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The safety and improvement in primary care (SIPC) pilot programme in Scotland: a qualitative evaluation

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ABSTRACT

Objectives

To explore GP team perceptions and experiences of participating in a large-scale safety and improvement pilot programme to develop and test a range of interventions that were largely new to this setting.

Design

Qualitative study utilising semi-structured interviews. Data were analysed thematically.

Subjects and setting

Purposive sample of multi-professional study participants from 11 GP teams based in three Scottish NHS Boards.

Results

27 participants were interviewed. Three themes were generated: 1. Programme experiences and benefits e.g. a majority of participants referred to gaining new theoretical and experiential safety knowledge (such as how unreliable evidence based care can be) and skills (such as how to search electronic records for undetected risks) related to the programme interventions; 2. Improvements to patient care systems e.g. improvements in care systems reliability using care bundles were reported by many, but this was an evolving process strongly dependent on closer working arrangements between clinical and administrative staff; 3. The utility of the programme improvement interventions e.g. mixed views and experiences of participating in the safety climate survey and meeting to reflect on the feedback report provided were apparent. Initial theories on the utilisation and potential impact of some interventions were refined based on evidence.

Conclusion

The pilot was positively received with many practices reporting improvements in safety systems, teamworking and communications with colleagues and patients. Barriers and facilitators were identified related to how interventions were utilised as the programme

evolved, while other challenges around spreading implementation beyond this pilot were highlighted.

For peer review only

Strengths and limitations

- This study used qualitative methods to uncover the social and technical issues of relevance in the testing of multiple and novel safety improvement interventions by general practice teams as part of a large-scale pilot collaborative programme. This approach provided some evidence of the potentially transferability and utility of most interventions after adaptation to this setting (e.g. safety climate assessment and clinical care bundles), although engagement with PDSA change cycles was problematic.
- With hindsight some programme aims, data collection and improvement measures were arguably over-ambitious and unrealistic in the short timeframe available, while related learning and improvement was self-reported. The study was likely biased by involvement of volunteer 'early adopters' who over-represented the general practice training environment.
- Although many findings are promising, further testing with larger groups of representative GP teams is necessary to more fully inform the ambitions of this type of programme, the utility of related interventions and their impacts on professional and organisational learning, and making care systems safer for patients.

Keywords: patient safety, quality improvement, primary care, collaboratives, general practice

INTRODUCTION

A recent evidence review estimates that approximately 1-2% of consultations in primary care may involve an ‘error’ which could lead to potential or actual physical or psychological harm to patients [1]. In the United Kingdom (UK), for example, around one million patients consult with primary care services on a daily basis [1] which provides a guide to the possible scale of patient safety incidents - although many have minor to moderate impacts on health and wellbeing, or are mitigated before harm actually occurs [2-5].

Evidence around the types and sources of avoidable harms in primary care is largely focused on clinical diagnoses, medicines management and wider systems issues such as test results handling and communications at care interfaces [1,5-10]. For example, prescribed medicines have inherent risks that are associated with unwanted side effects, inappropriate or incorrect usage and unsafe systems of monitoring [11]. Additionally medicine-related adverse events are reported to cause between 5–17% of hospital admissions, most of which are related to prescribing, monitoring and adherence problems with many considered preventable [12]. While in general practice, prescribing or monitoring errors and harms are often associated with high risk drugs that require careful monitoring such as Warfarin and Methotrexate [13].

Efforts at the multi-organisational level to improve the safety of patient care are more advanced in acute hospital settings (where historically most of the related policy focus and resource is concentrated) compared with primary care [14]. The reasoning for this imbalance may be explained partly by the prevailing policy view internationally that primary care is a comparatively low-technology environment where patient safety is not perceived as a major issue [15]. However, recent commitments by, for example, the Scottish Government [16], European Union [17] and World Health Organisation [18] demonstrates a shift in prioritisation and formal recognition that patient safety is a problem in primary care which requires necessary action to address these concerns.

