 2** **Go to Health Centre…….. 3** **Go to Health Post……4** **Bought medicine from pharmacy .. 5** **Go to TBA …… ….6** **Bought medicine from grocery….7** **Others……8** **Nothing ……9**		→
7.11	**When your child was born, was s/he very large, larger than average, average, smaller than average, or very small?**	**Very large …… 1** **Larger than average …… 2** **Average …… 3** **Smaller than average …… 4** **Very small …… 5** **Don't know …… 8**		For any Response given GO TO 7.15
7.12	**Was your child weighed at birth or at any time after birth?**	**No……0** **Yes……..1** **Don't know……98**		
7.13	**How old in days was your child when s/he was weighed for the first time?**	**In days:……** **Don't know …… 98**		
7.14	**Were you ever told by a health worker that your baby was smaller than average?**	**No……0** **Yes……..1**		
7.15	**Do you think that newborn babies that are smaller than**	**No……0**		

	average are at greater danger of dying than newborn babies that are of average or larger than average size?	**Yes……1** **Don't Know……98**	
7.16	**What things are most dangerous to the health of a newborn baby that is smaller than average?** (Circle all responses.)	**Can become cold easily……1** **Doesn't eat properly……2** **Becomes sick easily……3** **Other (specify)……4**	

SECTION H: BIRTH PREPAREDNESS

Interviewer: "*Now I will ask you some questions about how you prepared for the arrival of your child"*

No	Question	Codes	Skip rule
8.1	**During your last pregnancy did you make any preparations for your delivery?**	**No……..0** **Yes……1**	**→ 8.3**
8.2	**What preparation did you make for the delivery?** MULTIPLE RESPONSES	**Financial……1** **Transport……..2** **Food……..3** **Identification of birth attendant…..4** **Identification of facility……5** **Blood donor……..6** **Materials for clean delivery……..7** **Others……8**	
8.3	**Did you or any member of your family set aside any money specifically for care during the delivery?**	**No……..0** **Yes……1**	**→ 8.5**
8.4	**How much money did you set aside specifically for care during the delivery?**	**MK_____** **Don't Know……98**	
8.5	**During your last pregnancy did you arrange ahead of time to have someone attend your delivery?**	**No……..0** **Yes……1**	**→ 8.7**
8.6	**Who did you arrange to attend your delivery?** MULTIPLE RESPONSES	**Doctor……1** **Nurse……..2** **TBA……3** **Relatives/Friends……4** **Others……5**	
8.7	**During your last pregnancy did you arrange for a place to deliver your child?**	**No……..0** **Yes……1**	**→ 8.9**
8.8	**Where did you arrange to deliver your child?**	**Health Facility……1** **TBA……2** **At Home……..3** **Others……4**	
8.9	**Did you make any preparation for care of Yourself and newborn during the first month following the delivery?**	**No……0** **Yes……..1**	**→End**
8.10	**What preparations did you make for care of yourself and new born during the first month following the delivery?**	**Financial……1** **Indentification of health**	

	CIRCLE ALL RESPONSES	**worker……2** **Identification of health facility……..3** **Others…….4**	

End time : Hours……Minutes…….

THANK THE RESPONDENT

Appendix 10: Health Facility surveillance form

Health Facility Surveillance Form

Name of Health Facility *District*

Period Covered by the Data (dd/mm/yy) **to** **(dd/mm/yy)**

Line	Source	Deliveries and births in Hospital Only: Do not count BBAs or transfers from other health facilities	Total
Note: Line numbers refer to tally sheet line numbers			
4	Delivery Book	Spon. Vertex Del. (SVD)	
5	Theatre Book/Delivery Book	Caesarian Section (C/S)	
6	Delivery Book	Vacuum Extraction (VE)	
7	Delivery Book	Breech	
8	*SVD + C/S + VE + Breech =*	Total Deliveries in Hospital (Mothers)	
9	Delivery Book| Sets of Twins:	Additional twin babies (+1 for each set of twins)	
10	Delivery Book| Sets of Triplets:	Aditional triplet babies (+2 for each set of triplets)	
11	Delivery Book| Sets of Quads:	Additional Quad babies (+3 for each set of quads)	
12	Delivery Book	Fresh Stillborn (FSB) (-1 for each)	
13	Delivery Book	Macerated Stillborn (MSB) (-1 for each)	
14	*Tot Del + Twins (1) + Triplets (2) - stillborns =*	Live Births in Hospital (Babies)	

		Maternal Complications	***Total***	***Deaths***	***Refer***
15	Admission / Delivery Book	Prolonged Obstructed Labour			
16	Admission / Delivery Book	Ante-Partum Haemorrhage (APH)			
17	Admission / Delivery Book	Post-Partum Haemorrhage (PPH)			
18	Admission / Delivery Book	Severe pre-Eclampsia			
19	Admission / Delivery Book	Eclampsia			
20	Admission / Delivery Book	Puerperal Sepsis			
21	Theatre Book /Delivery Book	Ruptured Uterus			
22	Admission/Delivery Book, Female Ward Book	Retained Placenta			
23	Female Ward Book	Ectopic pregnancy			
24	Admission / Delivery Book, Female Ward Book	Abortion, Complications of abortion (miscarriage, other abortion)			
27	Admission / Delivery Book, Female Ward Book	Other unspecified complication			
		Baby Complications	***Total***	***Deaths***	***Refer***
39	Delivery Book	5 Min Apgar 5 or less/Asphyxia			
40	Delivery Book	Neonatal Sepsis			
41	Delivery Book	Born Before Arrival (BBA) (Mothers)			
42	Delivery Book	Referred from TBA (Mothers)			
43	Delivery Book	Other unspecified complication (babies)			
44	Delivery Book	Premature baby (total)			
45	Delivery Book	Baby less than 2500g (total)			
46	Delivery Book	Abnormal baby (malformation)			
47	Delivry Book/Nursery Book	HIV, Nevirapine, PMTCT Referral			
		Procedures			
52	Theatre Book/Delivery Book/Female Ward Book	Manual Removal of Placenta			
53	Delivery Book/Female Ward Book	Manual Vacuum Aspiration (MVA)			
54	Delivery Book/Female Ward Book	Evacuation			
		Total Deaths			
56	Nursery Book/ Delivery Book	Total Neo Natal Deaths			
57	Matron	Neonatal Deaths Audited			
59	Delivery Book/Laour Ward	Maternal Deaths in Labour Ward			
60	Female Ward Book	Maternal Deaths in Female Ward			
61	Labour and Female Ward	Total Maternal Deaths			
62	Matron	Maternal Deaths Audited			

Availability of EmOC Signal Functions

*Note: Ask Matron if these were **available** during the period of the report*

- ☐ Manual Removal of Placenta
- ☐ Manual vacuum aspiration (MVA)
- ☐ Vacuum extraction (VE)
- ☐ Breech delivery
- ☐ Parenteral antiobiotics
- ☐ Magnesium sulphate
- ☐ Oxytocic drugs (ergometrine or oxytocin)
- ☐ Caesarian Section
- ☐ Blood transfusion

Dates of Maternal Deaths This Month (line 59 and 60)

1	4	7
2	5	8
3	6	9

Dates of Neo-natal Deaths This Month (line 56)

1	6	11
2	7	12
3	8	13
4	9	14
5	10	15

Note: If necessary, continue dates of death in margin or on other side of page

Name of person completing form Position

Date completed Signature

Collected by: Collected on date (dd/mm/yy)

Appendix 11: Health Centre Resources Survey

Health Facility Survey

Health facility name		Date:	
Total catchment population		Review period	
Type of health facility			
Ownership of health facility			

Human resources - Clinical*

	Personnel name	Position	No. of Days worked last week	Average Hours worked per day

** Clinical staff include staff involved in direct care giving at the health facility (such as the clinical officers, nurses...)*

Health Facility Survey

Health facility name _____ Date: _____

Human resources

Position	Total numbers		At least one available during Day				At least one available at Night			
	Prescribed	Employed	Always	Sometimes	Rarely	Never	Always	Sometimes	Rarely	Never
Physicians										
Enrolled Nurses Midwives										
Enrolled Nurse Technicians										
Enrolled Community Nurses										
State Registered Nurses										
State Registered Nurse Midwives										
Auxiliary Nurses										
Clinical Officers										
Medical Assistants										
Lab Technicians										
Pharmacists										
Health Surveillance Assistants										
Engineers/Technicians										
Lecturers/Tutors										
Researchers										
Patient Attendants										
Security guards										
Drivers										
Other										

Training attended by clinical staff* in the last 3 months

	# of participants from this facility	# of days in training
Infection prevention		
Life saving skills (LSS) = emergency obstetric care		
Post-abortion care, including MVA (Manual Vacuum Aspiration)		
Focused antenatal care		
Maternal deaths reviews		
Family planning provider training		
Prevention of Mother to Child Transmission (PMTCT)		
Newborn/Neonatal care		
Voluntary Counselling and Testing		
Trainer of CBDAs (Community Based Distribution Agents)		
Trainer of Traditional Birth Attendants		
Baby friendly initiative training		
Other training relevant to safe motherhood + neonatal health: Specify:		
Other training relevant to safe motherhood + neonatal health: Specify:		

** Clinical staff include staff involved in direct care giving at the health facility (such as the clinical officers, nurses...)*

Health Facility Survey

Health facility name _____ Date: _____

Infrastructure

	Availability (please circle)	Comments
Electricity	Mains Solar None	
Water supply	Tap HF borehole other borehole	
No. of staff houses/accomodation available		

Inventory List-Materials

	Number Available	Number Functional	Comments
Stethoscope			
Thermometer			
BP apparatus			
Functioning clock in labour ward			
Weigh Scale in labour ward			
Screens for privacy (in labour ward)			
Ambu Bag			
Sharp bins			
Sterilizer			
Suction cup/forceps and suction			
Other			

	Availability (Please Tick)		
	Usually	Sometimes	Never
IV cannula			
IV fluids			
giving sets			
Sterile gloves			
Sterile blade to cut cord			

Transport

	Allocated to health facility		Owned by health facility	
	Number available	Number Functional	Number available	Number functional
Ambulance				
Motorcycle ambulance				
Bicycle ambulance				

Communication

	Available (Yes/No)	Functional (Yes/No)
Radio communication		
Telephone		
Health facility mobile phone		
Mobile network		
Referral forms		

Labour ward

	Available (Yes/No)
Maternity services 24 hrs/day	
Waiting area for mothers	
Partograph form available	
Partograph forms being used	
Delivery book	
Data summary at the end of each month	
HF surveillance complete for last 3 months	
	Number
# of beds in labour ward	
# of beds pre-natal ward	
# of beds post-natal ward	
toilets	
washrooms/bathrooms	

For CEmOCs only	Available (Yes/No)	Functional (Yes/No)
Operation Theatre		
Generator		
Anaesthetic machine		
Epidural kit & drugs		
Caesarean section surgical sets		
Surgical lamp		
Anaesthetist on call		

Appendix 12: Staff Psychology Survey

Survey Questionnaire: Psychology

Health Facility:_____ Month and year:_____

The Health Foundation Consortium is working on a maternal and neonatal health project which is in partnership with Reproductive Health Unit (RHU). This Questionnaire is designed by THFC to assess the work culture within the health facilities to provide quality health care services to the patients. We would highly appreciate if you provide us accurate and honest information, as this will help the system to develop ways of improving the services in the hospital. The information provided will be kept confidential.

Circle the appropriate options below

1. Age

18- 30 yrs	1
31- 40 yrs	2
41- 50 yrs	3
Above 50 years	4
Can't say/Don't know	99

2. Educational Qualification

Illiterate	1
Primary education (Std 1 – 5)	2
Secondary education (Std 6 – 8)	3
JCE	4
MCSE	5
Graduate and Above	6
Don't know/can't say	99

3. Professional training

None	0
Degree in clinical medicine	1
Certificate in Clinical medicine	2
Nursing degree	3
Diploma/Certificate in nursing	4
Diploma/certificate in environmental health.	5
Other (Specify)……..	98
Don't know/can't say	99

4. Health Facility

CEOC/DH	1
BEOC/H.Centre	2
Dispensary	3
Private	4
CHAM	5
Other:……...	98

5. Designation

Medical Assistant	1
Clinical Officer	2
Doctor	3
Nurse	4
Health Assistant	5
HSA	6
Ancillary Staff	7
Other ……...	98
Don't know/can't say	99

6. Work experience with MoH

0 - 5 yrs	1
6 – 10 yrs	2
11- 20 yrs	3
Above 20 yrs	4
Don't know/can't say	99

(tick one box for each question)

	Totally	Mostly	Sometimes	Rarely	No (not at all)
1. How Happy do you feel about your work?	☐	☐	☐	☐	☐
2. How motivated are you to do yo work?	☐	☐	☐	☐	☐
3. Does your job interest you?	☐	☐	☐	☐	☐
4. Are you satisfied with your salary?	☐	☐	☐	☐	☐
5. Do you enjoy working with your colleagues/subordinates?	☐	☐	☐	☐	☐
6. Would you work beyond your defin job responsibilities, if required?	☐	☐	☐	☐	☐

(tick one box for each question)

	Never	Rarely	Sometimes	Most times	All the time
7. How often do you experience conflict with other staff?	☐	☐	☐	☐	☐
8. How often do you experience confli with patients?	☐	☐	☐	☐	☐

(tick one box for each question)

	Excellent	Good	Average	Bad	Very Bad
9. What is your relationship like with your superiors?	☐	☐	☐	☐	☐

(tick one box for each question)

	All the time	Most times	Sometimes	Rarely	Never
10. Do you have freedom to take decisions about your work?	☐	☐	☐	☐	☐
11. How often do you come up with new ideas to test out at work?	☐	☐	☐	☐	☐
12. How often do you actually test the ideas?	☐	☐	☐	☐	☐
13. How often do you discuss work problems with colleagues at **your** facility?	☐	☐	☐	☐	☐
14. How often do you discuss work problems with colleagues at **other** facilities?	☐	☐	☐	☐	☐
15. Do you encourage/appreciate colleagues/subordinates at work?	☐	☐	☐	☐	☐
16. I know my patients by name	☐	☐	☐	☐	☐
17. Can you talk freely to your immediate Supervisor	☐	☐	☐	☐	☐
18. Does you immediate supervisor ask for your suggestions and comments on work related Issues?	☐	☐	☐	☐	☐
19. At some health facilities, staff speak rudely. Does it happen here?	☐	☐	☐	☐	☐

Appendix 13: Staff Psychology Interview Guidelines

PROFILE OF HEALTH SERVICE PROVIDER

Date of Interview (DD-Mon-YY)

Age (optional)	
Gender (Circle)	Male Female
Educational Qualification	
Professional training	
Designation	
Years of work experience	
Full-time/Part-time (Circle)	FT PT

QUALITATIVE ASSESSMENT TOOL

Rapport Building: First, I would like to ask you some general questions about you:

Q.1: Please tell me about yourself?

Checklist to cover:

- Where are they from?
- How do they travel from home to work? (and how long does it take them?)
- When did they first start working?
- How long have they been working in the facility?

Q.2: Please can you tell me about your work?

Checklist to cover:

- What do they do?

Q.3: Can you describe any memorable event during your career?

Q.4: How do you feel about your work?

Checklist to cover:

- How do they find their work?
- What do they like about their work?
- Are they happy in their work?
- How do they see their future?

Q.5: What motivates you to do your work?

Checklist to cover:

- Are there any special features of their facility that motivates them?
- Are there opportunities to test new ideas? If so have they tested any new ideas? And what were these ideas?
- Do they feel appreciated?
- How do they feel about their salary?
- Is there anything that they would change about their facility?

Q.6: Please tell me about any leaders that you have seen or met that inspire you?

Checklist to cover:

- What were these leaders doing?
- What are the qualities of this leader that they admire?

Q.7: Please tell me about your relationship with your colleagues:
Checklist to cover:

- Do people help them out? If so how?
- Who helps them out?
- Do they help their colleagues?
- Which colleagues do they help out?
- How do they help?
- Are they able to share experiences with their colleagues?
- Are their colleagues supportive if they have any problems?
- How do their colleagues feel about their own jobs?

Q.8: What is the relationship like with your supervisor?
Checklist to cover:

- Who do they report to?
- Are they able to approach them?
- How well do they communicate with their supervisor?
- What do they share with their supervisor?
- How does their supervisor respond to this sharing?

Q.9: Please tell me about any additional roles you may have:
Checklist to cover:

- Do they supervise any staff?
- What is their role as supervisor?
- Are they responsible for any reporting? If so, to whom?

Q.10: Can you please tell me about the hospital environment?
Checklist to cover:

- Have their ever been any conflicts?
- Can they talk about this conflict?
- Do they face any other difficulties?
- Can they discuss about these difficulties?

- Is there anything else that you would like to share about your work?

- **From the interview I have heard you say…**

End of interview: Thank participant for their time and effort in taking part in this interview.

Total Duration of interview:

Appendix 14: Provider Knowledge Survey

MaiKhanda provider questionnaire

MaiKhanda is an organization which has been working in maternal and newborn health in partnership with the RHU since 2006. It has three arms: the community intervention, facility intervention and monitoring+evaluation. Through a number of surveys and questionnaires we have been trying to develop an overall picture of all aspects of care. The next area we want to look at is knowledge and perceptions of care.
This questionnaire has been designed to assess knowledge of obstetric and newborn care. There are also some questions about your perceptions of the quality of care provided at your facility and questions about training and confidence in different areas.
The questionnaire is anonymous, so we are not recording respondents' name or health facility. The results will be compiled in a report which will show broad areas of strengths and learning needs across the MaiKhanda target districts rather than individual results. It will therefore help to identify important areas for future learning for various stakeholders.
After we receive your completed questionnaires we will provide you with depersonalized feedback to help you identify your learning needs. We would like to thank you for your involvement with this exercise and with the ongoing MaiKhanda project.

Please note the type of health facility you are working in:

Central hospital		**District hospital**	

Other:……
……..

Please note your job title:

Nurse	

Clinical officer	
Medical assistant	

Obstetrician	

1A. Emergency obstetric care

This section looks management of obstetric emergencies. For each question, please tick whichever box corresponds to the correct management (Only ONE unless otherwise indicated). Your answers should reflect what you believe to be correct practice, rather than practice with limited availability of resources.

	Give Magnesium Sulphate	Give Oxytocin	Give Antibiotics	Give Diazepam	Arrange blood transfusion	Consider C-section	Remove retained products of conception	Perform assisted delivery with vacuum extractor	Manually remove placenta	No action required	Don't know
A woman presents with a severe headache in early labour. Her diastolic blood pressure is 120mmHg. What is your first choice of immediate treatment?											
A woman is in the second stage of labour. Her membranes ruptured 13 hours ago. What is the most important thing to do?											
A woman has just delivered a healthy baby. What should you now do?											
A woman is 8 months pregnant. She is known to have high blood pressure and proteinuria. She is brought in to the facility convulsing. What is the first thing you should do?											
A woman has given birth and has delivered a complete placenta. Her temperature is 39℃. What should you do?											
A woman has given birth and delivered a complete placenta but she is still bleeding heavily. What should you do to stop the bleeding?											
A woman has been in labour with frequent contractions for 14 hours. Her cervix is only 5cm dilated. She is exhausted. What should you do?											
A woman in the second stage of labour has been pushing for 2 hours. The head is palpable on vaginal examination but she is very tired. What should you do?											
A woman presents with an offensive bloody discharge following an abortion 3 days ago. What 2 things should you do?											
A woman gave birth 90 minutes ago but despite oxytocin and massage, she has not yet delivered the placenta. What should you do next?											
A woman has been in labour for 5 hours and her cervix is 5 cm dilated, with no evidence of cord prolapse. You check the fetal heart rate and it is persistently 100bpm. What should you do?											
A woman presents following a home delivery 2 days ago. She is pale and breathless. Her Hb is 5g/dL. What is the most important thing to do?											

1B. Monitoring and routine labour

This section looks at monitoring during the first stage of a normal labour. How often should you monitor each of these factors?

	At least every 30 minutes	Approximately every hour	Approximately every 4 hours	Not more than every 4 hours
Blood pressure				
Maternal pulse				
Fetal heart rate				
Temperature				
Vaginal examination				

This section looks at management of routine labour. For each question, please tick either 'Yes' or 'No' depending on what you think is correct practice. Your answers should reflect ideal practice rather than practice with limited availability of resources.

	Yes	No
Do you think you should routinely shave women in labour?		
Do you think it is necessary to offer women pain-relief for surgical procedures such as episiotomy?		
Do you think you need to know every woman's HIV status when you care for her in labour?		
Do you think women should be encouraged to lie on their backs during labour?		
Do you think that women in normal labour should be examined more than every four hours?		
Do you think women should be encouraged to labour in their position of choice?		
Do you think husbands should be encouraged to attend delivery?		
Do you think women should be encouraged to have a friend or relative present for the delivery?		
Do you think episiotomy should be routinely performed on primigravidas?		
Do you think a partograph is necessary to monitor labour?		
Do you think a postnatal check is essential following an uncomplicated delivery?		

1C. Neonatal care

This section looks at care of newborns. For each question, please tick whichever box corresponds to the correct management (Only 1 unless otherwise indicated). Your answers should reflect what you believe to be correct practice, rather than practice with limited availability of resources.

	Give IM Antibiotics	Give oral antibiotics	Give air/oxygen via ambu bag	Perform chest compressions	Hold baby by his feet and slap him	Wash baby within 1 hour	Wrap baby in a cloth	Stimulate and dry him	Wrap baby against mother, skin-to-skin	Encourage breastfeeding	Encourage supplementary feeding with formula	No action required	Don't know
A baby is born after a difficult labour. He is not breathing. What is the first thing you should do?													
1 minute after delivery a baby still looks mottled, the heart rate is 120bpm and the respiratory rate is 26. What is the most important thing to do?													
A baby is born at 34 weeks gestation. He weighs only 1.9kg. What are the 2 most important things to do within the first 30 minutes?													
A baby is born after a prolonged labour. His temperature is 38.7C. What is the most important thing to do?													

2. Attitudes and perceptions of care

This section looks at your thoughts about provision of care. Please answer according to how you think patients are treated in your facility.

	Always	Mostly	Sometime	Never	Don't know
Do you think patients are treated with respect in your health facility?					
Do patients wait for too long to be attended?					
Do patients get an opportunity to ask questions?					
Do staff answer patients' questions fully?					
Do you think the health facility is clean enough?					
Would you recommend your health facility to a friend/relative?					
Do staff try to ensure patient privacy at your facility?					
Do patients get enough information to look after themselves at home?					
Do patients get enough information to care for their babies?					
Do patients get adequate explanation about treatments and medicines ?					

3. Confidence and training

	Monitoring and management of routine labour	Post-abortion care	Assisted delivery with vacuum	Management of postpartum haemorrhage	Emotional support of the woman in labour	Prevention of mother-to-child-transmission of HIV	Management of eclampsia and pre-eclampsia	Manual removal of placenta	Neonatal resuscitation	Care of the low birthweight infant
Please rate your confidence in each of these subjects: **5:** very confident **4**: confident **3**: average **2:** not very confident **1**: not confident at all										
Please mark with a tick all subjects that you have EVER studied										
Please mark with a tick all subjects that you have studied in the last 5 YEARS										
Please mark with a tick all subjects that you have studied in the last 1 YEAR										

How many months or years of professional training have you received?.....months…….years

Which year did you graduate from professional training?.....

Thank you for taking part in this questionnaire. Your responses will help us to learn about the strengths and knowledge gaps of healthcare providers assisting women in labour. You will receive depersonalized feedback to help you identify your own learning needs

Appendix 15: Women Friendly Care questionnaire

District _____ Health facility name _____
Interviewer
Date Interview starting time
I am at this health facility as a guardian patient
Respondent's age _____
Tick the appropriate image that best describes your feeling for each question.

Example Question	**Very unhappy**	**Unhappy**	**Happy**	**Very happy**
How happy are you with your harvest this year?				

SURVEILLANCE QUESTIONS	**Very unhappy**	**Unhappy**	**Happy**	**Very happy**
1. How do you feel about the way you were welcomed at this health facility?				
2. How do you feel about the time taken to attend to you?				
3. Were you given a chance to ask questions? I f so, how do you feel about it?				
4. How do you feel about being answered to your questions?				
5. How do you feel about the sanitation of the health facility?				
6. How do you feel about our stay at the health facility?				
7. How would you feel about telling someone to come to this health facility for delivery?				
8. How do you feel about the services you have received at this health facility?				
9. How do you feel about the advice that you have been given on how to take care of yourself and the baby?				
10. How do you feel about the prescription on the medication that you were given?				

Appendix 16: Women's Group Facilitator questionnaire

WGF Self-Complete Survey

Name of respondent (optional) _____

Name of Women's Group Supervisor _____

District _____

TA region _____

Name of village _____

Date of Survey _____

Health facility _____

A brief note here on what the survey is all about:
As you might be aware The Health Foundation Project (THF) for which you volunteer has the aim of reducing maternal and neonatal mortality in Malawi. In order to work towards this goal one of our project objectives is to understand how we can improve and scale up our women's group interventions with the help of Women's Group Facilitator (WGF). We are conducting this survey to gain knowledge of your experiences as a WGF and of your understanding of the project so that we can use this information to improve the intervention. Any information provided will be treated with confidentiality.
Your time and effort in filling up this questionnaire is greatly appreciated. However, in case you decide not to fill up the forms, we respect your decision.
So, are you interested in filling up this form?

Yes ☐ *Please continue to the next page*

No ☐ *Please return this form to your Supervisor*

This survey has three parts

A. General Information
B. Your experience as women's group facilitator
C. Your understanding of THF project

A. General Information

1. Gender (Tick Box)

Woman ☐ Man ☐

2. How old are you? (Age in years - Optional) _____

3. How much School Education have you had? (Tick ONE box for the highest class attended)

PSLC ☐ JCE ☐ MSCE ☐ Above ☐

4. Marital Status (Tick ONE box according to your current status)

Married ☐ Divorced ☐ Widowed ☐ Single ☐ Other ☐

Specify _____

5. How many times have you been pregnant/How many pregnancies have you had _____

6. How many children have you given birth to? _____

7. Have you lost any child during child birth/delivery, or within one month after delivery?

No ☐ Yes ☐ If Yes, How many? _____

B. Experience as a volunteer

8. Have you worked as a volunteer before in any another project?

Yes ☐ No ☐

9. Have you been involved as a WGF in any other project?

Yes ☐ No ☐

10. Have you ever been a facilitator before?

Yes ☐ No ☐

11. When did you start volunteering with THF project? Month _____ Year _____

12. How many women's groups do you have? _____

13a. Have any of your women's groups been disbanded?

Yes ☐ No ☐

13b.If yes, Why?

14. What do you think of the number of WG you are handling? (Tick ONE box)

Too little ☐ About right/OK ☐ More than I can handle ☐

15a. Do you think you have adequate time to prepare for the meetings?

Yes ☐ No ☐

15b. If no Why?

16a. How much time does it take to prepare for a WG meeting?

_____Hrs ____ Mins

16b. How much time on average do you think is actually spent on conducting the WG meeting?

_____Hrs ____ Mins

17. What do you think about the amount of supervision you are receiving from your SWGS?

Too little ☐ About right/OK ☐ Too much ☐

18a. How regularly do you attend the monthly meetings?

Always ☐ Most times ☐ Sometimes ☐ Never ☐

18b. If sometimes or never, why?

18c. Do you think the monthly meetings are important?

Yes ☐ No ☐

18d. If Yes/No, Why?

_____

_____

_____

_____

19a. Do you think that writing the reports is important?

Yes ☐ No ☐

19b.If Yes/ No, why?

_____

20. How do you find the amount of work/workload you have to do? *tick ONE box*

Too little ☐ About right ☐ Too much ☐

21. Do you think the local leaders/communities recognise your efforts?

Yes ☐ No ☐ Not sure ☐

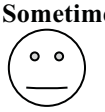
22. Do you think the local leaders/communities provide you with adequate support?

Yes ☐ No ☐ Not sure ☐

23. Do you like working as a women's group facilitator? *tick ONE box*

Yes ☐ No ☐ Don't know/can't say ☐

Some general questions about your work (tick ONE box for each question)

	Totally	**Mostly**	**Sometimes** 	**Rarely**	**No (not at all)**
24. How Happy do you feel about your work?	☐	☐	☐	☐	☐
25. Do you feel motivated working as volunteer?	☐	☐	☐	☐	☐

26. Do you enjoy working/interacting wi other women in the village? ☐ ☐ ☐ ☐ ☐

27. Does your work as a WGF improve your status in the community? *Tick ONE box*
Yes ☐ No ☐ Not sure ☐

28. How does your work as a volunteer affect your financial status? *Tick ONE box*
It improves it ☐
Does not make any difference ☐
Could earn more money doing something else ☐

29a. Are the resources you get adequate for your work as a volunteer?
Yes ☐ No ☐

29b. If no, why not?

30. Mention three motivating factors:

1.

2.

3.

31. Mention three major challenges in implementing a women's group

1.

2.

3. _____

_____

C. Understanding of Project

32. What do you think are the three most contributing factors to maternal health problems?

1. _____

_____

2. _____

_____

3. _____

_____

33. What do you think are the three most important contributing factors to in neonatal health problems?

1. _____

_____

2. _____

_____

3. _____

_____

34. Do you think women's group intervention will help to improve maternal and neonatal health in Malawi? *Tick ONE box*

Yes ☐ No ☐ Don't know/can't say ☐

35. If yes, How? If No, Why not?

_____

_____

_____

36a. Do you think 8 meetings are enough for the women to identify, prioritise and strategise the problems they face? *Tick ONE box*

Yes ☐ No ☐ Not sure ☐

36b. If No, how many meetings do you think are needed? _____

37a. Do you think 8 meetings gives enough time for the women to commit to the group and feel that they own it so that they can implement strategies?
Tick ONE box

Yes ☐ No ☐ Not sure ☐

37b. If No, how many meetings do you think are needed? _____

38. Do you think involving other stakeholders will be beneficial to the Women groups?

Yes ☐ No ☐ Not sure ☐

39. If yes, Could you list the following key stakeholders according to your order of priority?
Village Headman, TBA, HSA, Community members, Health facility staff,

Others, specify: …….. ……
…….

Order of Priority	*Key Stakeholders*
1	
2	
3	
4	
5	
6	
7	
8	

Thank you for your time and patience.

Appendix 17: Women's Group Facilitator Interview guidelines

PROFILE OF WOMENS GROUP FACILITATOR

Date of Interview (DD-Mon-YY)

Age (optional) _____

Gender (Circle) Male Female

QUALITATIVE ASSESSMENT TOOL

Rapport Building: First, I would like to ask you some general questions about you:

Q.1: Please tell me about yourself?

Checklist to cover:

- Where are you from?
- Discuss about educational status, marital status
- A brief description of her experiences with child birth.
- Previous work experiences
- Previous experiences of volunteering?
- When did you first start volunteering?
- How long have you been volunteering with THFC?

Q.2: What are your experiences as a WGF?

Checklist to cover:

- How do you find your work?
- How do you travel to the Women's Groups? (and how long does it take you?
- How do you feel about the distances you have to travel?
- What do you think about your current work load? How do you feel about the amount of time your work takes?
- What do you like about your work? Are there any special features of running a Women's Group that motivate you?
- If you could change anything about your work what would it be?
- How do you see your future?

Q.3: Support

Checklist to cover:

- Do you think you are receiving adequate supervision?
- In the absence of any supportive supervision, do you think you will be able to manage the WG all by yourself? (If yes, how? If no why not?)
- Do you think the training has been adequate for your effective facilitation of WG?

Q.4: Women's Group Action Cycle

Checklist to cover:

- If you were to run the women's groups again, what changes would you bring about to the action cycle?
- Do you think the 8 meetings in Phase I&II of the action cycle gives enough time for the women to identify and prioritise all the important maternal and neonatal health problems?
- Do you think the 8 meetings in Phase I&II of the action cycle gives enough time for the women to commit to the group and feel that they own it so that the implementation phase goes well?

Q.5: Women attending the women's group

Checklist to cover:

- What is your opinion of the characteristics of women attending the women's groups?
- What do you think drives the women in the women's groups to attend the meetings?
- Do you think women benefit from attending the WGs?

Q.6: The Community

Checklist to cover:

- What is your opinion of the level of understanding among the women in the communities regarding maternal and neonatal health issues?
- What is your opinion of the level of understanding among the men in the communities regarding maternal and neonatal health issues?
- How does the community respond to your efforts? Are they supportive? **(**if yes explain how they support you, if no please explain how / why they don't support you?) Have you met with any resistance?

Q.7: Experiences of volunteering?

Checklist to cover:

- What motivated you to become a volunteer?
- As a volunteer, how do you sustain yourself financially?
- Would you be able to get more money if you were not a volunteer?
- Does volunteering affect your status in the community? How?
- Do you think working as a WGF volunteer could contribute to better job prospects in future? How?
- Do you think your friends and family want to become volunteers after learning about your experiences?

Q.8 Do you feel that you are making a difference to the lives of people in the community?

Checklist to cover:

- If so, in what way? If not why not?
- Have you gained more knowledge on health matters? Is this important to you? has it helped you personally?

Is there anything else that you would like to share about your experience as a volunteer?

- **From the interview I have heard you say…**

End of interview: Thank participant for their time and effort in taking part in this interview.

Total Duration of interview:

Appendix 18: Women's Group Self Evaluation tools

1: Score Card Tool

The score card is a participatory tool that can be used to assess the severity/intensity/magnitude of an issue or problem. Any issue identified can be attached to a score which indicates its intensity. This helps to give a picture of how important an issue is to a community.

Process of Scoring in a Scorecard

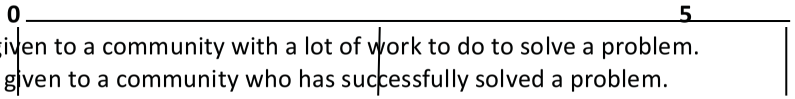
Some of the most critical factors in successfully using a scorecard process are ensuring that there is open and positive dialogue amongst the women's groups members themselves. Therefore a facilitator must have adequate listening and communication skills to make the participants aware of their own attitudes and behavior.

