

Closing the Gap through Clinical Communities

Final Report

Project Title: Safety Improvement in Primary Care

Lead Organisation: Healthcare Improvement Scotland

Partner organisations: NHS Education for Scotland, University of Dundee, NHS Forth Valley, NHS Highland, NHS Tayside and NHS Lothian

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Abstract:

The Safety Improvement in Primary Care (SIPC) work echoes the work the Scottish Patient Safety Programme is undertaking in the acute sector, promoting patient safety and improvement culture by developing the knowledge and skills of primary care teams to improve the reliability and safety of care within general practice.

Using the Institute for Healthcare Improvement's breakthrough collaborative model, the project team delivered National Learning Sessions, at which primary care teams (GPs, Nurses, Pharmacist, Practice Managers, Administrators etc) were taught to proactively identify areas where harm is occurring within their practice, to identify how to make changes, measure improvement and ensure safe and reliable care.

The work focussed on identifying and reducing harm and providing safer, more reliable care for patients with heart failure; or who are on high risk drugs, such as warfarin and methotrexate.

Participating practices undertook all elements of the programme listed below:

- Implemented care bundles to improve the safety and reliability of care for patients taking high risk medications and patients with Heart Failure/LVSD
- Conducted structured case note reviews using a trigger tool to identify where patients may have been harmed
- Undertook small tests of change - plan, do, study, act (PDSA)
- Involved patients to help identify areas for improvement
- Undertook safety climate surveys to improve their practice safety culture

This work tied in closely with the Healthcare Quality Strategy for NHS Scotland which was published in May 2010 declaring an intention to put quality right at the heart of all that the NHS does for the people of Scotland. *Delivering Quality in Primary Care* (August 2010) sets out the Scottish Government's plan for implementing this Quality Strategy in primary care. The work of the SIPC project, along with other initiatives, has therefore informed and contributed to the development and implementation of a National Programme for Patient Safety in Primary Care

1.1 The Quality Challenge Background Knowledge

Approximately 6% of hospital admissions are due to adverse drug reactions (ADRs), and 3.7% are drug related and preventable (Howard 2007). Half of these admissions are caused by three groups of drugs which are among the most commonly prescribed – warfarin and other anticoagulants, non steroidal anti-inflammatory drugs (NSAIDs) and anti-platelets, and diuretics and other renal toxic drugs (Howard, 2007). Since they are much less commonly prescribed, cytotoxic drugs like methotrexate, leflunomide and azathioprine do not cause emergency hospital admission on the same scale, but their inherent toxicity means that they do regularly cause severe harm including death (although because they are not commonly prescribed, such deaths are not that frequent overall), and have been the subject of regular National Patient Safety Agency alerts as a consequence (NPSA 2004). Improving the safety and reliability of prescribing and monitoring of these drugs is therefore likely to have considerable benefits for patients.

Heart failure also represents a serious health system challenge. It has a population prevalence of 1-3% overall, and up to 10% in the very elderly. Heart failure accounts for 1 million inpatient days (2 per cent of all National Health Service [NHS] inpatient bed days) and 5 per cent of all emergency medical admissions to hospital (NICE 2003). Hospital admissions for heart failure are expected to rise by 50 per cent over the next 25 years largely because of the ageing of the population and the accompanying increase in the underlying causes of heart failure such as coronary heart disease. Patients with heart failure tend to have frequent and prolonged hospital admissions. As a result, caring for these patients is costly, with estimates of the annual cost of heart failure to the NHS ranging from £400m (Cowie, 2002) to £716m (NICE 2003), or around 1.8 per cent of the total NHS budget; much of this cost is attributed to the cost of hospitalisation (NICE 2003). Work carried out in Scotland has shown that consultations in general practice for heart failure are more common than those for angina and only slightly less than those for hypertension (Mcmurray 2003).

Heart failure has been reported to be second only to hypertension as a cardiovascular reason for a visit to a family physician in the USA (O'Connell 1994) The aim of working in this area is to optimise the management of patients with heart failure to improve patients' quality of life by reducing symptoms of breathlessness, improving function, reducing hospital admissions, and potentially lengthening life. In addition, the group identified a gap in the reliable prescribing and monitoring of high risk medications and for patients with LVSD. One of the key aims of this project is to address this clinical gap by ensuring care in these two areas is reliable.

1.2 Local Problem and context

Clinical engagement and board support has been crucial to the success of the programme. Practices participating in the programme were supported by local board teams, which consisted of a public partner, GP clinical lead, quality improvement facilitator and manager for each area. These local health board teams were in turn supported by the central team within Healthcare Improvement Scotland (HIS), which consists of a clinical lead, programme manager, 2 project officers and 2 project administrators. Along with HIS, teams from NHS Forth Valley, NHS Lothian, NHS Tayside, and NHS Highland participated in the collaborative. NHS Education for Scotland and the University of Dundee developed a number of the tools the project would implement including Structured Case Note Reviews (Trigger Tool) and web-based databases for a number of data collection processes. In addition, NHS Education for Scotland undertook a project evaluation using a mixed method approach including semi-structured interviews, focus groups, cross sectional surveys, documentation reviews and field observation.

Our original plan was to work with 80 GP practices across 4 health boards in Scotland. In the first year of the project we recruited a total of 26 practices from 3 health boards (NHS Lothian, NHS Tayside and NHS Forth Valley) participated. In the second year this spread to include an additional health board (NHS Highland) and a further 17 practices amongst the other participating health boards.

The number of practices recruited in year two was lower than anticipated and the project team identified time commitment, changes to the contract and competing priorities as the key reasons practices recruitment was lower than anticipated. This was reflected in the practice interviews conducted by our external evaluators:

'that it has been too near to the contract, all sorts of extra work had to be done'

'the amount of money given to us to pay for back fill didn't pay for a quarter of the back fill, and it costs money to take people out to have meetings, it would have been easier to release time if I had more money to put in locum provision.'

The experience of Safer Patients Initiative in NHS Tayside and initial experience of the Scottish Patient Safety Programme in all acute hospitals is that using the Institute for Healthcare Improvement Breakthrough Collaborative Model engages both clinicians and managers, and improves care, although it requires considerable effort and commitment. The original primary care improvement collaborative focused on access, diabetes and coronary heart disease achieved reasonably high levels of engagement (>50% of GP practices across Scotland) and delivered significant improvements (e.g. approximately a 25% increase in the percentage of patients with Coronary Heart Disease receiving a statin, a B-blocker and maintaining a blood pressure <140/80mmHg).

HIS (formerly NHS QIS) funded Patient Safety in Primary Care pilot in 2007/8 also found that this collaborative approach was effective in engaging practices.

Key barriers to sustainability identified from this previous work were that some practices lost focus as other priorities took precedence, and that for some practices, measurement became too burdensome to continue at least partly because it was often labour intensive. The core topics being addressed are therefore local and national priorities, and address areas that practices themselves have identified as high risk and problematic. There are therefore professional and contractual reasons for practices to retain a focus on improving care in these areas

1.3 Intended Improvement

The high level aims of the SIPC work was to identify and reduce harm in primary care by developing more reliable systems within practices, and promoting a patient safety and improvement culture in general practice. Participating practices were taught skills in the use of general improvement methodologies, including:

- Small tests of change
- Care bundles
- Trigger tools
- Patient safety climate surveys, and
- Patient involvement

Specifically, practices were expected to:

- Become knowledgeable and skilled in general methods for identifying, reporting and reducing harm in primary care, in order to develop their knowledge and skills in quality improvement.
- Improve the reliability of care of patients with heart failure and implement reliable systems for the prescribing, management and monitoring of patient with high risk drugs including warfarin and prescribing of cytotoxic drugs such as methotrexate. For each clinical topic, we have identified process and outcome measures.
- To drive the improvements and ensure safe and reliable care, we developed care bundles. A care bundle is a structured way of improving processes of care to deliver enhanced patient safety and clinical outcomes, and should take into account the following criteria:
 - 4-5 elements
 - All or none compliance
 - Measurement done by a clerk if possible
 - Should encourage local definition/customisation
 - Mix of easy and hard
 - Spread over patients journey / functions
 - Designed for 95% reliability
 - Backed by scientific evidence
 - Creates teamwork and communication
 - Multiple functions of care essential for desired outcome

Practices collected regular data on a small sample of patients (5 patients every 2 weeks or 10 patients every 4 weeks) against individual measures of the bundle and calculate the composite score that measures which patients receive all elements of the bundle. For full details of our care bundles, please see Appendix 1.

- Develop their patient safety and improvement culture through structured case note reviews (Trigger Tool) and undertaking practice-based Safety Climate Survey's.

The use of these methodologies will deliver better patient safety and quality of care. Practices will achieve greater efficiencies through the development of reliable systems to reduce clinical risk, and they will be better placed to meet the requirements of the national Patient Safety in Primary Care Programme. Practices will also develop a networking culture, for the sharing of learning and best practice. As practices develop an improved safety culture, staff will feel part of a supportive and integrated team which regards patients safety as a priority.

1.4 Changes along the way

As we were testing different interventions over the lifetime of the project, a number of different changes were made in order to make to tools and approaches as relevant and useful to those working in Primary Care. Similar tools have been used in the Hospital setting. Our tools were developed specifically for Primary care where teams are smaller and self managing and the type of work undertaken is very different form secondary care.

Our Changes Along the Way

Steering Group

The steering group was set up in Dec 2009 and initially was very fluid but as the programme emerged and HIS took over the project management the steering group became more formed. We evaluated the functioning of the steering group midway through the programme and adapted the relationship between the steering group and the project management team to promote better decision making appropriate use of the steering groups and achieve more between steering group meetings as steering group meetings became less frequent

Collaborative Learning Events

The initial learning events were delivered by speakers who had little experience of primary care but a lot of experience in safety . As the learning sets evolved and oue own skills and experience developed the learning sets were delivered by members of the steering group and practice champions making the events more relevant to the participants

Each learning session provided an opportunity for practice teams feedback on their progress, discuss highlights and challenges and to have support to translate improvement theory into practice and share learning across practices and health boards.

Below is a picture of participants actively engaged in one of our learning events.



In developing the programmes for our collaborative learning events we used the model for improvement and asked delegates to give us feedback on:

- What went well?
- What didn't go so well
- What could we do differently.

We have implemented a number of changes using this direct feedback, for example, a number of delegates felt that

'The event felt geared towards clinicians, is there scope for a separate event, or even separate breakout sessions, for non clinical staff?'

We now ensure that are events offer a range of workshops that will be of interest to the multidisciplinary team.