Evidence of large-scale collaborative initiatives to improve patient safety in primary care settings is limited [14, 19]. However, central to these efforts is the need to agree a shared

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3 strategic vision of the safety issues to be prioritised, develop the necessary expert
4 leadership support and invest in infrastructure that can provide valid, timely data to
5 measure and monitor care improvement at the local, organisational and national levels [20-
6 21]. Building workforce capacity and capability through delivery of training in quality
7 improvement concepts, skills and methods, and to acquire knowledge of theory-based
8 change models, is recognised as another vital element for success [21-22].
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15 This study reports the findings of the qualitative evaluation of the pilot Safety and
16 Improvement in Primary Care (SIPC) collaborative programme. The SIPC pilot programme
17 aimed to apply a collaborative learning method to improve the safety of care for patients
18 with heart failure or taking high risk medications such as Methotrexate or Warfarin (where
19 high levels of avoidable morbidity and harm is well established known to occur). This was to
20 be achieved by building quality improvement knowledge, skills and behaviours in
21 participating GP teams during protected learning time. Participants then applied this
22 learning during 'action periods' to enhance the practice safety culture by prioritising the
23 identification and measurement of risks and safety incidents, and re-designing systems and
24 processes to reduce avoidable harm. Given that many of the safety improvement concepts
25 and methods were new to the great majority of participants, the pilot study offered a
26 perfect opportunity to develop, contextualise and test the usefulness of the programme
27 interventions in this care setting. The background context underpinning how the SIPC
28 programme was delivered is described briefly in Box 1.
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42 Against this background, the main evaluation aim was to explore the perceptions and
43 experiences of those participating in the pilot programme and identify the facilitators and
44 barriers associated with the range of novel improvement concepts and methods being
45 applied to this setting, mostly for the first time. In this way, evidence of their overall utility
46 could inform decision-making to further refine and spread the implementation of the
47 programme at scale on a national basis.
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53 54 55 METHODS

A qualitative study was undertaken using open-ended semi-structured interviews [23] with key programme participants: general practitioners (GPs; family doctors), practice nurses, and practice managers.

Programme theory

The programme aims were broadly informed by a theory driven approach [24-25] to assist programme leaders to gather evidence related to predicted theories of change and inform future planning. In the early stages of the evaluation the programme plans were reviewed and key elements of the theories inherent in these were identified. The theories were further refined with input from the programme leadership (NH and JG) and subsequently illustrated in a basic Logic Model to describe how the interventions were initially understood and what results they were expected to achieve (Appendix 1).

Setting and participants

The SIPC pilot programme was undertaken in two phases over a 24-month period from March 2012 in 45 (initially 22 in Wave 1) general practices across six (initially three in Wave 1) National Health Service (NHS) Board regional areas in Scotland. The practices were of varied sizes, location and socioeconomic status with some providing care to small rural community populations of around 1,100 and others being large urban practices with over 14,000 patients. Study participants were the members of the core GP teams (GPs, practice nurses and practice managers) in each of the three Wave 1 participating NHS Boards. Wave 1 participants were selected for interview based on the pragmatic decision that they had potentially the greatest programme experience and insights, as well as for availability of evaluation resource reasons. Purposive sampling was employed in an attempt to represent a wide range of views and reflect fundamental characteristics of interest to the evaluation such as NHS Board setting, professional grouping and programme withdrawal.

SIPC pilot programme interventions

A multi-intervention strategy was employed by the programme steering group based on related evidence of driving learning and improvement using similar methods in secondary care settings [22], and informed by professional consensus and experiences in frontline practice. The main interventions comprised: delivery of a quality improvement

collaborative based on the IHI Breakthrough Series [22]: application of the 'model for improvement' (MFI) [26], trigger review method (TRM) [27], clinical care bundles [28], safety climate assessment survey [29], infrastructure/advisory support from local NHS Boards, and formation of a multi-professional programme steering group to co-ordinate activities (Box 2).

Data collection

Semi-structured interviews were conducted face-to-face in a location of convenience to study participants and lasted between 50 and 85 minutes. They were undertaken by an experienced qualitative researcher and health psychologist (LH) over the final 9-month period of the SIPC programme during 2012/13 and informed by a brief topic guide (Box 3) designed to explore participant perceptions and experiences and reported barriers and facilitators related to the programme interventions. Interviews were tape-recorded with consent from participants and then digitally transcribed.