Scorecard process

- The facilitator should educate women's group members about how to use a scorecard.
- Each group should be able to give a score to the questions raised in this manual and justify why they gave a particular score. The reasons given help to justify the score given and provide direction to take in addressing the issues.

Scorecard Rating System

Scorecards use ratings from 0 to 5 to measure an issue. In the example of solving a problem, a score of 0 may mean there is a long way to go to solve the problem. A score of 5 may mean there is no problem and that the problem has been solved.



- **0**: Is the lowest score and may be given to a community with a lot of work to do to solve a problem.
- **5:** Is the highest score and may be given to a community who has successfully solved a problem.

How to help the community understand the concept of Scorecard

A) Food Example

- Use the example of being hungry and full. If you have 10 bananas and you eat them all, you would be considered full and score a high number such as 5 .

B) If no banana is eaten, you would be considered very hungry. In terms of scoring, a low score may be given as the community is still hungry and has not solved their problem.

C) Problem Pit

- Someone has fallen into a pit and he wants to climb out using a ladder that has 5 steps. Once he reaches step number 5 , it means he is out of the pit. In terms of the indictors attached to the issue raised, it means he is doing well, in other words, the problem is completely solved.
- If he is still at step 0 or 1, it means he still has a long way to go before he can get out of the pit. In terms of indicators it means he is not doing well in that area and more has to be done to improve the situation.

2: Meeting 2 Summary Form

Date	Group ID
Progress	
Main achievements	Main challenges
Strategies	

3: Meeting 2 Evaluating the Group Scorecard

Indicator	Score						Why has this vote given?	How to improve?
	0	1	2	3	4	5		
Participation								
Leadership								
Organisational structure								
Problem assessment								
Resource mobilisation								
Asking why								
Links with others								
External agents								
Programme Management								

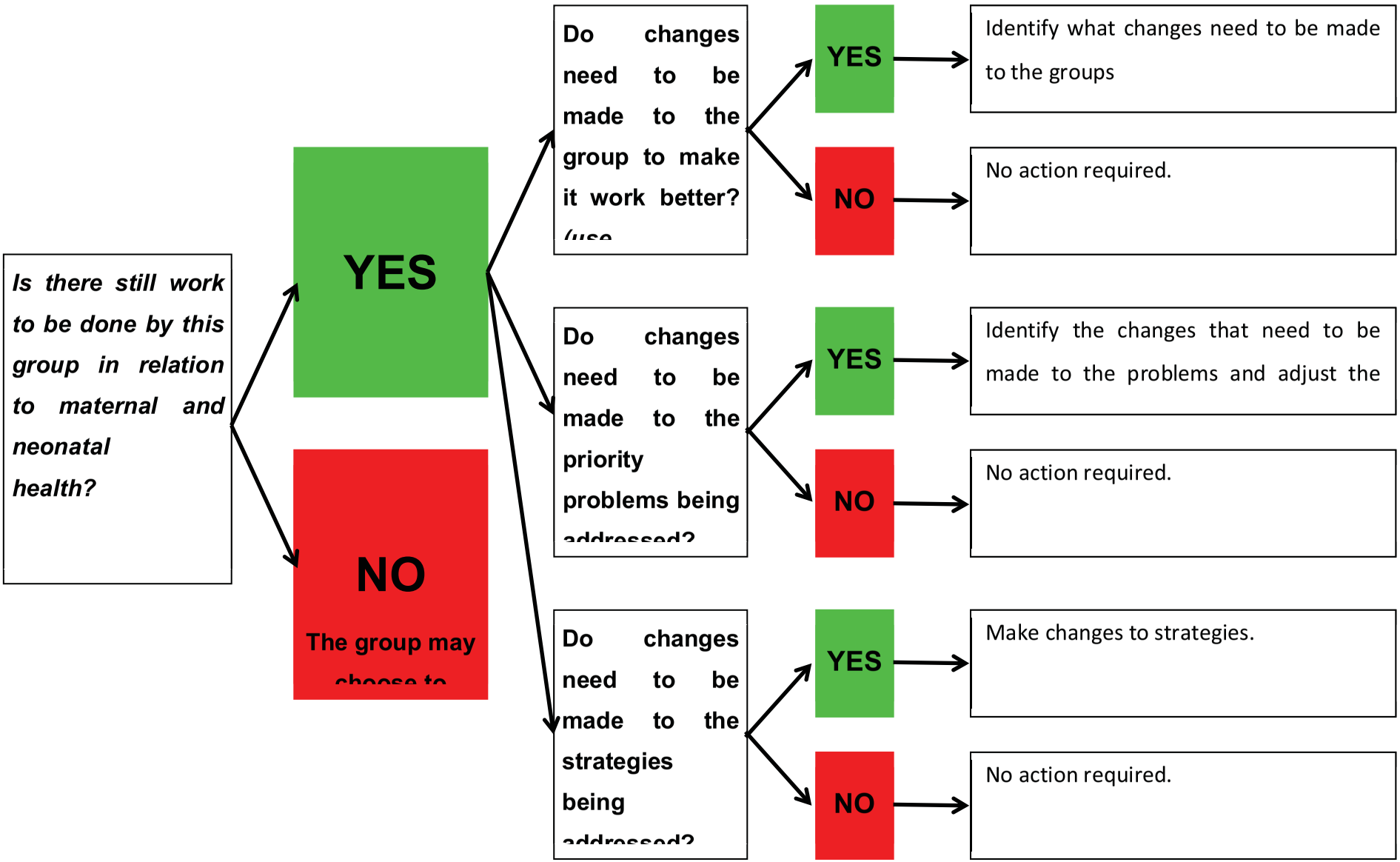
4: Meeting 3 Evaluating Problems Scorecard

List problems identified	Never	Score how often the problems occur					Why has this vote given?	How to improve?
	0	1	2	3	4	5		
1.								
2.								
3.								
4.								
5.								

5: Meeting 3 Evaluating Strategies Scorecard

List strategies identified	Not at all	Score how well the strategies have been implemented					Why has this vote given?	How to improve?
	0	1	2	3	4	5		
1.								
2.								
3.								
4.								
5.								

6: Meeting 4 Planning for the future diagram



7: Meeting 4 Future Action Plan

Action	Resources needed	People responsible	Timeline

Appendix 19: Observed vs. Expected births and deaths for each cluster for each MEO