Bundles

Following the first year of development and testing, the bundles were then refined in the second year, with additional measures to promote patient education and self management. The group also debated when sufficient reliability would be achieved. In the majority of improvement programmes, you are deemed to have achieved reliability when you have 7 or more consecutive data points at 95% or more. However, due to breadth of work undertaken by Primary care teams and the fact that practices have to focus on so many conditions and systems, there was a question as to whether practices would ever be able to achieve this. By concentrating and expending energy to achieve 95% in one domain, an effect of this is that there is then limited capacity to work on improving different aspects of care. Therefore, it was agreed that practices would be deemed reliable when they had 7 or more consecutive data points over 80% or above. Teams were then expected to choose an additional clinical domain and bundle to work on whilst still collecting data on the initial bundle but less frequently to ensure reliability did not fall

Safety Climate

Practices were asked to complete the climate survey 3 times, at the beginning, middle and end of the project. Following completion of the survey for the first time, a number of issues with the tool were highlighted. The majority of these were based on the processes and difficulty of implementing the survey, with the remainder focussing on the format of the report and accompanying guidance. Initially the steering group therefore discussed this and decided not to continue with the safety climate as an element of the programme. However following further reflection and feedback from practices via the independent evaluation team, which indicated that the tool was a useful part of the programme the steering group agreed that the climate survey would continue to be used as a valuable element of the project which involves the entire practice team. Significant work was undertaken to make the process of completing the survey easier for practices, to make the form of the report more useful and to provide clear guidance to practice son how to use it. For example guidance and reports, please see Appendix 2 of this document



Trigger Tool

Practices involved in the project were initially undertaking one of three different trigger tools, dependant on the specific clinical condition they were working on. However, when these practices moved into year 2 of the project, they were expected to begin implementing a new care bundle, which had implications for how the trigger tool was applied. It was therefore proposed that a single uniform trigger tool be used by all practices, targeting a broader population and practices would be asked to identify what they did when they identified harm. Following testing of this revised tool on the revised population, it was apparent that a number of practices weren't identifying harm in the broader population, with the potential for them to disengage with the process. The population was therefore refined further. Following testing, where, again, little harm was found, and discussion with NHS Education for Scotland, we agreed that we have been slightly too prescriptive with the trigger tool, and that moving forward, this should be more fluid, with practices able to define a target population dependant on their local focus, with example populations to help guide them if required. Please refer to Appendix 3 for trigger tool materials used throughout the project

Data collection methods

Initially, when practices were undertaking the trigger tool, they were expected to input data into an online database, however there were a number of issues with the functionality of the website. Rather than attempt to amend a website which the project had no ownership of, NHS Lothian (one of the collaborating health boards) developed a template for capturing the results of reviews in practices. Following testing of the spreadsheet, practices reported they felt this was an improvement. Additionally, there were similar problems identified with the care bundle data website, prompting the central team to adapt the trigger tool spreadsheet to allow data to be captured in the same way. After discussion however, it was agreed to continue using the short life website for the duration of this project, although other projects are currently testing the care bundle spreadsheet, and initial feedback as to whether this could be used when spreading the bundles looks promising.

Patient Involvement

An aim of the programme was to promote practices to involve patients in making care safer. Practices found the idea of involving patients challenging so we had to adapt and develop our approaches until we had a range of tools which practices could choose to use. Initially we explored whether the programme would have an impact on PROMS relating to the specific clinical areas but this did not seem feasible. We then developed a range of approaches to do this. Each of the care bundles had a measure to promote patient knowledge and self management, Boards recruited patients to attend board sessions to explore how care could be improved in the particular area of focus. Some practices then ran focus groups to explore the same issues from a service level perspective and the outputs from the board focus groups informed some the content of the focus groups. There were tests of patient experience questionnaires which initially were felt to be too complicated so some simple questions were developed to ask patients attending the practices were developed and tested. An example of a leaflet produced by NHS Forth Valley is below, with full examples of the tools developed in the appendix.

LVSD/HEART FAILURE ZONES

EVERY DAY:	<p>EVERY DAY:</p> <ul style="list-style-type: none"> • Take no more than 3 pints (1.5 litres) of fluid each day. • Reduce your salt intake (do not change to LO-SALT preparations) • Weigh yourself in the morning before breakfast, write it down and compare to yesterdays weight. • Check for swelling in your feet, ankles/legs. • Take medication as prescribed. • Balance activity and rest periods. <p>Which zone are you in today? GREEN, YELLOW or RED?</p>				
GREEN ZONE	<p>ALL CLEAR – This zone is your goal</p> <p>Your symptoms are under control if you have:</p> <ul style="list-style-type: none"> • No shortness of breath • No significant weight gain (3 pounds over 3 days) • No swelling of your feet, ankles/legs 				
YELLOW ZONE	<p>CAUTION – This zone is a warning</p> <p>Call your doctor or nurse if:</p> <ul style="list-style-type: none"> • You have a weight gain of 3 pounds over 3 days • More shortness of breathe • More swelling of your feet, ankles/legs • Dizziness • It is harder for you to breath when lying down • You are needing to sleep sitting upright in a chair 				
RED ZONE	<p>EMERGENCY – This zone requires immediate action</p> <p>Call 999 if you have any of the following:</p> <ul style="list-style-type: none"> • You are struggling to breathe • You have unrelieved shortness of breath while sitting still 				
When requiring advice call:	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;">GP or nurse's name</td> <td style="width: 50%; text-align: center;">GP or nurse's phone number</td> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> </table>	GP or nurse's name	GP or nurse's phone number		
GP or nurse's name	GP or nurse's phone number				

LVSD/Heart Failure Patient Information, Sep 2010, Quality Improvement Team, NHS Forth Valley

Overall practice participation

Initially we predicted approximately 80 practices participating in the project, however the actual numbers were lower than anticipated (as per table below) with the majority of non participating practices citing competing priorities as the main reason for non participation. These competing priorities included significant changes to the QOF, GP Contract and practices changing IT systems.

	Year 1 Practices	Year 2 Practices	Total Practices
Lothian	7	5	12
Tayside	12	4	16
Forth Valley	7	5	12
Highland	-	3	3
Totals	26	17	43

2. Methods

2.1 The Intervention

Using the IHI breakthrough collaborative model, which was tested and is used in the Scottish Patient Safety Programme, a number of interventions (outlined below) have been tested throughout the duration of the project.

At the beginning of the project, each participating practice identified a team of 3 to lead the project within practice. Each team consisted of a GP and Practice Manager, along with 1 additional member of staff, usually the Practice Nurse. Each team was expected to participate in 5 national learning events throughout the duration of the 2 year project – please see Appendix 4 for agendas from learning sessions.

As practices were expected to commit a high level of resource to the project we provided funding to cover backfill at learning events. To ensure clarity around the project expectations clear project timelines and Service Level Agreements (between both Health Boards and Healthcare Improvement, and Health Boards and Practices) were created, and can be found in Appendix 5 of this document.

Care Bundles

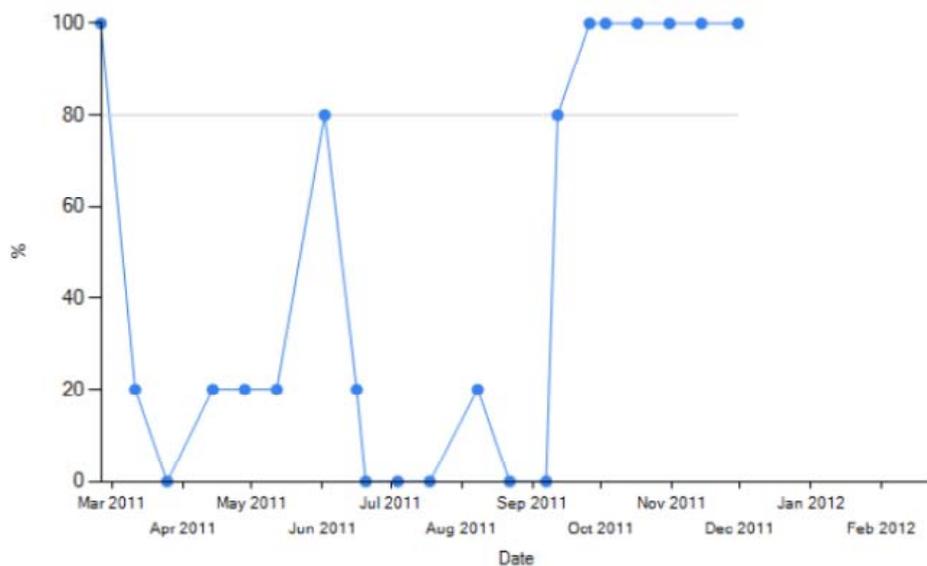
Reliability in healthcare is a failure-free operation over time. This equates to ensuring patients receive all the evidence-based care they are entitled to receive.

In relation to care bundles this means ensuring that patients receive optimum care at every contact. A care bundle is a structured way of improving processes of care to deliver enhanced patient safety and clinical outcomes. The process for achieving reliability is by testing individual measures to ensure they are the correct measures, and then testing a combination of measures (ie a bundle). Therefore the key measure in a care bundle is the composite score which measures the level of compliance with all measures for all patients.

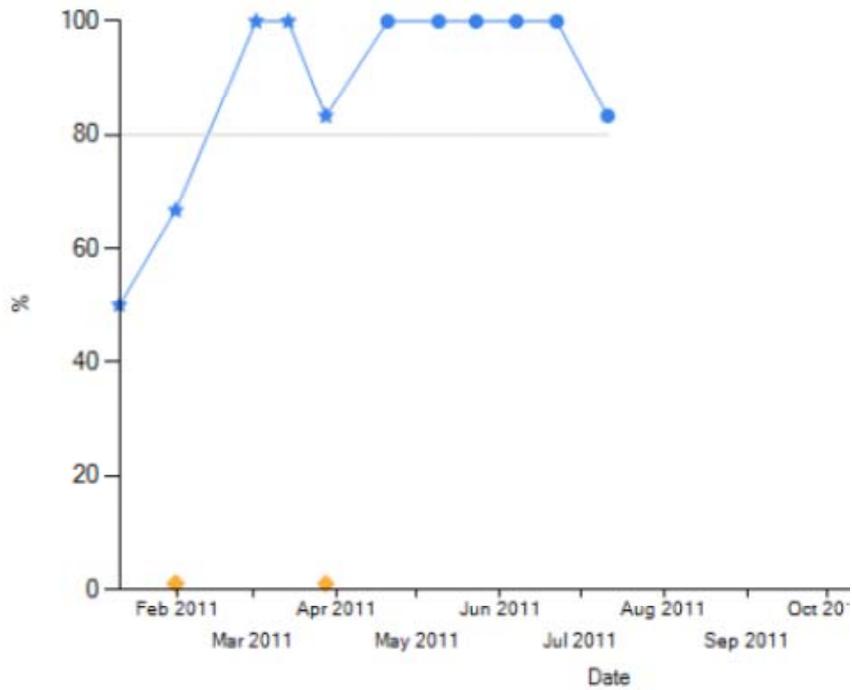
The care bundle data collection tool is a way of sampling whether optimum care is being delivered. It has been used extensively in improvement initiatives in the acute sector and in the Scottish Patient Safety Programme. Key guidance around the elements and processes which make up a bundle is listed in section 1.4 of this report. The key measure in a care bundle is the composite score which measures the level of compliance with all measures for all patients. The care bundle data collection tool is a

way of sampling whether optimum care is being delivered. This approach relies on improvement methodology which advocates measuring small frequent random samples to give you just enough information about your own system to make improvements. This approach is different from traditional auditing approaches which are designed to identify whether individual measures are being implemented for all patients, it is argued that 'aggregated data, presented in tabular formats or with summary statistics, will not help you measure the impact of process improvement or redesign efforts'. (Lloyd 2004)