Data analysis and interpretation

Data were coded and categorised on an iterative basis by LH immediately post-interview to inform further interviews and then subjected to a simple thematic analysis [30] by LH and PB independently. Both researchers met regularly to compare analyses and further co-develop and refine data categories to generate themes with any disagreements being resolved by consensus. From the outset the stated evaluation aim explicitly shaped how data were analysed and provided a basic framework to present the evolving themes that were generated. The findings were shared iteratively with the programme steering group leading to mid-programme activity corrections and refinement of related theories, and as a means of providing supporting evidence for learning outcomes and future implementation efforts at scale.

RESULTS

A total of 27 participants from 11 general practice teams took part in open-ended semi-structured, face-to-face interviews. Three main themes emerged:

- Programme perceptions, experiences and benefits;

- Improvements to patient care systems; and
- Utility of programme interventions.

1. Programme perceptions, experiences and benefits

Most participants believed that the programme had benefited their organisations, patient care and professional work performance. The programme was reported as well organised and providing an explicit focus for patient safety issues to be examined while also encouraging broader team working. The learning set sessions were generally well received and valued because they provided opportunity for participants to reflect on current practices, network with peer practices, discuss concerns, feed back on their progress, keep staff focused on the programme goals, and provide opportunities to share learning and improvement successes across practice teams as these evolved during the programme.

“...it was a good opportunity to systematically review how we do look after these patients and that was all very positive” [Practice Nurse 4]

“...they [learning sets] were thought provoking and change stimulating as well as informative and hard hitting” [GP2]

“I think it has been very positive, it has been a good way for me to work with other people, we have all kind of come together” [GP1]

“...listening to other practices doing other things has also been a benefit...it was good to meet with the other practices, good to share...you really do learn from others” [GP3]

A majority of participants referred to gaining new theoretical and experiential safety knowledge (e.g. how unreliable evidence based care can be) and skills (e.g. how to search electronic records for undetected clinical risks) related to the programme interventions. Some also reported improvements in aspects of their clinical knowledge with regard to specific drugs and their interactions, and the importance of educating patients taking high risk medications. A much greater awareness of improvement concepts, systems thinking, the potential for avoidable harm, the importance of safety culture, and the need to proactively manage risk was reported by most participants as positive programme outcomes.

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3 *"...in terms of the project globally I think it has been very well organised with*
4 *structured learning days and the support we have had from designated people in the*
5 *practice" [GP3]*
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8 *"I welcome the concept of identifying potential harm and preventing it rather than*
9 *waiting until it occurs" [GP7]*
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12 *"...it has certainly increased my knowledge so hopefully we may have an increased*
13 *knowledge I am delivering better patient care...[and]...made the doctors think a bit*
14 *more on how they see their patients, how they read their patient's records and what*
15 *action they take" [Practice Nurse 2]*
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19 Multiple competing workload priorities, time demands, difficulties in communicating with
20 and engaging colleagues, and managing the necessary change processes were highlighted
21 as major challenges due to heavy workload constraints. Participants described problems in
22 physically getting team members together in a meeting room to feed back and reflect on
23 programme learning and agree improvement steps from the learning sets. Some practice
24 managers and nurses believed they could have offered much greater support to the
25 programme, but felt largely excluded because their delegated roles were very limited or
26 even diminished by the decision-making of medical hierarchies. Others reported a lack of
27 medical involvement and support, and the shifting of much of the programme workload and
28 responsibility onto practice nurses and managers.
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38 Many participants reported a significant mismatch between the comparatively low level of
39 backfill funding received and the time and resources actually committed to the workload
40 demands of the programme. For some these were the key factors informing their decisions
41 to withdraw from the programme, while others gave serious consideration to future
42 participation due to similar financial concerns. Three practices disengaged from the
43 programme citing lack of time-out for staff, staff stress due to workloads and time with
44 patients potentially being compromised.
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53 *"...the work has basically fallen to myself and the practice nurse, the doctors haven't*
54 *really engaged with it...the first [GP partner] who came with me she was very cynical and*
55 *very critical and I found that challenging because I wasn't want to carry the sole*
56 *responsibility, that was a struggle to the practice to begin with to have, we brought the*
57 *wrong one [GP partner] along [Practice Manager 3]*
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5 *"...the main challenge was keeping the rest of the team inspired, pulling the team on*
6 *board was difficult...if it is going to fail it's going to fail because we just can't all get*
7 *together, that is just not achievable"* [Practice Manager 2]
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10 *"...feeding back things from learning events to the rest of the team, feeding that back to*
11 *the wider practice group...coming back to a busy practice back into all the time*
12 *constraints and all the demands on your time to then try and pass on that energy is*
13 *extremely difficult, that's where a lot of it falters, it is actually very, very difficult to pass*
14 *that onto the wider group"* [GP 4]
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17 *"...the amount of money given to us to pay for back fill didn't pay for a quarter of the*
18 *back fill, and it costs money to take people out to have meetings, it would have been*
19 *easier to release time if I had more money to put in locum provision"* [Practice Manager
20 4]
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26 **2. Improvements to patient care systems**