Figure 3: Observed and Expected Births in clusters managed by MEO 1

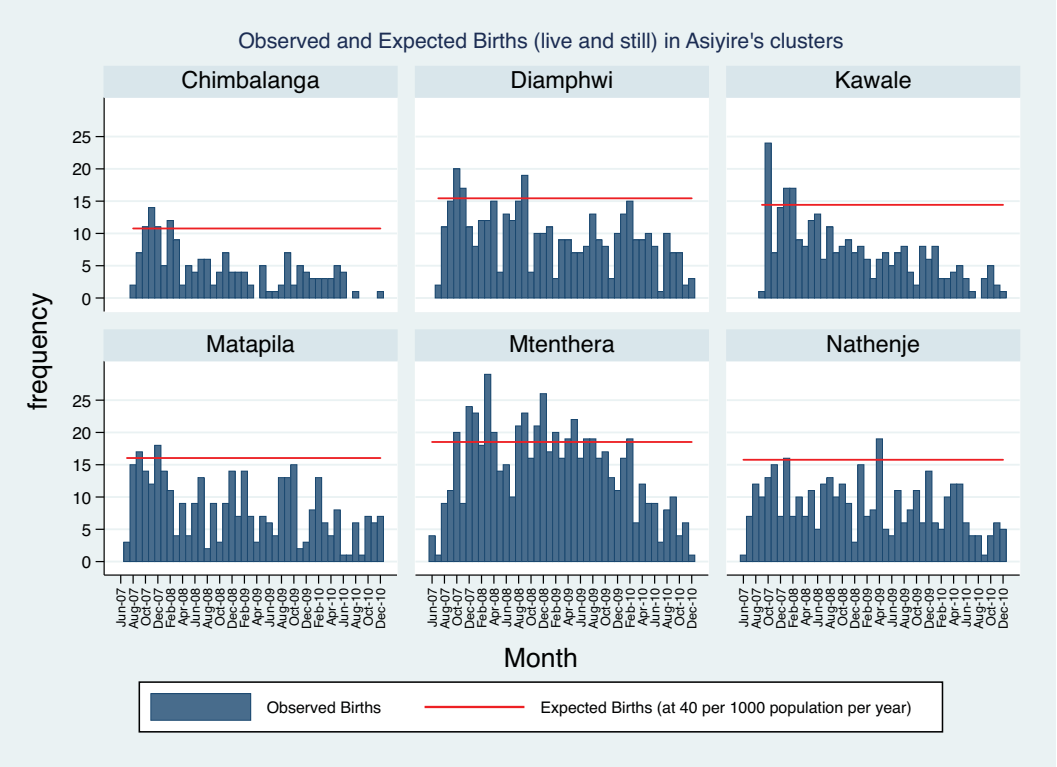


Figure 4: Observed and Expected Stillbirths in clusters managed by MEO 1

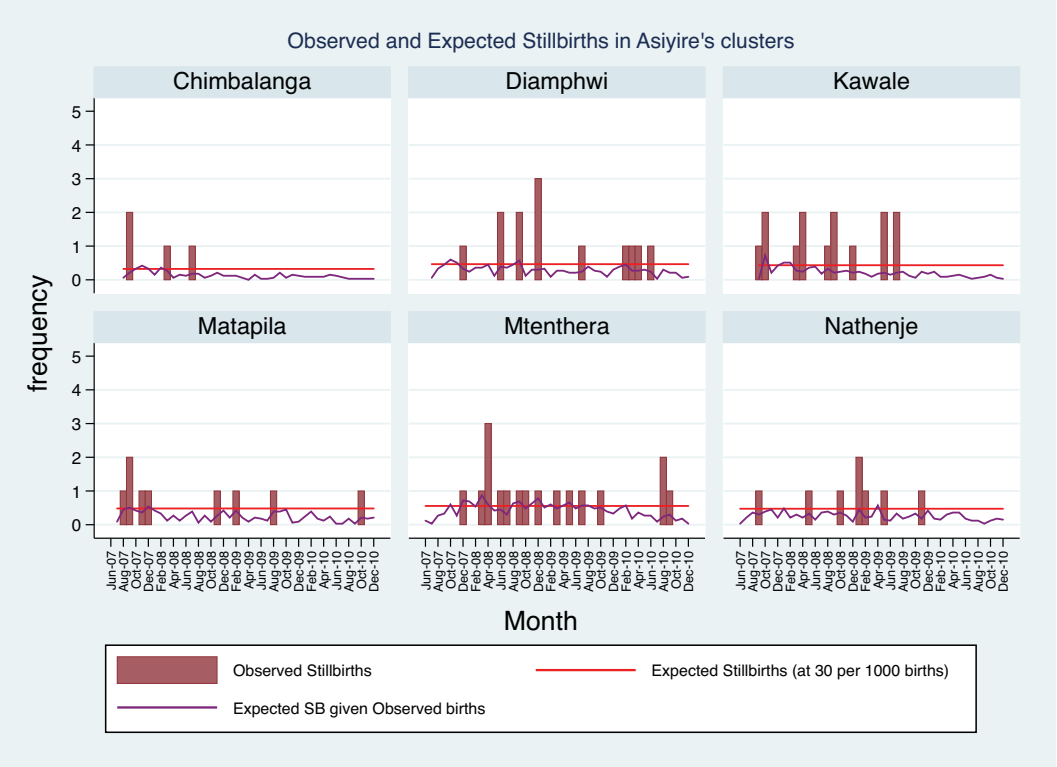


Figure 5: Observed and Expected Neonatal Deaths in clusters managed by MEO 1

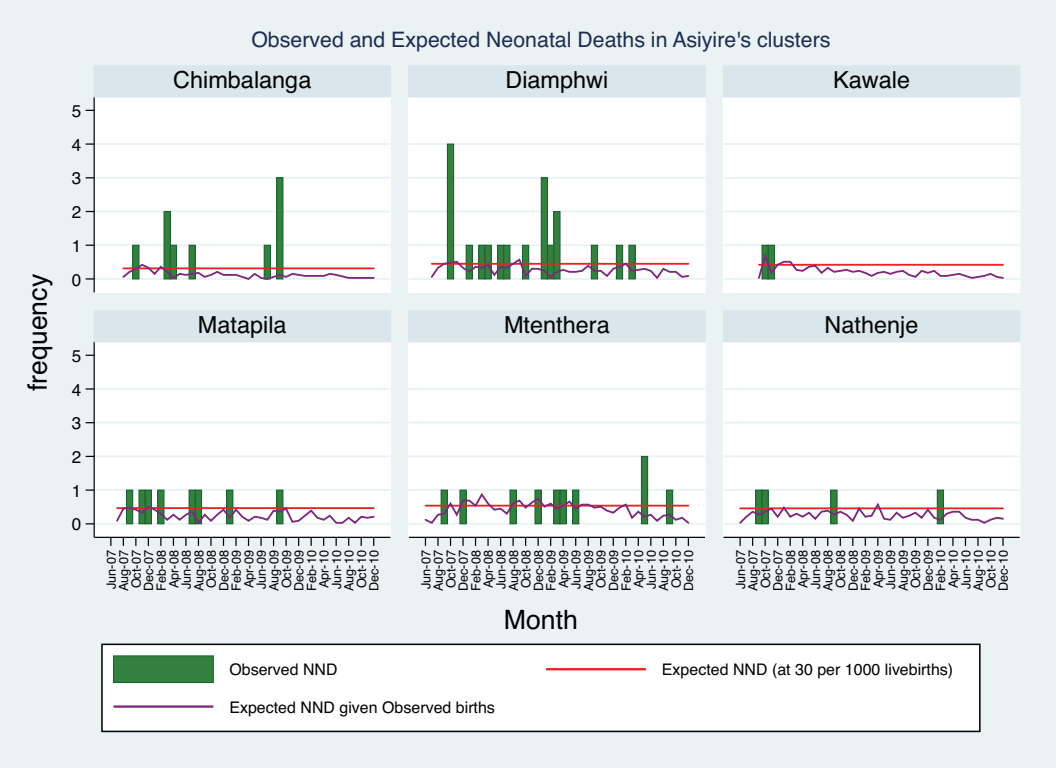


Figure 6: Observed and Expected Maternal Deaths in clusters managed by MEO 1

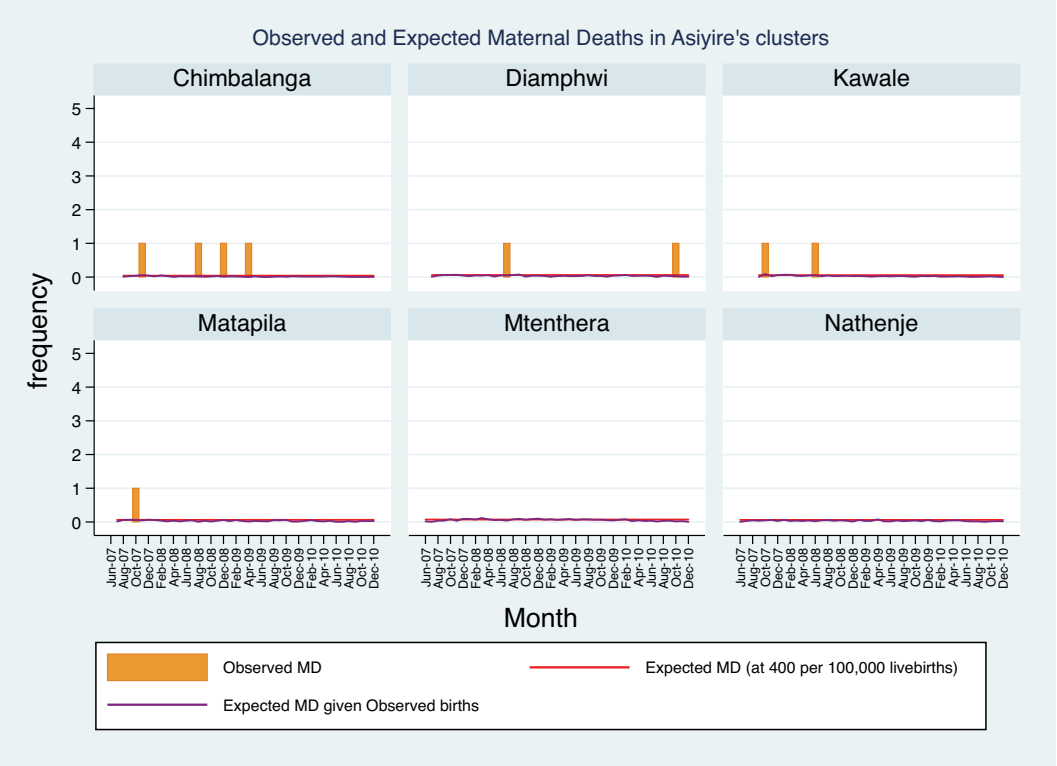


Figure 7: Observed and Expected Births in clusters managed by MEO 2

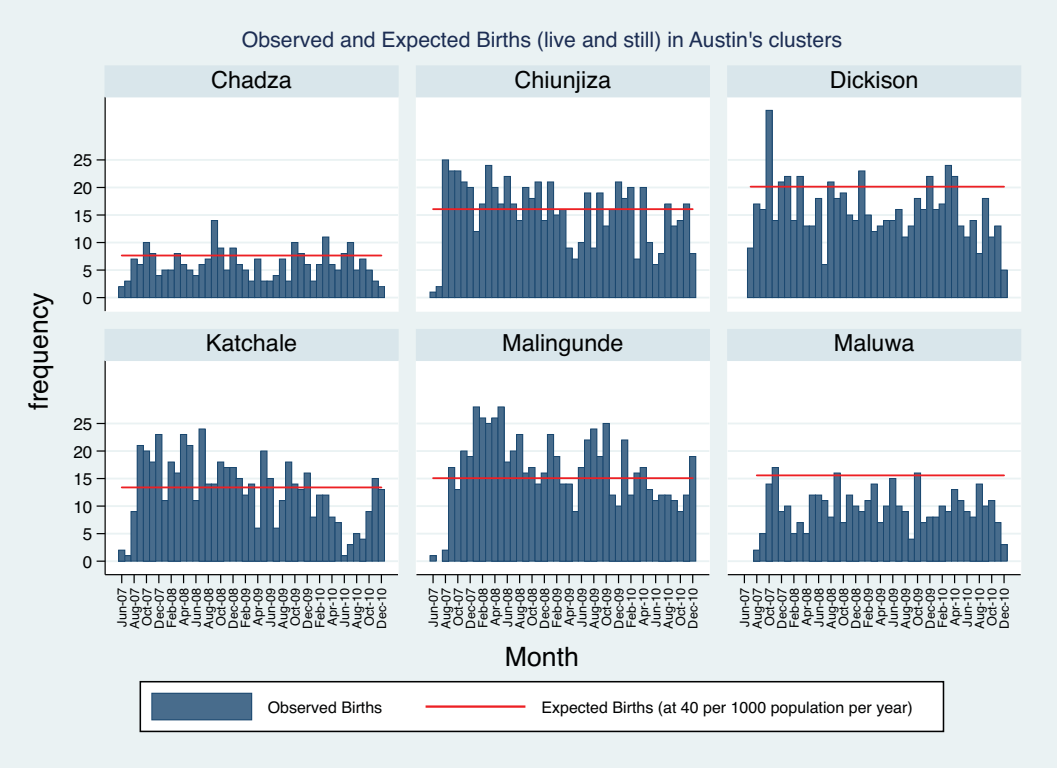


Figure 8: Observed and Expected Stillbirths in clusters managed by MEO 2

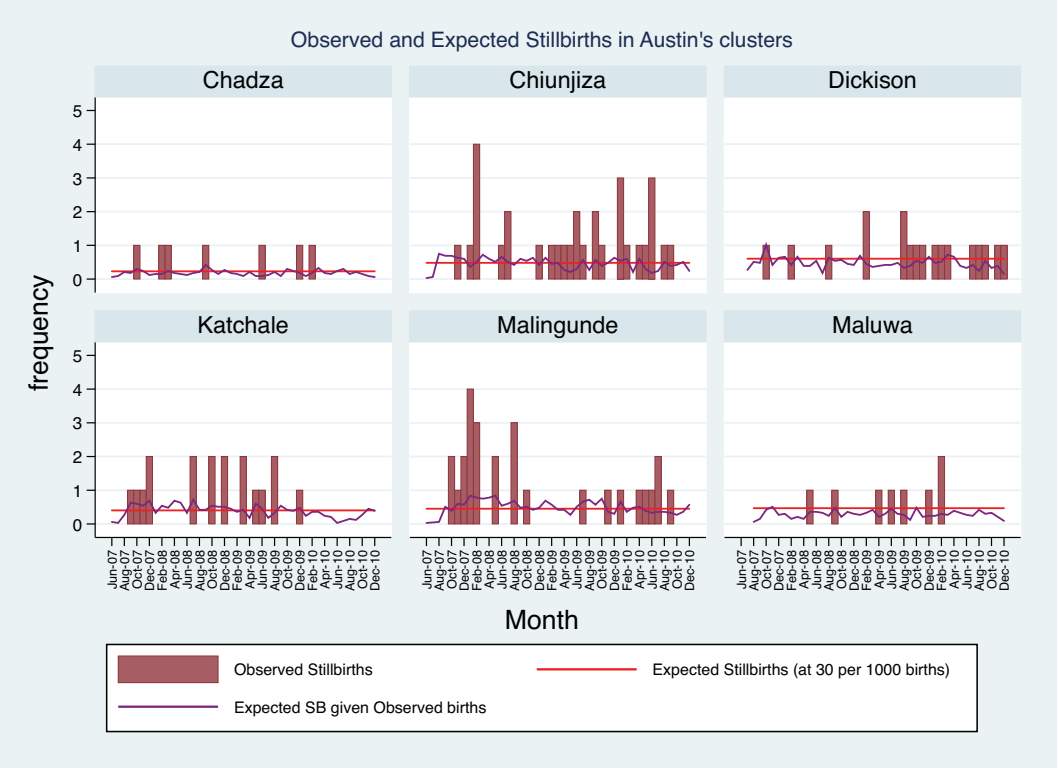


Figure 9: Observed and Expected Neonatal Deaths in clusters managed by MEO 2

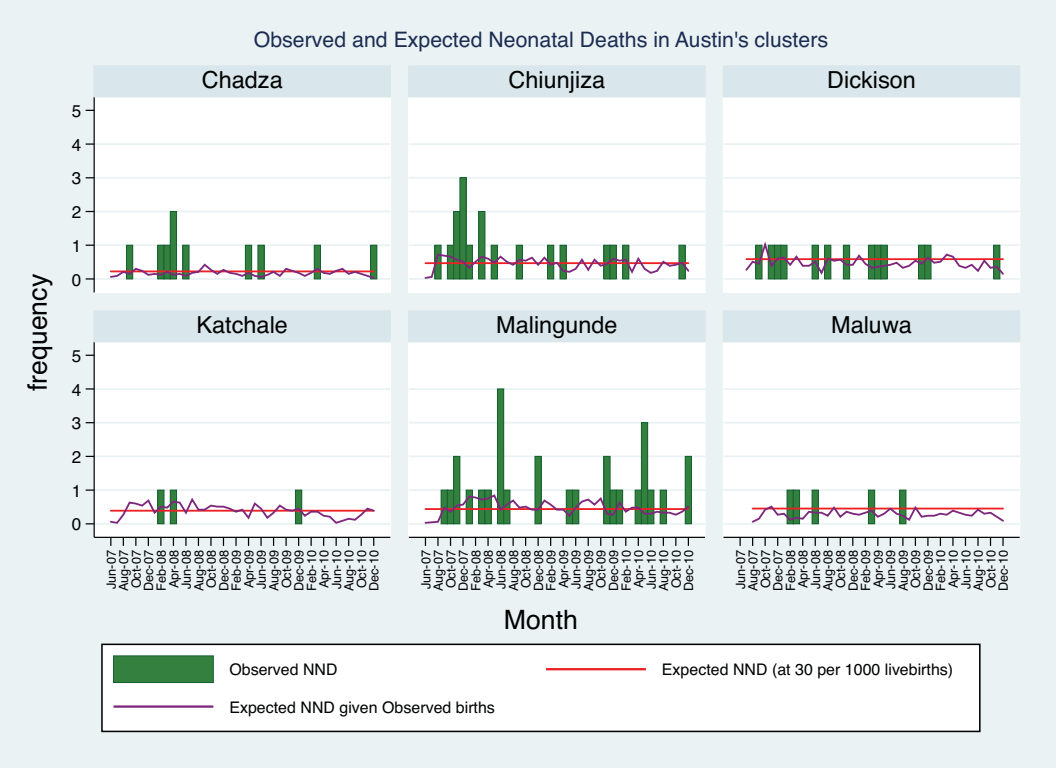


Figure 10: Observed and Expected Maternal Deaths in clusters managed by MEO 2

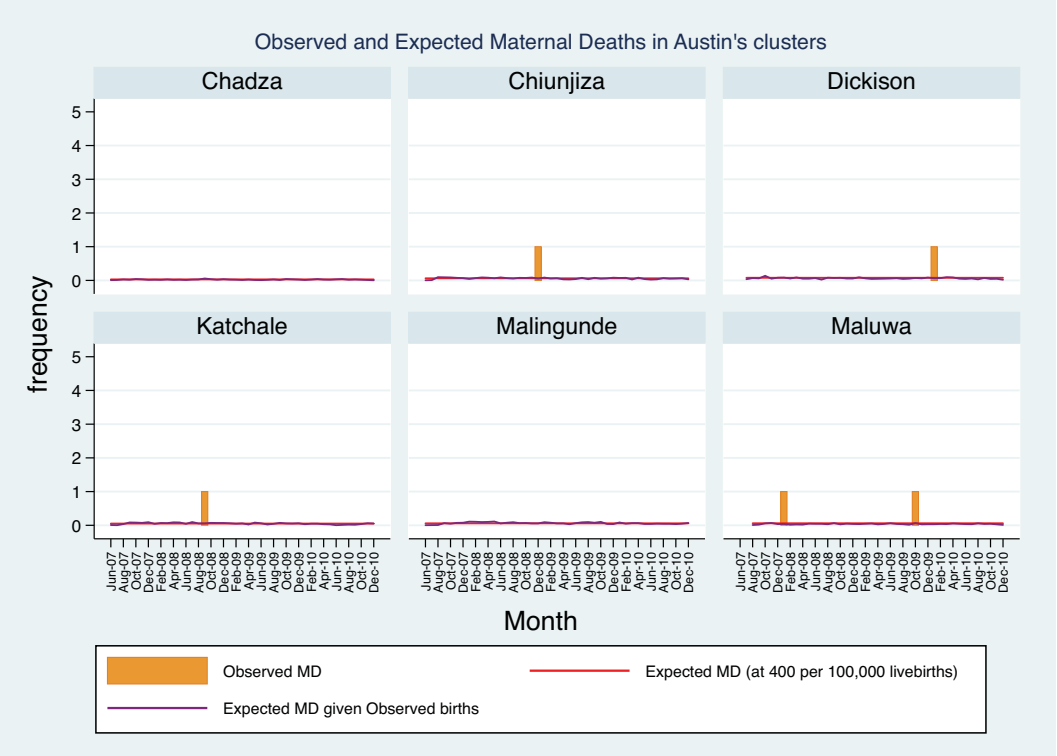


Figure 11: Observed and Expected Births in clusters managed by MEO 3

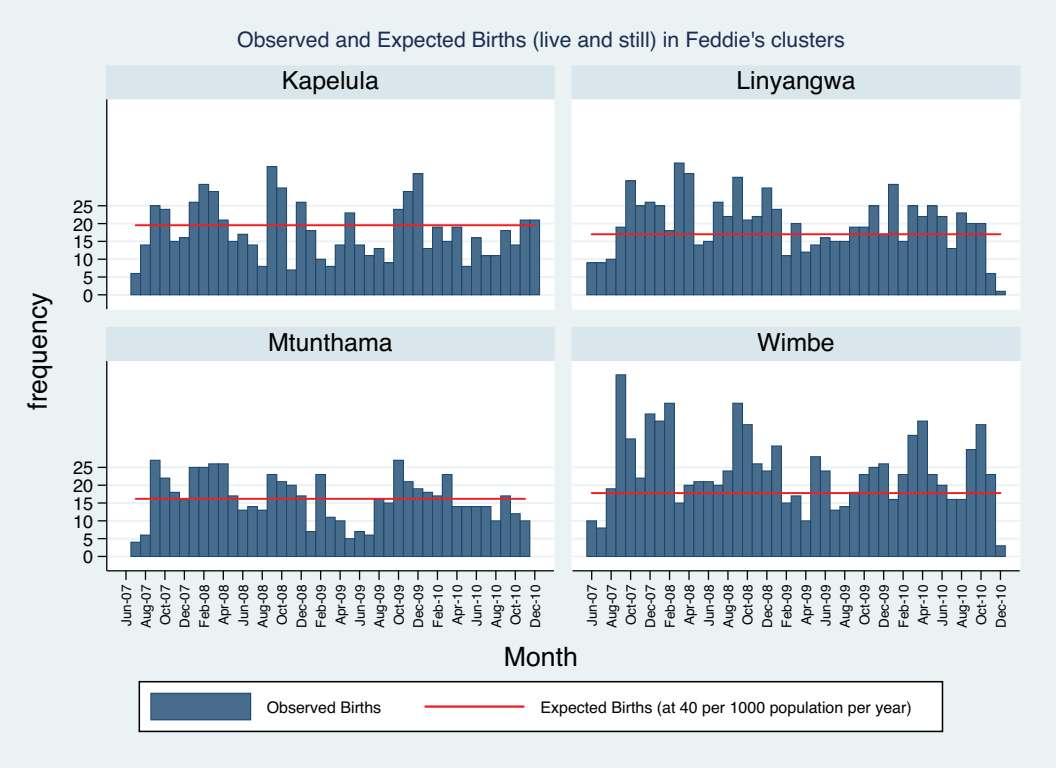


Figure 12: Observed and Expected Stillbirths in clusters managed by MEO 3

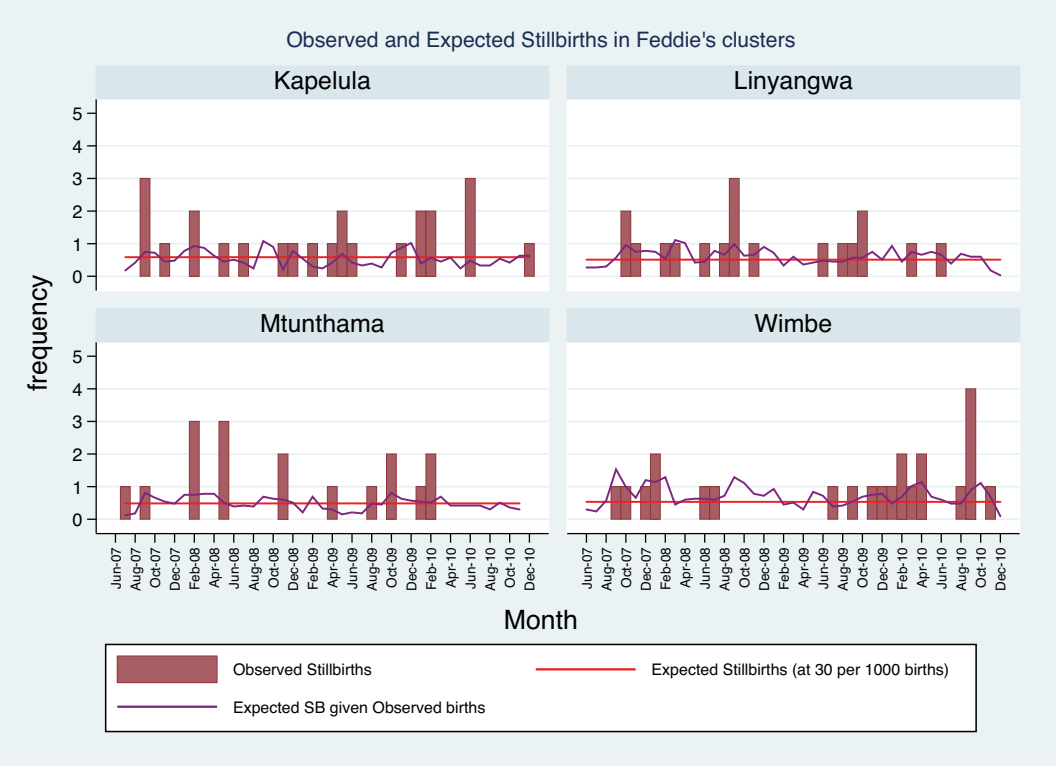


Figure 13: Observed and Expected Neonatal Deaths in clusters managed by MEO 3

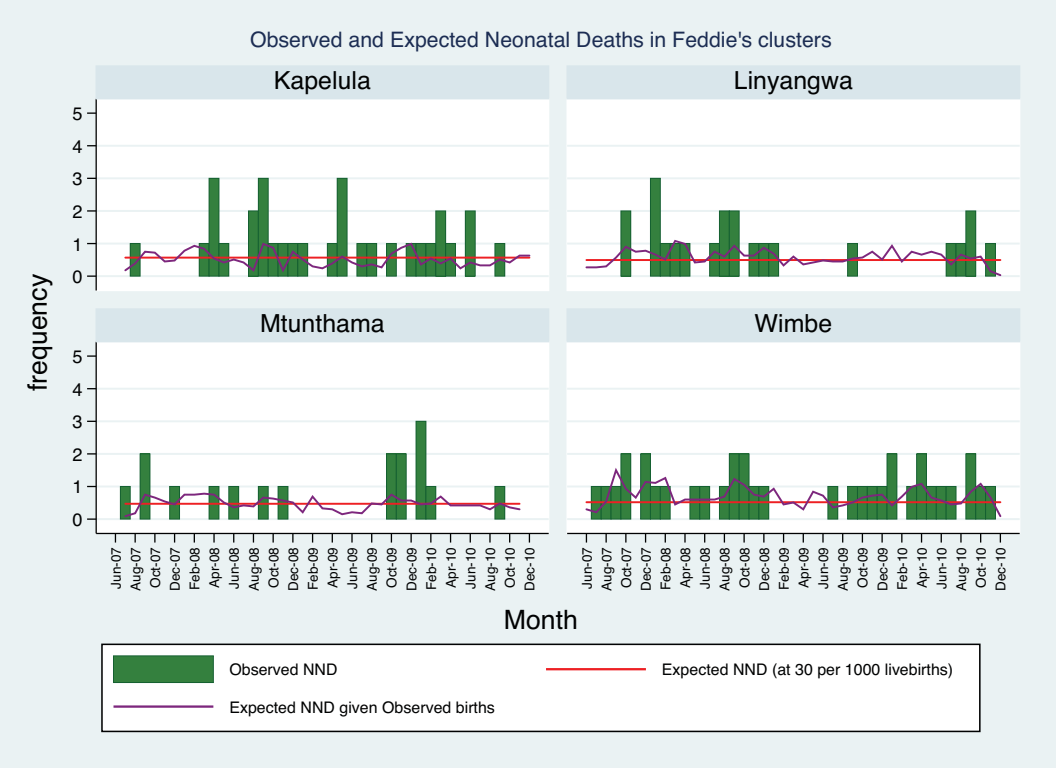


Figure 14: Observed and Expected Maternal Deaths in clusters managed by MEO 3

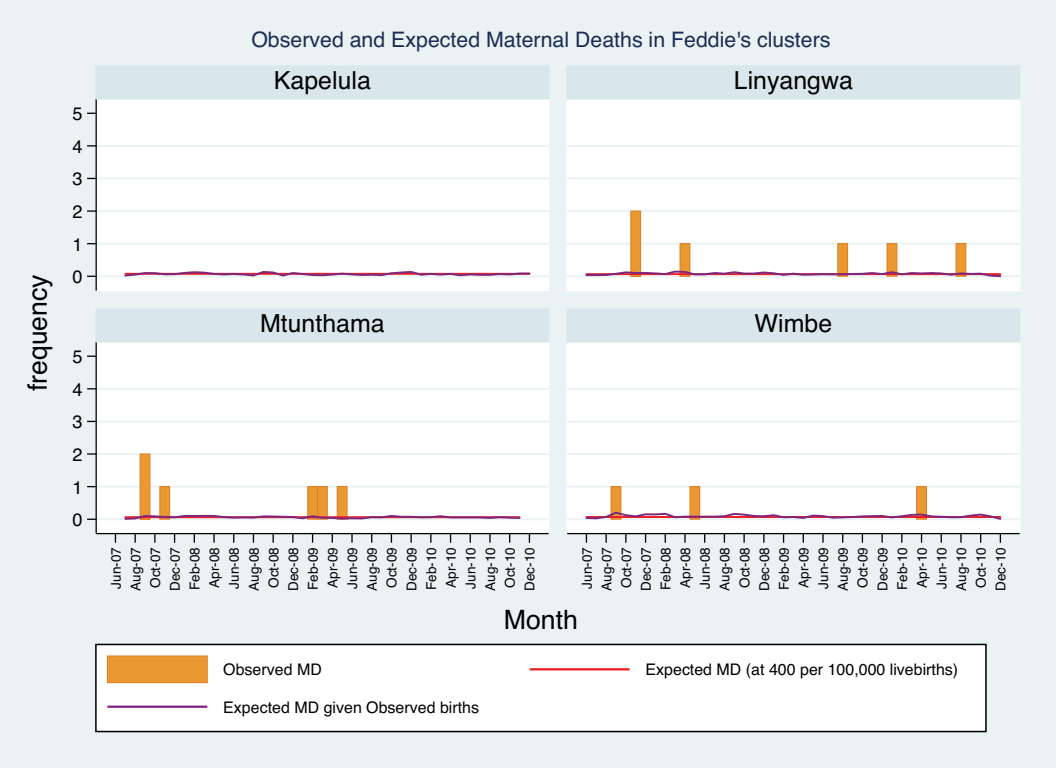


Figure 15: Observed and Expected Births in clusters managed by MEO 4

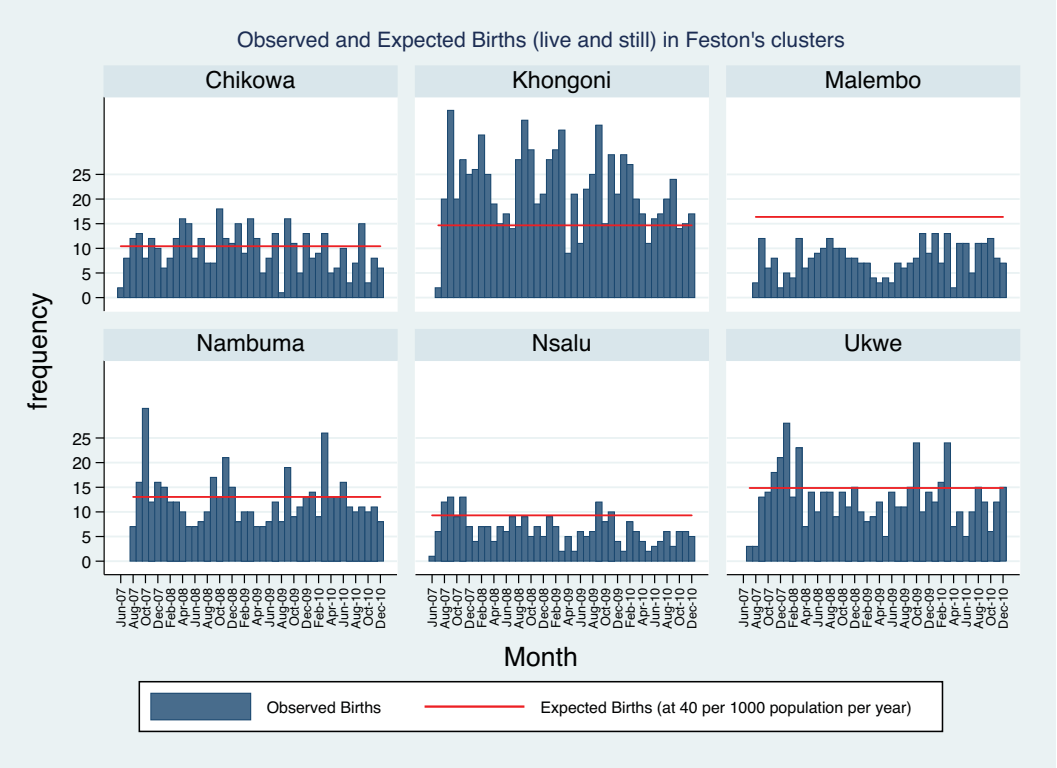


Figure 16: Observed and Expected Stillbirths in clusters managed by MEO 4

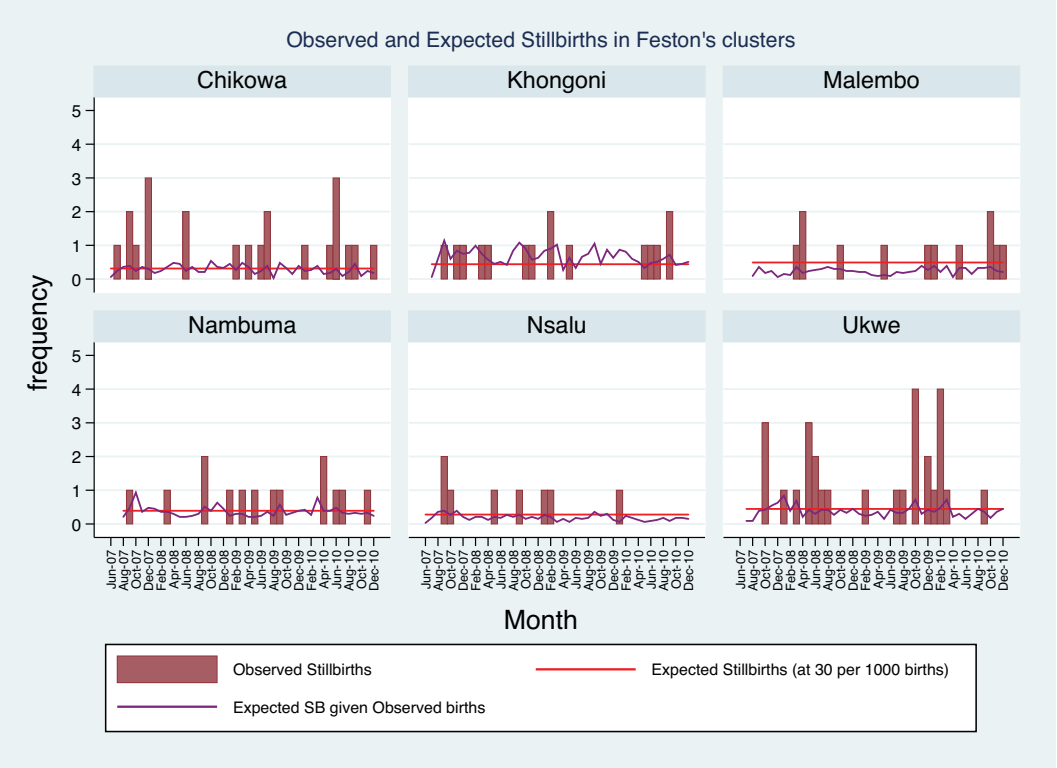


Figure 17: Observed and Expected Neonatal Deaths in clusters managed by MEO 4

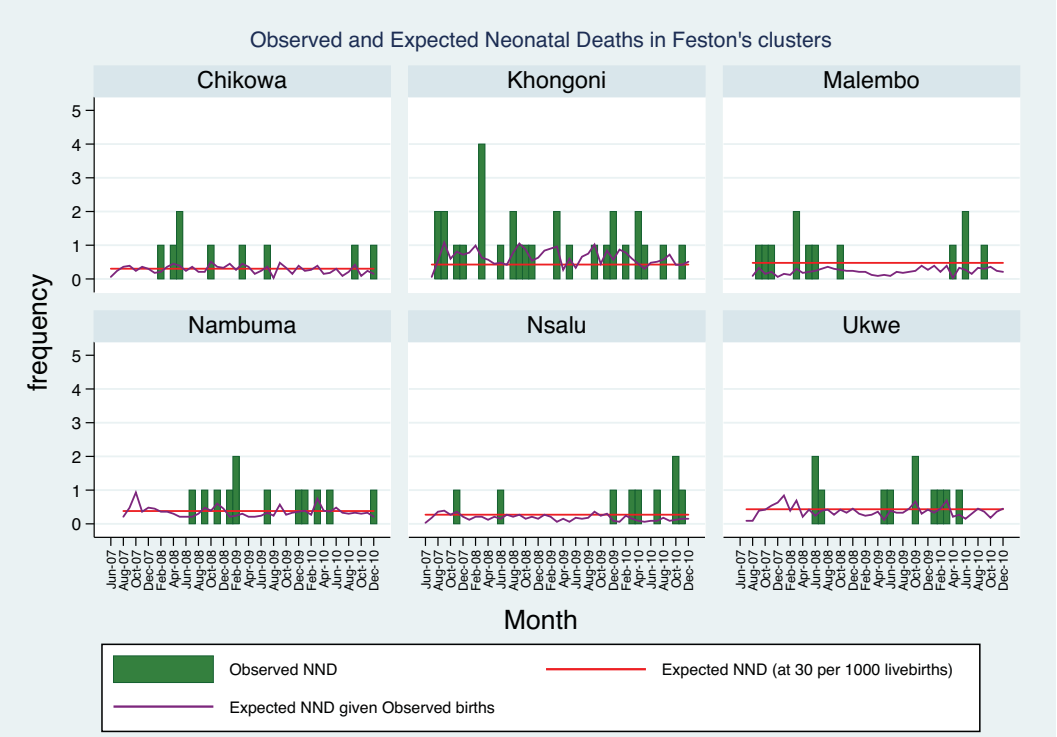


Figure 18: Observed and Expected Maternal Deaths in clusters managed by MEO 4

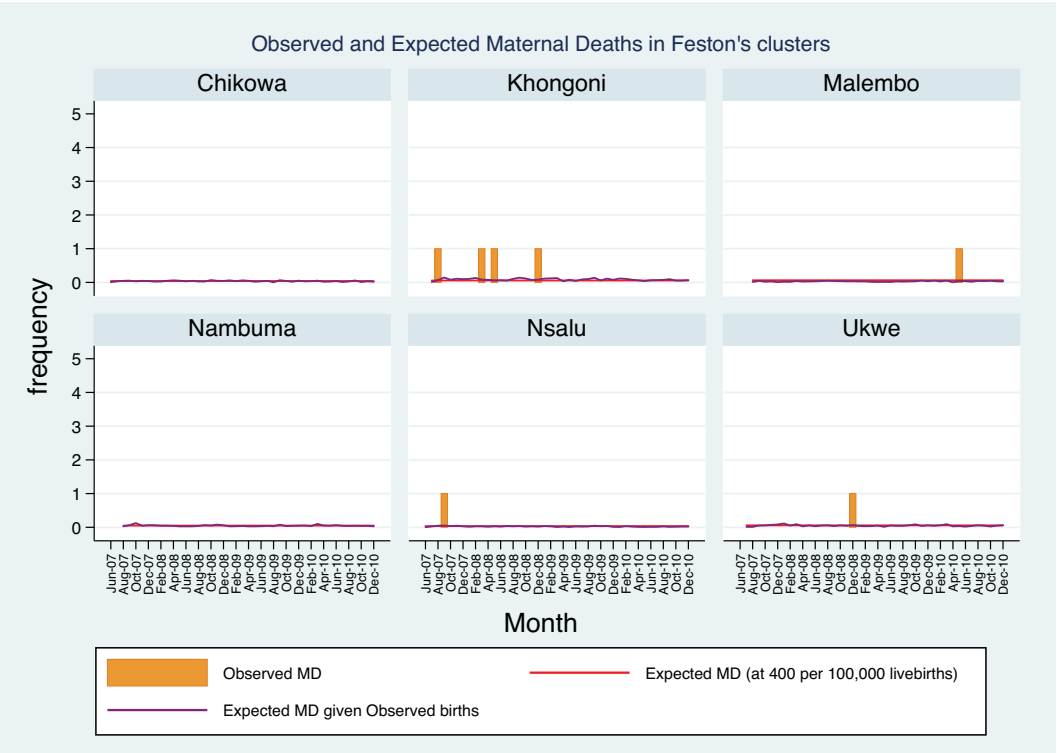


Figure 19: Observed and Expected Births in clusters managed by MEO 5

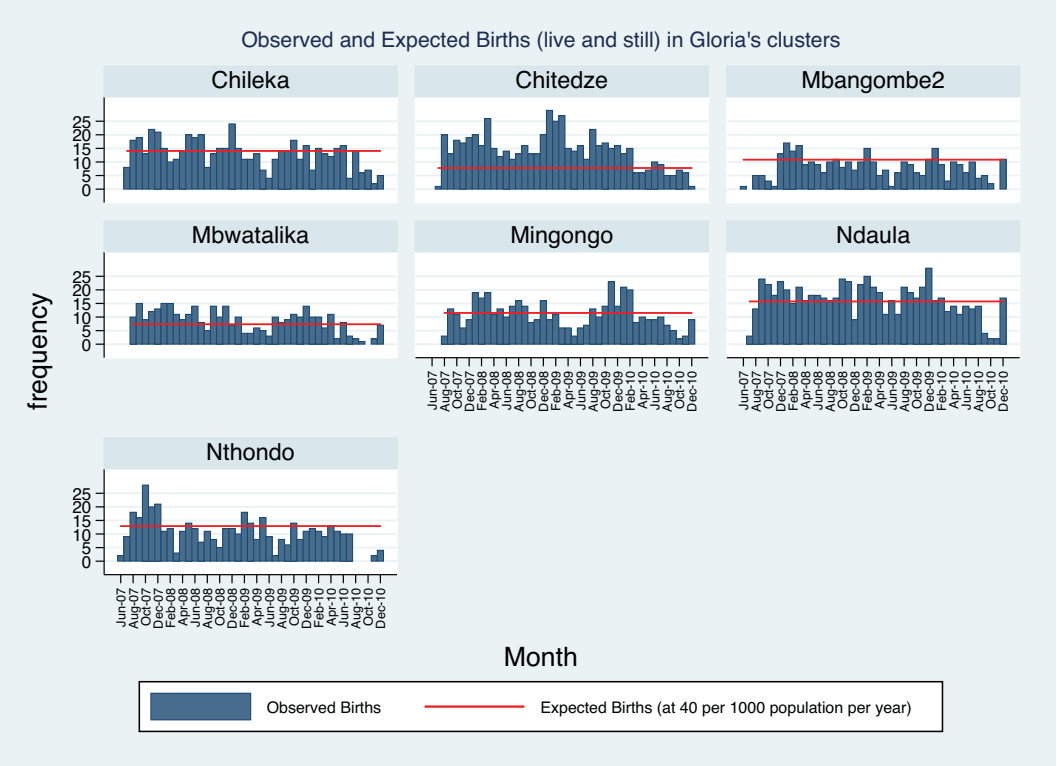


Figure 20: Observed and Expected Stillbirths in clusters managed by MEO 5

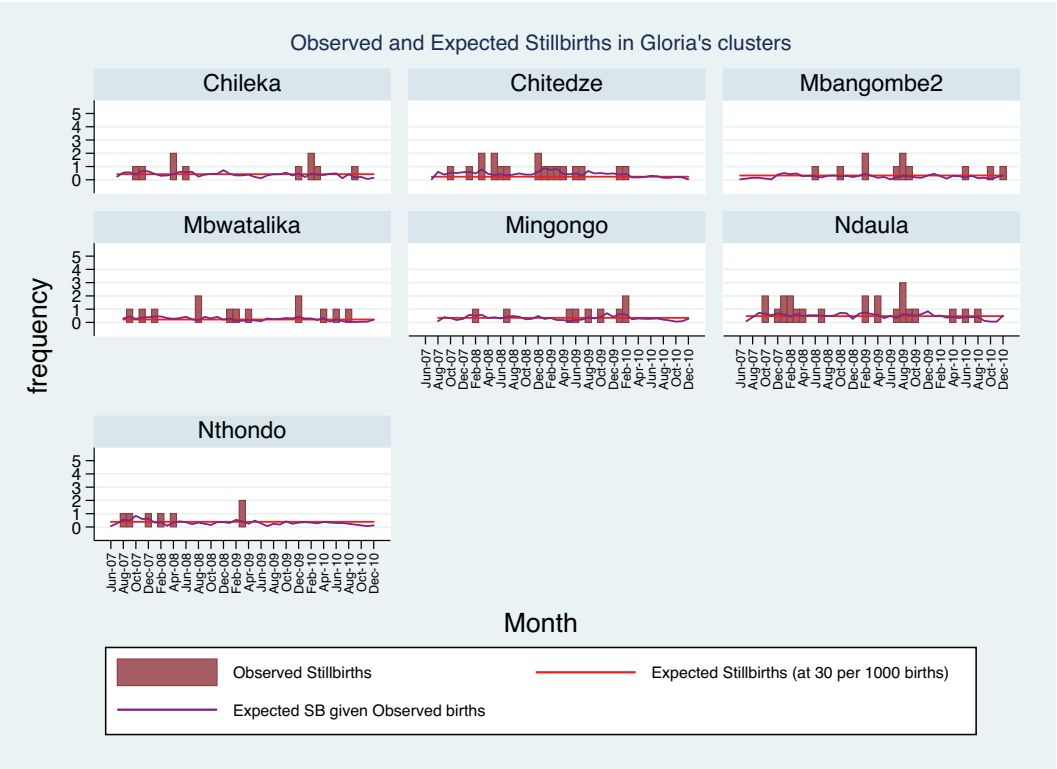


Figure 21: Observed and Expected Neonatal Deaths in clusters managed by MEO 5

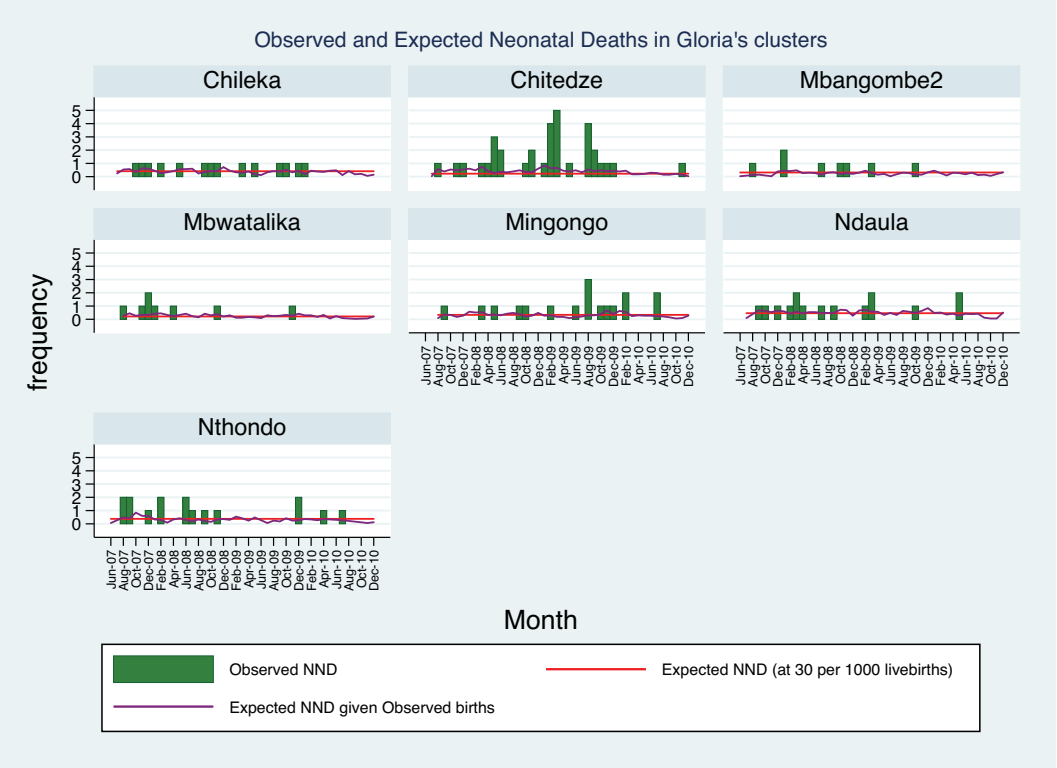


Figure 22: Observed and Expected Maternal Deaths in clusters managed by MEO 5

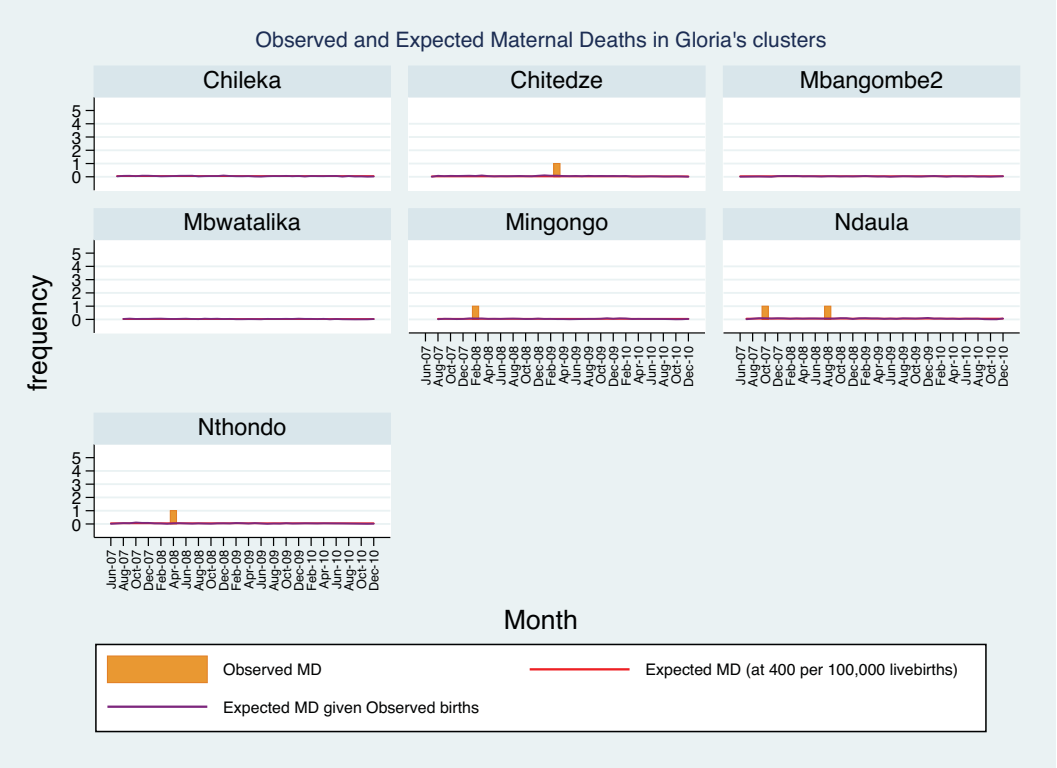


Figure 23: Observed and Expected Births in clusters managed by MEO 6

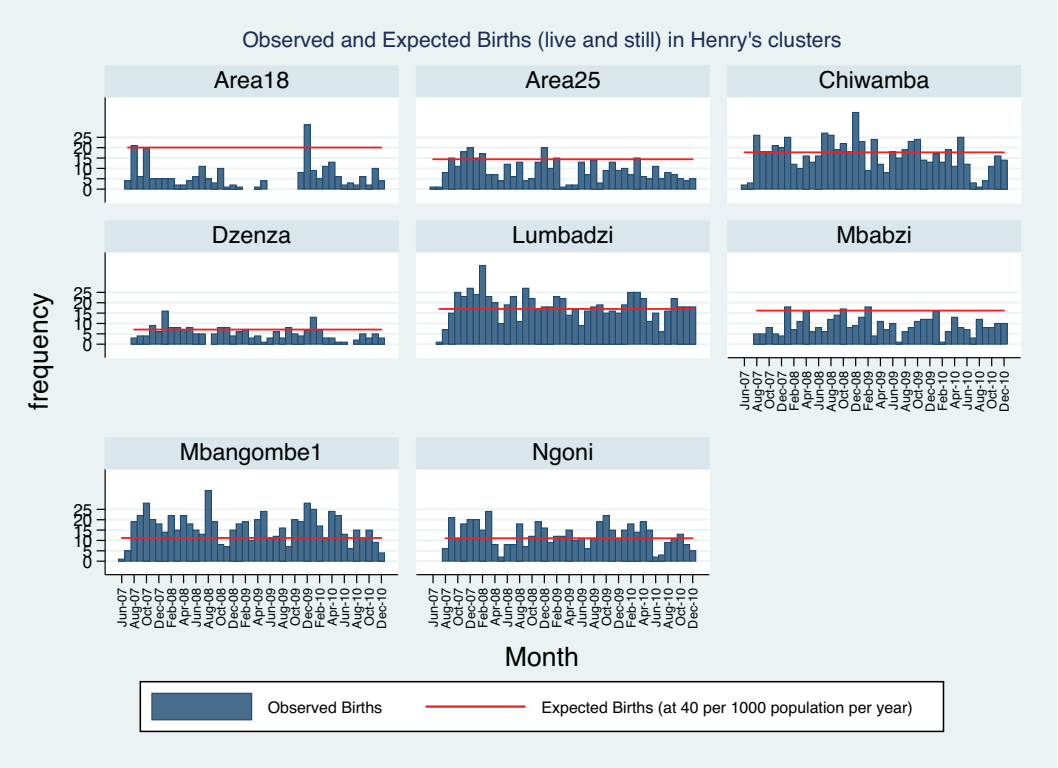


Figure 24: Observed and Expected Stillbirths in clusters managed by MEO 6

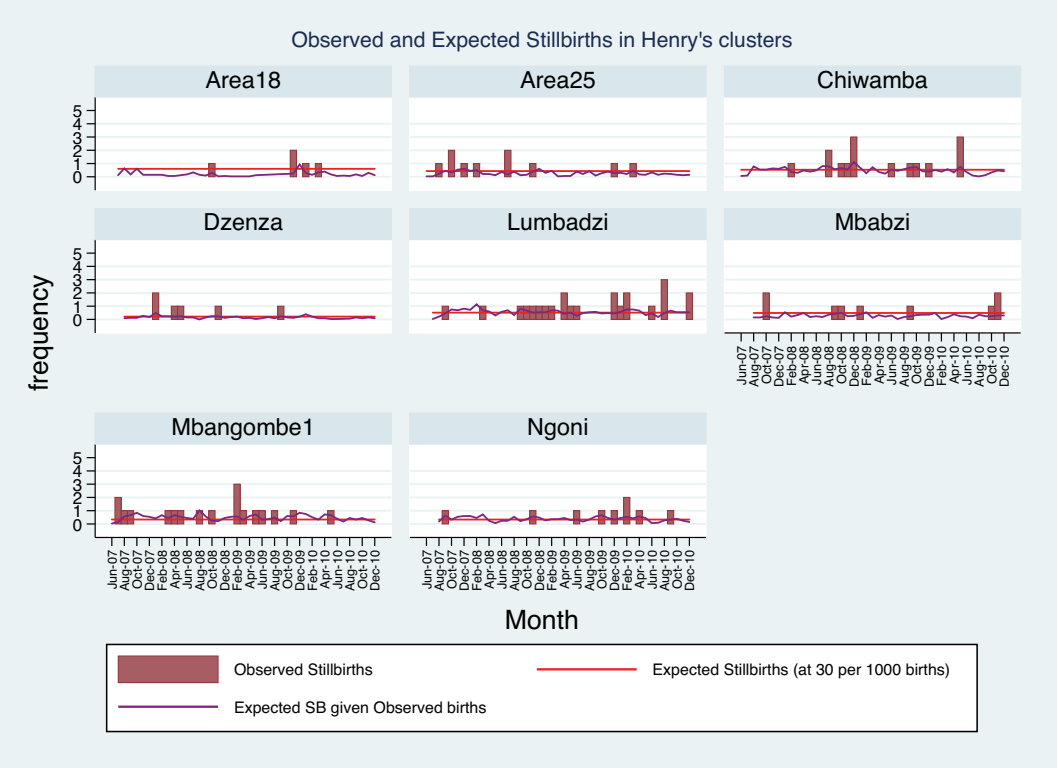


Figure 25: Observed and Expected Neonatal Deaths in clusters managed by MEO 6

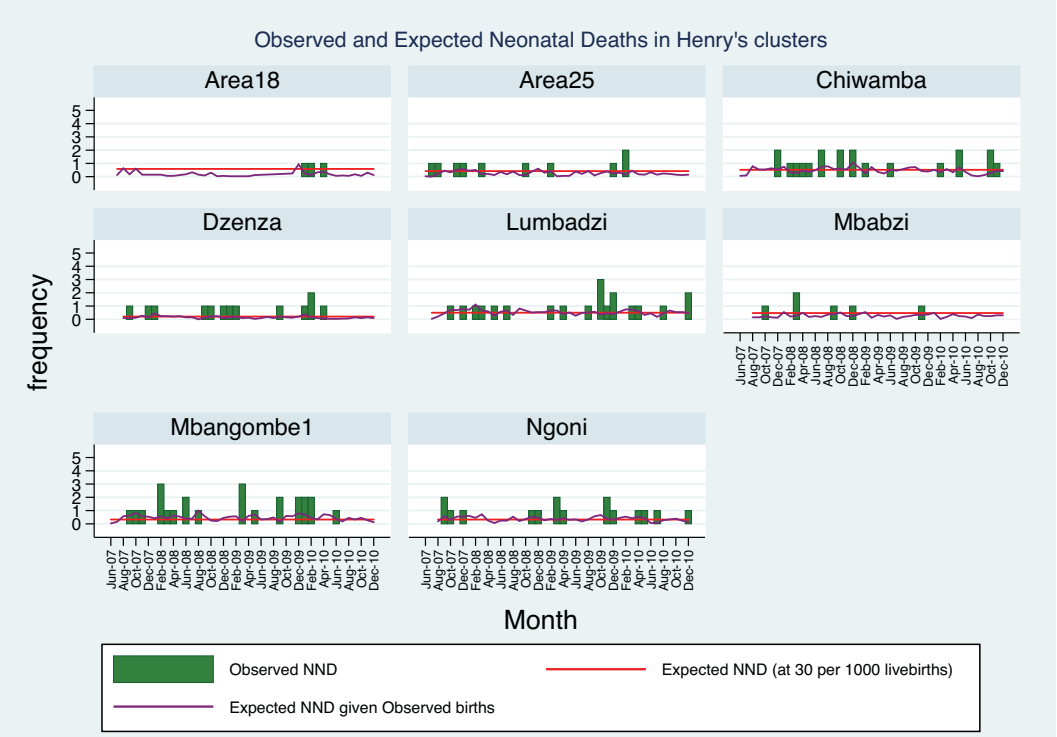


Figure 26: Observed and Expected Maternal Deaths in clusters managed by MEO 6

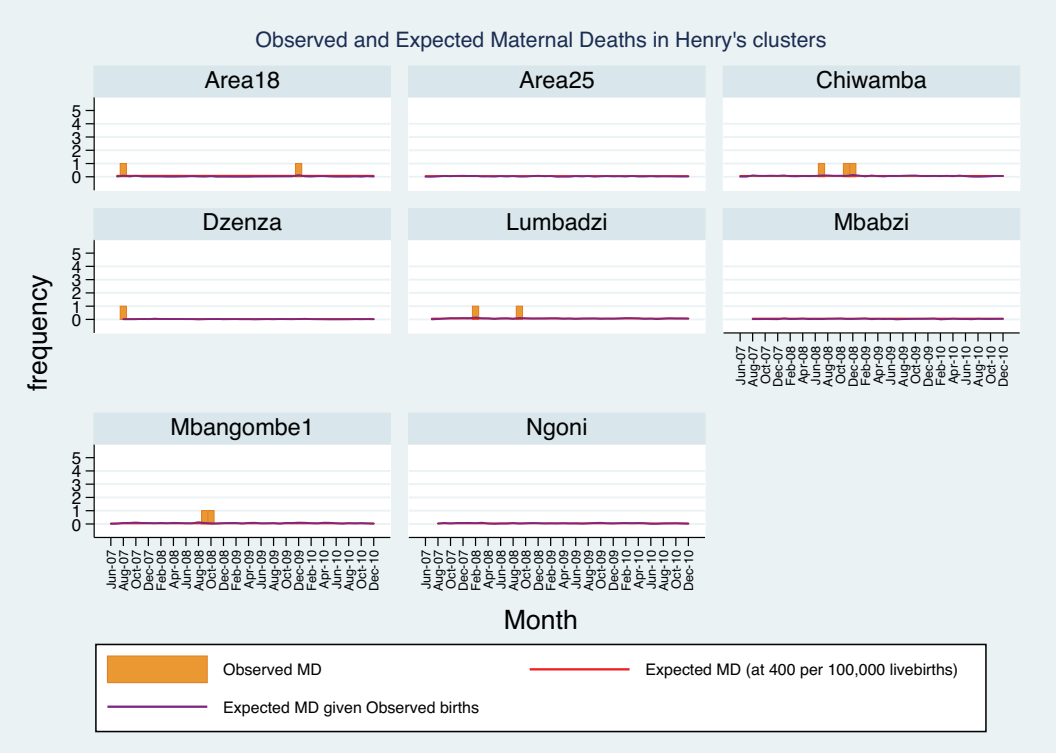


Figure 27: Observed and Expected Births in clusters managed by MEO 7

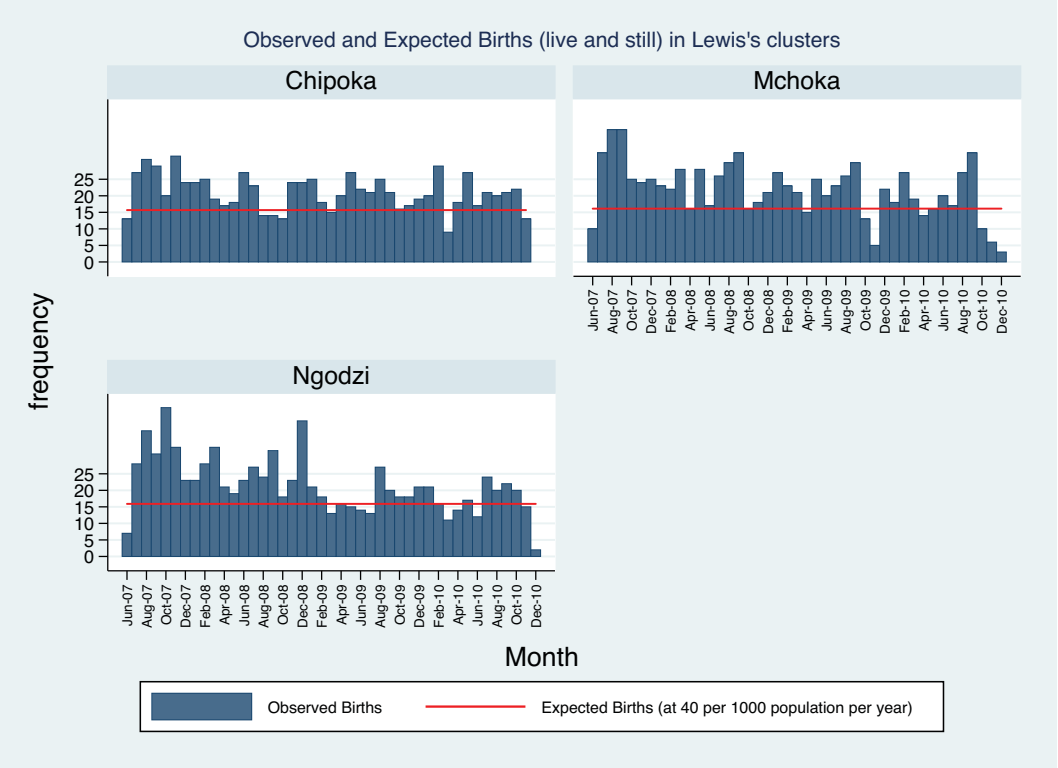


Figure 28: Observed and Expected Stillbirths in clusters managed by MEO 7

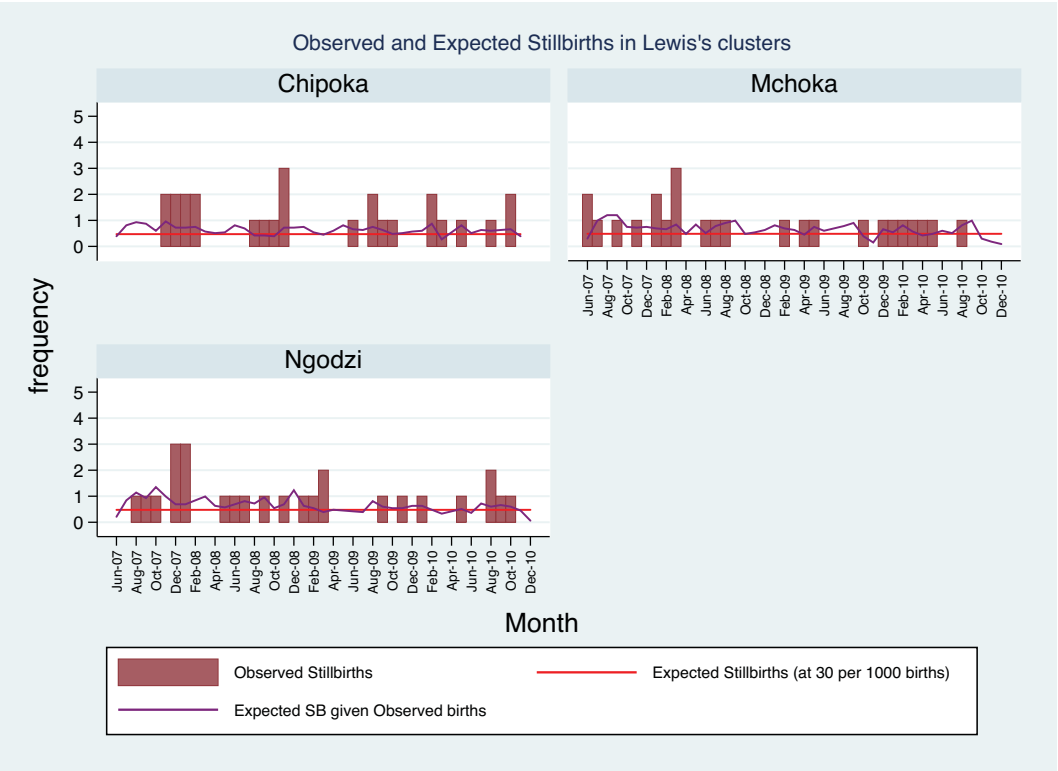


Figure 29: Observed and Expected Neonatal Deaths in clusters managed by MEO 7

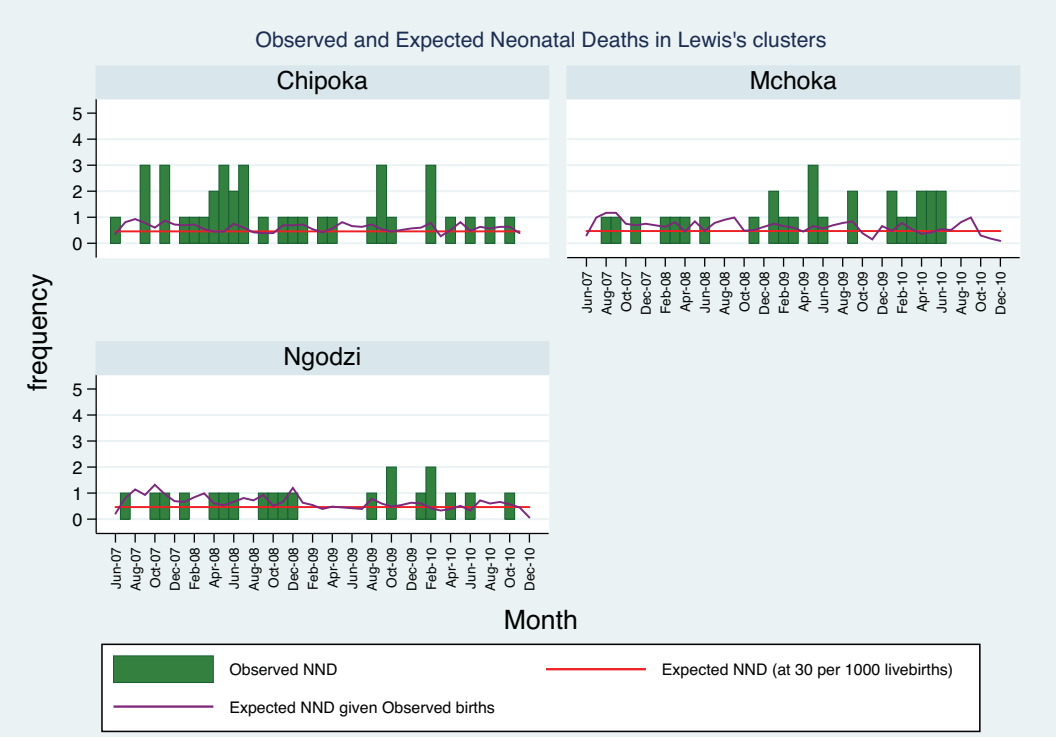


Figure 30: Observed and Expected Maternal Deaths in clusters managed by MEO 7

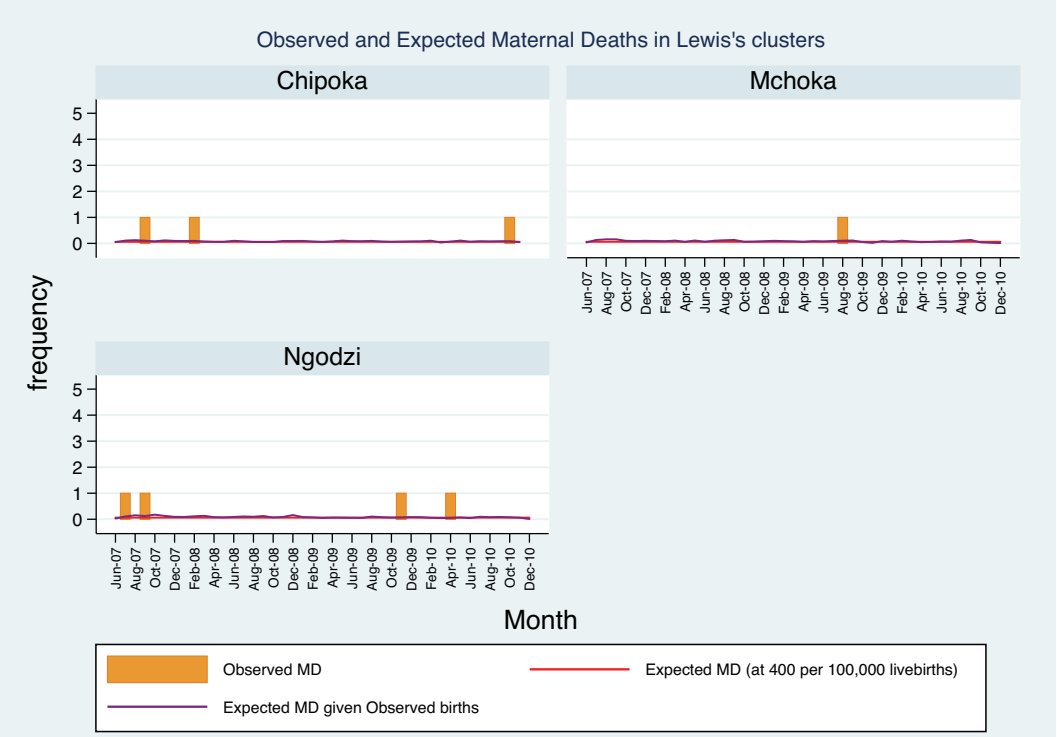


Figure 31: Observed and Expected Births in clusters managed by MEO 8

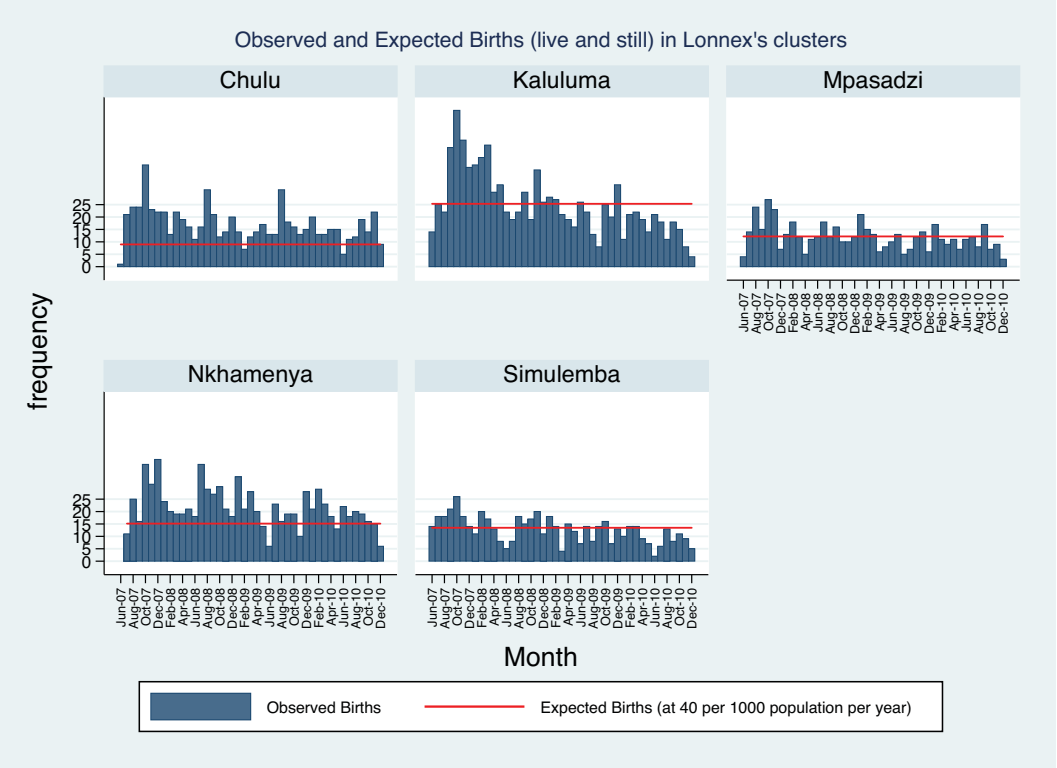


Figure 32: Observed and Expected Stillbirths in clusters managed by MEO 8

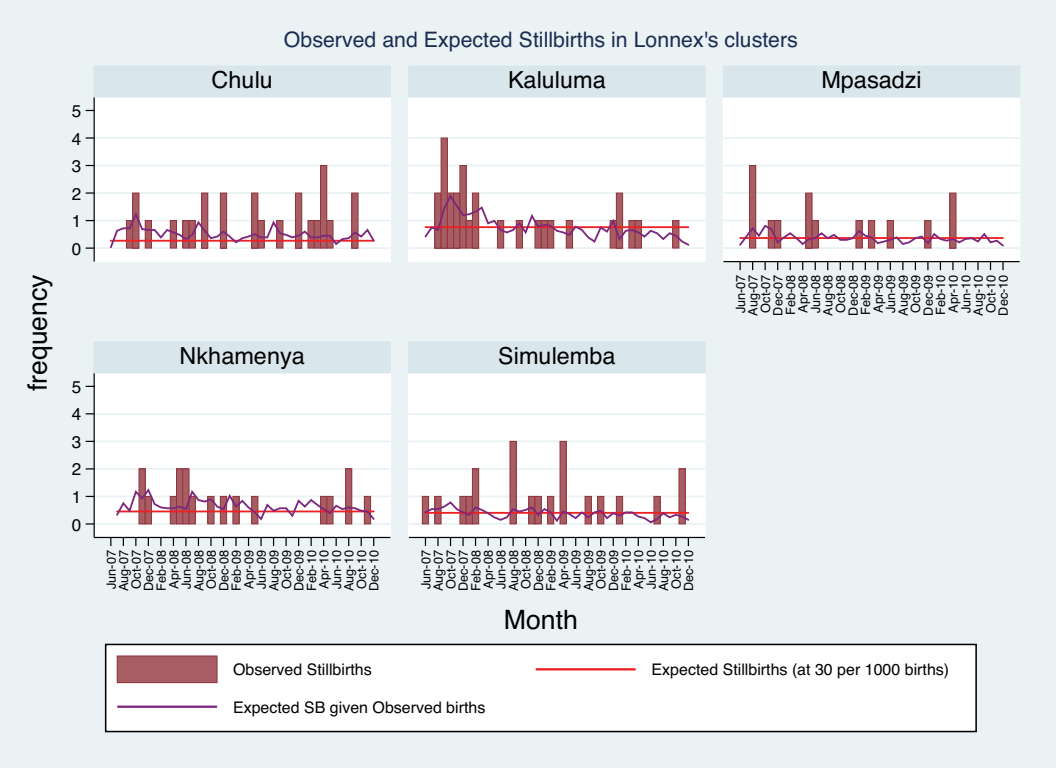


Figure 33: Observed and Expected Neonatal Deaths in clusters managed by MEO 8

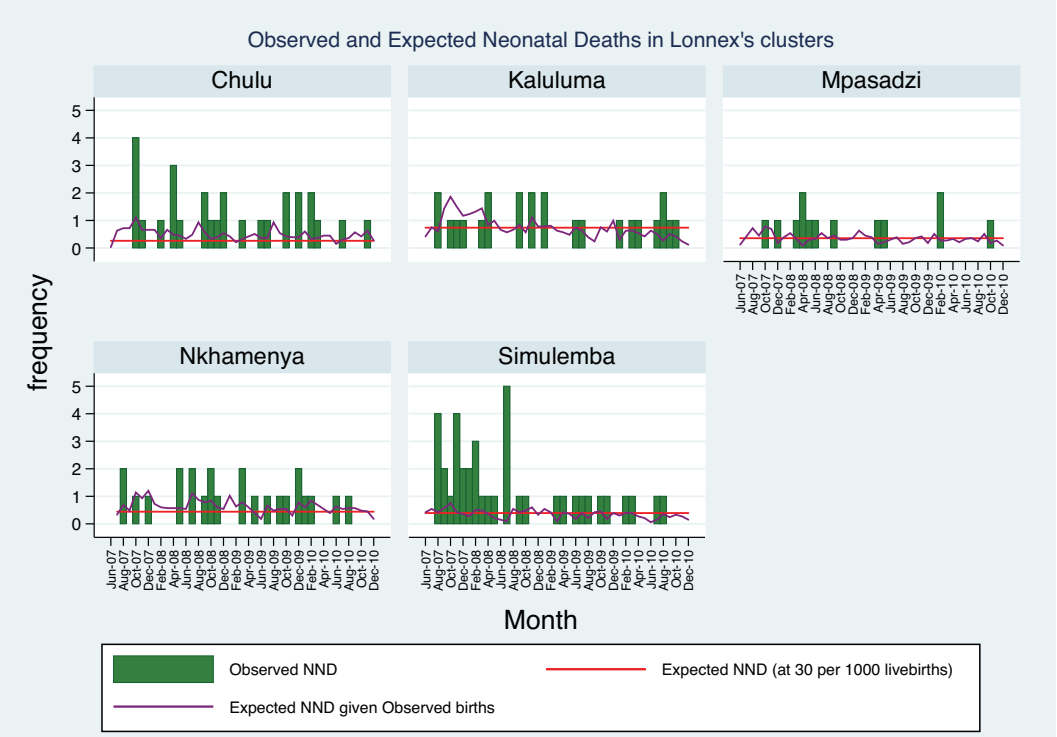


Figure 34: Observed and Expected Maternal Deaths in clusters managed by MEO 8

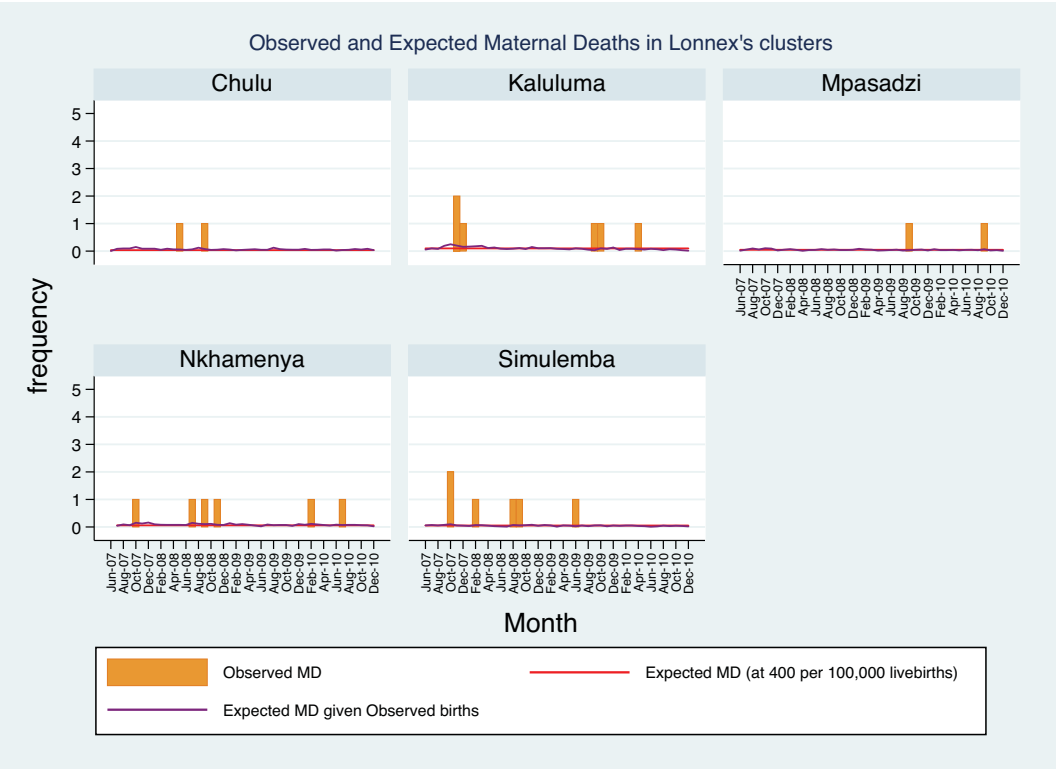


Figure 35: Observed and Expected Births in clusters managed by MEO 9

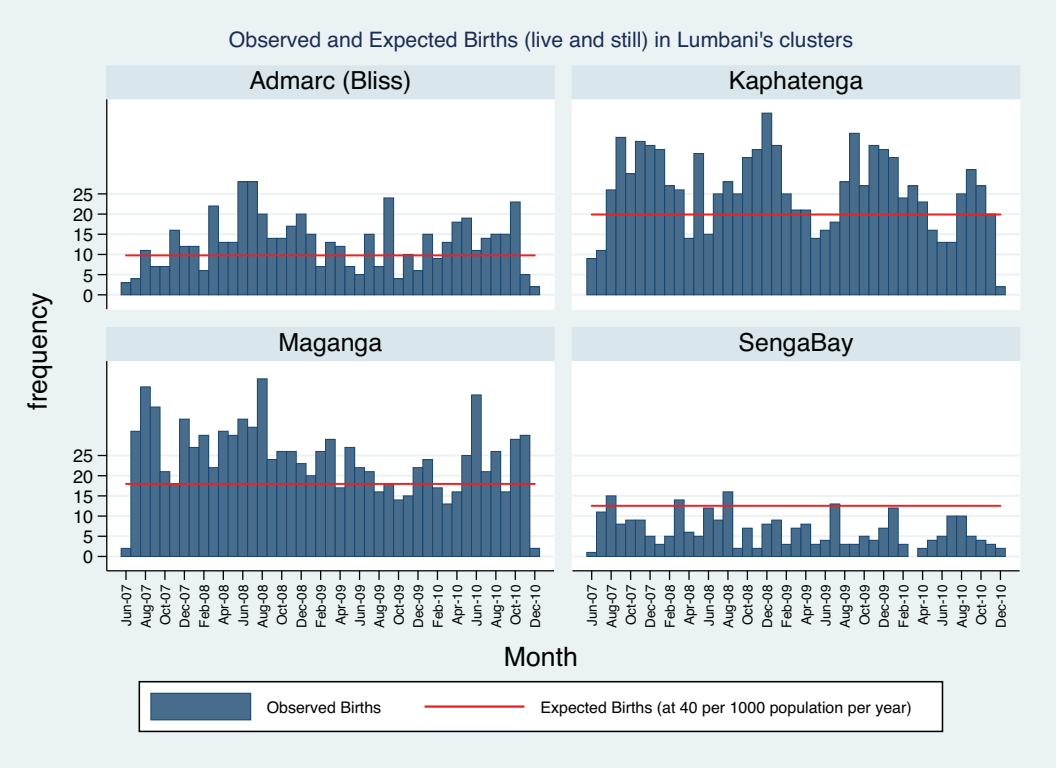


Figure 36: Observed and Expected Stillbirths in clusters managed by MEO 9

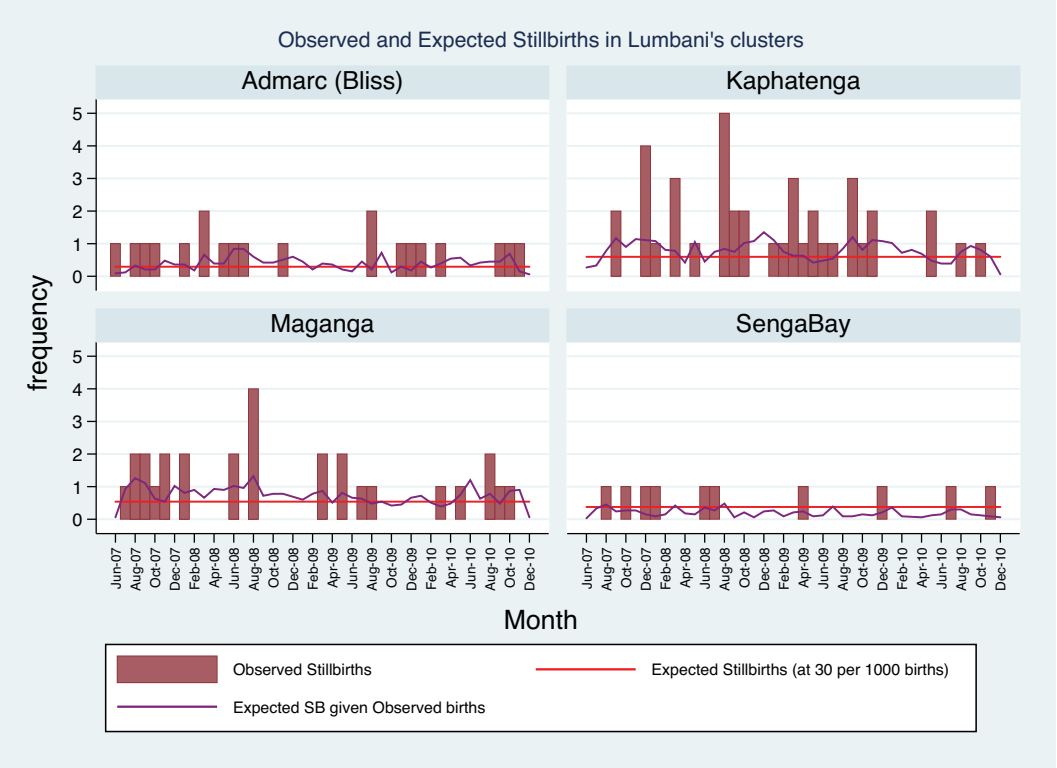


Figure 37: Observed and Expected Neonatal Deaths in clusters managed by MEO 9

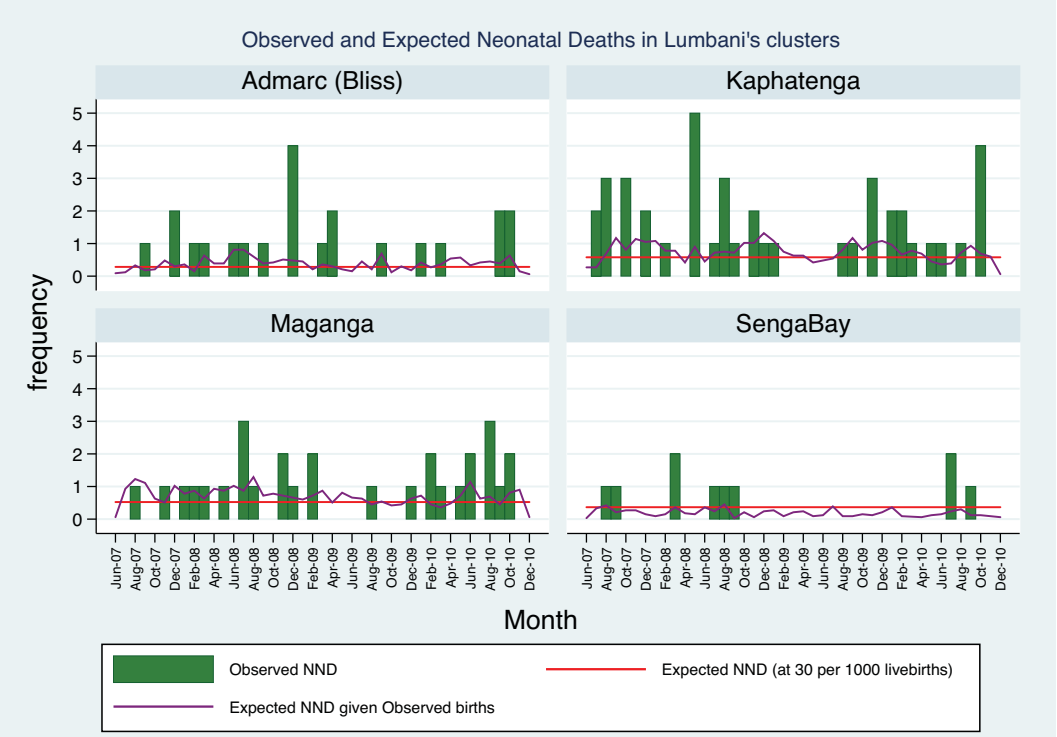


Figure 38: Observed and Expected Maternal Deaths in clusters managed by MEO 9

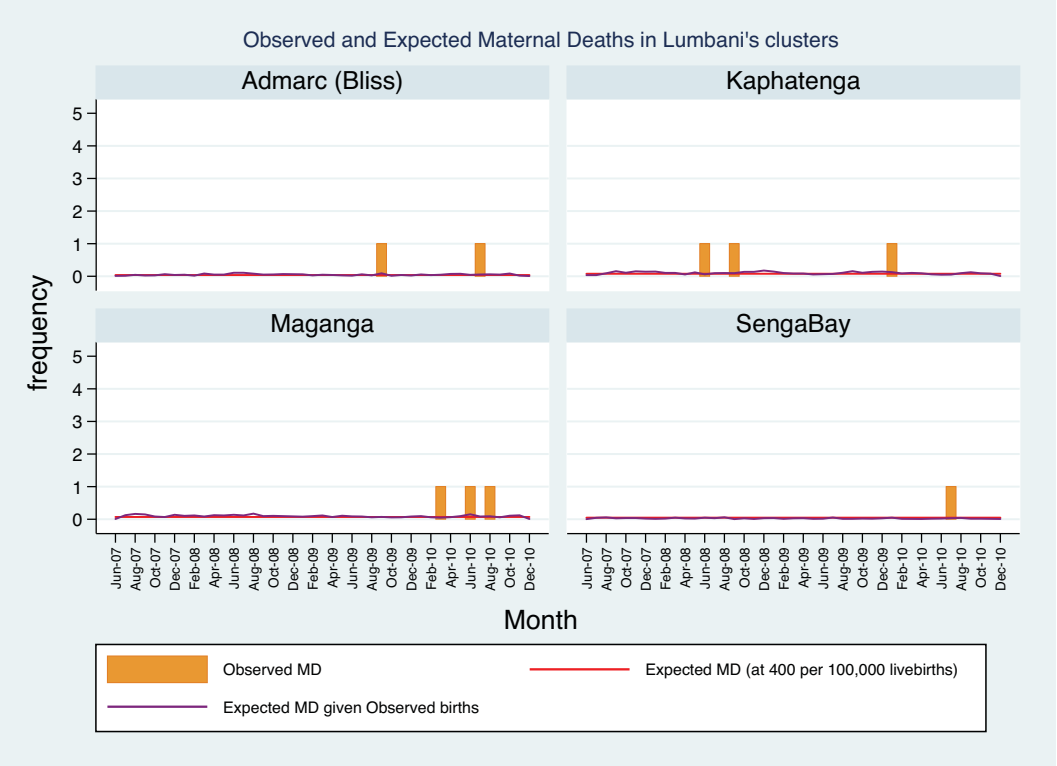


Figure 39: Observed and Expected Births in clusters managed by MEO 10

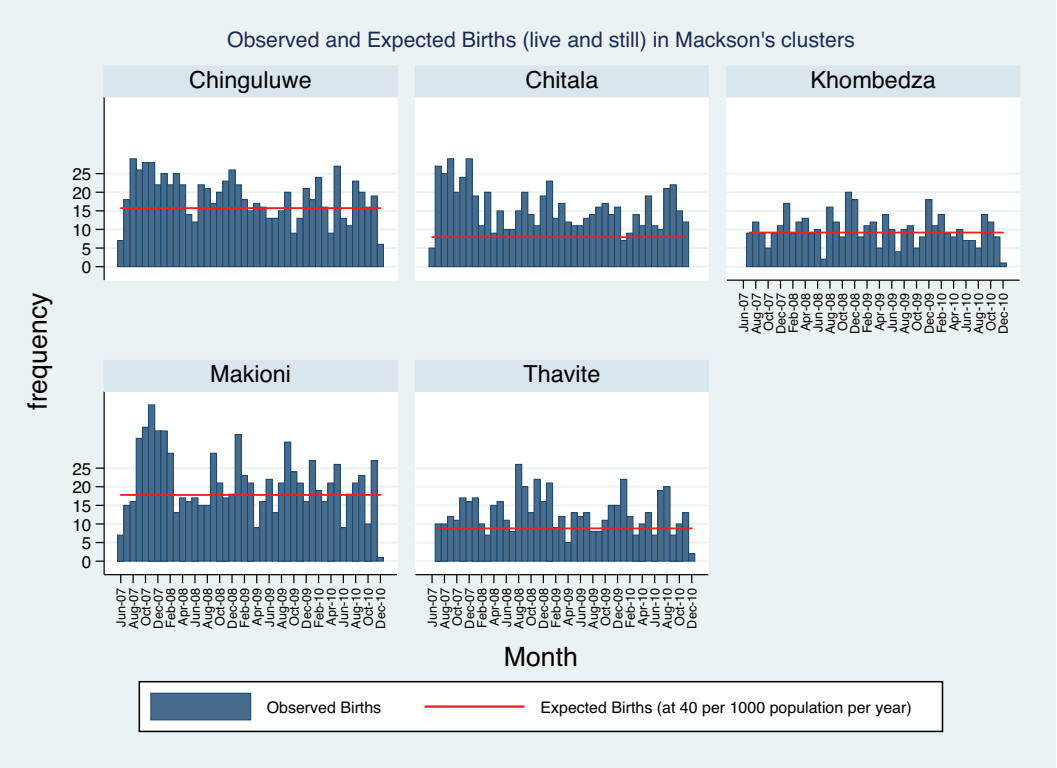


Figure 40: Observed and Expected Stillbirths in clusters managed by MEO 10

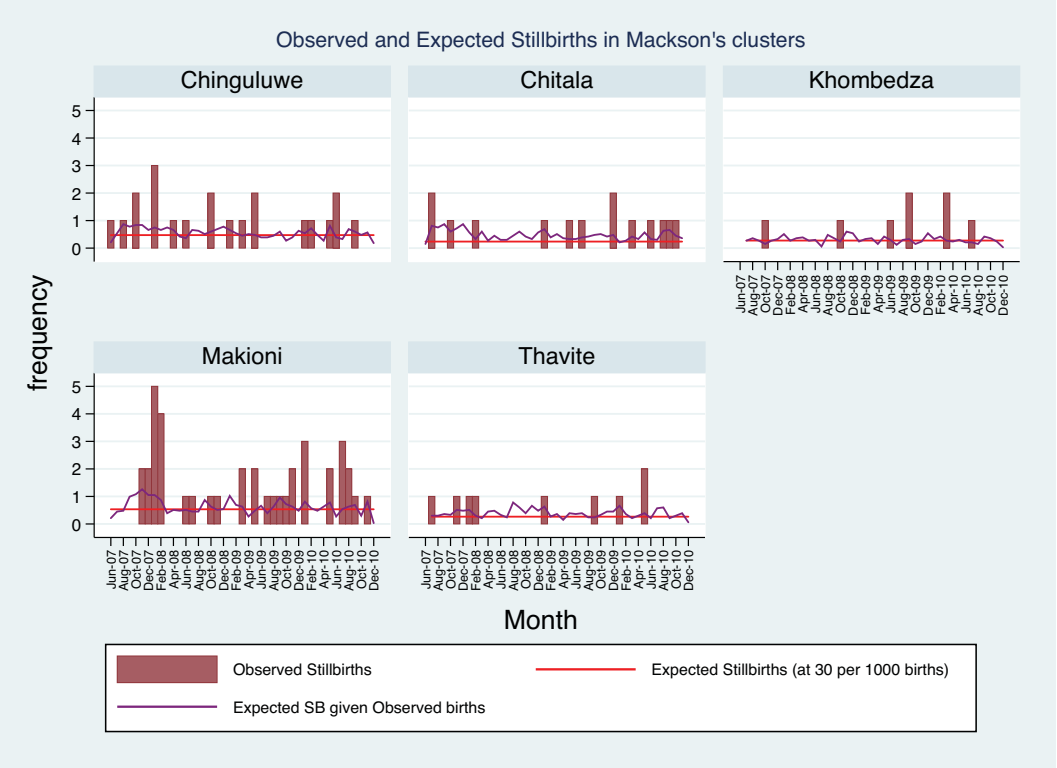


Figure 41: Observed and Expected Neonatal Deaths in clusters managed by MEO 10

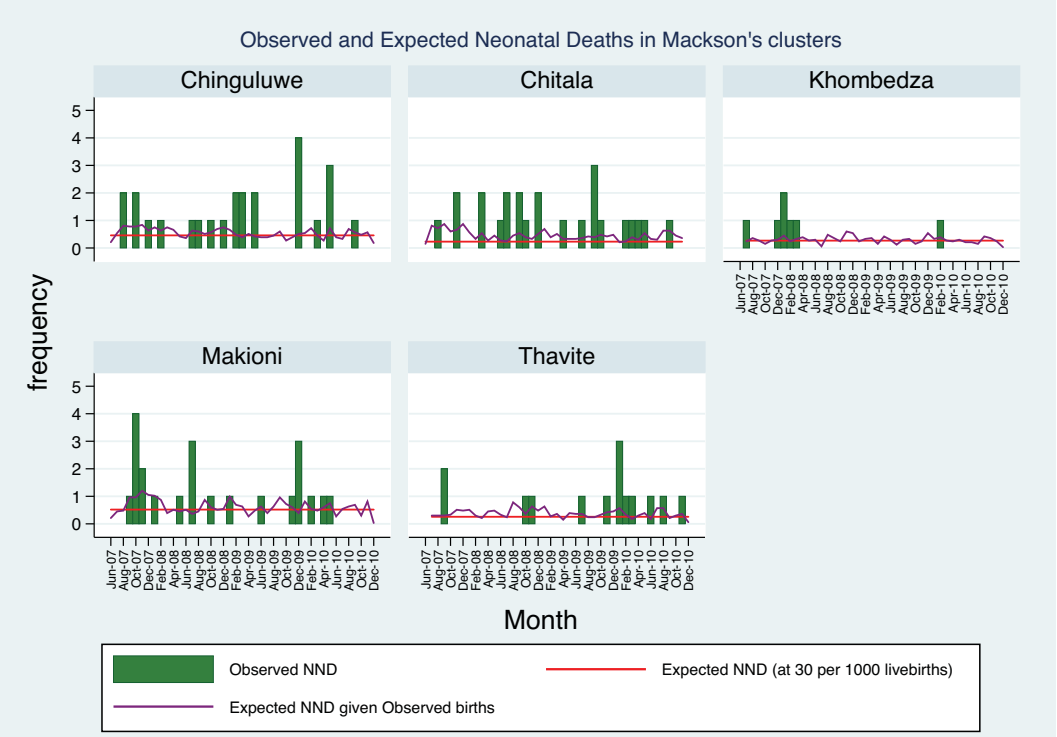


Figure 42: Observed and Expected Maternal Deaths in clusters managed by MEO 10

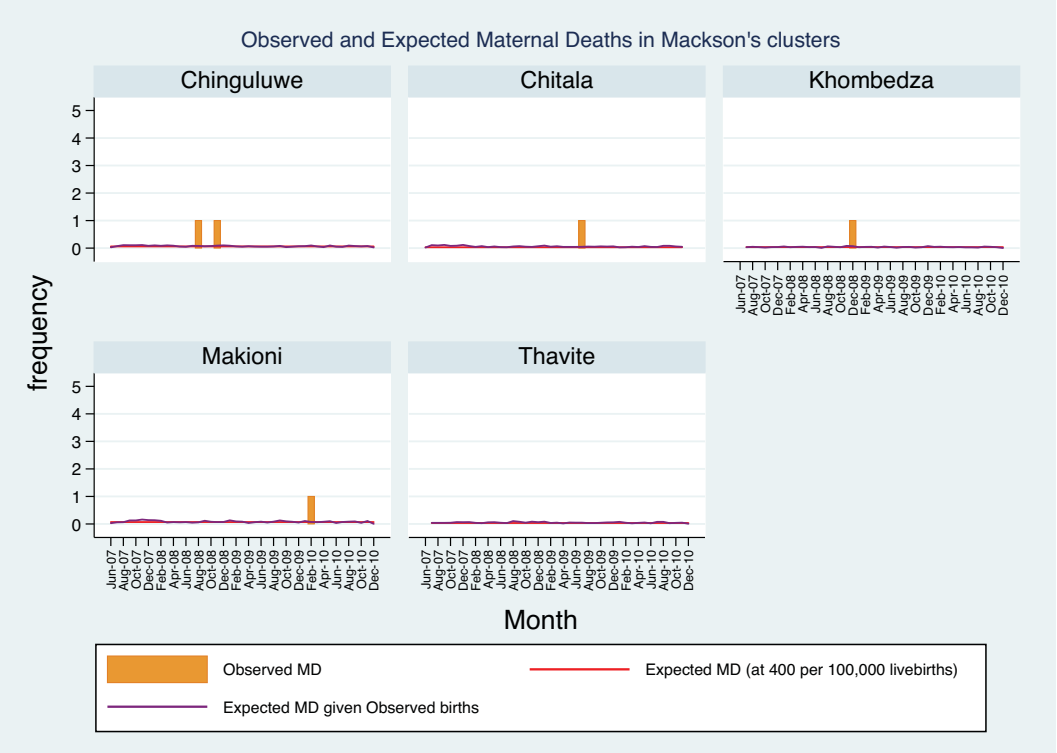


Figure 43: Observed and Expected Births in clusters managed by MEO 11

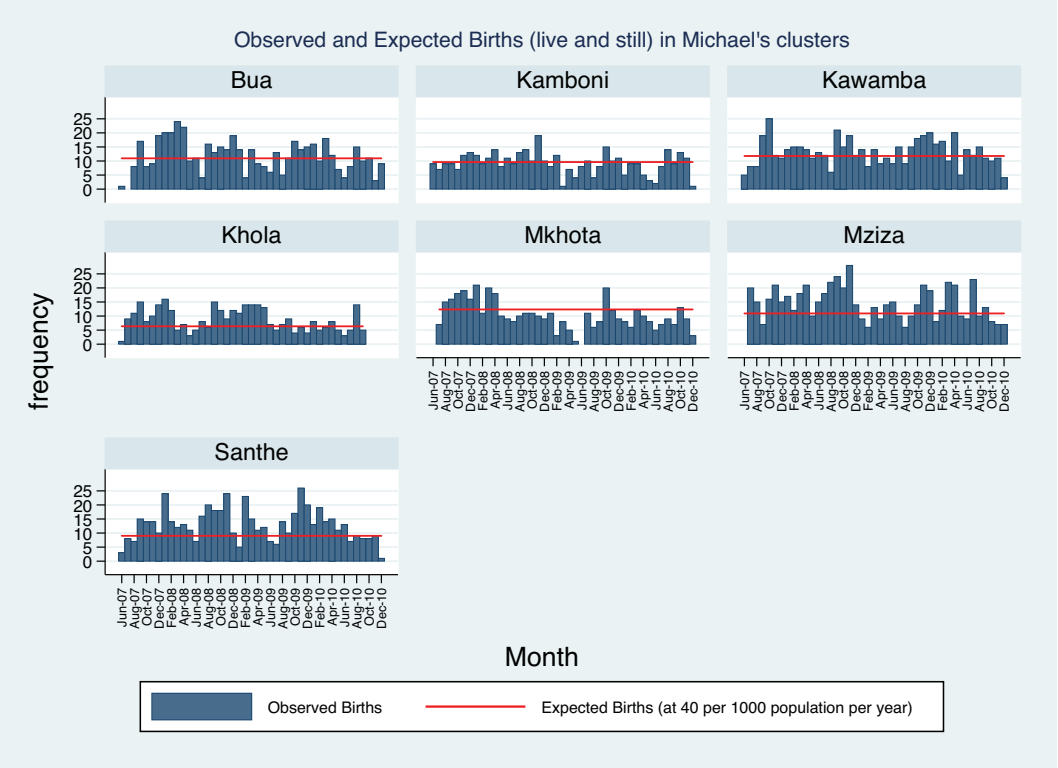


Figure 44: Observed and Expected Stillbirths in clusters managed by MEO 11

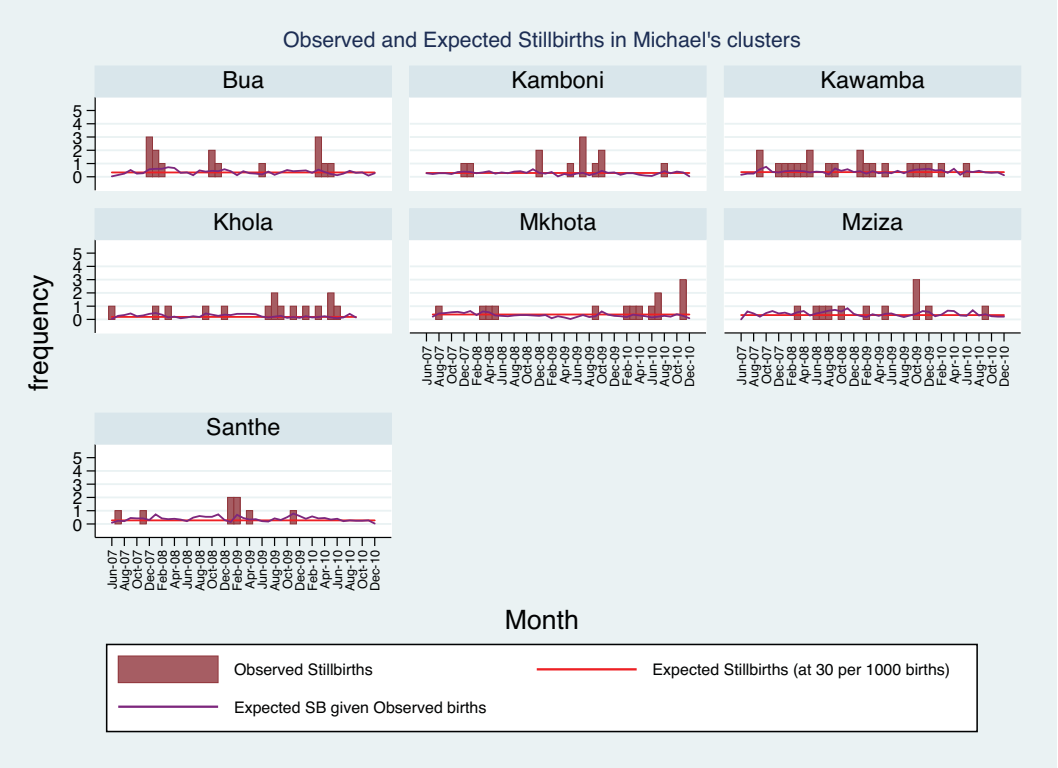


Figure 45: Observed and Expected Neonatal Deaths in clusters managed by MEO 11

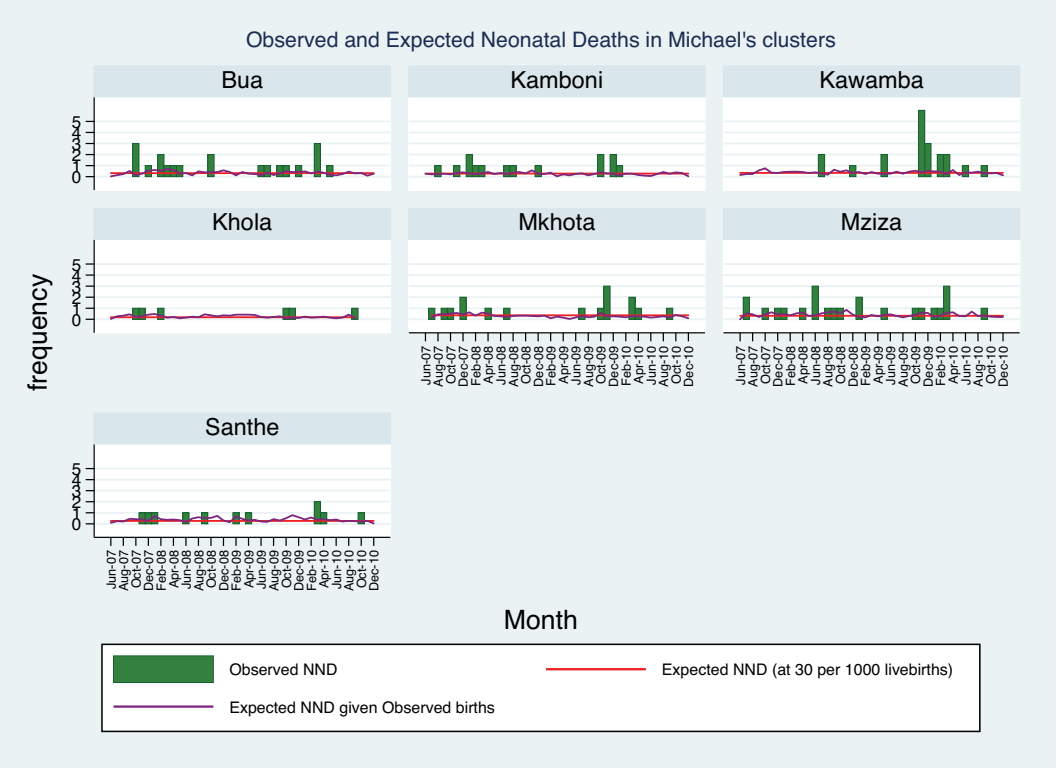
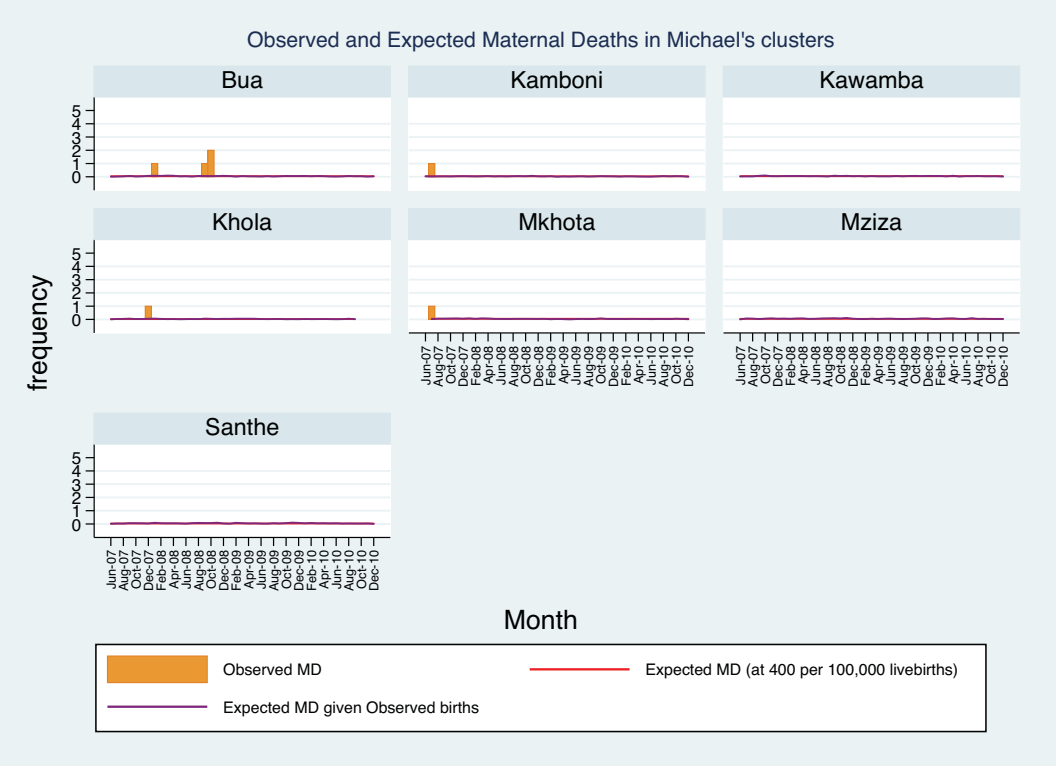


Figure 46: Observed and Expected Maternal Deaths in clusters managed by MEO 11



