

Innovating for Improvement

Simulation Training for Operative vaginal Birth – Evaluation (**STROBE**)

Evaluation of the ROBUST training course

North Bristol NHS Trust

About the project

Project title:

Simulation Training for Operative vaginal Birth – Evaluation (**STROBE**)

Lead organisation:

North Bristol NHS Trust

Partner organisation(s):

Royal College of Obstetricians and Gynaecologists

Project lead:

Dr Stephen O'Brien

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Part 1: Abstract

We are implementing structured, locally-delivered simulation training for operative vaginal birth in four units within the West of England. We are evaluating the impact of this training on maternal and neonatal outcomes. This is the first attempt to systematically implement and evaluate a training package for operative vaginal birth (OVB) in more than one centre anywhere around the world.

Should it prove beneficial to women and babies undergoing OVB, it has enormous potential to directly impact the care received by the 80,000 women who have an OVB in the UK every year.

Implementation of the training has been greatly facilitated by the backing of the national professional body, the Royal College of Obstetricians and Gynaecologists (RCOG), as well as the support of The Health Foundation. Despite this, one site has been unable to implement the training – this highlights the need for evidence for this intervention, as well as mandatory implementation and evaluation of impact of this training package by national statutory bodies.

Training has now been implemented in three sites, and data is being collected, cleaned and analysed for all sites.

Following completion of the project and reporting of results (including publication in a high-impact peer-reviewed journal), and assuming positive results, the RCOG has committed to making the training mandatory for all units within the UK.

Part 2: Progress and outcomes

This project seeks to implement and evaluate structured simulation training in operative vaginal birth on real-world clinical outcomes for mothers and their babies.

Over 80,000 women undergo an operative vaginal birth (OVB) in the UK every year – this is a birth where the doctor uses either forceps or a ventouse (suction cup) to assist the birth of the baby. This occurs in late labour when the cervix is fully dilated and the baby has either stopped progressing down the birth canal or is showing signs of distress. These births are important because they are associated with predictably poorer outcomes for both mothers and babies – mothers are between two and four times more likely to sustain serious trauma such as anal sphincter injuries and babies are between two and 22 times more likely to suffer from bleeds into the brain (subgaleal haemorrhage), facial trauma and shoulder dystocia. Despite these complications, OVB is superior to the alternative management option for failure to progress in labour or presumed fetal distress, a caesarean section. Mothers who have a caesarean section are twice as likely to have a significant haemorrhage and babies are between two and three times more likely to sustain an injury and be admitted to a Neonatal Intensive Care Unit (NICU).

Despite the clear need for OVB, and the significant burden of morbidity it imposes on mothers and their babies within the UK, there are no evidence-based interventions to improve outcomes associated with OVB. The Royal College of Obstetricians and Gynaecologists (RCOG) has developed, with a multi-disciplinary team, a structured simulation-based training course in OVB skills for doctors (the RCOG Operative Birth Skills Training (ROBuST) course).

At present this course is undertaken sporadically across the UK by junior doctors training within obstetrics (within the first 3 years of their training). This is in contrast to simulation-based obstetric emergencies training, which is now widespread throughout the UK and is usually undertaken by all staff on an annual basis.

Our project is innovative in that it has been the first to implement regular, local simulation training in OVB for all staff who perform it. Our project is also the first to attempt to prospectively quantify the effect of this training on direct, patient-level outcomes. Combined with the support of the national professional body, these features make our project potentially highly impactful on the births experienced by 80,000 women and their babies every year.

Over the course of the project, one significant alteration has been made – the project has changed one implementation site to a control site. This was due to a lack of enthusiasm and buy-in from the local team which prevented us from delivering training as we had planned. To account for this, we have extended the data collection periods in our other sites to ensure a balanced and meaningful sample. Although a set-back in the project timeline, we have obtained valuable learning points to take forward. The interaction highlights the importance of strong incentives

to encourage universal adoption within units. While this project seeks to provide evidence of efficacy of an intervention, this must be backed by strong monitoring and evaluation of implementation by national regulatory bodies, such as the RCOG or NICE.

We have still delivered eight training courses in three maternity units, training over 40 doctors and having a direct impact on the birth experiences of over 2,200 women.

At present (April 2018), the training has been fully implemented and we are collecting outcome data for the period covered by the project (April 2017 – April 2018). Data is being gathered from routinely collected maternity databases within each unit, with missing data being gathered from hand-searching patient notes. As of the 5th of April, complete data has been received for just over 700 women and their babies. Our team will perform all data cleaning and analysis.

In an effort to spread awareness of this project, we have engaged with social media tools (our team has combined > 690 Twitter followers) and have submitted an academic paper describing the protocol of this study to a peer-reviewed journal with a significant impact factor (BMC Pregnancy & Childbirth, IF 2.6). Moreover, we have the support of the RCOG who have committed to making our training mandatory should we achieve positive results.

We look forward to being able to quantify the effect of our training intervention on women and their babies, and then spreading this learning throughout the quality improvement and patient safety ecosystem, with a particular emphasis on incorporating our findings into national-level guidance, in order to improve and preserve maternal and neonatal outcomes following OVB.