27 Improvements in care bundle data collection methods and the reliability of related systems
28 were reported by most practices over the course of the programme, but this was an
29 evolving process that was strongly dependent on closer working arrangements between
30 clinical and administrative staff. These changes led to improved systematic monitoring of
31 patients (e.g. blood tests and side-effects) and documentation; greater personal vigilance
32 when, for example, handling repeat medication prescriptions and the prescribing of
33 antibiotics; developing more robust systems for managing laboratory tests results for
34 patients; and more proactive patient contact, education and involvement in their care,
35 including checking understanding of medication regimes and how to seek further support.
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45 A majority of practices believed they were now gradually providing safer, more reliable care
46 for patients with Heart Failure or Left Ventricular Systolic Dysfunction. Programme
47 participation enabled them to identify sub-optimal care in these areas; clean up related
48 patient registers and improve identification of LVSD patients; optimise Heart Failure
49 management through specialist clinics leading to improvements in, for example, NYHA [New
50 York Heart Association] recording and increased Pneumococcal Vaccinations; more robust
51 monitoring of medications and improved patient contacts and care education.
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A small minority of participants reported on the very positive impact heart failure clinics and education had, for example, on patients' awareness, knowledge and self-management of their conditions. This had led to some patients feeling more in control in terms of self management and having a greater understanding of their illness and with respect to high risk medications.

"...[Patients] weighing themselves every day.....and they have got it written down, they have never done that before...they are also now fully aware of what side effects to look out for from the outset". [Practice Nurse 4]

"We have drafted information cards for the patients on methotrexate and isothyoprine, we have had positive feedback, they have actually participated and helped us revise the cards" {Practice Nurse 4}

"We have tidied up our DMARD programme, we have got the new guidelines, our safety has improved with regards to the DMARDS...and we have put together a pre-initiation check list which is working really, really well, everyone in the practice is aware of that..." [GP 1]

3. Utility of programme interventions

Clinical Care Bundles

Most participants favoured the care bundle intervention as having potentially the greatest positive impact in improving care safety and reliability. They considered the compliance monitoring and visual nature of the 'bundle graphs' as important for encouraging and motivating staff and driving improvement. The bundles were effective in highlighting unreliable practice and participants reported that this led to improved care systems, and enhanced patient education and involvement in self-management of illness.

For some, however, the bundles were viewed as having a limited evidence base, lacking coherence and challenging in terms of achieving reliability [i.e. practices would be deemed reliable when they had 7 or more consecutive data points over 80% or above, as evident from the Bundle run-chart graphs] which equates to ensuring patients are receiving high levels of evidence-based care. Their relevance to the chosen clinical topics (e.g. heart failure) was also questioned.

Adapting, re-designing and gaining consensus on care bundles was problematic and challenging for those involved in the second year of the programme, which included additional measures to promote patient education and self-management; however these adaptations also created some confusion for practices. Practices further struggled with patient compliance issues, interpreting statistical relevance with small samples, IT technical issues and access problems with the online data collection site, which often hindered effective bundle application for some.