Appendix 20: Associations between potential confounders at baseline and intervention period mortality outcomes (individual-level logistic regressions)

Possible confounding variable	Intervention Period (01oct2008 to 31dec2012) MMR	NMR	PMR
Baseline Maternal Mortality			
Odds Ratio:	1.0007	1.000	1.000
Lower 95%	1.0001	0.99970	0.9998
Upper 95%	1.0013	1.00017	1.0002
p-value (covariate coefficient)	0.008	0.611	0.897
Change in -2 log likelihood of model after including covariate	6.04	0.26	0.02
p-value (Likelihood Ratio Test)	0.014	0.610	0.897
sig.[a]	*	ns	ns
notes	include in adjusted model (same as for cluster-level)		
Baseline Neonatal Mortality			
Odds Ratio:	1.006	1.004	1.005
Lower 95%	0.983	0.997	1.000
Upper 95%	1.028	1.011	1.01
p-value (covariate coefficient)	0.629	0.263	0.068
Change in -2 log likelihood of model after including covariate	0.23	1.22	3.22
p-value (Likelihood Ratio Test)	0.630	0.269	0.073
sig.[a]	ns	ns	ns
notes			
Baseline Perinatal Mortality			
Odds Ratio:	1.000	1.003	1.003
Lower 95%	0.988	0.999	1.0001
Upper 95%	1.014	1.007	1.007
p-value (covariate coefficient)	0.903	0.129	0.043
Change in -2 log likelihood of model after including covariate	0.01	2.19	3.91
p-value (Likelihood Ratio Test)	0.904	0.139	0.048
sig.[a]	ns	ns	*
notes			include in adjusted model (include this rather than also including b_nmr which is almost significant)
Baseline Skilled Birth Attendance (%)			
Odds Ratio:	1.012	0.999	0.997
Lower 95%	0.994	0.993	0.993
Upper 95%	1.03	1.005	1.002
p-value (covariate coefficient)	0.185	0.760	0.270
Change in -2 log likelihood of model after including covariate	1.75	0.09	1.20
p-value (Likelihood Ratio Test)	0.186	0.760	0.273
sig.[a]	ns	ns	ns
notes	this is included in the cluster level (T-Test) adjusted analyses (is p=0.028)		
Deliveries per month per nurse at nearest HC			
Odds Ratio:	0.997	1.006	1.0046
Lower 95%	0.975	0.9996	0.9993
Upper 95%	1.019	1.0130	1.0099
p-value (covariate coefficient)	0.771	0.066	0.091
Change in -2 log likelihood of model after including covariate	LRT not possible due to missing nursedel data, but coefficients are far from signficance so don't include. (In the case of nursedel and int_nmr and nursedel and int_pmr although the associations are p<0.1 significant, the effect is very small)		
p-value (Likelihood Ratio Test)			
sig.[a]			
notes			

Possible confounding variable	Intervention Period (01oct2008 to 31dec2012) MMR	NMR	PMR
Signal Function availability at HC (number of functions)			
Odds Ratio:	1.102	0.994	1.003
Lower 95%	0.853	0.906	0.938
Upper 95%	1.423	1.091	1.072
p-value (covariate coefficient)	0.456	0.900	0.936
Change in -2 log likelihood of model after including covariate	LRT not possible due to missing nursedel data, but coefficients are far from signficance so don't include		
p-value (Likelihood Ratio Test)			
sig [a]			
notes			
Baseline staff psychology score (average of 19 questions on 1(=bad) - 5(=good) scale)			
Odds Ratio:	1.107	0.950	0.857
Lower 95%	0.422	0.706	0.685
Upper 95%	2.907	1.279	1.074
p-value (covariate coefficient)	0.836	0.737	0.180
Change in -2 log likelihood of model after including covariate	LRT not possible due to missing staffpsy data, but coefficients are far from signficance so don't include		
p-value (Likelihood Ratio Test)			
sig [a]			
notes			
Urban (=1), Peri-urban (=0.5), Rural (=0) setting			
Odds Ratio (peri-urban):	1.952	0.801	0.871
Lower 95% (peri-urban)	0.965	0.591	0.697
Upper 95% (peri-urban)	3.950	1.086	1.089
p-value (peri-urban)	0.063	0.154	0.225
Odds Ratio (urban):	0.537	1.105	1.397
Lower 95% (urban)	0.070	0.702	1.045
Upper 95% (urban)	4.133	1.556	1.867
p-value (urban)	0.550	0.827	0.024
Change in -2 log likelihood of model after including covariate	3.74	2.10	5.84
p-value (Likelihood Ratio Test)	0.155	0.349	0.054
sig.[a]	ns	ns	*
notes			include in model as urban is significant
Access by Tar Road (=1) or dirt road (=0)			
Odds Ratio:	1.250	0.814	0.897
Lower 95%	0.649	0.668	0.765
Upper 95%	2.210	0.992	1.052
p-value (covariate coefficient)	0.614	0.042	0.182
Change in -2 log likelihood of model after including covariate	0.25	4.15	1.78
p-value (Likelihood Ratio Test)	0.615	0.042	0.183
sig.[a]	ns	*	ns
notes		Include in adjusted analysis	
Government (=1) or CHAM (=0) run			
Odds Ratio:	0.738	0.856	1.005
Lower 95%	0.334	0.661	0.82
Upper 95%	1.63	1.111	1.233
p-value (covariate coefficient)	0.452	0.237	0.960
Change in -2 log likelihood of model after including covariate	0.60	1.41	0.00
p-value (Likelihood Ratio Test)	0.439	0.236	0.960
sig.[a]	ns	ns	ns
notes			
Tobacco Estates (=1) or not (=0)			
Odds Ratio:	0.716	1.130	1.097
Lower 95%	0.282	0.776	0.816
Upper 95%	1.816	1.646	1.475
p-value (covariate coefficient)	0.481	0.524	0.541
Change in -2 log likelihood of model after including covariate	0.49	0.41	0.38
p-value (Likelihood Ratio Test)	0.485	0.522	0.540
sig.[a]	ns	ns	ns
notes			

[a] ns=not significant=p>0.05 *=p<0.05 **=p<0.01 ***=p<0.001

Appendix 21: Internal consistency analyses split by first and second intervention periods

Table 2. Consistency between individual FI and CI effects and combined FI+CI effects, during the first intervention period (Oct-08 to Sep-09)

		RCT results: Intervention effects on mortality									Observed FIxCI interaction effect:				