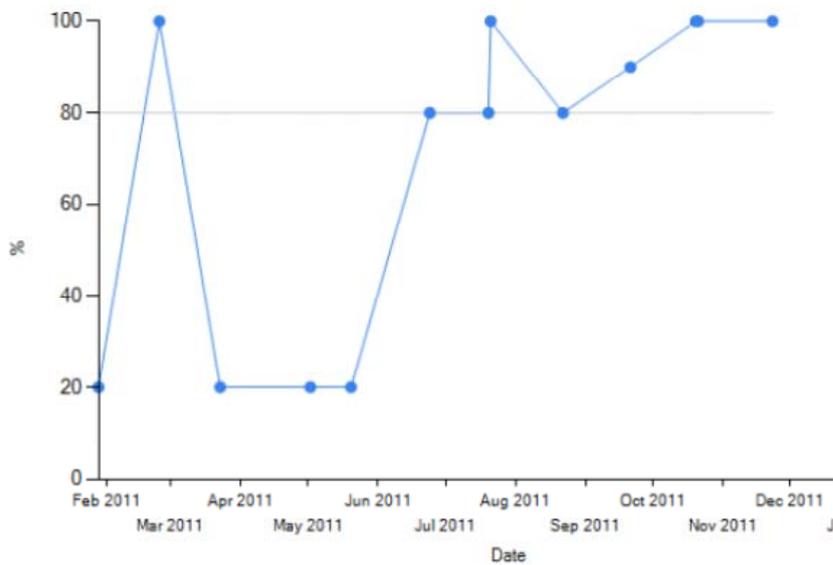
Care bundles were developed for each of the clinical areas SIPC focussed on, Warfarin, DMARDS and LVSD. Practices collected data on a sample group of patients, and inputted this data into a website designed for purpose. Following regular data submissions, practices began to create run charts, showing improvements of each element of the bundle, as well as the composite score. Please refer to run chart below as an example of a practice which has achieved reliability, which in the case of the SIPC work, was set at 80%.



The above run chart shows a practice which has achieved reliability when implementing the Warfarin care bundle.



The above run chart shows a practice which has achieved reliability when implementing the DMARDS care bundle.



The above run chart shows a practice which has achieved reliability when implementing the Heart Failure care bundle.

See Appendix 1 for detailed information relating to our care bundles.

Trigger Tool

A trigger tool is a simple checklist containing a selected number of clinical 'triggers' that a reviewer searches for when screening medical records for patients who may have been unintentionally harmed. The trigger tool process facilitates the structured, focused and rapid review of a sample of medical records by primary care clinicians. Practices were asked to undertake a review of a random sample of 20 patient records every 3 months, and an example of the trigger tool resources shared with participants is available under Appendix 3 of this report.

Patient Involvement

Patient involvement is an integral element in delivering patient centred care, and practices were encouraged to involve patients when planning and testing changes, and make patients part of the interventions. Practices were expected to develop information with and for patients, to allow them to participate in making their care safer, for example, patient education leaflets were developed locally (see appendix 6).

Safety Climate Survey

A positive and strong safety culture is essential to improve and assure patient safety. The validated tool consists of an online survey which all practice team members completed, following which an individualised practice report is automatically generated. The report compares practice results with the results of other practices, as well as a comparison of clinical vs. non clinical staff and management vs. non management, within the practice. The report also compares the results of practices each time they complete the survey, allowing those who have previously completed it to see if there has been a change in the perception of safety culture within practice. The report should then be discussed at a team meeting, and should be used as a tool and catalyst within practices for discussing patient safety, thereby developing safety climate in practice and improving care for patients.

Model for Improvement

The Institute for Healthcare Improvement's model for improvement encourages practices to make small tests of change, by addressing 3 fundamental questions, and introduces the PDSA cycle as a way to test and implement these changes. Please see below for the model for improvement questions and cycle. Practices were encouraged to document each small test of change, and upload them to be shared with other participating practices, example PDSA's are shared under Appendix 6 of this report.



2.2 Measurement

How did you measure the impact and outcomes of your project in terms of improved quality to care.

Practices were asked to measure the improvement of care when using care bundles; the measures for each bundle were tested and refined by the clinical leads for each health board. Care bundles differ from a traditional audit approach, emphasising the quality improvement approach by encouraging clinicians to consider the importance of ensuring ALL elements of care are completed, rather than considering each individual element, to ensure that care is delivered reliably.

For each bundle, practices were asked to bring baseline data of a selection of 10 patients from their chosen disease register to the first Learning event in June 2011. Subsequent data collection then took place every 2 weeks on a selection of 5 patients for DMARDS and warfarin, and 10 patients a month for LVSD. Reliability would be achieved for practices when they achieved a composite measure of 80% compliance. Refer to Appendix 1 for more information regarding the clinical bundles, the individual measures, data collection guidance and the outcome measures for each clinical area. Measuring outcome data has proved challenging, as we can only measure data which is obtainable. We are currently analysing whether the bundles will have an effect on outcomes measures. The following outcome measures have been identified

- % of INRS which are <1.5 or >5
- Reduction in admissions to hospital with heart failure
- Reduction in DMARD related Admissions

Using routine data will allow us to do a comparative analysis over time, but we can then only measure what the available data allows us which is more limited than the overall aim of the bundle. The small size of the first year of the programme (5-7 practices per Board) also limits the analysis.

There is currently discussion ongoing within participating health boards and Healthcare Improvement Scotland to examine whether the clinical bundles have an effect on the outcome measures, and whether a bundle approach is more effective than a traditional

audit approach – although practices did feel the bundle approach did provide insights into how unreliable their care is and highlight areas for improvement.

Trigger Tool

When testing the trigger tool, the original intention was to measure harm rates in the sub populations which practices were testing, however the tool has been refined throughout the duration of the SIPC project, to enable practices to review records to optimal benefit. Prioritising this has meant that measuring became less reliable, and more of a distraction – the optimal benefit of the tool is now seen helping to identify patient safety related learning needs for individuals and teams. There were also concerns around whether it was being reliably applied when different people in the practice were undertaking it. Whilst the tool is now not being used for measurement, it has enabled practices to identify a number of areas of harm and other areas of suboptimal care, and these have been recorded on spreadsheet, and common themes shared and used as a focus for improvement.

Climate Survey

Practices also completed a safety climate survey. Each individual's responses were automatically submitted to an online database, which then produced individualised practice reports. The database also measured responses over time, each time practices completed it, which in turn allowed them to measure any improvements in attitudes and perceptions each time the survey was completed.

External Evaluation

NHS Education for Scotland was commissioned to carry out a theory-driven Realistic Evaluation study of the SIPC Programme to explain how and why the programme causes change and improvement; and to identify what is it about the programme that works, for whom, in what contexts, in what respects and how. This evaluation took the form of interviews with practices, as well as the steering group, and an impact survey to all practice participating in the project.

Project impact is being assessed by capturing the outcomes and benefits (e.g. for healthcare teams, organisations, and patients); describing how the programme is delivered and experienced and explaining how the outcomes generated were achieved (i.e. what aspects of the programme were a "success" and why; and what factors contributed to less successful elements).

The Evaluation will further attempt to capture the contextual issues which lead to, for example: behaviour modification; cultural shifts; improvements in patient care etc. Further detailed information regarding the evaluation is available under Appendix 7 of this report.

Results

3.1 Outcomes

Practices were asked to apply the care bundle methodology to their chosen clinical area. Each care bundle consists of a number of process measures, the below shows the measures in each bundle.

DMARDS

For Azathioprine and Methotrexate

1. Appropriate tests carried out in correct time scale.
Measure - Has there been a full blood count in the past 6 weeks?
2. Appropriate action taken and documented for any abnormal results in previous - 12 weeks? Measure - If any abnormal results in previous 12 weeks (WBC < 4, neutrophils < 2, platelets < 150, ALT > x2 normal upper limit (>60).) has action been recorded in the consultation record
3. Blood tests reviewed prior to prescription?
Measure - Is there a documented review of blood tests prior to issue of last prescription?
4. Appropriate immunization - Has the patient ever had pneumococcal vaccine?
5. Patient asked about any side effects following last time blood was taken?
6. Have all measures been met

Outcome measures

Reduction in DMARD related hospital admission

Warfarin

1. Warfarin dose is prescribed according to local guidance
Measure - Is there evidence that the last advice re warfarin dosing given to patient followed current local guidance?
2. INR test is planned according to local guidance
Measure - Is there evidence that the last advice re the interval for blood testing given to patient followed current Lothian Guidance/ INR Star/ RAT?
3. Patient complying with dosage instructions
Measure - Has patient been taking the advised dose since last blood test?
4. INR is taken according to previous recommendation
Measure - INR is taken within 7 days of planned repeat INR?