Part 3: Cost impact

Any further training provided to trainees within O&G is dependent on positive results from our project. Should this be forthcoming, the training will be mandatory by the RCOG – this will mean that individual hospitals will have a responsibility to deliver the training within current budgets, most likely by utilising existing training budgets and senior consultant supervision time. An accurate estimation of this cost is difficult due to the novel nature of such an intervention, and cannot be compared to any impact on maternal and neonatal outcomes until final results are available.

However, a pragmatic estimation can be made using the following assumptions. Previous work by Yau et al. has shown that the provision of mandatory training for all employees within women's health is approximately £19,000 per 1,000 births in any given unit.

Given that only a small minority of staff perform OVB (approximately 12.5% of all maternity staff), the cost is likely to be substantially lower – scaling this cost by 12.5% would give a value of £2,375 per 1,000 births. This would represent a cost to a large unit of 6,500 births/year of £14,250.

Estimates from NICE calculate the cost of a caesarean birth as £700 greater than that of a vaginal birth. Therefore, using these assumptions, to be cost effective, our training package would need to result in 20 fewer caesarean sections per year in order to counter-balance the cost of the £14,250 per year cost of implementing the training. Given that North Bristol NHS Trust, a unit that performs 6,500 births/year performs approximately 940 attempted OVBs per year (which is in line with the national average), this would represent an improvement in the overall success rate of OVB of 2% (current estimated success rates in UK units are between 75% to 85%).

Our final data analysis will demonstrate any impact that our training package has had on OVB success rate. Should this be positive and the training implemented nationally, we anticipate a further project where we will work with a Health Economist, units and the RCOG to determine the cost of regular training in-vivo, and provide a determination of real-world cost-effectiveness.

Part 4: Learning from your project

As a quality improvement and implementation team we have found the project to be a learning-rich experience. We have succeeded in implementing our training in three units within the West of England, but failed to implement it in one unit.

The support of the national body (the RCOG) was extremely valuable in persuading units of the necessity of our project. Combined with the support from The Health Foundation and the leads for our local Health Education England region, this helped create an atmosphere that ROBuST training was expected, supported and likely to be beneficial – our project was seen as a natural evolution in quality improvement. Recent moves within O&G training to ensure that trainees have access to simulation training (for example in laparoscopic surgery) also helped deepen a perception that ROBuST training was a normal part of any curriculum.

This however led to a situation where, despite the novelty of our training, we suffered from barriers that more usually afflict established training programs. We frequently encountered situations where senior decision makers in units were extremely happy to have the training within their units and helped smooth our ways with local permissions and approvals. However, these senior clinicians did then not engage with the actual delivery of the training – it was perceived as a normal part of the unit and not something ‘special’ or new that deserved senior input on a practical level. This mirrors recent experience of older, more established training programs within O&G (emergencies training, cardiotocograph (CTG) teaching), which are mandated by the RCOG but not seem as a daily priority by some units.

This was shown in extreme by one unit which - although the senior team raised no objections at having the training take place (and indeed solicited it proactively) they then delegated the task of organising the training to a junior member of staff who was unable to co-ordinate effectively. This resulted in the training not being able to be delivered within the study time period.

As a team we have reflected on this. We feel that this points to a system where although there are many tools in place for effective quality improvement, many of which already have a substantial evidence base (i.e. PROMPT training), implementation of these interventions is highly variable and often dependent on personally committed local senior decision-makers. We feel that a structured analysis of what factors can help motivate such senior decision makers would be a highly relevant and useful additional project. While national bodies such as NICE or the RCOG can mandate that units must put implement an intervention, we know that intervention is highly variable. Finding ways to improve the uniformity and quality of implementation would be of great relevance to a broader QI agenda.

Part 5: Sustainability and spread

Our project will be sustained beyond the funding period dependent on the results of our analysis – should the analysis be positive, the RCOG have committed to making local ROBuST training a compulsory part of the curriculum for trainees on an annual basis. Since the commencement of our project the RCOG have already made training compulsory for trainees at some point before the end of their third year of training – unless our analysis reveals a deeply negative set of findings, we would expect this stance to continue. We were able to gain this change in policy by making a persuasive case to the Training Committee of the RCOG, including leveraging published support from trainees for greater training.

In order to highlight the forthcoming results of our project to the QI ecosystem and policy-makers, we have submitted an academic paper of our study protocol to the journal BMC Pregnancy & Childbirth. We have also applied for registration on the 'International Standard Randomised Controlled Trial Number Registry, lending our eventual results both the required academic rigour and transparency.

We plan to disseminate our findings at conferences and will therefore submit abstracts to the RCOG Annual Congress in March 2019.

The next milestone for the broader project will be a cost/benefit analysis. Assuming positive results and implementation across the UK as per the RCOG commitment, we will seek to secure funding to allow for a rigorous assessment of the costs associated with providing regular local training and weighing these against any subsequent benefit to both the patient and wider health ecosystem (including primary care). We anticipate making such an application in Q1 of 2019.

Appendix 1: Project Logo