Outcome	Intervention	Odds Ratio	lower 95%	upper 95%	p-value	sig.[a]	% change in mortality	Sum of FI and CI effects	Observed FI+CI effect	Inconsistency between observed sum and observed combined effects	For discrepancies over 2%: greatest Discrepancy in:	Odds Ratio	lower 95%	upper 95%	p-value	sig.[a]
Stillbirth rate	FI (FI only and FI+CI)	1.18	0.83	1.69	0.360	ns	18%									
	CI (CI only and FI+CI)	0.70	0.49	1.00	0.051	**	-30%	-12.1%		5.45%						
	FI only	1.17	0.72	1.92	0.526	ns	17%					1.02	0.50	2.08	0.966	ns
	CI only	0.69	0.41	1.17	0.168	*	-31%	-13.5%		4.02%						
	FI+CI	0.82	0.50	1.36	0.454	ns	-18%		-17.5%							
NMR	FI (FI only and FI+CI)	0.82	0.63	1.06	0.124	*	-18%									
	CI (CI only and FI+CI)	1.05	0.81	1.36	0.700	ns	5%	-13.0%		0.84%		1.11	0.66	1.86	0.690	ns
	FI only	0.77	0.53	1.12	0.177	*	-23%									
	CI only	1.00	0.70	1.43	0.992	ns	0%	-22.3%		-8.54%	CI effects (ns)					
	FI+CI	0.86	0.60	1.24	0.423	ns	-14%		-13.8%							
early (0-6 day) NMR	FI (FI only and FI+CI)	0.92	0.67	1.26	0.599	ns	-8%									
	CI (CI only and FI+CI)	0.95	0.69	1.29	0.727	ns	-5%	-13.4%		-0.53%		1.27	0.68	2.38	0.451	ns
	FI	0.82	0.52	1.27	0.365	ns	-18%									
	CI	0.84	0.54	1.31	0.438	ns	-16%	-34.5%		-21.55%	FI effects (ns)					
	FI+CI	0.87	0.56	1.35	0.534	ns	-13%		-12.9%							
late (7-28 day) NMR	FI (FI only and FI+CI)	0.54	0.31	0.92	0.025	***	-46%									
	CI (CI only and FI+CI)	1.62	0.93	2.80	0.089	**	62%	15.5%		28.85%		0.86	0.29	2.57	0.787	ns
	FI	0.59	0.25	1.37	0.218	*	-41%									
	CI	1.71	0.86	3.39	0.126	*	71%	29.8%		43.12%	CI effects (ns)					
	FI+CI	0.87	0.39	1.91	0.722	ns	-13%		-13.4%							
Perinatal: Stillbirths + early NND	FI (FI only and FI+CI)	1.04	0.83	1.31	0.719	ns	4%									
	CI (CI only and FI+CI)	0.81	0.65	1.02	0.074	**	-19%	-14.6%		0.81%		1.10	0.69	1.74	0.688	ns
	FI	1.00	0.72	1.37	0.980	ns	0%									
	CI	0.77	0.55	1.08	0.127	*	-23%	-23.1%		-7.71%	FI effects (ns)					
	FI+CI	0.85	0.61	1.17	0.309	ns	-15%		-15.4%							
MMR	FI	1.91	0.82	4.48	0.135	*	91%									
	CI	1.37	0.60	3.09	0.455	ns	37%	127.9%		-133.58%	FI and CI effects (both ns)	0.63	0.20	1.97	0.427	ns
	FI	3.58	0.76	16.91	0.107	*	258%									
	CI	2.71	0.55	13.45	0.222	*	171%	429.6%		168.11%	FI and CI effects (both ns)					
	FI+CI	3.62	0.77	17.07	0.105	*	262%		261.5%							

[a] Given smaller sample size for some categories and the need to compare non-significant effects we have recoded significance as follows: ns = not significant = p>0.25 * = 0.25>p>0.1 ** = 0.1>p0.05 *** = 0.05>p>0.01 **** = p<0.01

Table 3. Consistency between individual FI and CI effects and combined FI+CI effects, during the second intervention period (Oct-09 to Dec-10)

		RCT results: Intervention effects on mortality								Observed FIxCI interaction effect:				
Outcome	Intervention	Odds Ratio	lower 95%	upper 95%	p-value	sig.[a]	% change in mortality	Sum of FI and CI effects	Observed FI+CI effect	Inconsistency between observed sum and observed combined effects	For discrepancies over 2%: greatest Discrepancy in:	Odds Ratio	lower 95%	upper 95%	p-value	sig.[a]
Stillbirth rate	FI (FI only and FI+CI)	0.97	0.77	1.21	0.767	ns	-3%									
	CI (CI only and FI+CI)	0.94	0.75	1.18	0.621	ns	-6%	-8.9%		-0.22%						
	FI only	0.95	0.69	1.29	0.724	ns	-5%					1.05	0.67	1.64	0.841	ns
	CI only	0.92	0.67	1.27	0.623	ns	-8%	-13.2%		-4.52%						
	FI+CI	0.91	0.66	1.25	0.576	ns	-9%		-8.7%							
NMR	FI (FI only and FI+CI)	0.90	0.69	1.17	0.431	ns	-10%									
	CI (CI only and FI+CI)	0.80	0.61	1.04	0.098	**	-20%	-30.1%		-2.20%		1.08	0.64	1.82	0.782	ns
	FI only	0.87	0.61	1.24	0.443	ns	-13%									
	CI only	0.77	0.53	1.12	0.169	*	-23%	-36.1%		-8.14%	CI effects (ns)					
	FI+CI	0.72	0.50	1.05	0.084	**	-28%		-27.9%							
early (0-6 day) NMR	FI (FI only and FI+CI)	0.92	0.70	1.19	0.516	ns	-8%									
	CI (CI only and FI+CI)	0.79	0.60	1.03	0.083	**	-21%	-29.7%		-1.79%		1.00	0.59	1.70	0.994	ns
	FI	0.92	0.64	1.31	0.634	ns	-8%									
	CI	0.79	0.54	1.15	0.219	*	-21%	-29.6%		-1.63%	FI effects (ns)					
	FI+CI	0.72	0.49	1.06	0.093	**	-28%		-27.9%							
late (7-28 day) NMR	FI (FI only and FI+CI)	0.83	0.49	1.39	0.473	ns	-17%									
	CI (CI only and FI+CI)	0.81	0.48	1.37	0.432	ns	-19%	-36.2%		-5.19%		1.57	0.55	4.45	0.398	ns
	FI	0.67	0.33	1.37	0.274	ns	-33%									
	CI	0.66	0.32	1.35	0.252	ns	-34%	-67.3%		-36.31%	CI effects (ns)					
	FI+CI	0.69	0.34	1.40	0.303	ns	-31%		-31.0%							
Perinatal: Stillbirths + early NND	FI (FI only and FI+CI)	0.94	0.77	1.15	0.555	ns	-6%									
	CI (CI only and FI+CI)	0.87	0.71	1.06	0.179	*	-13%	-18.6%		-0.75%		1.01	0.68	1.50	0.967	ns
	FI	0.94	0.71	1.23	0.650	ns	-6%									
	CI	0.87	0.65	1.15	0.329	ns	-13%	-19.4%		-1.49%	FI effects (ns)					
	FI+CI	0.82	0.62	1.09	0.171	*	-18%		-17.9%							
MMR	FI	0.74	0.32	1.69	0.476	ns	-26%									
	CI	0.58	0.24	1.39	0.223	*	-42%	-67.9%		-8.16%	FI and CI effects (both ns)	0.63	0.20	1.97	0.427	ns
	FI	0.81	0.29	2.25	0.687	ns	-19%									
	CI	0.65	0.21	2.02	0.459	ns	-35%	-53.7%		6.02%	FI and CI effects (both ns)					
	FI+CI	0.40	0.11	1.54	0.184	*	-60%		-59.7%							

[a] Given smaller sample size for some categories and the need to compare non-significant effects we have recoded significance as follows: ns = not significant = p>0.25 * = 0.25>p>0.1 ** = 0.1>p0.05 *** = 0.05>p>0.01 **** = p<0.01

Figure 47: Individual and combined effects of the MaiKhanda interventions on NMR and PMR, during the first intervention period (Oct-08 to Sep-09)