“...you can see week by week, month by month, whether or not you are showing any improvement, we seem to be improving and that’s good because we are able to see our graphs and what not and how we were doing with that” [GP3]

“...the [Care] Bundle is the thing that forces you to make changes everything else is driven by that...they are straight forward, it is not too complicated” [GP1]

Model for Improvement (PDSA Change Cycles)

Although there were some reported successes, multi-factorial barriers were apparent which challenges the assumed theory of MFI/PDSA Cycles being applied within everyday working contexts to facilitate small tests of change and drive care improvements. Time constraints and competing work priorities for many meant they quickly lost momentum and motivation after initially implementing the PDSA cycle process. There was some confusion with fully grasping the concept, the PDSA link with ‘measurement’ and its improvement relevance to the general practice setting, while others found the method a little ‘contrived’ and ‘unnecessary’ for everyday work. For most it was also a challenge to formally document a record of PDSA cycles as many viewed it as an ‘instinctive’ or ‘mental’ thought process that is routinely done ‘automatically’ when making small scale adjustments to ways of working.

“In some ways it feels almost it’s quite contrived what you are doing with it because you have got to do each individual step rather than just say this is how I think we should deal with it...you just tend to make changes and just roll with it, maybe why it is a bit more difficult for us to try and sort of implement it in the way we work” [GP 7]

“I would say they are a bit of a pain...probably about 50% of the [improvement] work that we have done has not been recorded by a PDSA...just breaking it down and

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3 *recording it is time consuming and a bit of a faff...too many paper exercises for us as*
4 *practitioners" [Practice Nurse 3]*
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8 *"...it's a good way to implement change, how to make your systems better*
9 *you can make changes quickly you know it doesn't need to be as cumbersome as, you*
10 *know, audit..." [GP 2]*
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12 *Safety climate assessment survey*

14 Mixed views and experiences of participating in the climate survey and holding a team-based
15 meeting to discuss and reflect on the feedback report provided were apparent. For some
16 undertaking the survey in the early stages of the programme there were multiple technical,
17 timing and results interpretation issues highlighted by the survey participation that caused
18 confusion, raised concerns around statistical meaningfulness and involving 'attached' staff
19 in the process, all of which and fomented negativity about the activity. Ultimately these
20 proved to be barriers to collectively considering the findings and discussing potential
21 learning and improvement. This prompted how the survey was designed and delivered by
22 the programme leadership, and a number of technical and educational support refinements
23 were made to enhance usability over the course of the study leading to increasingly positive
24 feedback on its purpose and impact.
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36 For others this activity led to valuable, if occasionally difficult, team discussions on patient
37 safety systems, internal and external communication issues, and the nature of the practice
38 leadership. Participation provided welcome reassurance on safety performance, highlighted
39 misplaced perceptions of how safe the practice was thought to be, teased out why there
40 were marked differences in clinical and non-clinical responses to the survey, and identified
41 areas for improvement. The more positive feedback responses were apparent from GP
42 teams who participated once the online technical issues had been resolved, the feedback
43 report was made less 'statistical' and greater levels of guidance was provided on how to
44 interpret the findings and facilitate a related team discussion.
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53 *"..the whole area round the climate survey was disappointing, I would say that was the*
54 *failure point of the programme for us...the way it is done just now just hasn't worked in*
55 *this practice" [Practice Nurse 1]*
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3 *"I felt that we didn't get enough input prior to completing it, it was just e-mailed, asked*
4 *to complete it but we didn't know what it was about...we felt we didn't have enough*
5 *explanation" [Practice Manager 3]*
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8 *"Many of us in the practice doctors and staff hadn't really made the link that us failing*
9 *to communicate in some other ways was a threat to patient safety so we opened that*
10 *up for discussion, we had a lot of really good stuff came out of it, a lot of very open*
11 *discussion" [GP7]*
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14 *Trigger Review Method (TRM)*
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16 Mixed views were reported on the perceived usefulness and actual measurement purpose
17 of TRM, with some finding the underlying concept both daunting and threatening. It was
18 immediately clear from early evaluation that 'reliable measurement' of harm rates in
19 specific patient groups was not being attempted by most. Variation in how participants
20 interpreted this 'measurement' concept was evident and many struggled to identify
21 sufficient harm cases to calculate a reliable measure over the short intervention time-frame,
22 or to interpret whether a harm incident had actually occurred. Instead those who engaged
23 well with the tool reported an alternative application in actually finding potential and
24 avoidable harm cases associated with, for example, altering medications, inadequate
25 recording of adverse drug reactions and drug allergies, and lack of clinical follow-up of
26 patients. This prompted greater scrutiny in medication-prescribing and monitoring systems
27 as well as improved coding of adverse events as a means to manage clinical risks and
28 potentially reduce avoidable harm to patients in future.
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40 Based on these experiences early in year one the TRM purpose and application was adapted
41 as a method of 'flagging up' previously undetected patient safety incidents (e.g. 'latent
42 risks', 'near miss events' and 'adverse events') in specific high risk patient groups (e.g. those
43 taking Warfarin). In this regard the TRM purpose was altered by these participants to a
44 method for *identifying* patient safety-related learning needs though highlighting sub-
45 optimal processes and general quality of care issues. A clear facilitating factor was the
46 provision of one-to-one training by a medical doctor experienced in the method, which was
47 associated with its perceived successful application by participants.
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3 *"[we] discovered quite a few people whose haemoglobin was quite low for no*
4 *obvious reason, we've now built in a regular haemoglobin review into patients on*
5 *Warfarin therapy". [GP2]*
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8 *"...occasionally trends in blood counts rather than absolute values had been missed,*
9 *we have definitely now got procedures in place that pick those up". [GP4]*
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11 *"[The TRM] identified near misses that would never have otherwise been unveiled to*
12 *anybody ever but had very significant learning". [GP1]*
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15 16 17 **DISCUSSION**