5. Patient receives regular education –
Measure - Face to face education recorded every 3 months?
6. Have all measures been met

Outcome Measures

% or numbers of patients on warfarin who have had an INR of over 8 in the last 3 months

% or numbers of patients on warfarin who have been referred to hospital for advice or treatment because of a high INR or complication of warfarin use

Numbers of patients who have harm identified through the structured case review

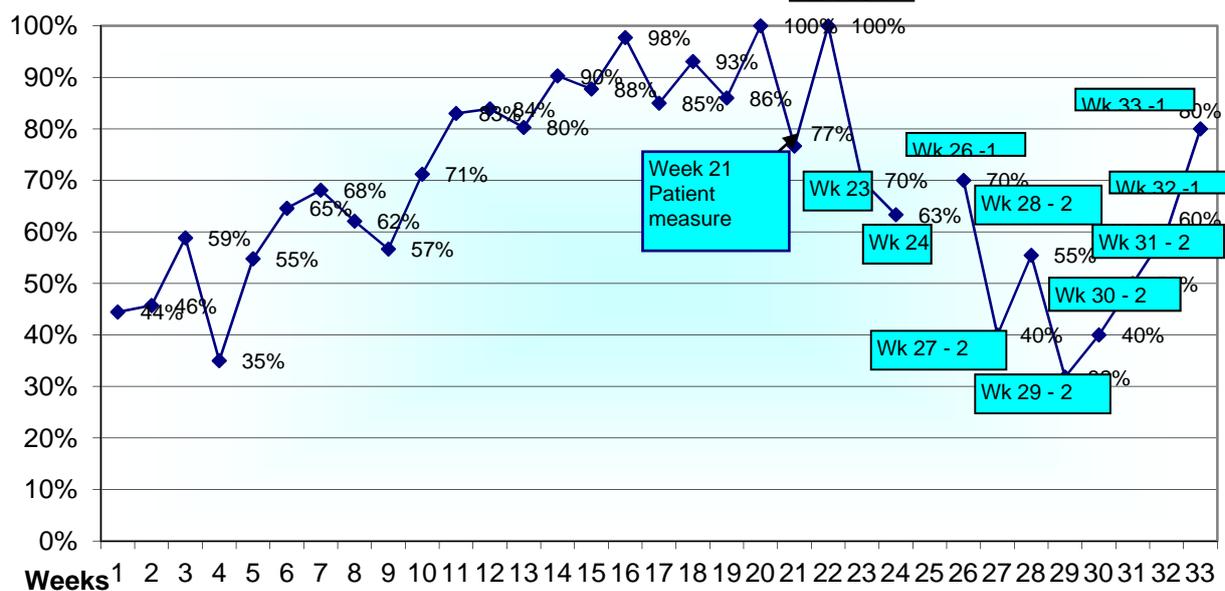
Heart Failure/LVSD Bundle

1. Appropriate medical therapy - Current use of licensed B Blocker Bisoprolol, Carvedilol and Nebivolol
2. Maximise medical therapy - B blocker prescribed at target or max tolerated dose
3. Functional Assessment Documented - NYHA recorded in last year
4. Self management - Recorded that patient given information about the recognition of worsening of heart function/condition
5. Immunise Appropriately - Pneumococcal vaccine given
6. Have all measures been met?

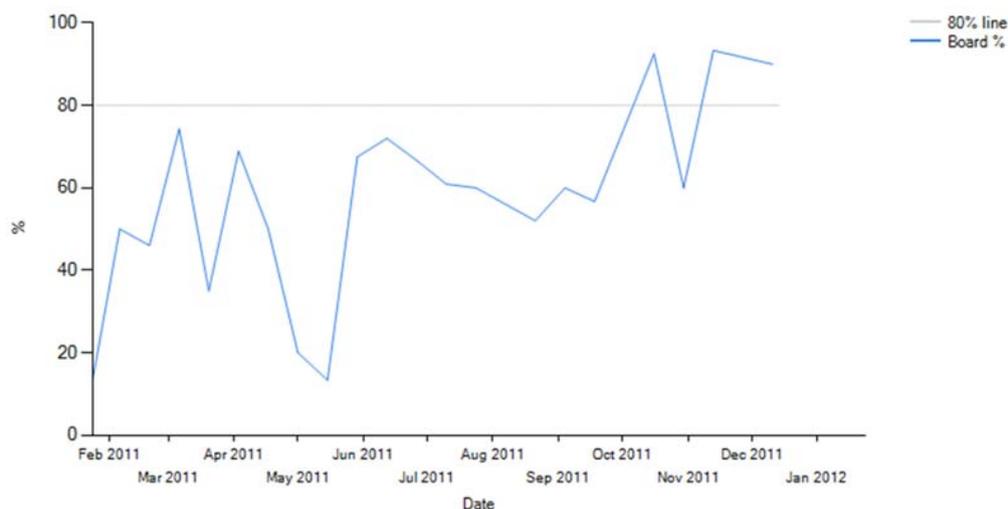
Outcome measures

Reduction in admissions with LVSD

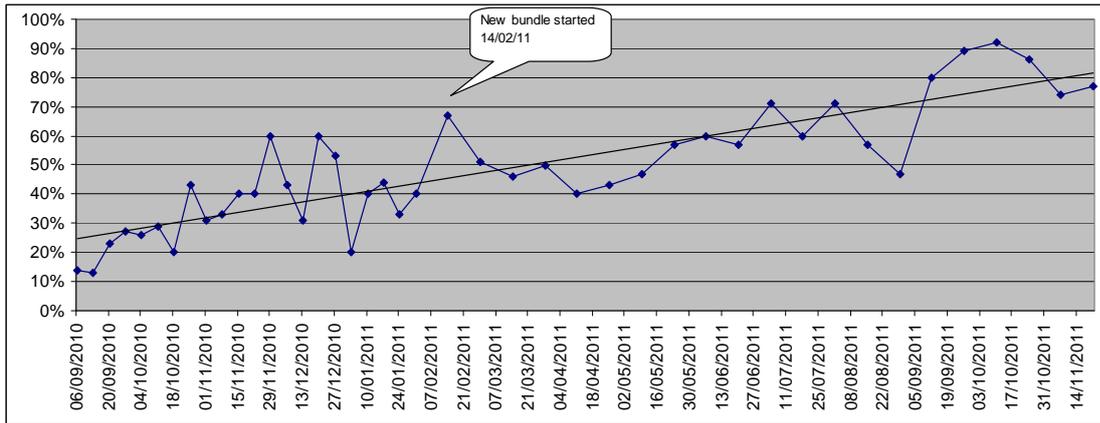
Wave 1 DMARDS - Composite Aug 2010-Dec2011 - 6 practices



The above chart shows the improvement journey in NHS Tayside when implementing the DMARDS bundle – the introduction of a patient measure produced varied results as seen, as well as the introduction of LVSD as a second topic - some practices were not reliable but still moved onto LVSD despite attempts from facilitators to encourage practices to implement both bundles.



The above chart shows the overall NHS Forth Valley composite measure for the LVSD bundle.



The above chart shows the overall NHS Lothian compliance with the Warfarin bundle. Around February 2011, there is a dip in the reliability levels: this was due to changing the bundle to incorporate a patient education measure.

SIPC Programme Awareness & Level of Direct Involvement:

- A total of 121 respondents out of a potential 398 (approximately) programme participants in 20 General Practices completed the SIPC Impact Survey questionnaire, which equates to a response rate of 30% approximately.
- 83.2% of respondents were aware of the SIPC programme, the majority (66.7%) knew what the SIPC Programme aims to achieve, while a significant minority (around 34%) either did not or were unsure.
- Almost half of all respondents (49.1%) reported that they have had an opportunity to be directly involved with the SIPC programme, while 42.9% indicated that they did not have this opportunity.
- Of the total participant response, the greatest programme awareness was in Lothian, the greatest involvement was in Forth Valley and Lothian. Of the individual health board responses, the greatest programme awareness and involvement was in Forth Valley. Of the total response, more participants at Tayside were not aware of the SIPC Programme and at Lothian; with respect to the total and individual Health Board response, least had the opportunity to be directly involved in the programme.
- Levels of Programme Awareness and Direct Involvement is displayed in Figures 1 and 2 per total participant response and further broken down by individual health board response respectively.

Figure 1: SIPC Programme Awareness/Involvement- Total Response

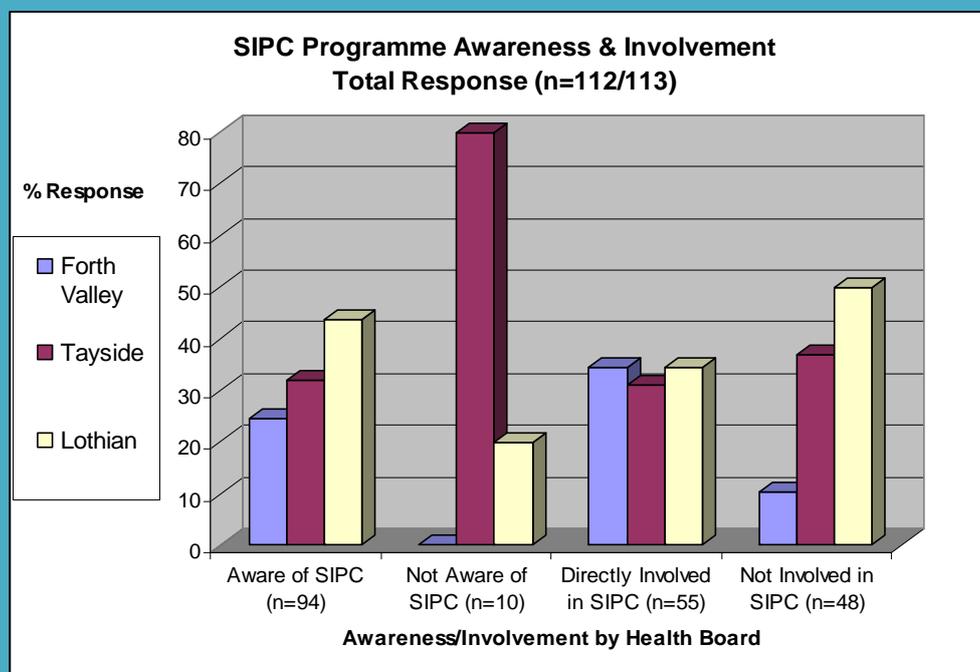
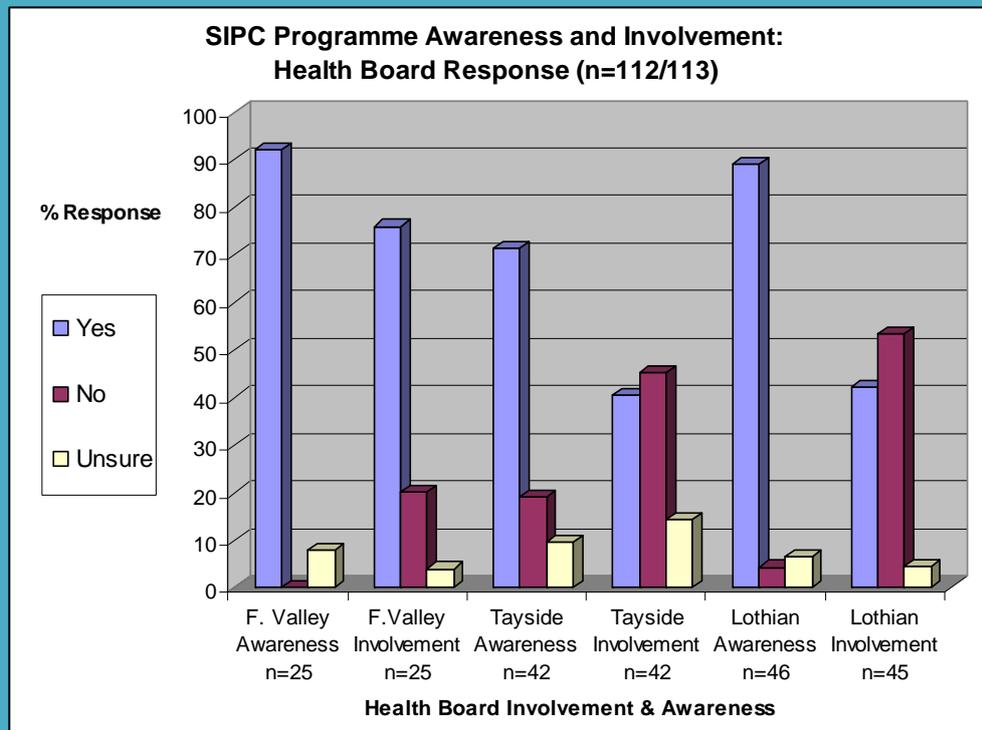