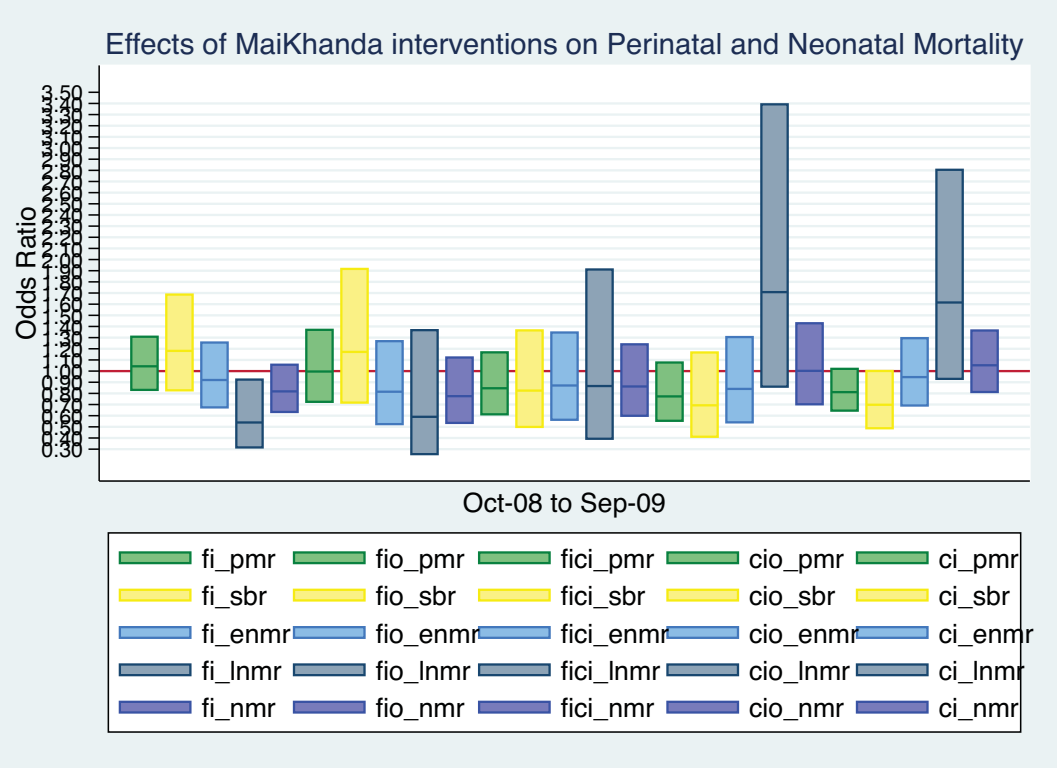


Figure 48: Individual and combined effects of the MaiKhanda interventions on NMR and PMR, during the second intervention period (Oct-09 to Dec-10)

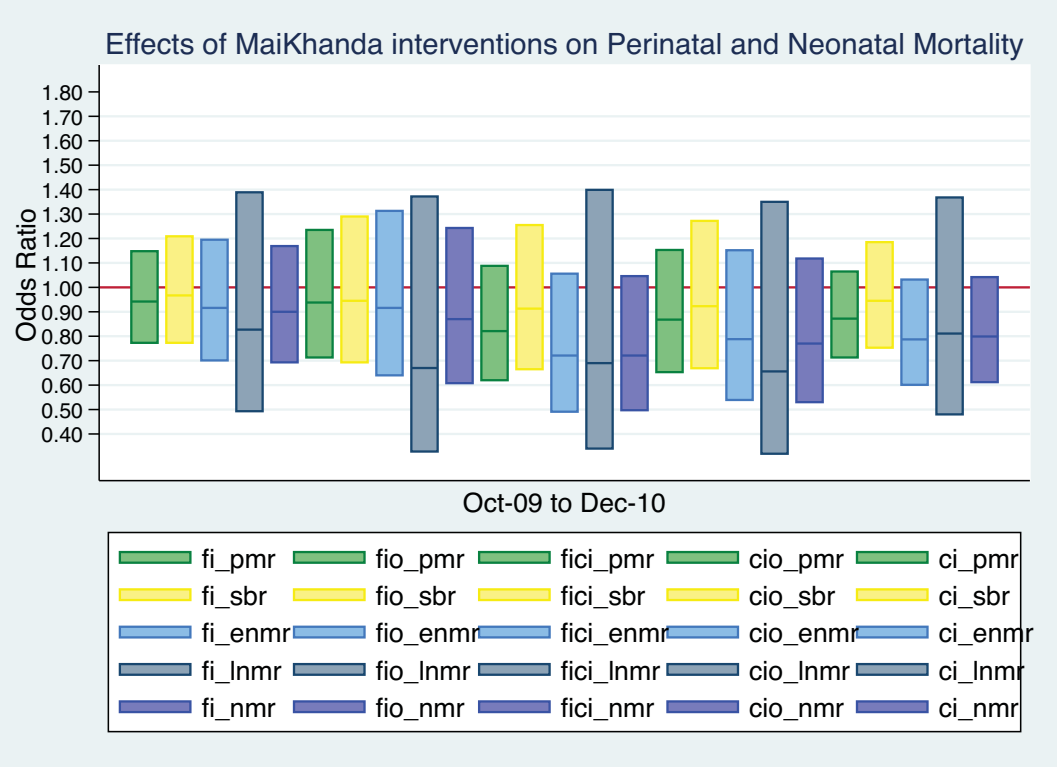


Figure 49: Percentages of observed PMR and NMR reductions due to reductions in Stillbirth rate, Early NMR, and Late NMR by RCT comparison groups, during the first intervention period (Oct-08 to Sep-09)

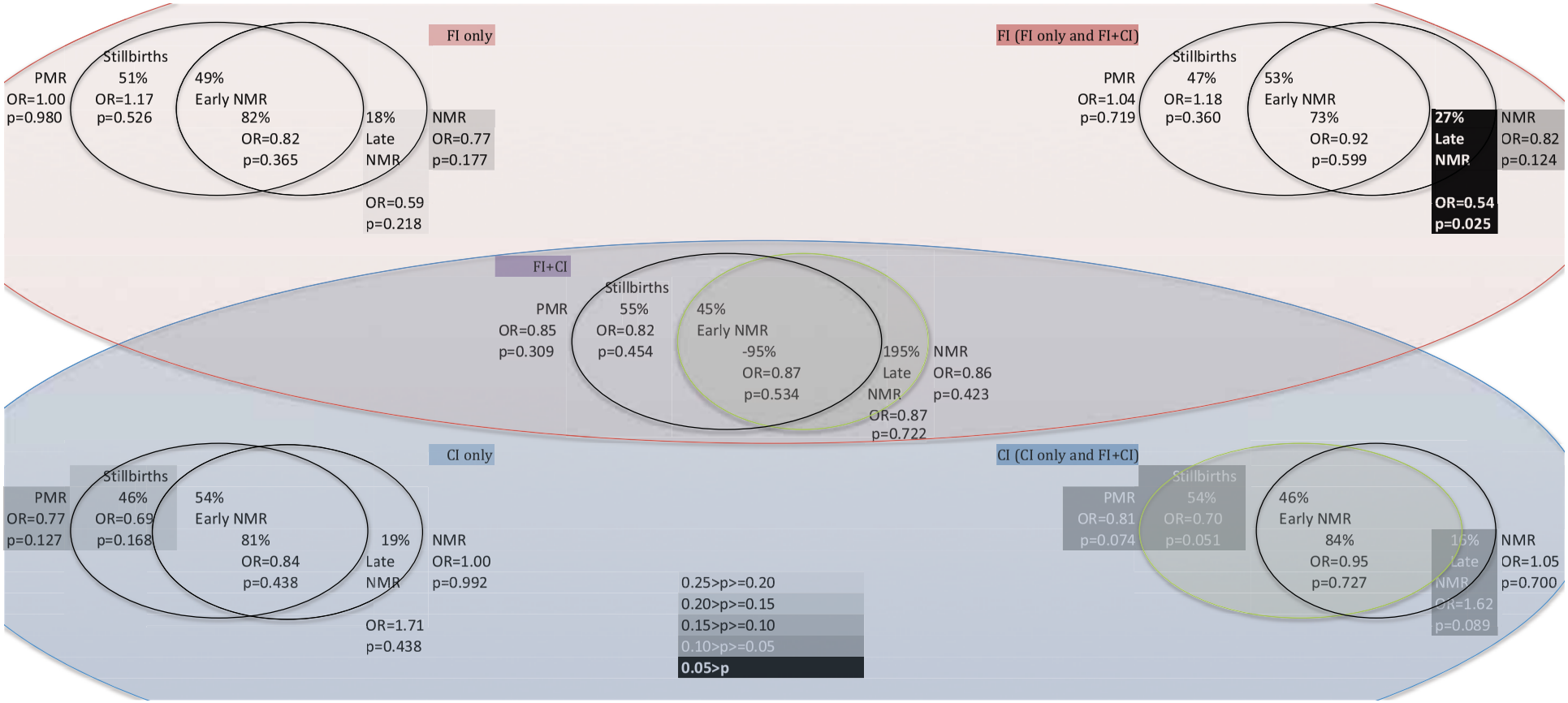
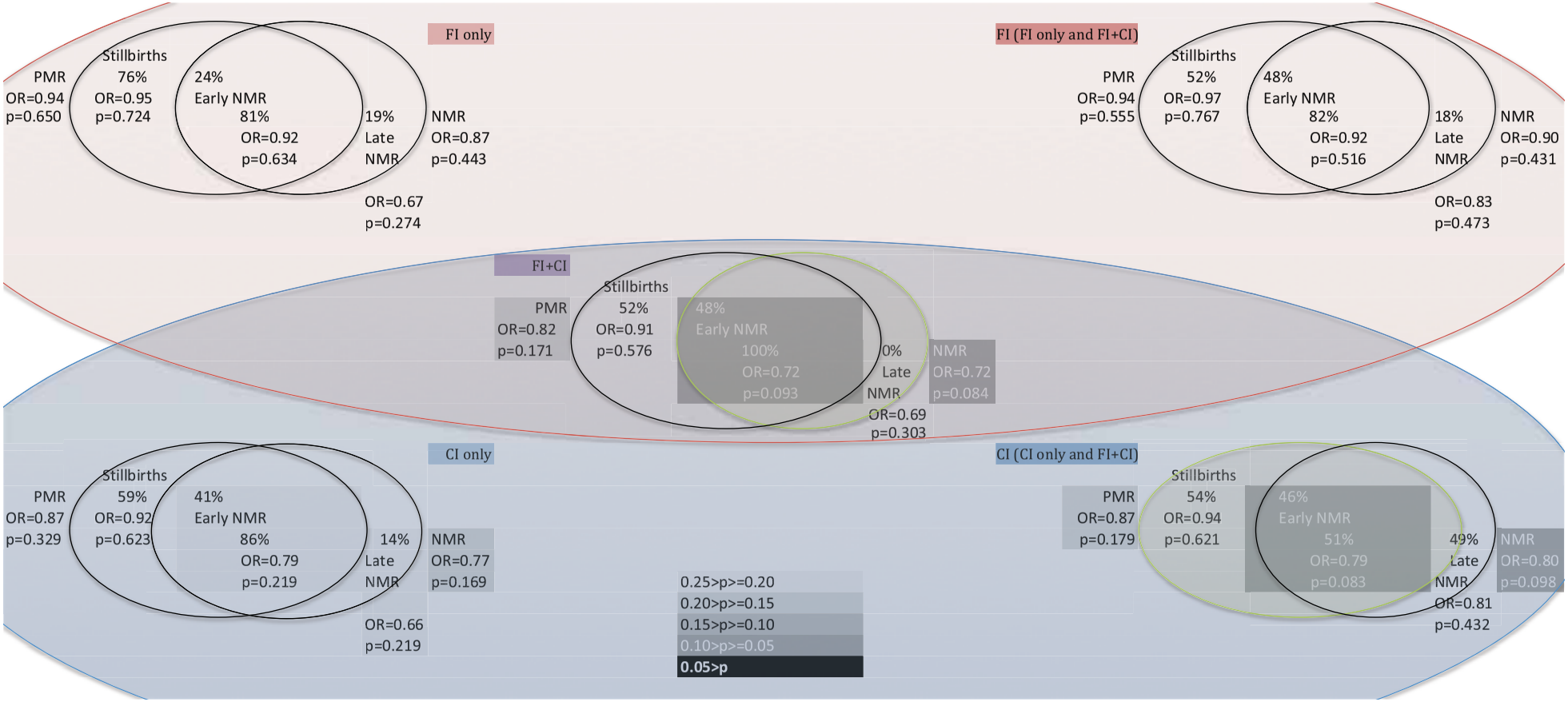
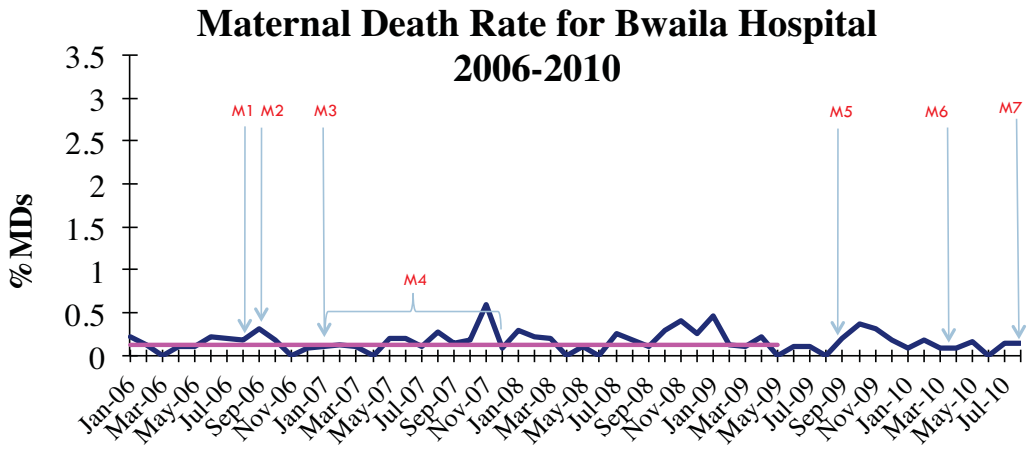


Figure 50: Percentages of observed PMR and NMR reductions due to reductions in Stillbirth rate, Early NMR, and Late NMR by RCT comparison groups, during the second intervention period (Oct-09 to Dec-10)



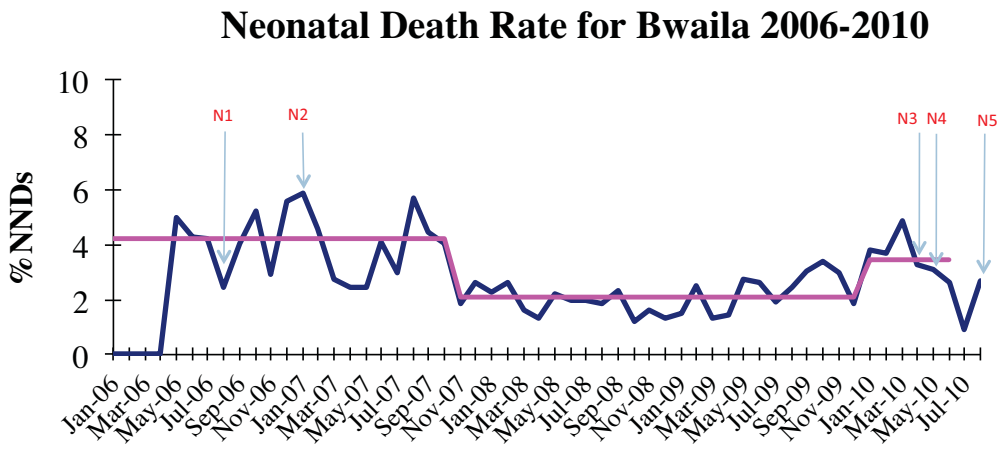
Appendix 22: Annotated maternal and neonatal case-fatality run-charts for each hospital (CEmOC)

Figure 51: Annotated run-chart of MCFR at Bwaila Hospital



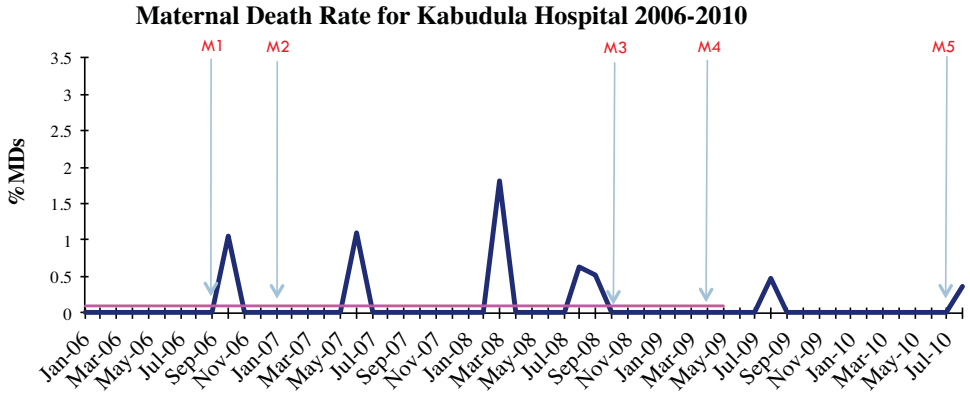
M1. <Aug 06- Improve monitoring of 3rd & 4th stage of labour
M2. <Sept 06 - Improve recording and use of Partograph; patient satisfaction
M3. Jan 07 - Reduce incidence of Puerperal Sepsis; patient satisfaction
M4. 2007- Active resuscitation of haemorrhage cases
M5. Sept 09 - Prevention of Post Partum Haemorrhage (PPH) protocol
M6. Mar 10 - "Monitor me" posters introduced
M7. Aug 10 - PPH refresher training

Figure 52: Annotated run-chart of NCFR at Bwaila Hospital



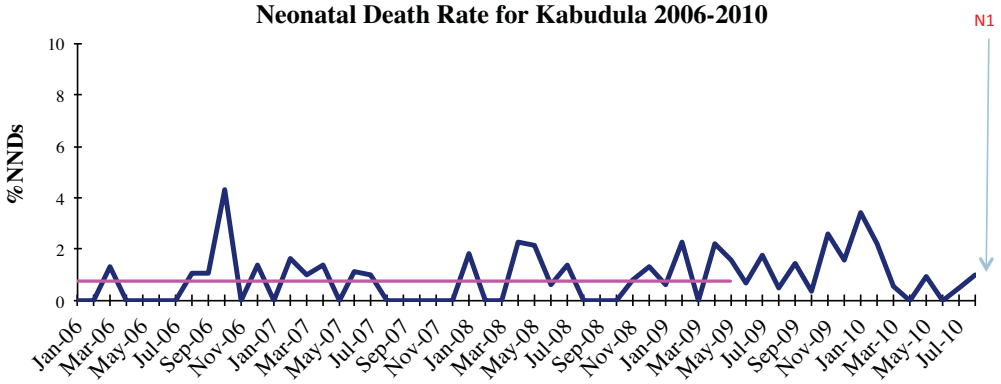
N1. <Aug 06 - Improve recording and use of Partograph
N2. Jan 07 - Prevention of Neonatal Sepsis and treatment according to protocol
N3. Apr 10 - Neonatal death audits; improve monitoring
N4. May 10 - Training on vacuum extraction
N5. Aug 10 - Kangaroo Mother Care nurses trained

Figure 53: Annotated run-chart of MCFR at Kabudula Hospital



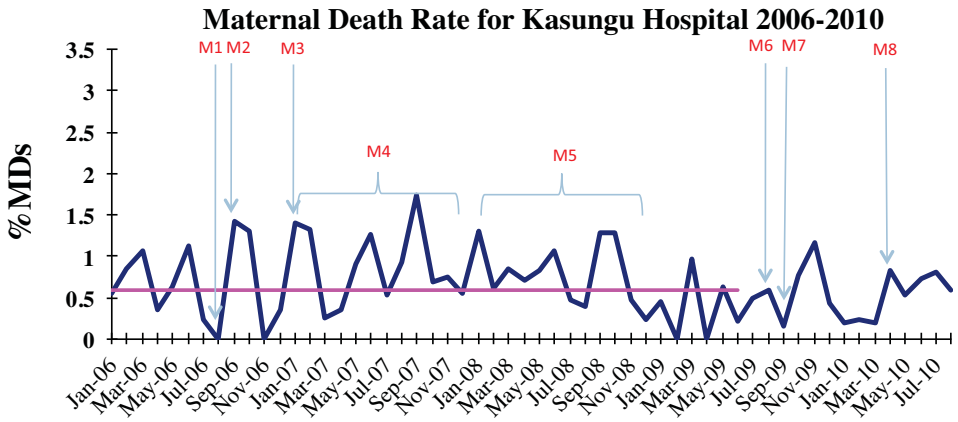
M1. <Sept 06 - Assess all maternal admissions within <15-30 mins
M2. Jan 07 - Task shifting
M3. <Oct 08 - Reducing incidence of Puerperal Sepsis
M4. ?Apr 09 - Reducing incidence fo Post Partum Haemorrhage
M5. July 09 - Started bleeding donors after receiving correct supplies
(Sept 09 - Told by national blood transfusion service to stop bleeding donors)

Figure 54: Annotated run-chart of NCFR at Kabudula Hospital



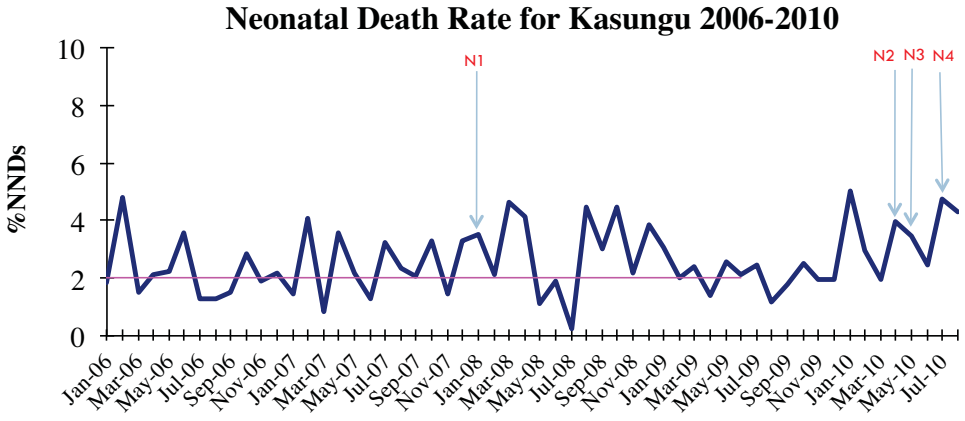
N1. Sept 10 - Resuscitating asphyxiated newborns training

Figure 55: Annotated run-chart of MCFR at Kasungu Hospital



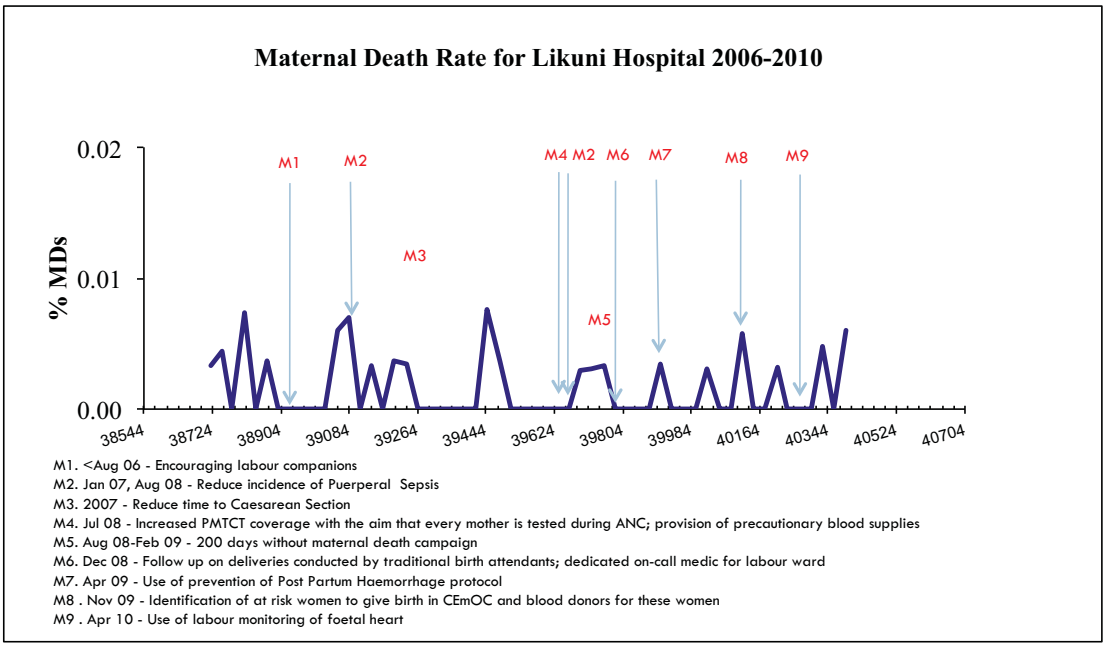
M1. <Aug 06 - "Dorcas" volunteers acting as labour companions
M2. <Sept 06 - Improving patient satisfaction
M3. Jan 07 - Introduction of new admissions form/register
M4. 2007 - Improve time to Caesarean Section
M5. ?2008 - Emergency obstetric admissions treated within 30 mins; improved recording and use of Partograph
M6. Aug 09 - Prevention of Post Partum Haemorrhage
M7. Sept 09 - Separation of maternity into two wards - labour and post natal
M8. Apr 10 - Daily admission of "ANC" women waiting at CEmOC to deliver

Figure 56: Annotated run-chart of NCFR at Kasungu Hospital



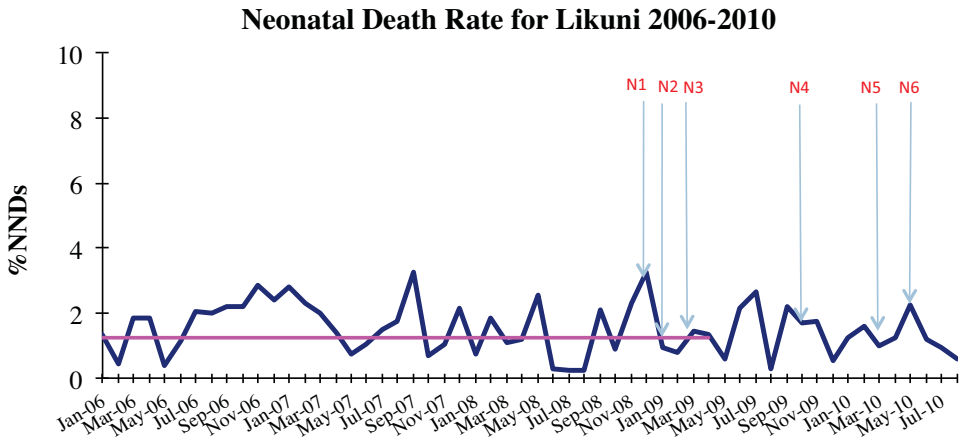
N1. ? Jan 08 - Use of Neonatal Sepsis protocol
N2 . Apr 10 - Resuscitation of the asphyxiated newborn training
N3. May 10 - Kangaroo Mother Care commences
N4. July 10 - Improved recording and use of Partographs; weekly neonatal death audits

Figure 57: Annotated run-chart of MCFR at Likuni Hospital



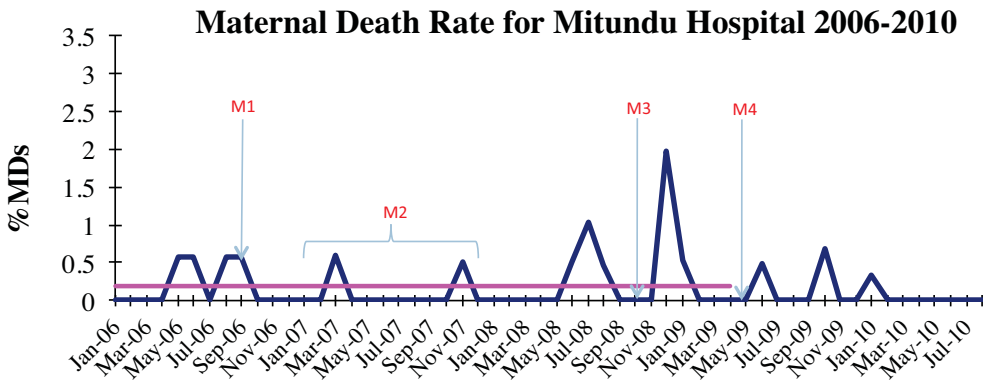
M1. <Aug 06 - Encouraging labour companions
M2. Jan 07, Aug 08 - Reduce incidence of Puerperal Sepsis
M3. 2007 - Reduce time to Caesarean Section
M4. Jul 08 - Increased PMTCT coverage with the aim that every mother is tested during ANC; provision of precautionary blood supplies
M5. Aug 08-Feb 09 - 200 days without maternal death campaign
M6. Dec 08 - Follow up on deliveries conducted by traditional birth attendants; dedicated on-call medic for labour ward
M7. Apr 09 - Use of prevention of Post Partum Haemorrhage protocol
M8 . Nov 09 - Identification of at risk women to give birth in CEmOC and blood donors for these women
M9 . Apr 10 - Use of labour monitoring of foetal heart

Figure 58: Annotated run-chart of NCFR at Likuni Hospital



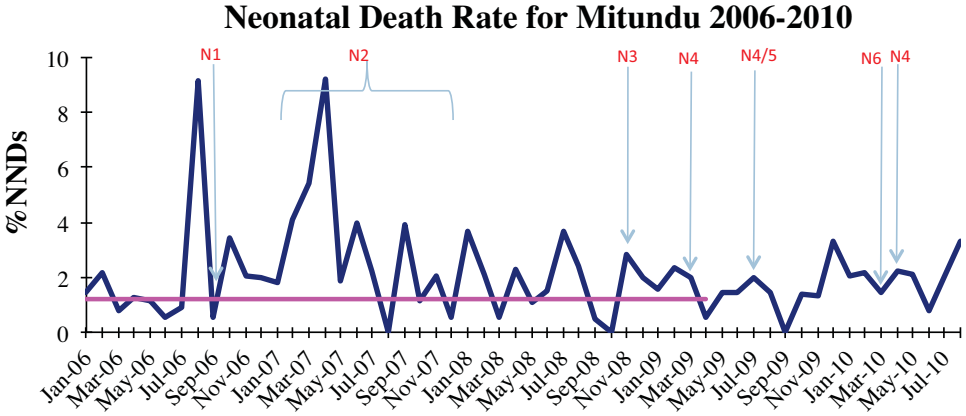
N1. Dec 08 - Use of Neonatal Sepsis protocol and checklist; follow up on traditional birth attendants deliveries
N2. Jan 09- Improved recording and use of Partograph
N3. Mar 09 - Weekly resuscitation drills
N4. Oct 09 - Neonatal death log instituted to help identify contributing causes
N5. Mar 10 - Introduction of comprehensive Kangaroo Mother Care
N6. May 10 - Two-hourly monitoring of high risk babies (resuscitated, meconium aspiration, neonatal sepsis) with support from mothers "bring your baby for monitoring"; provide prophylaxis antibiotics; adapt recording forms

Figure 59: Annotated run-chart of MCFR at Mitundu Hospital



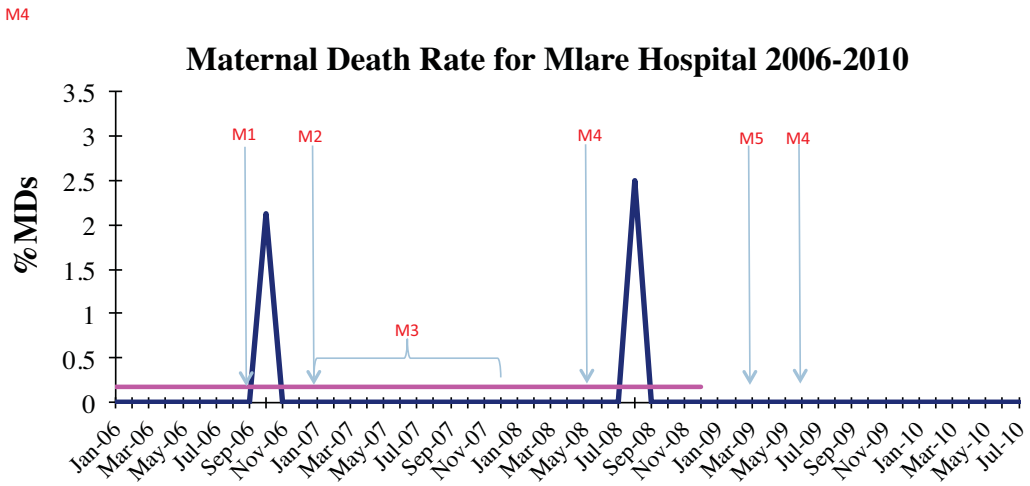
M1. <Sept 06 - Improved recording and use of Partograph
M2. 2007 - Improving drug and supplies inventory system
M3. Oct 08 - Reducing incidence of Puerperal Sepsis
M4. May 09 - Introducing prevention of Post Partum Haemorrhage protocol

Figure 60: Annotated run-chart of NCFR at Mitundu Hospital



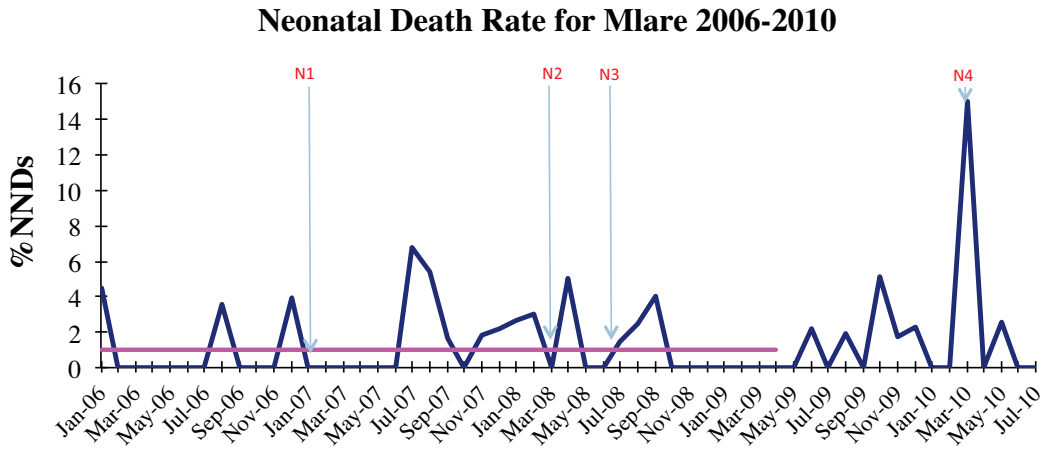
N1. <Sept 06 - Improved recording and use of Partograph
N2. 2007 - Improving drug and supplies inventory system
N3. Nov 08 - Identification and application of treatment protocol for premature babies
N4. Mar 09, July 09, Apr 10 - Introduction of Neonatal Sepsis protocol
N5. July 09 - Training in resuscitating an asphyxiated neonate
N6. Mar 10 - Identified maids to support Kangaroo Mother Care