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19 The pilot collaborative programme largely achieved its objective of educating practice teams
20 in safety and improvement theory and methods, and providing protected time for team-
21 based reflection, peer-to-peer learning, problem formulation and progress reporting, which
22 were all highly valued by participants. The findings confirmed and refuted some aspects of
23 the initial programme theories, which enabled us to refine initial assumptions about how
24 some of the interventions were working (or otherwise) and why, and make mid or end of
25 programme corrections to their purpose and delivery.
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29 While the Breakthrough Series collaborative concept was well received, similar to previous
30 research [19], the overall approach also provided some evidence of the potential
31 transferability and utility of most interventions after adaptation to the Scottish primary care
32 context (particularly clinical care bundles, but also safety climate assessment and TRM).
33 However, engagement with MFI/PDSA change cycles was more problematic and is perhaps
34 worthy of future research exploration, particularly given the findings of a recent systematic
35 review [31] which also found issues with the understanding, application and reporting of
36 this method.
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40 Additionally clear challenges were identified around protected time to participate,
41 competing workload priorities and wider engagement of GP teams beyond core programme
42 participants. Further work is also necessary to ensure data collection and monitoring
43 systems are improved, there is greater realism around what can be achieved, and the
44 unintended consequences of participation in such programmes are considered – all are well
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established improvement challenges [32-34]. The main theory-related learning suggests the following refinements:

- High system reliability appears difficult to achieve in some circumstances with care bundles as success can be strongly dependent on patient compliance issues.
- Care bundle content should be based on strong evidence to be professionally acceptable, while larger patient sample sizes are needed to demonstrate system improvements and clinical impacts.
- The TRM is unreliable as a tool for *measuring* harms and more useful for *identifying* learning and improvement opportunities related to (previously undetected) patient safety incidents.
- TRM training was associated with enhancing the success of implementation, while the method appeared to have greater utility when used with specific 'high risk' patient populations, rather than random samples of the GP patient population.
- Feedback related to safety climate measures and performance needs to be simplified and illustrated by graphs, with minimal use of even basic statistical concepts as these may not be well understood by many and can cause confusion. Careful consideration should be given to introducing the concept, explaining its purpose, the formatting of reports and the need for basic guidance for participants.
- PDSA cycles were not generally well utilised as these were frequently viewed as unnecessary for rapid improvements, while related documentation processes were also thought unnecessary and cumbersome.