Figure 2: SIPC Programme Awareness/Involvement- Individual Health Board Response



Results from Individual Programme Elements/Tools

With respect to outcomes potentially generated by the individual programme elements:

- **The Clinical Care Bundles** have been highlighting unreliable practice, indicating areas for improvement within practices and prompting change. They have potentially further enhanced patient education/involvement and contributed to potential improvement in patient self-management of illness.
- **The Primary Care Trigger Tool** has allowed Practices to identify and find harm thus learning and safety awareness among Practice staff is increasing. It has been effective in identifying “near misses that would never have otherwise been unveiled to anybody ever but had very significant learning”. Its’ use has further prompted greater scrutiny in drug-prescribing and note review and is “picking up on areas where (practices) can improve”.
- Practices have found **PDSA Cycles** a good structured way to way “to implement and evaluate change” in making improvements and assessing “how to make your systems better”. Their use has prompted “better compliance from the patients” in some practices.
- The use of the **Safety Climate Survey** has raised awareness with respect to practice safety culture and prompted some “very open discussion” within Practice teams. It has further identified poor communication/team-working environments, training needs and a “disparity in subjective views between professional & administrative staff” of Climate and Safety. For our final report in April, we hope to include examples of a practices safety climate journey, comparing the baseline data to that of the final survey they undertook.

- With respect to **Patient Involvement**, Practices have reported that patients have “more knowledge to influence and manage their care” and are “attending more regularly for blood monitoring”. Patients have appreciated being involved in their care; Practices are finding the patient’s perspective valuable and are receiving positive feedback from patients to being more involved in their own care and to the education and information leaflets.

Reported Results and Outcomes from Independent Evaluation

General Practice staff interviewed (qualitative) in March/April 11 and surveyed (quantitative) in July/August 11 reported various positive outcomes as a result of their participation in the SIPC programme. These included:

- *Improvements in Patient Safety & Care (education & experience) & Reported Patient Benefits.*
Practices reported they are “reducing the risk of harm” to patients, they have created successful Patient Education leaflets and received positive feedback from patients about these and their experience of care. Practices have further reported on a “more holistic approach to treatment of LVSD” and “improved care of patients on high risk drugs”.
- *Improved Systems, Monitoring & Safety Procedures*
Practices have reported the “systematic monitoring of patients on high risk drugs” has been improved, “Routine annual checks” introduced, “Guidelines developed” and “specialist clinics (are) now taking place”. Patient Records are being examined with greater scrutiny using the Primary Care Trigger Tool e.g. “doctors are looking at the patients' records rather than just the INR results.
- *Improved Knowledge, Skills & Attitudes of Practice Staff with respect to safety and improvement*
General Practice Staff have reported greater practice team awareness of the “possibility of harm to the patients” and “Improved clinical knowledge”. Improvements in SIPC participant self-reported knowledge of safety and improvement issues were evident following attendance at the various SIPC National Learning Events and comparison of Participants' Estimated Knowledge Levels of ‘Selected Patient Safety and Improvement Issues’ before and after Learning Set attendance; Table 1 demonstrates significant knowledge differences. Practice staff members reported an impact upon their communication skills, skills in the use of Trigger tools, PDSAs and face to face education of patients.
- *Positive Programme Experience & Greater Team-working/Involvement*
According to Practice teams, participation in the SIPC programme is encouraging greater team-working & practice involvement, Sharing & Reflection and signs of improvements in Safety Culture within participating practices.

3.2 Please provide an assessment of the quality and robustness of the data that you have used, including comment on the validity and reliability of your measures, both qualitative and quantitative.

The programme is collecting 'internal' quantitative data relating to the care bundles in participating practices. We are also seeking to gather external data to assess the impact of the SIPC1 programme to complement the care bundle data. Matching the year 1 focus of each Health Board, the three datasets we are planning to use are:

- In Lothian, laboratory International Normalised Ratio (INR) data to assess changes in coagulation control in participating and non-participating practices
- In Tayside, data on cytotoxic drug laboratory monitoring in participating and non-participating practices
- In Forth Valley, data on emergency admissions to hospital with heart failure in participating and non-participating practices

The key barrier is that we can only use data that is routinely available, and obtaining such data is not always straightforward. The Lothian INR and Forth Valley admission data have been obtained, and the Tayside prescription/laboratory data has been requested. Using routine data will allow us to do a comparative analysis over time (a key strength), but we can then only measure what the available data allows us which is more limited than the overall aim of the bundle. The small size of the first year of the programme (5-7 practices per Board) will also significantly limit the power of the analysis, particularly the Forth Valley admissions data since the numbers are small).

Another barrier to obtaining good quality data became apparent in the interim evaluation of the project. This evaluation reflected a number of queries from the steering group around the methodology for developing the bundles, the evidence base for those that have been developed, whether they are coherent, and whether it is clear to practices that care bundles are about measuring reliability. The clinical leads involved in the project agreed to undertake a review of the care bundles and develop documents outlining the rationale involved in each bundle element (please see appendix 1 for full rationale documents). Additionally, there were some initial concerns regarding the data collection frequency for year 1 practices who were moving onto a new clinical area in year 2 – there was discussion regarding whether or not it was feasible to expect practices to collect fortnightly data on 2 different areas, therefore it was agreed that when practices had achieved reliability in the first bundle, they could collect data on a smaller basis: 5 patients every 2 months – it was agreed that this approach would ensure a sustained improvement, rather than simply an area of focus at one time.

Some of the outcome data may take a long time to become apparent e.g. in Forth Valley, data on emergency admissions to hospital with heart failure in participating and non-participating practices, the numbers are small and differences may emerge only after a few years as practices were concentrating on patients who had left ventricular systolic dysfunction many of whom were only mildly affected.

Examples of the key barriers to obtaining good quality data and the limitations of evaluation findings and their wider applicability can be found in Appendix 7:

3.3 What impact has this project had?

Impact reported through Independent Evaluation

Evaluation Aims

The evaluation of the SIPC programme was carried out at arms length by NHS Education Scotland and aimed to:

- Assess the outcomes of the programme, the benefits to those involved (e.g. for healthcare teams, organisations, and patients).
- Describe the way the programme is delivered and experienced to generate the information needed to carry out any necessary mid-course corrections, and so that other interested organisations can replicate what was done.
- Explain how the outcomes generated were achieved. The key question to be shared with others is: which things made the programme successful?

EVALUATION METHODS

- A *mixed methods approach* is being employed using a range of qualitative and quantitative tools including semi-structured interviews, focus groups, cross sectional surveys, documentation reviews and field observation. Qualitative data are being subjected to content analysis to generate key themes.
- From Jan - April 2011, voluntary confidential *semi-structured interviews* were conducted with purposive samples of the SIPC Programme Steering Group (n=17) and General Practice Clinicians and Staff (n=27) to examine their experiences, learning and any early improvement of the programme as well as assessing the impact upon their knowledge, skills, and attitudes with regard to Patient Safety and Improvement.
- The SIPC Programme *Impact survey* was disseminated in July/August 2011 to all staff in all of the 20 General Practices still participating in Wave 1 of the programme (2 practices had disengaged) to establish the level of programme spread (e.g. levels of programme awareness and direct involvement within Practices/Boards) and the Individual and Practice level impact of the programme as well as exploring key learning and implemented changes in practices with respect to each of the programme elements.

Programme Successes

Practices have reported a range of programme successes and positive impacts including -

- Improvements in Patient Safety/Care & Reported Patient Benefits:
Practices reported that they are “*reducing the risk of harm*” to patients, they have created successful Patient Education leaflets and received positive feedback from patients about these and their experience of care. Practices have further reported on a “*more holistic approach to treatment of LVSD*” and “*improved care of patients on high risk drugs*”.
- Improved Systems, Monitoring & Safety Procedures:
Practices have reported that the “*systematic monitoring of patients on high risk drugs*” has been improved, “*Routine annual checks*” introduced, “*Guidelines developed*” and “*specialist clinics (are) now taking place*”. Patient Records are being examined with greater scrutiny using the Primary Care Trigger Tool e.g. “*doctors are looking at the patients' records rather than just the INR results*”.
- Improved Knowledge, Skills & Attitudes of Staff with respect to safety and improvement:
General Practice Staff have reported greater practice team awareness of the “*possibility of harm to patients*” and “*Improved clinical knowledge*”. Improvements in participant self-reported estimated knowledge levels of safety and improvement issues were evident following attendance at the various SIPC National Learning Events. Practice staff members reported the programme has further impacted upon their communication skills, skills in the use of Trigger tools, PDSAs and face to face education of patients.
- Positive Programme Experience & Greater Team-working/Involvement:
Many participants have described their programme participation as mostly a positive experience. According to Practice teams, participation in the programme is encouraging greater team-working & practice involvement, sharing & reflection and signs of improvements in safety culture within participating practices.