Figure 61: Annotated run-chart of MCFR at Mlale Hospital



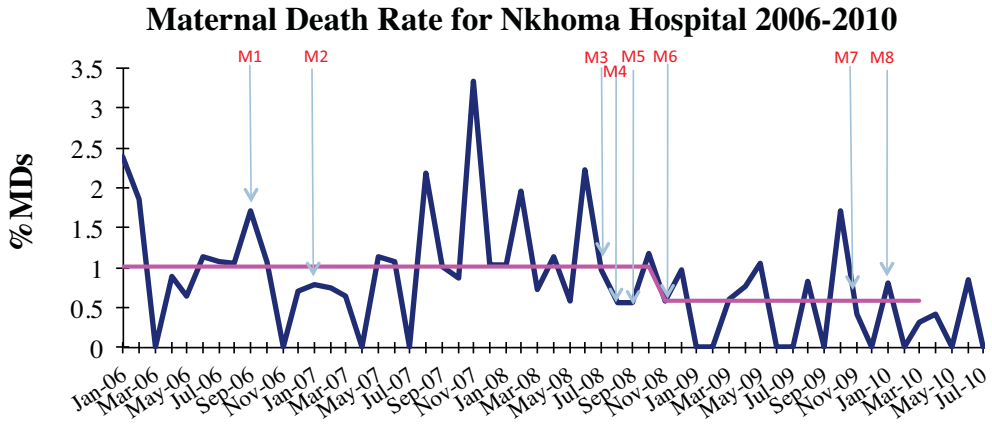
M1. <Sept 06 - Improve recording and use of Partograph
M2. Jan 07 - Facilitate transfers/referrals from traditional birth attendants
M3. 2007 - Reduce time to Caesarean Section
M4. May 08, Jun 09 - Use of prevention of Post Partum Haemorrhage protocol
M5. Mar 09 - Work with community to try and increase skilled deliveries

Figure 62: Annotated run-chart of NCFR at Mlale Hospital



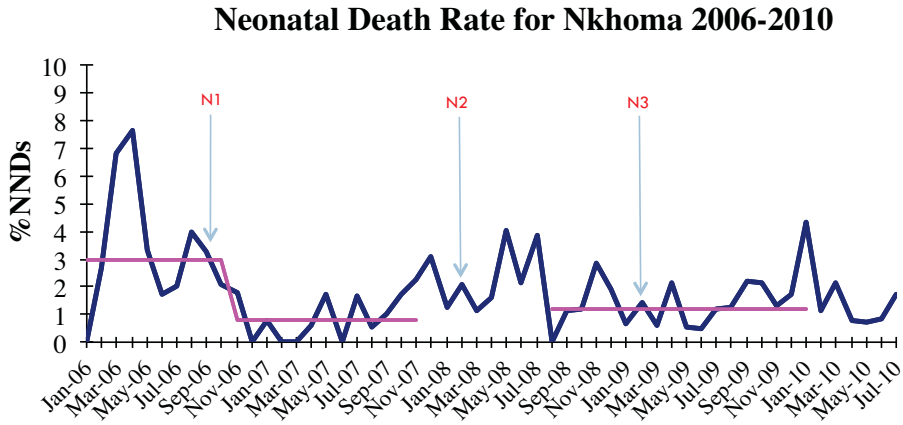
N1. Jan 07 - Introduction of Kangaroo Mother Care
N2. Mar 08 - Improved recording and use of Partograph
N3. Jul 08 - Started training on resuscitating an asphyxiated neonate; use of Neonatal Sepsis protocol
N4. Mar 10 - Use of maids to support Kangaroo Mother Care

Figure 63: Annotated run-chart of MCFR at Nkhoma Hospital



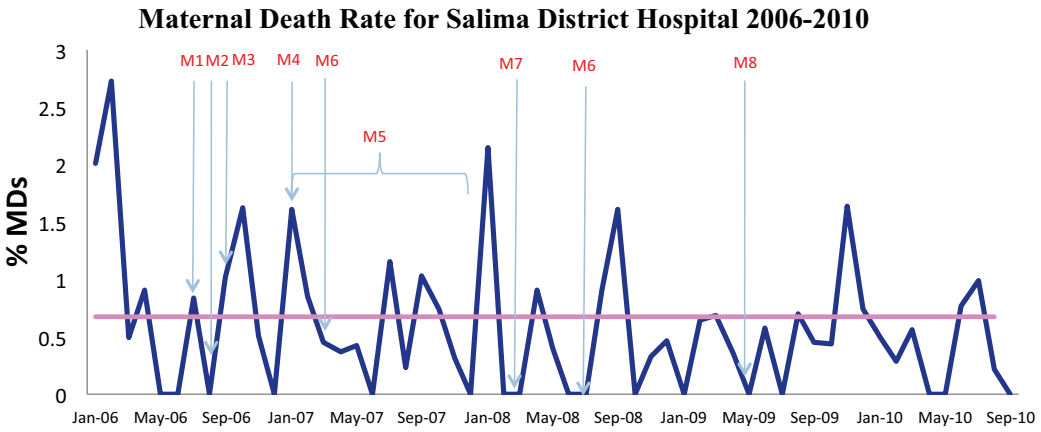
M1. <Sept 06- Improved monitoring for 3rd and 4th stage of labour; assessment of all new admissions on labour ward within 15-30mins; improved recording and use of Partograph
M2. Jan 07 - New admissions form/register
M3. Jul 08 - Piloted checklist for emergency referrals at 2 health centres in catchment area
M4. Aug 08 - reformation of blood transfusion committee
M5. Sept 08 - Reducing delays 1 & 2 through community engagement
M6. Nov 08 - Reorientate new staff on maternity ward about QI
M7. Nov 09 - Introduction of prevention of Post Partum Haemorrhage protocol
M8. Jan 10 - Scale up use of emergency referral checklist by all Health Centres in catchment area

Figure 64: Annotated run-chart of NCFR at Nkhoma Hospital



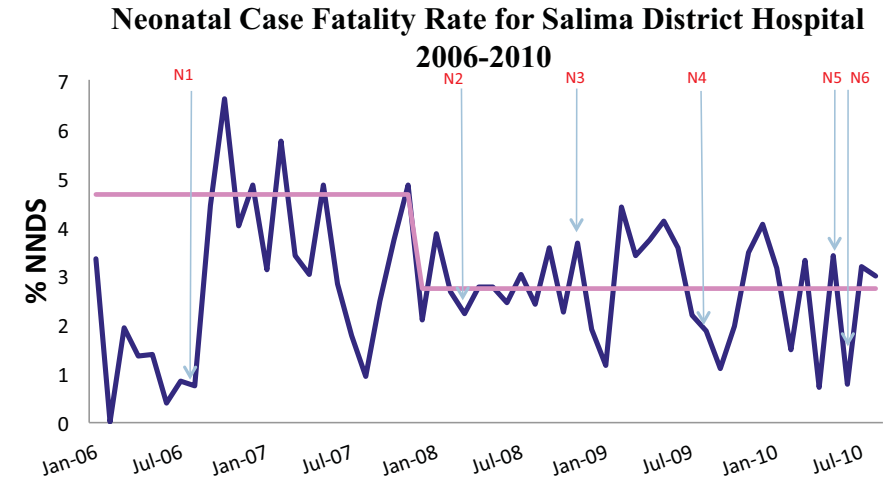
N1. <Sept 06 - Identification, monitoring and appropriate treatment of high risk neonates
N2. Feb 08 - Early recognition and treatment of Neonatal Sepsis following internally developed protocol
N3. Feb 09- Introduction of trained nurses to assist Kangaroo Mother Care

Figure 65: Annotated run-chart of MCFR at Salima Hospital



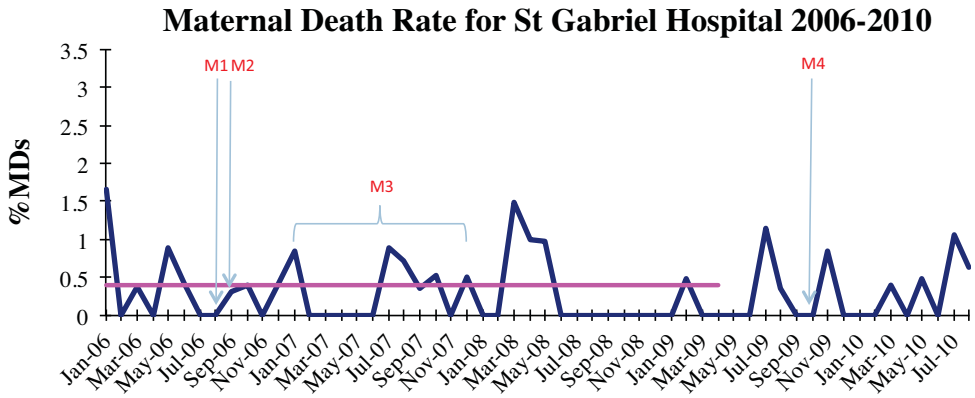
M1. July 06 - Encourage delivery in the facility
M2. <Aug 06 - Improved monitoring during 3rd and 4th stage of labour
M3. <Sept 06 - Reduce Peurperal Sepsis
M4. Jan 07 - Task shifting
M5. 2007 - Reduce time to Caesarean Section
M6. Mar 07, Jul 08 - Partograph training for midwives from all Health Centres
M7. Mar 08 - District Health Management Team's engagement in QI activity
M8. May 09 - Introduction of prevention of Post Partum Haemorrhage protocol

Figure 66: Annotated run-chart of NCFR at Salima Hospital



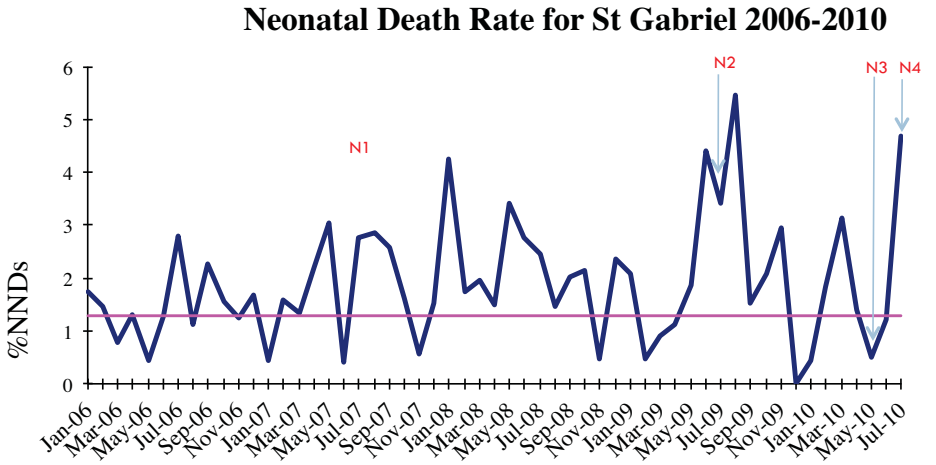
N1. <Aug 06 - Prevention of Neonatal Sepsis and/or treatment according to a protocol
N2. Mar 08 - District Health Management Team's engagement in QI activity
N3. Nov 08 - Started doing neonatal death audits
N4. Aug 09 - Developed and started using an admissions form for neonates
N5. May 10 - Trained two auxiliary nurses to manage kangaroo mother care
N6. June 10 - Started training on resuscitating an asphyxiated neonate

Figure 67: Annotated run-chart of MCFR at St. Gabriel Hospital



M1. <Aug 06 - Encouraging women to visit labour ward prior to delivery
M2. <Sept 06 - Improved recording & use of Partograph; improve patient satisfaction
M3. 2007 - Active resuscitation of haemorrhage cases
M4. Oct 09 - Use of prevention of Post Partum Haemorrhage protocol

Figure 68: Annotated run-chart of NCFR at St. Gabriel Hospital



N1. 2007 - Neonatal death audits/logs; Neonatal Sepsis prevention &/or treatment
N2. July 09 - Drills on resuscitation of asphyxiated newborn started but not sustained
N3. May 10 - Drills on resuscitation resurrected following a learning session; idea of introducing trained maids to work in Kangaroo Mother Care started. This triggered the monitoring and proper recording of feeds, weight and temperature checks
N4. July 10 - Clinical review of Partographs; learning from actual and best practice re. response to indicators

Appendix 23: Additional Place of Death by Cause of death graphs

Please note that because InterVA (see section 2.1.8) assigns probabilities of cause of death for each case that don't add to 100% (i.e. there is remaining uncertainty) the actual mortality rates for each of the causes of death are slightly (typically 20-30%) higher. Also note that there is no place of death data for typically around 10-20% of perinatal and neonatal deaths in each category, but that these deaths also have no cause of death data (as they have no verbal autopsy) and are therefore also not on these graphs. The small fractions of mortality without place of death (.) on the graphs are those with verbal autopsies where the place of death was not recorded but the cause was.

Also note, for the perinatal mortality graphs, that given the following numbers of total perinatal deaths and births in each group: No CI: baseline: deaths: 405, births: 7574; 1st Intervention: deaths: 248, births: 4788; 2nd Intervention: deaths: 325, births: 5472; CI: Baseline: deaths: 395, births: 6986; 1st Intervention: deaths: 223, births: 4910; 2nd Intervention: deaths: 276, births: 5421; each 1 per 1000 mortality rate given on the graphs represents around 5 to 7 deaths. Therefore the numbers of deaths represented on some of the graphs are quite small and caution should be exercised when interpreting the trends shown, as it is possible that they may have been observed due to random chance sampling error.

For the neonatal mortality graphs, given the following numbers of total neonatal deaths and births in each group: control: baseline: deaths: 108, births: 2290; 1st Intervention: deaths: 72, births: 2290; 2nd Intervention: deaths: 92, births: 2625; CI: Baseline: deaths: 79, births: 3356; 1st Intervention: deaths: 69, births: 2475; 2nd Intervention: deaths: 69, births: 2775; each 1 per 1000 mortality rate given on the graphs represents around 2 to 3 deaths. Therefore the numbers of deaths represented on some of the graphs is very small meaning interpretation of the trends shown is difficult, as it is likely that many of the trends may have been observed due to random chance sampling error.

Figure 69: Changes in place of perinatal mortality due to Macerated Stillbirth in CI and No CI areas

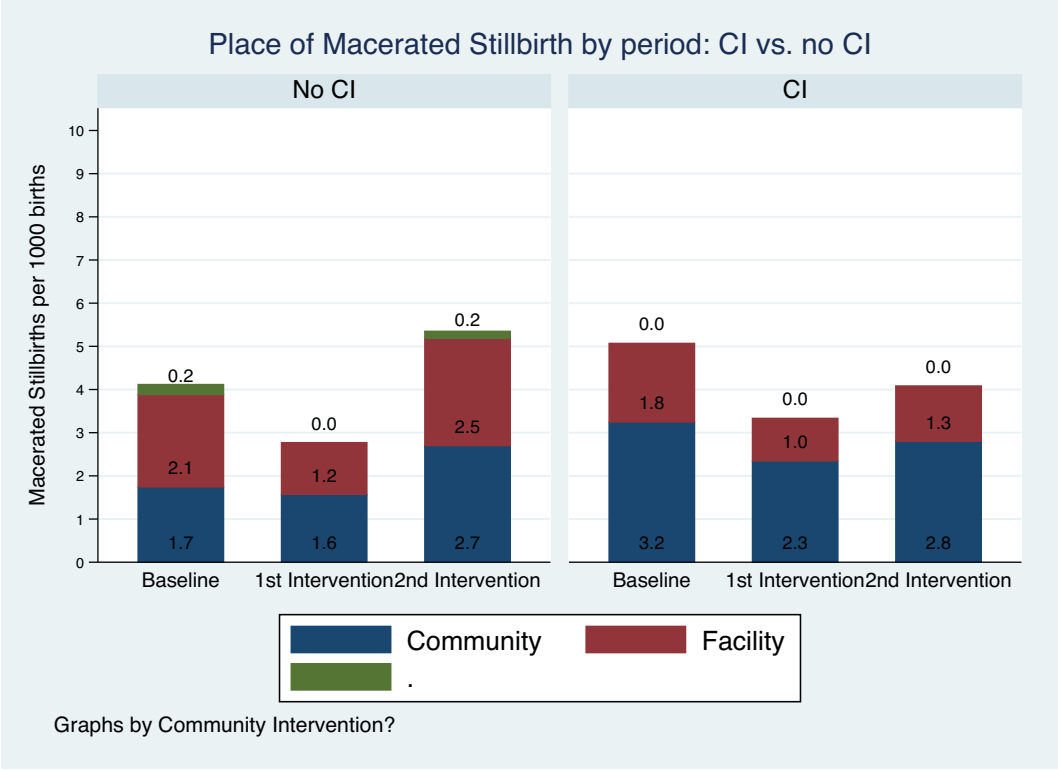


Figure 70: Changes in place of perinatal mortality due to Fresh Stillbirth in CI and No CI areas

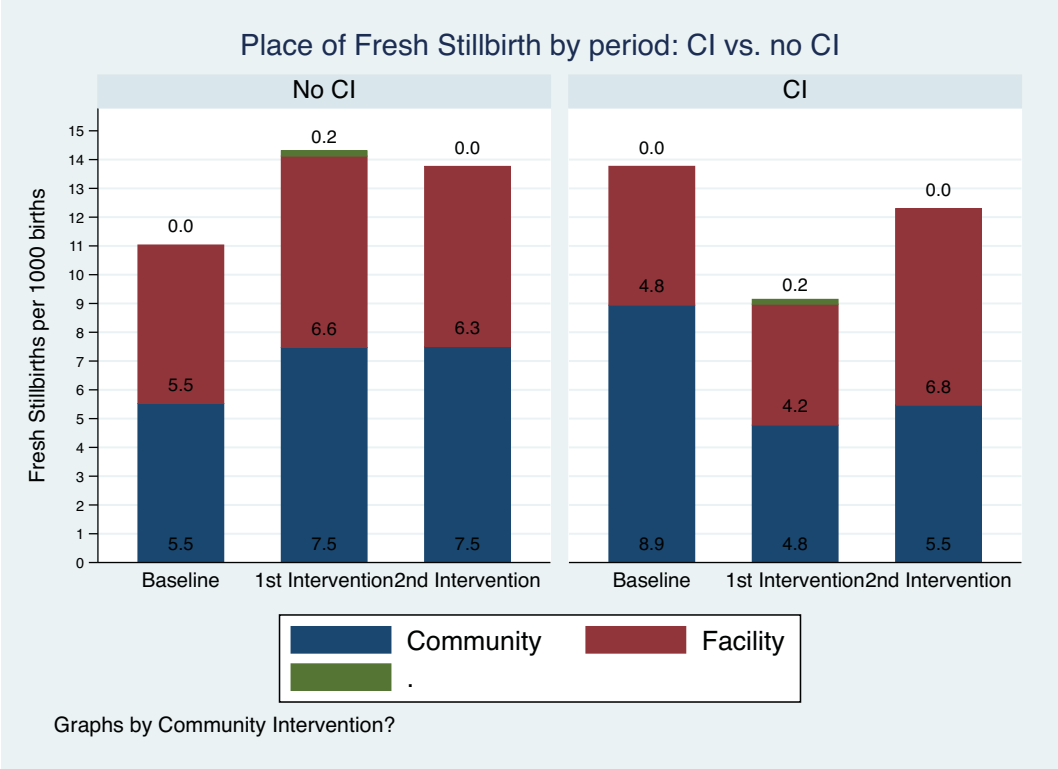


Figure 71: Changes in place of perinatal mortality due to Sepsis in CI and No CI areas

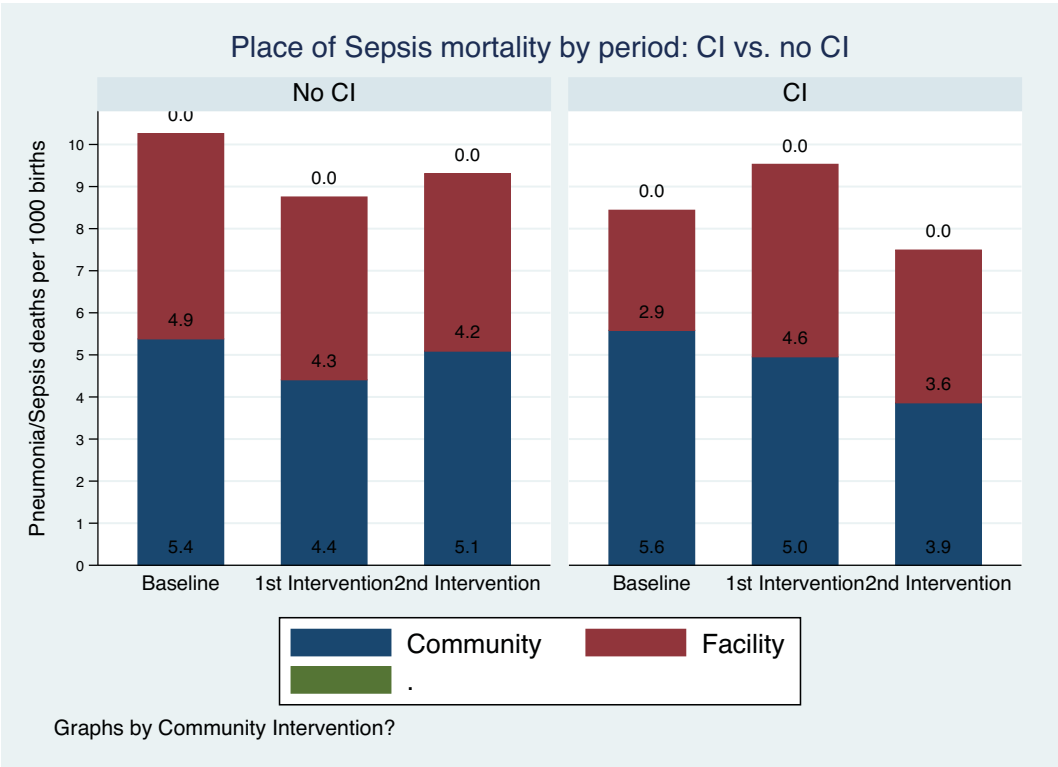


Figure 72: Changes in place of perinatal mortality due to Prematurity in CI and No CI areas

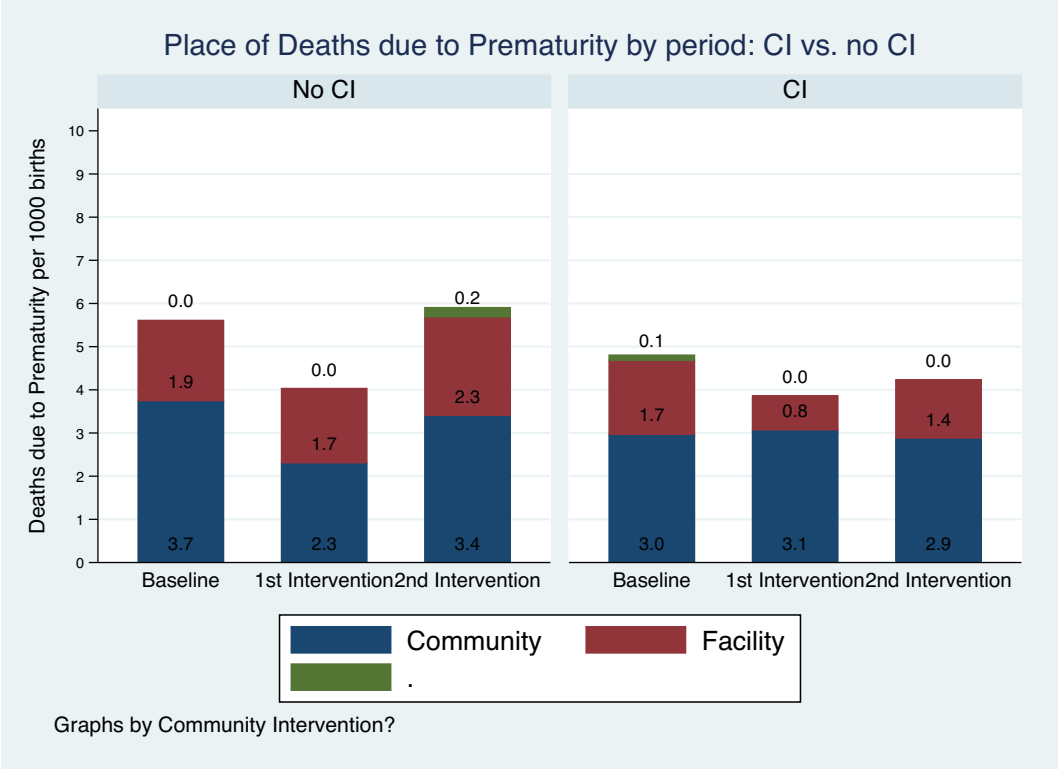


Figure 73: Changes in place of perinatal mortality due to Asphyxia in CI and No CI areas

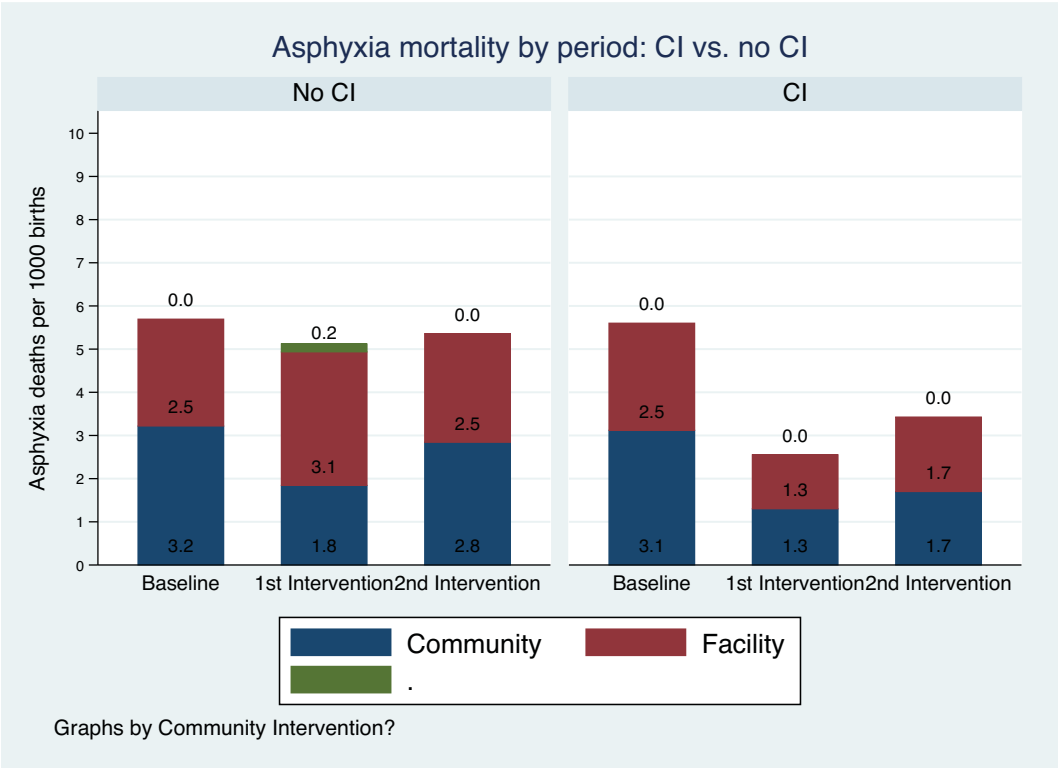


Figure 74: Changes in place of perinatal mortality due to Meningitis in CI and No CI areas

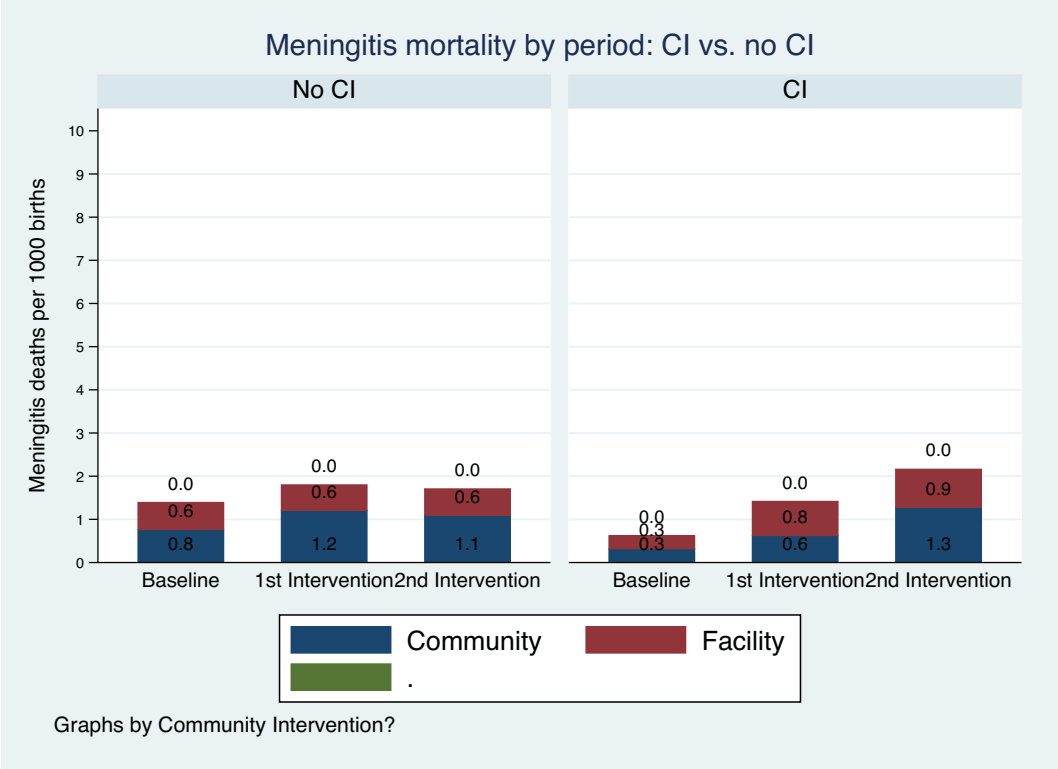


Figure 75: Changes in place of perinatal mortality due to other causes in CI and No CI areas

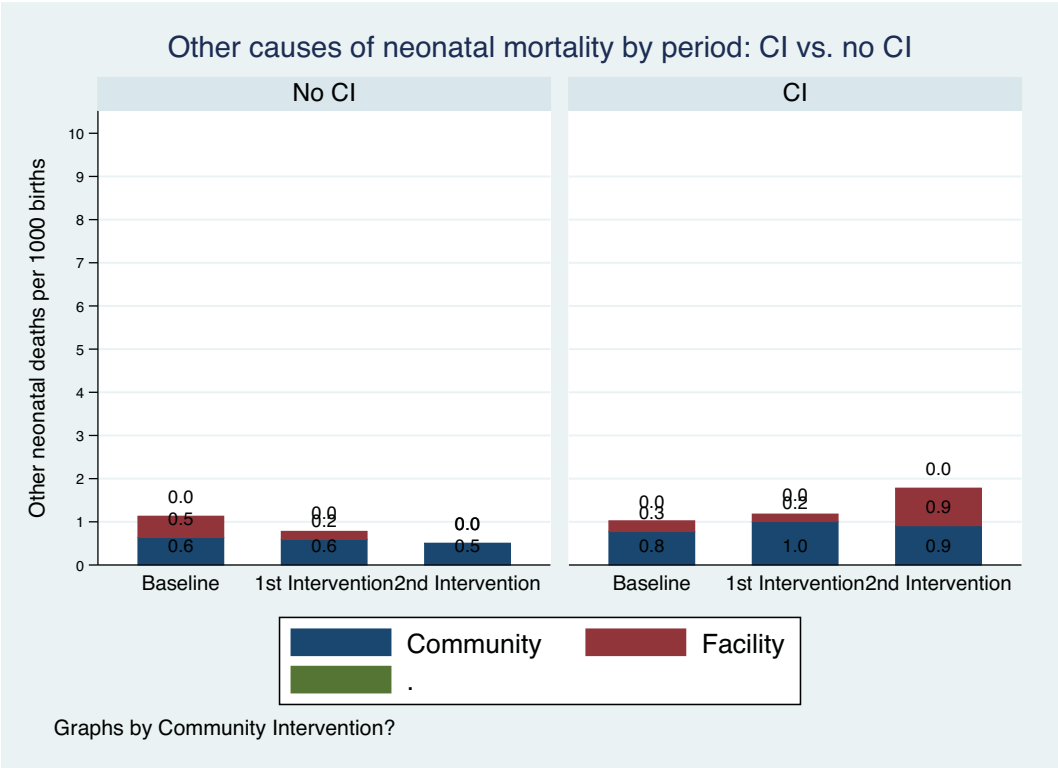


Figure 76: Changes in place of Neonatal mortality due to Sepsis in FI+CI and control areas