Study limitations

Caution must be exercised when interpreting the findings, largely due to potential bias because of the comparatively small number of mainly enthusiastic volunteer participants (early adopters) who over-represented GP speciality training community. The programme was primarily a feasibility pilot and relatively short-term which resulted in a lack of objective, longer term outcome measures. The evaluation process was largely descriptive and would have benefited from a greater analytical focus, which is perhaps a reflection of the over-ambitious programme goals and the broad evaluation approach employed. Future

study of these specific improvement interventions (and related evaluation) will require much greater clarity about the social, technical and behavioural processes that need to be measured and altered to achieve the desired impacts on frontline practice [34].

While improvement collaboratives, including the Breakthrough Series approach [22], are well-established in many acute hospital settings, there is limited evidence of their implementation in primary care. Several studies have, however, been undertaken and reported mixed findings in improving COPD [35], diabetes care [36-39], advanced patient access [40-41], pressure ulcer care in nursing homes [42], chronic heart failure [43] and prehospital care for acute myocardial infarction and stroke [44]. The common thread amongst these studies is that they focused improvement efforts entirely on a specific, well-defined disease or patient group using a standard collaborative approach. In contrast, the approach adopted in this pilot study was arguably unorthodox and, with hindsight, over-ambitious. Efforts were focused on multiple interventions simultaneously including the number of patient safety topics prioritised, testing the feasibility of the Breakthrough series collaborative approach at scale, and piloting many nascent improvement methods which hitherto had largely never been applied in this setting in Scotland and internationally.

The study findings are informing the (re)design and delivery of a planned future safety and improvement programme to be implemented nationally in Scottish general practices, before spreading to other primary care professional groups. Further testing and refinement of the programme interventions are ongoing with more representative groups of GP teams, with some having demonstrated promise in their reported potential to improve the reliability of clinical safety systems [45] and identify previously undetected patient safety concerns [46]. The potential for some of the tools to support QI evidence requirements for GP specialty training and medical appraisal and revalidation is also apparent [45-48].

There is growing evidence of the impact of interventions to improve the safety and reliability of specific aspects of specialist hospital care - such as through the successful implementation of surgical checklists [49-50] and clinical care bundles [51] to reduce avoidable harms. However there are still question marks over the effectiveness of such initiatives - and also large-scale collaborative programmes - in achieving and sustaining the

desired improvements in the quality and safety of patient care [52-54]. Overall the evidence of what interventions work to enhance safety in primary care is less well developed [15], with related evaluations being predominantly observational, conducted in single sites and of variable quality [25, 33-34]. This evaluation provides some evidence of the transferability and utility of specific safety improvement methods in primary care, and sheds some light on related implementation issues that can arise.

CONCLUSIONS

The delivery of the SIPC pilot programme was positively received by the great majority of participants, with many reporting improvements in practice safety systems, teamworking and communications with colleagues and patients. However, some practices struggled with understanding the concepts, relevance and application of many of the improvement interventions tested. The evaluation provided valuable insights into how the interventions were utilised and even adapted and contextualised as the programme evolved, which has already led to further refinements and improvements in application. A number of social and technical implementation challenges (e.g. appropriate use of financial incentives, IT support and availability of data, and workload demands) were also identified that need to be taken into consideration when spreading this approach at larger scale. To achieve this, policy and organisational levers will be necessary to implement the programme interventions on a formal basis at the national level in general practice. However this will require significant resources to support the design of infrastructure to enable the routine collection of data for improvement (both narrative and numerical) and the requirement to systematically build capacity and capability in improvement skills amongst the primary care workforce.

FOOTNOTES:

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Contributors

PB was principal investigator, co-designed the study, assisted with data analysis and interpretation and co-wrote the initial manuscript. LH co-designed the study, conducted interviews and analysed and interpreted data, and co-wrote the paper. AB provided advice on study design and theory, data analysis and interpretation and contributed to the writing and critical appraisal of the manuscript. NH and JG designed and led the programme intervention, contributed to evaluation data interpretation and to the critical evaluation and writing of the manuscript. All authors approved the final version of the manuscript.

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Ethical review

The study and evaluation protocols were pre-screened by the west of Scotland Research Ethics Committee, but it was judged to be a service development which did not require ethical approval.