Programme Challenges

Practices have experienced a number of challenges and less positive impacts as a result of programme participation, these pertained to -

- Time Pressures/Constraints & competing priorities e.g. “*getting protected time to use the tools, attend away days, demands of contract*”
- Difficulties getting the whole Practice Team on board & building an improved safety culture e.g. around half of Impact Survey respondents have not had an opportunity to be involved in the programme.
- Challenges impacting upon knowledge/skills and safety culture with respect to all aspects of work
- Inadequate resources and remuneration e.g. “*Insufficient funding to cover GP / PN / PM time required*”

- *Challenges* associated with Practice Environment/Working culture e.g.
 - Lack of leadership and low morale
 - Lack of inclusive communication and Miscommunication
 - Lack of open culture
 - Lack of Inclusive Programme Involvement
 - Work of the Programme not evenly distributed
 - Hierarchical Practices and communication structures
 - Some cynical GP partners
- Various Other *Challenges* e.g.
 - Reluctance to change ingrained ways of working
 - Complicated and unwieldy Programme methods e.g. time spent on PDSAs
 - Improving self knowledge of LVSD may have caused anxiety for some patients with minimal/no symptoms
 - Continual bundling (Warfarin bundles) - mostly same patients being seen
 - Lack of continuity, locums and part-time staff
 - Errors occurring as a result of system change-overs e.g. EMIS
 - Challenge in taking on new Programme topic
 - Involving patients

Individual Programme Elements/Tools Summary

The main successes, challenges and implemented changes in practice (reported by practice participants) with regard to each of the programme elements/tools are summarised below:

- The **Clinical Care Bundles** have been highlighting unreliable practice, indicating areas for improvement within practices and prompting change. They have potentially further enhanced patient education/involvement and contributed to potential improvement in patient self-management of illness. Practices have reported that the use of the bundles has led to improved care systems with regard to repeat prescriptions, blood monitoring, immunisation, review of patients for the pneumococcal vaccine and the introduction of a *“computer based warfarin recording system”*. However, a few participants have doubted whether the bundles have the ability to *“contribute anything to the actual care of the patients at practice level”*; others felt it might be of *“limited value to keep doing (bundles) in a tedious way”*. Practices have further struggled with patient compliance issues, statistical relevance with small samples, technical and access problems with the SIPC Data site and challenges with the Beta Blocker Optimal Dose.

- The **Primary Care Trigger Tool** has allowed Practices to identify and find harm thus learning and safety awareness among Practice staff is reportedly increasing. It has been effective in identifying *“near misses that would never have otherwise been unveiled to anybody ever but had very significant learning”*. Some cases/types of harm practices reported finding were associated with altering/changed medication, recording of adverse drug/anti-biotic reactions, lack of follow-up etc. Practices have acted upon such findings by implementing e.g. a *“red flag alert when prescribing an antibiotic for patients on a DMARD”*, and *“haemoglobin checks worked into care pathways for various illnesses”*. The use of the Trigger Tool has further prompted greater scrutiny in drug-prescribing/note review, improved *“coding of adverse events”*, the levelling out of INR results and is *“picking up on areas where (practices) can improve”*. However, the tool has also been described as *“elusive”, “threatening”, “daunting” and “cumbersome”*. Some practices have struggled with the interpretation and prevention of harm while others were not identifying sufficient cases of harm to prompt change. Practices found the use of the tool time-consuming and further struggled with various technical issues regarding the data website and spreadsheet.
- Practices have found **PDSA Cycles** a good structured way *“to implement and evaluate change”* when instigating improvements and assessing *“how to make systems better”*. It has also led to *“better compliance from the patients”* in some practices. Through the use of PDSAs, practices have reported implementing *“pneumococcal vaccination for methotrexate patients”*, introducing *“annual blood tests for all patients on warfarin”* and in some practices, achieving *“better compliance from patients”*. However some practices have not *“quite bought into it”* as a method for improvement, they have struggled to find time to record and share PDSAs, consequently their use has been limited in some practices. It was reported that the PDSA methodology may potentially be more difficult to apply *“under the heart failure scenario”* in identifying *“small tests of change”* and having a Practice Manager involved in the process may be necessary to *“push these things on”*.
- The use of the **Safety Climate Survey** has raised awareness with respect to team-based perceptions of the prevailing practice safety culture and prompted some *“very open discussion”* within Practice teams. It has further identified poor communication/team-working environments, training needs and a *“disparity in subjective views between professional & administrative staff”* of climate and safety. Lack of a clear initial explanation of the purpose of the Climate Survey contributed to some misunderstanding, varied interpretation and limited completion in some practices; in others, engaging all staff in the process has proved challenging. Further, some staff members had concerns regarding potential skewing of results and anonymity in completion.

- With respect to **Patient Involvement**, practices have reported that patients have *“more knowledge to influence and manage their care”* and are *“attending more regularly for blood monitoring”*. Patients have appreciated being involved in their care; Practices are finding the patient’s perspective valuable and are receiving positive feedback from patients to being more involved in their own care and to the education and information leaflets. However, many participants felt they had not *“involved patients to a great extent”*, some suggesting that potentially the *“barriers have just been (themselves) in taking the step forward”*. Practices were further concerned about *“managing patient expectations”* and *“patient contact/communication”* and time constraints/competing priorities further challenged practice staff in involving patients effectively.

Programme Communication & Spread

Perceptions and evidence of programme communication and spread throughout the first Wave of the SIPC are summarised below:

- Wider knowledge and awareness of the SIPC programme varies within the SIPC participating practices. In terms of involvement in the Programme some practices have reported that they *“haven’t got everybody on board 100%”*
- Participants have reported a *disparity* in the programme knowledge between those clinical staff - *“people who are dealing with the patients”* - compared to Administrative staff - *“clinical staff will know about it, the administrative staff are far less involved”*.
- In most cases, it appears from the limited evidence that the influence of the programme did not spread beyond the key SIPC Programme Representatives within participating practices. An impact survey circulated to all staff members in all participating practices achieved approximately a 30% response rate. The majority of these respondents were based in Specialty Training Practices and aware of the programme though only half had an opportunity to directly participate; there was a sense in some practices that the programme was not perceived as part of the remit of all staff.

RECOMMENDATIONS

Based on the implications from the evidence outlined, the Evaluation Team suggest a number of recommendations that Programme Stakeholders may wish to consider:

- Greater clarity and agreement around the SIPC Programme Theory, key aims and objectives is necessary from the outset.
- Develop and implement an effective strategy for spread, provide practice staff with training and skills in influencing, communication, leadership, dealing with change/change management etc.
- Encourage a philosophy of even distribution of programme work and inclusive programme involvement within practices.
- Provide greater remuneration for backfill/sessional staff and more protected time for practice staff.
- Address technical and access issues with data websites swiftly and effectively to limit inconvenience to participants.
- Address perceptions of some programme tools e.g. Trigger review should not be perceived as a threatening/blame-tool.
- Build expert capacity to facilitate in-practice Trigger review training to aide practice staff with the interpretation of harm and how to feed back learning.
- Promote further training in the PDSA method to assist practices in grasping the concept and understand why this approach can be worthwhile to use i.e. get buy-in. Improve clarity around what needs to be recorded and shared in terms of the PDSA.
- Rationalise beforehand if the PDSA method is relevant and/or feasible with every Programme topic in identifying small tests of change.

CONCLUSIONS

- The pilot programme was positively received by most stakeholders, although a number of difficult technical and socio-cultural implementation challenges are to be overcome if this type of approach is to have wider potential and impact. Caution must be exercised when interpreting the findings from a collaborative programme perspective largely because of the small, volunteer sample of mainly enthusiastic participants (early adopters) who were based mostly in speciality training practices. Importantly, however, the programme facilitated the further development and testing of a small number of improvement techniques that were mostly new to this healthcare setting and provided empirical evidence of their validity, acceptability, feasibility and impact on patient care. The learning from the SIPC Programme is now informing development of a national programme of safety improvement in primary care across Scotland's Health Service. Furthermore, NHS leaders with responsibility for GP speciality training and GP appraisal have agreed in principle to some of the core interventions (care bundle audit, trigger review and safety climate assessment) playing a role in these educational systems.

According to evaluation interviews & surveys, Steering group members including Board teams and General Practice staff reported upon how their participation in the programme has benefited themselves as individuals, their team/practice/organisation and perceived benefits to patients/service users.

Patients/Service users

Improvements in Patient Safety & Care (education & experience) have been reported as a successful outcome of the programme. Perceived benefits to Patients have been described by Practices who are potentially improving patient care through “reducing the risk of harm” to patients and creating successful Patient Education leaflets (See Appendix 6 for patient education PDSA). Practices have received positive feedback from patients about these, their experience of care and have further reported on a “more holistic approach to treatment of LVSD” and “improved care of patients on high risk drugs”.

Steering Group Members & Board teams

Many Steering Group members and Board teams have described their involvement in the programme as a “positive experience”, some have gained considerable “personal development” and it has been a “huge learning curve” for others to be “involved in real life implementation” of a safety and improvement programme.

4. Discussion/ learning

4.1 Summary

Key successes of the programme

- Setting up a functioning steering group with all stakeholders which worked collaboratively and had a good mix of skills and approaches including project management , research QI clinical facilitation educational and IT- the help of Berkshire Consulting in this regard very helpful
- Adapting the way the steering group worked as the programme developed
- Collaboration between health boards
- Recruiting 45 practices and motivating them to attend collaborative events and test and help us develop the tools and approaches
- The development of cohort of people with the skills and knowledge to build further capacity in NSH Scotland
- Improving the reliability of care practices delivered to patients in three clinical areas
- Developing practice safety cultures through being part of the programme
- Developing practice and board team skills and knowledge in safety and quality improvement

- The development and testing of new tools and approaches to highlight and improve safety in practice teams including specifically care bundles trigger tools and climate surveys
- Developing and testing approaches to involving patients in improving the quality of care they receive and promote self management
- An evaluation programme that informed the programme as it evolved eg the adaptation and continuation of the climate survey and the functioning of the steering group
- Identified and are actively pursuing routes to ensure the successes of the programme are adopted where appropriate in the emerging safety programme for primary care in NHS Scotland to be rolled out in April 2013
- Having trigger tools and climate surveys accepted as evidence for GP appraisal in NHS Scotland
- The opportunity for the learning for the programme to inform the GP contract firm 2013
- Sharing the learning at international conferences including the IHI Office Practice Summit in march 2012 and international forum in Paris in April 2102
- Feeding out learning into the WHO expert panel group on safety in Primary care in Geneva February 2012

Specific Changes Observed

A major area of success in the implementation of the project has been collaboration at different levels. Each health board had a local core team assigned to supporting the implementation of the interventions. The collaboration of the board facilitators has been a key success - these individuals formed a supportive network, thereby when health boards were facing and overcoming challenges, the learning was able to be shared, thus driving continuous quality improvement

Collaboration between partner organisations has been key: both the Trigger Tool and the Climate Survey initially presented challenges (summarised below) however through mutual support and collaborative working, had successful outcomes.

Practices have reported through interviews and surveys various implemented changes in practice with respect to each programme element:

Care Bundles:

The learning identified in practices has been the realisation that care and practice are currently unreliable. There is an awareness that processes in place are not as reliable and safe as thought, and a willingness to improve these. Practices report improved patient education and procedures, for example: repeat prescriptions, Heart Failure Classification, Blood monitoring Protocol, Immunisation, Reviewing patients for pneumococcal vaccine, Safety check-lists, Systematic approach & entry into recall system, Optimising doses, Use of Guidelines, Computer based warfarin recording systems introduced, involvement of phlebotomists in patient use of yellow books. Bundle data indicated care had become more reliable and safe in these key clinical areas

Trigger Tool

In March 2011, a number of issues with the trigger tool and its processes were identified. Practices reported difficulties inputting data to the website, and were

unable to access the results once the data was entered. In addition, practices fed back that they were identifying incidental learning and there was no way of capturing this. It was agreed that for the third Structured Case Note Review it would be simpler for practices to enter the results of these reviews into a template spreadsheet developed by NHS Lothian. The move from website to spreadsheet was successful, with the spreadsheet later being adapted for care bundles and use in a national programme. Other key successes of the trigger tool were, amongst others, ensuring greater scrutiny in areas of potential harm, the introduction of new systems, and educating staff on standards of care and areas to focus on.