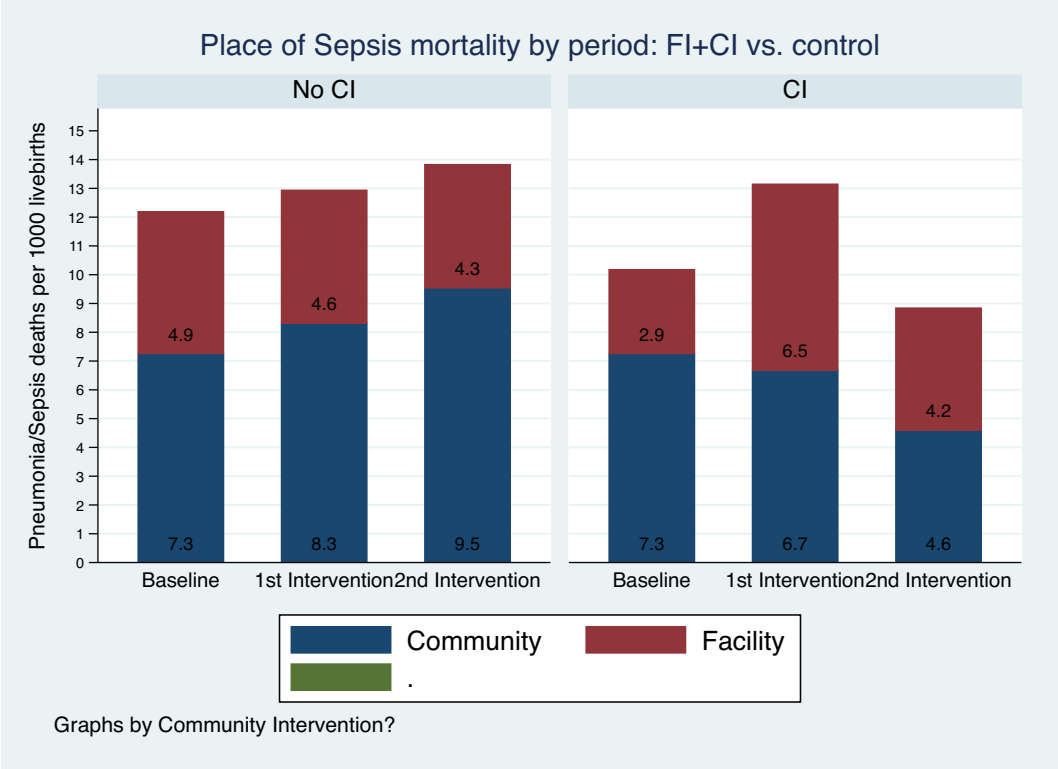


Figure 77: Changes in place of Neonatal mortality due to Prematurity in FI+CI and control areas

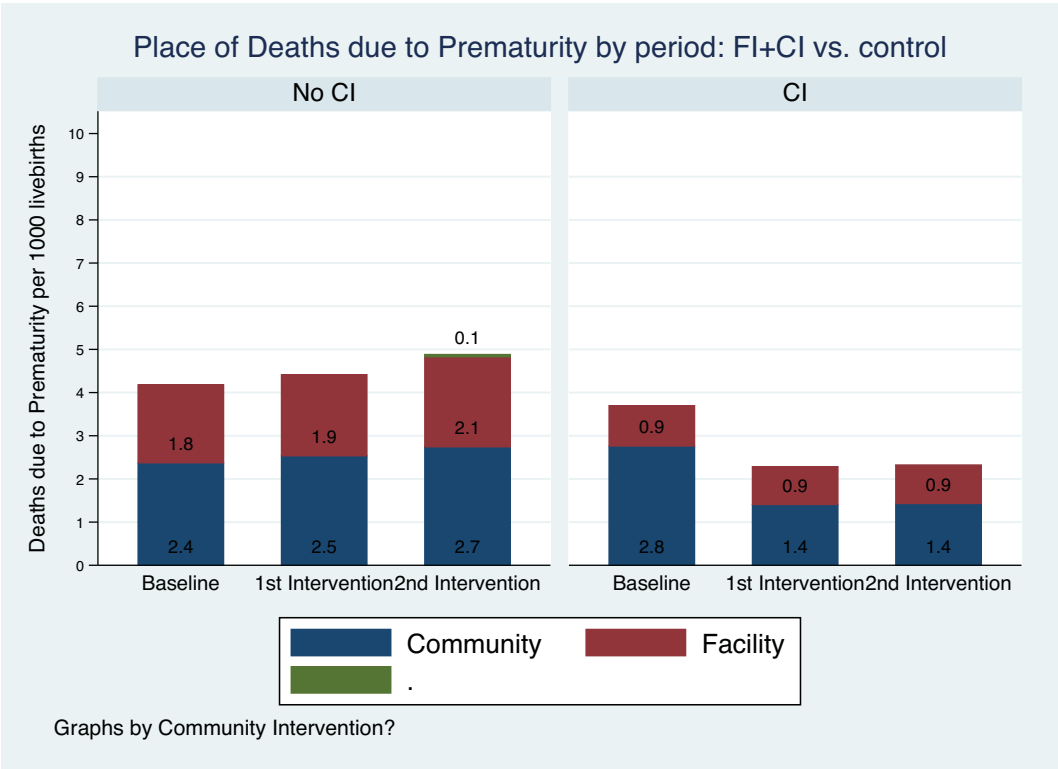


Figure 78: Changes in place of Neonatal mortality due to Asphyxia in FI+CI and control areas

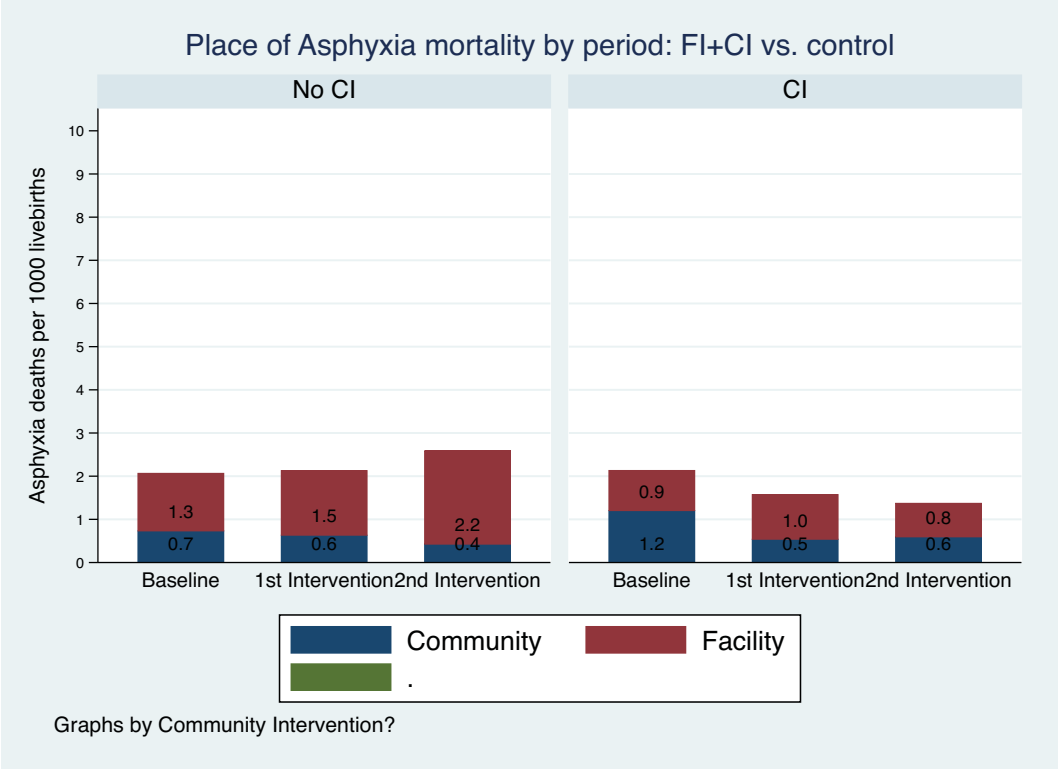


Figure 79: Changes in place of Neonatal mortality due to Meningitis in FI+CI and control areas

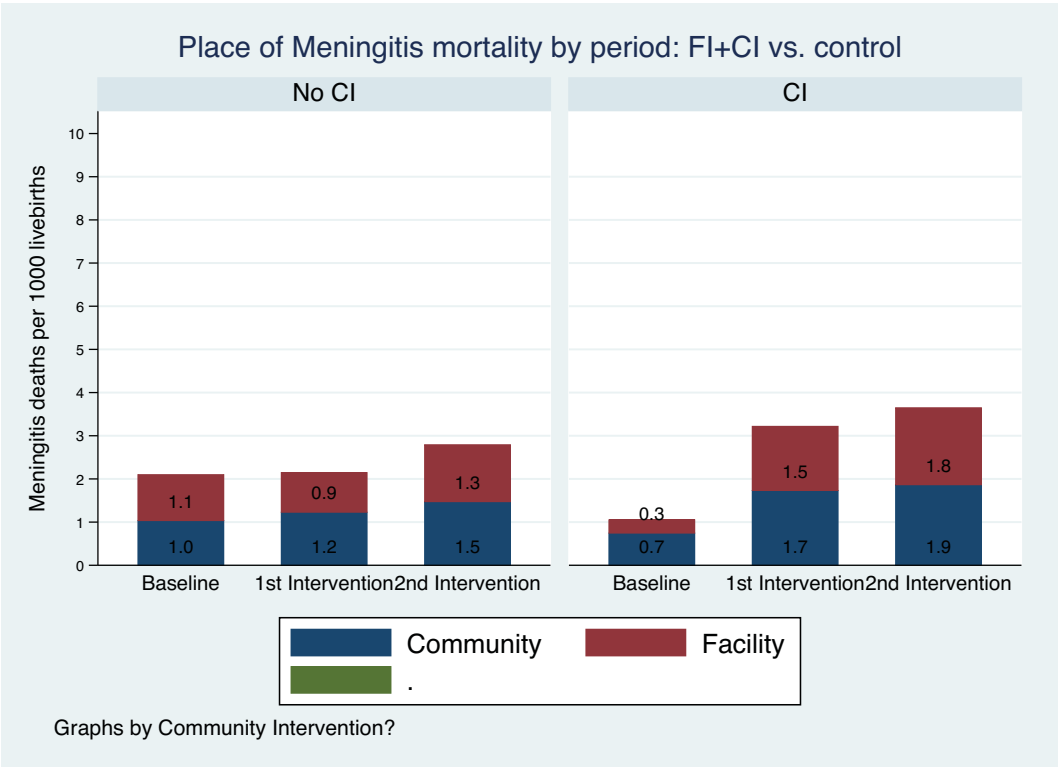
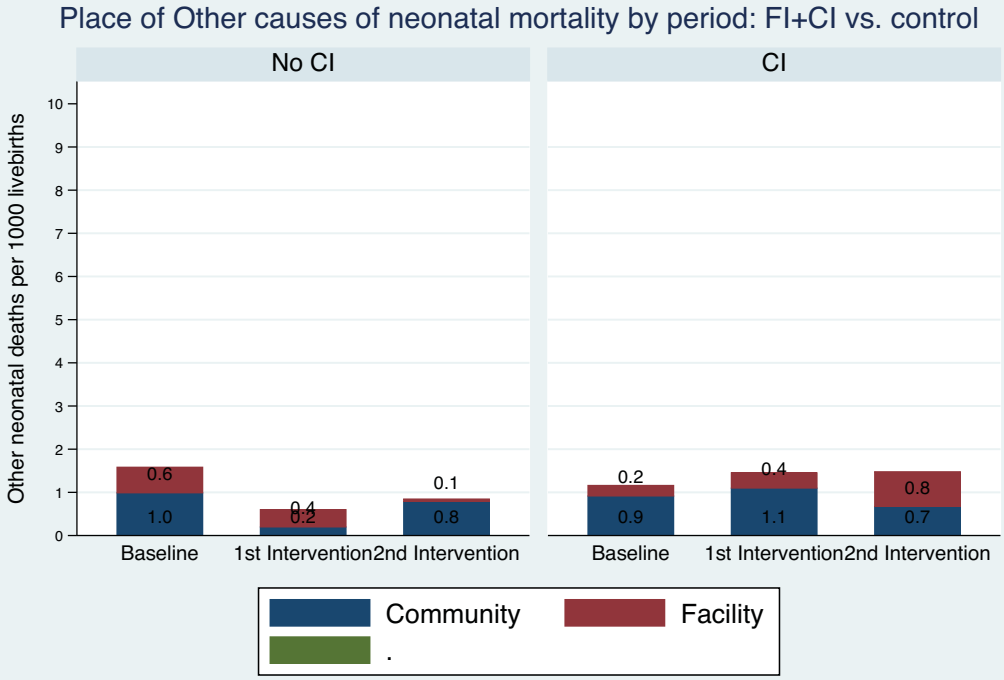


Figure 80: Changes in place of Neonatal mortality due to other causes in FI+CI and control areas



Appendix 24: Place of Death by Place of Birth additional figures

Figure 81: Place of Death by Place of Birth: NND; Intervention period; control clusters

Deaths: NND **RCT arm:** control **Time period:** 01oct2008 to 31dec2010 (Intervention)

Community/Facility split

Birth in:	n	%
Community	86	100

Death in:	n	% with data	%
Community	70	90%	81%
Facility	8	**10%**	9%
Total with data	78	100%	91%
missing death place	8		9%
Total	86		100%

Birth in:	n	%
Facility	74	100

Death in:	n	% with data	%
Community	19	**28%**	26%
Facility	49	72%	66%
Total with data	68	100%	92%
missing death place	6		8%
Total	74		100%

Birth in:	n	%
missing birth place	4	100

Death in:	n	% with data	%
Community	1	25%	25%
Facility	3	75%	75%
Total with data	4	100%	100%
missing death place	0		0%
Total	4		100%

Total Births in:	n	%	
Total			
	160	98%	with birth place
	4	2%	without birth place
	164	100%	Total

Total Deaths in:	n	% with data	%
Community	90	60%	55%
Facility	60	40%	37%
Total with data	150	100%	91%
missing death place	14		9%
Total	164		100%

Facility Type breakdown for Place of Death (type of facility was not recorded for births)

Birth in:	n	%
Community	86	100

Death in:	n	% with data	%
Community	70	90%	81%
Health Centre within RCT	4	5%	5%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	2	3%	2%
Hospital - other	0	0%	0%
Facility - other unspecified	2	3%	2%
Total with data	78	100%	91%
missing death place	8		9%
Total	86		100%

Birth in:	n	%
Facility	74	100

Death in:	n	% with data	%
Community	19	28%	26%
Health Centre within RCT	22	32%	30%
Health Centre outside RCT	1	1%	1%
Hospital - MaiKhanda FI	21	31%	28%
Hospital - other	0	0%	0%
Facility - other unspecified	5	7%	7%
Total with data	68	100%	92%
missing death place	6		8%
Total	74		100%

Birth in:	n	%
missing birth place	4	100

Death in:	n	% with data	%
Community	1	25%	25%
Health Centre within RCT	1	25%	25%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	2	50%	50%
Hospital - other	0	0%	0%
Facility - other unspecified	0	0%	0%
Total with data	4	100%	100%
missing death place	0		0%
Total	4		100%

Total Births in:	n	%	
Total			
	160	98%	with birth place
	4	2%	without birth place
	164	100%	Total

Total Deaths in:	n	% with data	%
Community	90	60%	55%
Health Centre within RCT	27	18%	16%
Health Centre outside RCT	1	1%	1%
Hospital - MaiKhanda FI	25	17%	15%
Hospital - other	0	0%	0%
Facility - other unspecified	7	5%	4%
Total with data	150	100%	91%
missing death place	14		9%
Total	164		100%

Figure 82: Place of Death by Place of Birth: NND; Intervention period; FI only clusters

Deaths: NND **RCT arm:** FI only **Time period:** 01oct2008 to 31dec2010 (Intervention)

Community/Facility split

Birth in:	n	%
Community	68	100

Death in:	n	% with data	%
Community	51	86%	75%
Facility	8	**14%**	12%
Total with data	59	100%	87%
missing death place	9		13%
Total	68		100%

Birth in:	n	%
Facility	78	100

Death in:	n	% with data	%
Community	17	**23%**	22%
Facility	58	77%	74%
Total with data	75	100%	96%
missing death place	3		4%
Total	78		100%

Birth in:	n	%
missing birth place	6	100

Death in:	n	% with data	%
Community	4	80%	67%
Facility	1	20%	17%
Total with data	5	100%	83%
missing death place	1		17%
Total	6		100%

Total Births in:	n	%	
Total			
	146	96%	with birth place
	6	4%	without birth place
	152	100%	Total

Total Deaths in:	n	% with data	%
Community	72	52%	47%
Facility	67	48%	44%
Total with data	139	100%	91%
missing death place	13		9%
Total	152		100%

Facility Type breakdown for Place of Death (type of facility was not recorded for births)

Birth in:	n	%
Community	68	100

Death in:	n	% with data	%
Community	51	86%	75%
Health Centre within RCT	5	8%	7%
Health Centre outside RCT	1	2%	1%
Hospital - MaiKhanda FI	1	2%	1%
Hospital - other	0	0%	0%
Facility - other unspecified	1	2%	1%
Total with data	59	100%	87%
missing death place	9		13%
Total	68		100%

Birth in:	n	%
Facility	78	100

Death in:	n	% with data	%
Community	17	23%	22%
Health Centre within RCT	24	32%	31%
Health Centre outside RCT	1	1%	1%
Hospital - MaiKhanda FI	23	31%	29%
Hospital - other	0	0%	0%
Facility - other unspecified	10	13%	13%
Total with data	75	100%	96%
missing death place	3		4%
Total	78		100%

Birth in:	n	%
missing birth place	6	100

Death in:	n	% with data	%
Community	4	80%	67%
Health Centre within RCT	1	20%	17%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	0	0%	0%
Hospital - other	0	0%	0%
Facility - other unspecified	0	0%	0%
Total with data	5	100%	83%
missing death place	1		17%
Total	6		100%

Total Births in:	n	%	
Total			
	146	96%	with birth place
	6	4%	without birth place
	152	100%	Total

Total Deaths in:	n	% with data	%
Community	72	52%	47%
Health Centre within RCT	30	22%	20%
Health Centre outside RCT	2	1%	1%
Hospital - MaiKhanda FI	24	17%	16%
Hospital - other	0	0%	0%
Facility - other unspecified	11	8%	7%
Total with data	139	100%	91%
missing death place	13		9%
Total	152		100%

Figure 83: Place of Death by Place of Birth: NND; Intervention period; CI only clusters

Deaths: NND **RCT arm:** CI only **Time period:** 01oct2008 to 31dec2010 (Intervention)

Community/Facility split

Birth in:	n	%
Community	69	100

Death in:	n	% with data	%
Community	58	94%	84%
Facility	4	**6%**	6%
Total with data	62	100%	90%
missing death place	7		10%
Total	69		100%

Birth in:	n	%
Facility	78	100

Death in:	n	% with data	%
Community	20	**29%**	26%
Facility	49	71%	63%
Total with data	69	100%	88%
missing death place	9		12%
Total	78		100%

Birth in:	n	%
missing birth place	3	100

Death in:	n	% with data	%
Community	3	100%	100%
Facility	0	0%	0%
Total with data	3	100%	100%
missing death place	0		0%
Total	3		100%

Total Births in:	n	%	
Total			
	147	98%	with birth place
	3	2%	without birth place
	150	100%	Total

Total Deaths in:	n	% with data	%
Community	81	60%	54%
Facility	53	40%	35%
Total with data	134	100%	89%
missing death place	16		11%
Total	150		100%

Facility Type breakdown for Place of Death (type of facility was not recorded for births)

Birth in:	n	%
Community	69	100

Death in:	n	% with data	%
Community	58	94%	84%
Health Centre within RCT	2	3%	3%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	1	2%	1%
Hospital - other	0	0%	0%
Facility - other unspecified	1	2%	1%
Total with data	62	100%	90%
missing death place	7		10%
Total	69		100%

Birth in:	n	%
Facility	78	100

Death in:	n	% with data	%
Community	20	29%	26%
Health Centre within RCT	12	17%	15%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	29	42%	37%
Hospital - other	0	0%	0%
Facility - other unspecified	8	12%	10%
Total with data	69	100%	88%
missing death place	9		12%
Total	78		100%

Birth in:	n	%
missing birth place	3	100

Death in:	n	% with data	%
Community	3	100%	100%
Health Centre within RCT	0	0%	0%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	0	0%	0%
Hospital - other	0	0%	0%
Facility - other unspecified	0	0%	0%
Total with data	3	100%	100%
missing death place	0		0%
Total	3		100%

Total Births in:	n	%	
Total			
	147	98%	with birth place
	3	2%	without birth place
	150	100%	Total

Total Deaths in:	n	% with data	%
Community	81	60%	54%
Health Centre within RCT	14	10%	9%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	30	22%	20%
Hospital - other	0	0%	0%
Facility - other unspecified	9	7%	6%
Total with data	134	100%	89%
missing death place	16		11%
Total	150		100%

Figure 84: Place of Death by Place of Birth: NND; Intervention period; FI+CI clusters

Deaths: NND **RCT arm:** FI+CI **Time period:** 01oct2008 to 31dec2010 (Intervention)

Community/Facility split

Birth in:	n	%
Community	63	100

Death in:	n	% with data	%
Community	49	88%	78%
Facility	7	**13%**	11%
Total with data	56	100%	89%
missing death place	7		11%
Total	63		100%

Birth in:	n	%
Facility	72	100

Death in:	n	% with data	%
Community	16	**24%**	22%
Facility	51	76%	71%
Total with data	67	100%	93%
missing death place	5		7%
Total	72		100%

Birth in:	n	%
missing birth place	3	100

Death in:	n	% with data	%
Community	1	50%	33%
Facility	1	50%	33%
Total with data	2	100%	67%
missing death place	1		33%
Total	3		100%

Total Births in:		
Total		
n	%	
135	98%	with birth place
3	2%	without birth place
138	100%	Total

Total Deaths in:	n	% with data	%
Community	66	53%	48%
Facility	59	47%	43%
Total with data	125	100%	91%
missing death place	13		9%
Total	138		100%

Facility Type breakdown for Place of Death (type of facility was not recorded for births)

Birth in:	n	%
Community	63	100

Death in:	n	% with data	%
Community	49	88%	78%
Health Centre within RCT	2	4%	3%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	4	7%	6%
Hospital - other	0	0%	0%
Facility - other unspecified	1	2%	2%
Total with data	56	100%	89%
missing death place	7		11%
Total	63		100%

Birth in:	n	%
Facility	72	100

Death in:	n	% with data	%
Community	16	24%	22%
Health Centre within RCT	14	21%	19%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	23	34%	32%
Hospital - other	0	0%	0%
Facility - other unspecified	14	21%	19%
Total with data	67	100%	93%
missing death place	5		7%
Total	72		100%

Birth in:	n	%
missing birth place	3	100

Death in:	n	% with data	%
Community	1	50%	33%
Health Centre within RCT	1	50%	33%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	0	0%	0%
Hospital - other	0	0%	0%
Facility - other unspecified	0	0%	0%
Total with data	2	100%	67%
missing death place	1		33%
Total	3		100%

Total Births in:		
Total		
n	%	
135	98%	with birth place
3	2%	without birth place
138	100%	Total

Total Deaths in:	n	% with data	%
Community	66	53%	48%
Health Centre within RCT	17	14%	12%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	27	22%	20%
Hospital - other	0	0%	0%
Facility - other unspecified	15	12%	11%
Total with data	125	100%	91%
missing death place	13		9%
Total	138		100%

Figure 85: Place of Death by Place of Birth: NND; Intervention period; No CI clusters

Deaths: NND **RCT arm:** No CI **Time period:** 01oct2008 to 31dec2010 (Intervention)

Community/Facility split

Birth in:	n	%
Community	154	100

Death in:	n	% with data	%
Community	121	88%	79%
Facility	16	**12%**	10%
Total with data	137	100%	89%
missing death place	17		11%
Total	154		100%

Birth in:	n	%
Facility	152	100

Death in:	n	% with data	%
Community	36	**25%**	24%
Facility	107	75%	70%
Total with data	143	100%	94%
missing death place	9		6%
Total	152		100%

Birth in:	n	%
missing birth place	10	100

Death in:	n	% with data	%
Community	5	56%	50%
Facility	4	44%	40%
Total with data	9	100%	90%
missing death place	1		10%
Total	10		100%

Total Births in:		
Total		
n	%	
306	97%	with birth place
10	3%	without birth place
316	100%	Total

Total Deaths in:	n	% with data	%
Community	162	56%	51%
Facility	127	44%	40%
Total with data	289	100%	91%
missing death place	27		9%
Total	316		100%

Facility Type breakdown for Place of Death (type of facility was not recorded for births)

Birth in:	n	%
Community	154	100

Death in:	n	% with data	%
Community	121	88%	79%
Health Centre within RCT	9	7%	6%
Health Centre outside RCT	1	1%	1%
Hospital - MaiKhanda FI	3	2%	2%
Hospital - other	0	0%	0%
Facility - other unspecified	3	2%	2%
Total with data	137	100%	89%
missing death place	17		11%
Total	154		100%

Birth in:	n	%
Facility	152	100

Death in:	n	% with data	%
Community	36	25%	24%
Health Centre within RCT	46	32%	30%
Health Centre outside RCT	2	1%	1%
Hospital - MaiKhanda FI	44	31%	29%
Hospital - other	0	0%	0%
Facility - other unspecified	15	10%	10%
Total with data	143	100%	94%
missing death place	9		6%
Total	152		100%

Birth in:	n	%
missing birth place	10	100

Death in:	n	% with data	%
Community	5	56%	50%
Health Centre within RCT	2	22%	20%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	2	22%	20%
Hospital - other	0	0%	0%
Facility - other unspecified	0	0%	0%
Total with data	9	100%	90%
missing death place	1		10%
Total	10		100%

Total Births in:		
Total		
n	%	
306	97%	with birth place
10	3%	without birth place
316	100%	Total

Total Deaths in:	n	% with data	%
Community	162	56%	51%
Health Centre within RCT	57	20%	18%
Health Centre outside RCT	3	1%	1%
Hospital - MaiKhanda FI	49	17%	16%
Hospital - other	0	0%	0%
Facility - other unspecified	18	6%	6%
Total with data	289	100%	91%
missing death place	27		9%
Total	316		100%

Figure 86: Place of Death by Place of Birth: NND; Intervention period; CI clusters

Deaths: NND **RCT arm:** CI **Time period:** 01oct2008 to 31dec2010 (Intervention)

Community/Facility split

Birth in:	n	%
Community	132	100

Death in:	n	% with data	%
Community	107	91%	81%
Facility	11	**9%**	8%
Total with data	118	100%	89%
missing death place	14		11%
Total	132		100%

Birth in:	n	%
Facility	150	100

Death in:	n	% with data	%
Community	36	**26%**	24%
Facility	100	74%	67%
Total with data	136	100%	91%
missing death place	14		9%
Total	150		100%

Birth in:	n	%
missing birth place	6	100

Death in:	n	% with data	%
Community	4	80%	67%
Facility	1	20%	17%
Total with data	5	100%	83%
missing death place	1		17%
Total	6		100%

Total Births in:	n	%	
Total			
	282	98%	with birth place
	6	2%	without birth place
	288	100%	Total

Total Deaths in:	n	% with data	%
Community	147	57%	51%
Facility	112	43%	39%
Total with data	259	100%	90%
missing death place	29		10%
Total	288		100%

Facility Type breakdown for Place of Death (type of facility was not recorded for births)

Birth in:	n	%
Community	132	100

Death in:	n	% with data	%
Community	107	91%	81%
Health Centre within RCT	4	3%	3%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	5	4%	4%
Hospital - other	0	0%	0%
Facility - other unspecified	2	2%	2%
Total with data	118	100%	89%
missing death place	14		11%
Total	132		100%

Birth in:	n	%
Facility	150	100

Death in:	n	% with data	%
Community	36	26%	24%
Health Centre within RCT	26	19%	17%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	52	38%	35%
Hospital - other	0	0%	0%
Facility - other unspecified	22	16%	15%
Total with data	136	100%	91%
missing death place	14		9%
Total	150		100%

Birth in:	n	%
missing birth place	6	100

Death in:	n	% with data	%
Community	4	80%	67%
Health Centre within RCT	1	20%	17%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	0	0%	0%
Hospital - other	0	0%	0%
Facility - other unspecified	0	0%	0%
Total with data	5	100%	83%
missing death place	1		17%
Total	6		100%

Total Births in:	n	%	
Total			
	282	98%	with birth place
	6	2%	without birth place
	288	100%	Total

Total Deaths in:	n	% with data	%
Community	147	57%	51%
Health Centre within RCT	31	12%	11%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	57	22%	20%
Hospital - other	0	0%	0%
Facility - other unspecified	24	9%	8%
Total with data	259	100%	90%
missing death place	29		10%
Total	288		100%

Figure 87: Place of Death by Place of Birth: NND; Intervention period; No FI clusters

Deaths: NND **RCT arm:** No FI **Time period:** 01oct2008 to 31dec2010 (Intervention)

Community/Facility split

Birth in:	n	%
Community	155	100

Death in:	n	% with data	%
Community	128	91%	83%
Facility	12	**9%**	8%
Total with data	140	100%	90%
missing death place	15		10%
Total	155		100%

Birth in:	n	%
Facility	152	100

Death in:	n	% with data	%
Community	39	**28%**	26%
Facility	98	72%	64%
Total with data	137	100%	90%
missing death place	15		10%
Total	152		100%

Birth in:	n	%
missing birth place	7	100

Death in:	n	% with data	%
Community	4	57%	57%
Facility	3	43%	43%
Total with data	7	100%	100%
missing death place	0		0%
Total	7		100%

Total Births in:		
Total		
n	%	
307	98%	with birth place
7	2%	without birth place
314	100%	Total

Total Deaths in:	n	% with data	%
Community	171	60%	54%
Facility	113	40%	36%
Total with data	284	100%	90%
missing death place	30		10%
Total	314		100%

Facility Type breakdown for Place of Death (type of facility was not recorded for births)

Birth in:	n	%
Community	155	100

Death in:	n	% with data	%
Community	128	91%	83%
Health Centre within RCT	6	4%	4%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	3	2%	2%
Hospital - other	0	0%	0%
Facility - other unspecified	3	2%	2%
Total with data	140	100%	90%
missing death place	15		10%
Total	155		100%

Birth in:	n	%
Facility	152	100

Death in:	n	% with data	%
Community	39	28%	26%
Health Centre within RCT	34	25%	22%
Health Centre outside RCT	1	1%	1%
Hospital - MaiKhanda FI	50	36%	33%
Hospital - other	0	0%	0%
Facility - other unspecified	13	9%	9%
Total with data	137	100%	90%
missing death place	15		10%
Total	152		100%

Birth in:	n	%
missing birth place	7	100

Death in:	n	% with data	%
Community	4	57%	57%
Health Centre within RCT	1	14%	14%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	2	29%	29%
Hospital - other	0	0%	0%
Facility - other unspecified	0	0%	0%
Total with data	7	100%	100%
missing death place	0		0%
Total	7		100%

Total Births in:		
Total		
n	%	
307	98%	with birth place
7	2%	without birth place
314	100%	Total

Total Deaths in:	n	% with data	%
Community	171	60%	54%
Health Centre within RCT	41	14%	13%
Health Centre outside RCT	1	0%	0%
Hospital - MaiKhanda FI	55	19%	18%
Hospital - other	0	0%	0%
Facility - other unspecified	16	6%	5%
Total with data	284	100%	90%
missing death place	30		10%
Total	314		100%

Figure 88: Place of Death by Place of Birth: NND; Intervention period; FI clusters

Deaths: NND **RCT arm:** FI **Time period:** 01oct2008 to 31dec2010 (Intervention)

Community/Facility split

Birth in:	n	%
Community	131	100

Death in:	n	% with data	%
Community	100	87%	76%
Facility	15	**13%**	11%
Total with data	115	100%	88%
missing death place	16		12%
Total	131		100%

Birth in:	n	%
Facility	150	100

Death in:	n	% with data	%
Community	33	**23%**	22%
Facility	109	77%	73%
Total with data	142	100%	95%
missing death place	8		5%
Total	150		100%

Birth in:	n	%
missing birth place	9	100

Death in:	n	% with data	%
Community	5	71%	56%
Facility	2	29%	22%
Total with data	7	100%	78%
missing death place	2		22%
Total	9		100%

Total Births in:	n	%	
Total			
	281	97%	with birth place
	9	3%	without birth place
	290	100%	Total

Total Deaths in:	n	% with data	%
Community	138	52%	48%
Facility	126	48%	43%
Total with data	264	100%	91%
missing death place	26		9%
Total	290		100%

Facility Type breakdown for Place of Death (type of facility was not recorded for births)

Birth in:	n	%
Community	131	100

Death in:	n	% with data	%
Community	100	87%	76%
Health Centre within RCT	7	6%	5%
Health Centre outside RCT	1	1%	1%
Hospital - MaiKhanda FI	5	4%	4%
Hospital - other	0	0%	0%
Facility - other unspecified	2	2%	2%
Total with data	115	100%	88%
missing death place	16		12%
Total	131		100%

Birth in:	n	%
Facility	150	100

Death in:	n	% with data	%
Community	33	23%	22%
Health Centre within RCT	38	27%	25%
Health Centre outside RCT	1	1%	1%
Hospital - MaiKhanda FI	46	32%	31%
Hospital - other	0	0%	0%
Facility - other unspecified	24	17%	16%
Total with data	142	100%	95%
missing death place	8		5%
Total	150		100%

Birth in:	n	%
missing birth place	9	100

Death in:	n	% with data	%
Community	5	71%	56%
Health Centre within RCT	2	29%	22%
Health Centre outside RCT	0	0%	0%
Hospital - MaiKhanda FI	0	0%	0%
Hospital - other	0	0%	0%
Facility - other unspecified	0	0%	0%
Total with data	7	100%	78%
missing death place	2		22%
Total	9		100%

Total Births in:	n	%	
Total			
	281	97%	with birth place
	9	3%	without birth place
	290	100%	Total

Total Deaths in:	n	% with data	%
Community	138	52%	48%
Health Centre within RCT	47	18%	16%
Health Centre outside RCT	2	1%	1%
Hospital - MaiKhanda FI	51	19%	18%
Hospital - other	0	0%	0%
Facility - other unspecified	26	10%	9%
Total with data	264	100%	91%
missing death place	26		9%
Total	290		100%