PDSAs

The use of PDSAs as an improvement tool in practices has prompted reports of improved systems, and staff and patient education – however there have been difficulties in encouraging practices to document and share their PDSAs – a number of practices reported that although PDSAs were being undertaken automatically when testing new systems, recording them was time consuming:

Assessing Safety Climate

Initially a number of difficulties were apparent when implementing the safety climate survey; feedback indicated that practices found the result reports too complex and questions were raised whether the time and effort required to make the climate survey work would divert resources from the project elements which were perceived to be more effective. Some methodological issues were highlighted in relation to the survey, including: the validity of longitudinal comparisons when the survey populations will be different before and after; the intended use was as a cultural tool not a tool for measurement; without proper facilitation there is a risk that the survey may upset practices. Although the steering group discussed and initially agreed to the option of not continuing with the survey, following extensive discussions and with substantial changes to the process it was agreed to reinstate the Patient Safety Climate Survey. Working closely with partners in NHS Education for Scotland, a revised process for disseminating and reporting practice results was implemented, this included guidance to practice managers administering the survey, operational definitions, guidance on how to complete the survey, and guidance on how to interpret the results. A revised report format was also created, and feedback from practices relating to the improvement of the revised tool was positive. Though actual reported changes in Practice were limited with respect to this programme element, the use and completion of the Safety Climate Survey has prompted practice discussion around safety culture and promoted a more 'inclusive' way to work.

Patient Involvement

Patient Involvement has been one of the more challenging aspects of the project; although practices held focus groups / developed patient questionnaires, they are unsure how to use these results for improvement.

Although a number of practices have found this difficult, there were implemented changes feedback, notably more contact and greater involvement with patients, through focus groups, patient education sessions, and working with patients to develop patient information.

Key challenges

- Developing and implementing the programme with so many different organisations and agendas
- Developing tools and approaches where few existed beforehand – felt we were following a lonely furrow- very little work has been done in improving safety in primary care
- Recruitment of practices when so many other conflicting priorities
- Capacity of board teams and practices to carry out the work
- Spread of the programme within practice teams
- IT issues websites that worked to catch data and deliver safety climate surveys

4.2 Please explain how you established the clinical community; how you think it impacted on the success of your project; what was the added value of approaching the problem through a clinical community?

The steering group had representation from each participating health board, in the form of a clinical lead, facilitator and a quality improvement manager – this tiered approach ensured practices would be supported at all levels, throughout the project. A public partner from each health board was also on the group, ensuring that the best interests of the public were represented, and focused on. Additionally, colleagues from NHS Education for Scotland were members, along with a professor of Primary Care from the University of Dundee, who would input to measure and process development. Steering groups members interviewed in Jan 2011 about their experiences during Wave 1 of the programme reported that relationship building and collaboration between NHS Boards and Primary Care Teams and strong personal and professional development were key early successes. Being involved in real life programme implementation has been an “interesting and positive experience” for some and a “huge learning curve” for others.

Though it was acknowledged the steering group can, at times, work well together to negotiate amicable conclusions, competing vested interests; strong personalities; challenging behaviour; over-inclusivity; and a variety of communication issues are all reported, at various times, to have hindered decision-making, cooperation and progress.

Engaging and sustaining the involvement of stakeholders and balancing effective levels of support and communication - when time, resources and capacity are limited - is arguably the key learning outcome.

A clinical community was also created in each health board of practices involved in the collaborative whereby practices learnt from and supported one another. As mentioned, a shared knowledge website was developed for all participating in the project, and proved a key resource for this community.

4.3 Please tell us about your achievements, the challenges and the things that didn't work out quite as you planned.

The overall aim of the project for health boards was to improve the care and systems for patients on DMARDS, warfarin, and those patients who have LVSD. Practices were recruited for the project via the local health boards, who held recruitment events, and organised local practice visits where the background and aims of the programme were explained, along with the benefits of participating. This gave teams the opportunity to ask questions with key steering group members on hand to answer and encourage. A Patient Safety in Primary Care programme is in development therefore teams were able to use this as a driver for encouraging teams thinking about taking part in SIPC: they would be established and familiar with the methods and tools when the national programme was introduced.

The clinical community has played a vital role in the successes of the project – practices have had full support from a local steering group and dedicated facilitated time provided by local health boards, and it is clear that it would have been difficult to co-ordinate the programme within the health board without this dedicated Quality Improvement support. Local health board teams met regularly however could not have worked effectively without the direction of the National Steering Group which was provided on an ongoing basis. The collaboration between health boards has proved a great success. The facilitators built a strong network of support for one another where both learning and solutions could be shared. This has not only benefited the programme but will be helpful in moving forward with other national initiatives. The learning events both national and local also allowed for this between practices, and this has been noted in after event evaluations as one of a highlight.

Clinical drive has also been integral to the success of these practices, as this has encouraged others in the practices who were involved in the journey. Buy in to the project was again, practice dependent upon culture and teamwork and where clinicians were leading, and feedback suggests that this worked better in practices who shared project and its result in team meetings rather than those who worked in isolation.

Clinical engagement varies according to practice and interest of the GPs. As expected, where the decision to join was by some team members and it was imposed on the team there were some difficulties. It is clear from this learning that to drive improvements the whole team needs to be engaged – there needs to be clear communication regarding the rationale for the work, and the improvements it will lead to.

Although many practices showed significant improvement in the clinical areas of focus, it is apparent that there is a huge variance between practices when it comes to the achievement of these aims, depending on engagement of team members. It became apparent that strong leadership within practices made a big difference to the adoption and development of the project over two years. Individuals from different practices picked up the methodology and took it to another level, and this helped encourage others. They encouraged others with their ideas. It is important to engage these individuals and develop new ways of working, particularly with a pilot project where work around the work streams has never been done before, and there is no plan already available to implement.

The National Healthcare Quality Strategy introduced in May 2010 which provided a basis for all healthcare providers in Scotland and linked strongly with the aims of the SIPC programme has created an opportunity to engage with health care professionals. The project was aided by having a National steering group to guide the development of the project in line with the National agenda. Until now there has been no contractual obligation for practices to engage with a patient safety programme. There are many other competing interests – primarily around the QoF achievement that focuses the work load within the practice.

As reported above, technology has at times been difficult particularly in relating to the care bundle site – the issues on this site caused some frustration to practices, facilitators and the central team. Another barrier was time; during the recruitment process, many practices felt that they were unable to commit to the project, due to a number of competing priorities and initiatives. Smaller practices could have problems implementing bundles, due to the small numbers of patients with the specific condition, this affected motivation and momentum in these practices. Despite these barriers, the data illustrates improvements can be made even in a short period of time.

Ideally, if this project were to run again, we would hope that better IT systems would be in place to avoid the frustrations noted above, although the team have always been mindful of the developmental nature of the programme.

We would also reinforce the message to practices that that the project is about reliability and sustained improvement, ensuring that they understand its about having sustainable systems for all patients. Additionally, we would reinforce the message of the 'away team' as per IHI's breakthrough collaborative model – that the team members in attendance at the learning set have a responsibility to go back and share and spread the learning throughout all team members – this would address a number of the issues identified in the evaluation regarding the difficulties of spread at a practice level. On wider roll out, careful consideration will be given to the workload implications for staff.

4.4 Interpretation

Explore possible reasons for differences between observed and expected outcomes paying particular attention to components of the intervention and contextual factors that helped determine the effectiveness (or lack thereof).

When interviewed in March/April 2011, Practices listed a variety of factors/characteristics which may be driving their successful participation in the SIPC; these included motivated, highly organised and committed individuals with a genuine interest in the programme topics and Practices with an open culture, flat structure, efficient administrative staff, strong team working and regular communication. Additionally, effective programme support/training, sharing with others and the allocation of protected time were further reported success factors.

As part of the Programme Impact Survey, SIPC Participants were asked to identify key factors that are allowing them and their practice to have success in the programme, these were described as follows:

Practice & Staff Characteristics

- Excellent Leadership & Teamwork
- Positive Attitudes, Enthusiastic Individuals, Forward-thinking practice
- Commitment, Determination, Diligence, Perseverance of Staff
- Keeness/Willingness of team (to improve patient safety and makes things better)
- Excellent input from practice pharmacist and her links with other colleagues
- Appreciation of the ethos of the programme & belief in Improvement methodologies
- Individual/Practice interests in particular programme areas

Good Communication & Programme support

- The full days away which have been reimbursed/funding
- Regular information from SIPC organisers
- Regular meetings and Feeding back at Practice meetings
- Good communication and a non critical atmosphere
- Consistent message

Various other drivers of success

- Simple, easy to use tools
- Free rein to implement changes
- Protected time, Specific allocated time e.g. in PLT
- Building on existing systems
- Seeing results/positive outcomes for patients

Participants were further asked to identify what might be causing them and their practice to struggle with particular aspects of the programme, these were reported as follows:

Time Pressures/Competing Priorities/Heavy workloads

- Time constraints, lack of protected time, lack of time within practice hours to complete tasks, competing priorities/projects
- Lack of time & motivation with so many other commitments
- increasing demands on General Practice coupled with the demands of the contract
- prescribing pressures and QOFQIP.
- Heavy workloads
- pressures from other areas practices have to work in to allow them to survive as a business
- practices serving the most deprived populations in Scotland, "practice staff are working flat out".

Struggles grasping particular Programme aspects

- Lack of familiarity with PDSAs
- Trigger tool concept and aims still difficult to grasp.

Getting the whole team involved

- "opportunity to involve the whole practice team (in complicated systems)", "getting together to discuss progress e.g. PDSAs"

Costs to the Practice

- “The participation in projects like SIPC requires dedicated time which can only be done either out of normal working hours, by sacrificing appointments or by backfilling with locums, all of which come at a price to the practice”.

In addition to the themes noted above, other challenges of the project included staff attitudes – teams found that some clinicians found the terminology of the project irritating, whilst others found a reluctance to change in some practice members. Additionally, IT challenges were apparent throughout the duration of the project, both in house practice systems, and IT databases provided by the project.

Include the types of settings in which this intervention is most likely to be effective. Suggest steps that might be modified to improve future performance and finally review issues of opportunity cost and actual financial cost of the intervention (where possible). 400 words

5. Resources to share

Please attach any information or materials created as part of your work. These help The Health Foundation to really understand your approach and to promote it to the wider world, for example, government, patient organisations and professional bodies. Information could include:

- Please see Appendix contents

6. Plans for Sustainability

In May 2010, Scottish Government launched the Healthcare Quality Strategy for NHSScotland, declaring its intention to put quality right at the heart of all that the NHS does for the people of Scotland. The Delivering Quality in Primary Care National Action Plan set out the plan for implementing the Quality Strategy in primary and community care and included a key commitment to develop and implement a National Patient Safety in Primary Care Programme.

The SIPC work has been testing a number of tools and interventions, and as the national programme develops, it has become apparent that a number of these will be adopted nationally as part of the safety programme. One of the obvious challenges in sustaining the work is the financial element; practices participating in SIPC have been financially compensated, however clearly, this method is not sustainable.]

The trigger tools and safety climate surveys are to be accepted as evidence submitted as part of the national GP appraisal scheme and contributing to current GP Revalidation proposals. Competing priorities will always be a problem for any new innovation, therefore there is an obvious need to incorporate elements of the work into contractual requirements where appropriate.

Meetings have been held with Scottish Government to discuss the potential of adapting the enhanced service for warfarin and DMARDS to include regular data collection including care bundles developed in SIPC and for the climate survey to be an organisational indicator in the GP contract

The infrastructure within HIS which has supported, led and managed the SIPC programmed is also the team leading the development of the national safety

programme for primary care to be launched in March 2013, ensuring that the expertise and knowledge of these individuals is continuing and informing the national programme

7. Plans for Spread

7.1 Explain your plans for spreading the learning and outputs of this project.

SIPC is a 2 year project, and in its second year, was extended to an additional NHS board and to 18 additional general practices to continue testing. The tools and techniques which have been used within the project can be taken up by any other primary care teams outwith these participating practices throughout the UK. The structured case note review using the trigger tool has been well received by primary care teams. The care bundles are generally transferable subject to minor amendments for local processes. The safety climate survey has widespread applicability to all primary care teams in the UK, and there are already links to this being made by the Productive General Practice Series. In addition, the work has organically spread throughout NHSScotland, tools and educational materials developed by the programme are already being taken up by other NHS Boards, in particular NHS Greater Glasgow and Clyde, NHS Dumfries and Galloway and NHS Lanarkshire, who have taken on many aspects of the project, and have developed further clinical bundles.

The learning from SIPC will feed into the development of a national Patient Safety in Primary Care Programme in NHS Scotland which is a key output from the Scottish Government's Delivery Quality in Primary Care Action Plan and underpins the Healthcare Quality Strategy. This programme is currently in development with planned launch and roll out in 2013. The primary care programme will complement the current Scottish Patient Safety Programme which has a focus on making hospital care safer. Learning and tools will also feed into the national GP Appraisal system and revalidation. It is also envisaged that as part of a National Programme for Patient Safety in Primary Care, the approaches and learning from this project will be shared with colleagues from other primary care professions such as pharmacists and community nursing. Additionally, the work of SIPC is being spread through participation in national and international events.

7.2 How are you going to promote your innovation and convince others of its value?

As SIPC is informing the development of a national programme, there is a lot of interest in the project from other healthcare professionals. As mentioned above, the work of SIPC is being promoted through a number of different channels, most notably national and international events. Amongst others, the clinical lead for the project presented at the Patient Safety Congress in Birmingham in May 2011 and the methodology and tools developed for SIPC were showcased to a national audience (ie policy makers, clinicians, public partners, service providers) at the NHSScotland Event in August 2011.

The project team has also submitted a successful application to present at the 2012 International Forum for Safety and Quality in Healthcare in Paris, which is attended by over 2000 delegates from over 60 countries. Additionally, the programme manager and clinical lead have been invited to present at IHI's Annual International Summit on Improving Patient Care in Washington in 2012. In collaboration with other primary care work within Healthcare Improvement Scotland, we are also submitting a joint application to present the work of SIPC at the 2012 RCGP annual conference. A number of posters

highlighting different areas of the project have also been successfully submitted for events, including amongst others, the NHSScotland event and the international forum for quality and safety in healthcare.

There are a number of websites which also promote the project, including a community website which participating practices use, and the Healthcare Improvement Scotland website. Other improvement programmes which are aligned to the national programme also point to the tools used throughout SIPC.

There is also the opportunity to promote this work at a practice level, individual practices have been encouraged to showcase their results, displaying data on notice boards, so that team members can be able to relate the work they have been doing to improvements in practice.

7.3 What advice would you give to someone attempting to replicate your work in another organisation / setting? In your answer to this question please consider:

If someone was attempting to replicate this work, using the knowledge that we have gained throughout the duration of the project, there would be a number of areas of learning we would share.

- To sustain any improvement, it needs to become part of everyday business, therefore where possible, it is beneficial to align interventions with current and potential contractual requirements.
- Many people are resistant to the idea of change, for many reasons, including competing priorities, time limitations, and a 'we already do it fine' attitude, therefore it is useful to refer to the innovation adoption curve, and focus your efforts on the early adopters.
- We would also strongly recommend that anyone implementing an improvement programme keeps a narrow focus – there can be a temptation to encompass as much as possible, however our learning shows that starting small, and showing improvements will help with engagement, and spread the programme further.
- Another strong recommendation is that when defining measures and operational definitions, these should be clear, with no room for interpretation – it is important that all participants are working to the same guidance in order to produce meaningful results.
- A vital component for the success of the project was in the selection of clinical areas practices could focus – these should be relevant, and of interest to those improving them, participants will disengage if they feel the project is of no interest, or will not lead to improvement.
- Additionally, strong leadership, both clinical and management, and at a board facilitation level, have been identified as integral to the successes of the project
- Sharing of data and improvements is also an important aspect of the project – our project encouraged practices to share PDSAs on a community website available for all to view, and feedback following learning events rated networking and sharing of ideas as a highlight.
- The importance of clinical champions should not be underestimated – in our experience, clinicians are more likely to buy into something this way. At the first learning event for year one practices, a training session on the trigger tool received sceptical feedback in the evaluation of the event. The same session was then delivered to year 2 practices, and included a presentation from a year 1 champion GP, who spoke positively of his experience and gave examples of how it had benefitted his practice – following this event, the feedback referring to this session was much more positive.

- Looking back at the life of the project, it is clear that it would have been helpful to develop a 'core group' of clinicians from those involved in the clinical community – it can be challenging at times to make decisions by committee, which contributed to frustration from participating practices when individual aspects of the programme changed a number of times.
- Although it can be tempting to spread as early as possible, we would recommend ensuring that the tools you are using are ready for this, and will not need further refined.

7.4 What do you see as the main challenges to the future spread of your work?

Although elements of the work of SIPC will be spread through a national programme, using contractual levers, there will be challenges in spreading the work. Capacity to support this work within health boards has been identified as a risk, as the current structure which is in place to support the work will no longer be in place once the project ends. All territorial health boards within Scotland are implementing the work of the Scottish Patient Safety Programme, and there are links to be made with the teams who are supporting this to ensure that the skills and knowledge of the individuals who have been supporting the project are not lost.

Training has also been identified as a potential risk. Throughout the project practices have received training from experts at national learning events, however this is not sustainable on an ongoing basis. NHS Highland has tested delivering training locally and feedback shows that with minor changes, this is a viable option when spreading the programme. Another area of potential challenge relating to training relates to the trigger tool in particular. Learning from the evaluation of the project suggests that those individuals who were trained by an external expert are more likely to find harm than those who were trained by local clinical leads. As mentioned earlier in the report, clinical engagement will continue to be a challenge, although hopefully this will be addressed in part by the contractual levers.

8. Return on investment

8.1 Can you estimate the cost of the intervention and the benefits accrued?

Unfortunately we haven't undertaken any cost benefit analysis, so are unable to answer this question

8.2 What have been the cost implications to your work?

The main cost implications to the work have been in backfill payments to cover the time of participants, from clinical leads and other health boards costs, to payments to each practice involved in the project.

8.3 What were the main difficulties you encountered in identifying cost and benefits of your work?

For those teams involved in the additional support from Springfield Consultancy please include the results of the work and explain how you have or intend to use the information.

600 words

Unfortunately we haven't undertaken any cost benefit analysis, so are unable to answer this question

9. Conclusions

The original aims of Closing the Gap through Clinical Communities were to

- *build the knowledge and skills of clinical teams in how to make improvements in the quality of care*
- *contribute to the creation of a systematic body of knowledge concerning how best to engage clinicians in quality improvement activity*
- *stimulate learning about quality improvement amongst health professionals*
- *support clinical communities to make demonstrable improvements in quality by tackling known gaps between best practice*
- *support routine delivery of care*

Reflecting on the previous sections of the report how well do you feel the project met these aims?

Through the duration of the project, participants were invited to both national and local learning events, where they were taught to use a variety of tools to make improvements in the quality of the care they provided to patients. Some of these tools have been more successful than others, feedback from those involved was particularly positive when referring to care bundles and trigger tools, however others, namely safety climate and patient involvement have been difficult for practices to implement, and may require further support. A number of practices have found small tests of change a useful tool, however encouraging practices to document and share these has proved challenging. Individuals reported a positive impact on their knowledge and skills following involvement in the project – following the learning event held in June, an evaluation survey showed that 94% agreed that they had achieved an increased understanding of the importance of quality improvement – this encouraging response would suggest that the project has been largely successful in furthering participants knowledge of quality improvement.

An underlying principle of the project was to pilot tools and encourage practice or clinician ownership of the development of these tools. The clinicians were given the responsibility to implement these tools as they saw fit within their own clinical practice. It has proved important to demonstrate the impact QI methodologies can make in practice: where we could demonstrate that the tools would be relevant, time efficient, would provide quick results and would be beneficial to all involved, clinicians have become more engaged. It is also important that clinicians are able to engage with the topics and that they are relevant to them on a day to day basis.

Throughout the duration of the project, care bundles have been consistently rated highly by those implementing them in practice. Data collected has shown that reliability of care has improved in the care of specific clinical areas and the evaluation indicates that the programme has had a positive effect on practices safety culture.

Following testing of these bundles throughout SIPC there are now ongoing discussions relating to spread and inclusion in GP appraisal, the national programme, and enhanced services and GP Contract proposals have been developed. Local spread is occurring within boards and to additional boards.

In conclusion, we believe our *Closing the Gap through Clinical Communities* project has contributed to achieving a number of our original aims, specifically building the knowledge and skills of our clinical teams to make local improvements to their systems and demonstrably improving the quality and safety of the care they deliver. The project has exceeded our expectation in stimulating learning around quality improvement tools amongst health professionals. A number of our board teams are nurturing and developing local clinical champions and teams who are embedding quality improvement methodology into their everyday activities.