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Competing Interest

No, there are no competing interests

Data Sharing Statement

None available

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Table 1. Characteristics of SIPC programme evaluation participants (n=27)

Factor	n
Gender:	
Female	19
Male	8
Professional Group:	
General Practitioner	9
Practice Nurse	7
Practice Manager	11
NHS Board Area:	
Forth Valley	11
Lothian	9
Tayside	7
Specialty Training Practice Accreditation:	
Yes	15
No	12

Box 1. A brief summary of how the SIPC Pilot Programme was delivered and guided by the IHI Breakthrough Series Collaborative Method

- The programme was implemented over a 24-month period through adherence to the IHI's Breakthrough Series Collaborative Method i.e. A combination of Learning Events for multi-disciplinary practice teams followed by Action Periods to measure and improve the safety and reliability of care.
- Participant attended three 1-day Learning Events intersped with 3-month Action Periods in frontline clinical practice to deliver on programme aims (with local leadership, advice and support provided in each NHS Board area, and the programme being managed centrally by a core leadership and advisory team)
- The SIPC project steering team delivered the 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 Model for Improvement (incorporating PDSA cycles) was taught to participants as a method for them to test its usefulness in facilitating rapid improvements in care processes and systems
- The Trigger Review Method for primary care was taught to participants (in groups sessions and face-to-face) to test its usefulness in serially measuring undetected harm events in electronic patient records and identify areas for improvement
- The principles of Clinical Care Bundles were taught to participants who developed and tested these locally to assess their potential for improving the reliability of patient care delivery in selected clinical areas.
- A web based online questionnaire survey was developed to assess perceptions of safety climate in participating practices and determine its usefulness for team-based reflection and acting on the quantitative feedback reports provided as a way to enhance the prevailing safety culture

The focus of this study is the first wave of the SIPC programme which was initiated in August 2012.

- This involved three clinical and management representatives from 22 GP teams based in three regional NHS Board areas in Scotland. Participating NHS Boards and general practices were recruited on a voluntary basis.
- Financial support for backfill costs was provided to enable core GP team representatives to attend Learning Sets and have some protected time for improvement activities.
- Participants were supported by a local NHS Board level team consisting of a public partner; GP Clinical Lead; manager; and quality improvement facilitator.
- The expectation was that NHS Boards would also develop their expertise in supporting practices in improving their care through collaborative working, and in co-ordinating system-wide approaches to complex patient care
- The overall pilot programme was managed and co-ordinated by a core team from Healthcare Improvement Scotland (HIS) - the national organisation responsible for the - which consisted of a GP Clinical Lead, Programme Manager, two Project Officers and two Project Administrators. The expectation was that this team would gain insights into how to patient safety improvement might be further developed in primary care
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Box 2. Main SPIC Interventions tested and developed: Purpose and Evidence

Intervention	Original Programme Purpose	Relevant evidence
Quality Improvement Collaborative	To apply QIC methodology to improve knowledge, change behaviours, and share learning and experiences with peers	de Silva, 2014 [19] IHI Breakthrough Series [22]
Implementation of Care Bundles	To measure the reliability of selected evidence based clinical care processes and direct improvement efforts	Institute for Healthcare Improvement, Innovation Series [28]
Trigger Review Method (Structured Review of Electronic Patient Records)	To facilitate periodic measurement of avoidable harm rates within general practices using a Trigger Tool	de Wet & Bowie, 2009 [3]
Model for Improvement (PDSA Change Cycles)	To apply the Model of Improvement as the main mechanism for driving rapid change and improvements in practice	Langley et al, 2006 [26]
Safety Climate Assessment	To formatively measure perceptions of the safety climate within primary care teams at key junctures in the programme To feed back climate scores to primary care teams to help direct safety related learning and improvement and build a postive safety culture	de Wet et al, 2010 [29]

Box 3. Brief interview topic guide

Programme goals, information and improvement support

What did you understand about the programme goals

What was your experience of the Learning sets? How did you and the team benefit?

Explore sharing and spread of programme concept and practices with the wider practice team

Interventions

Explore barriers and facilitators with each intervention

What is realistic and feasible and why? If not, why is this?

Explore programme impact at different levels:

Personal and team learning

Internal relationships

Practice safety system improvements

Direct patient care improvements

Consequences, good and not so good, for everyday practice

Overall experience of SIPC programme

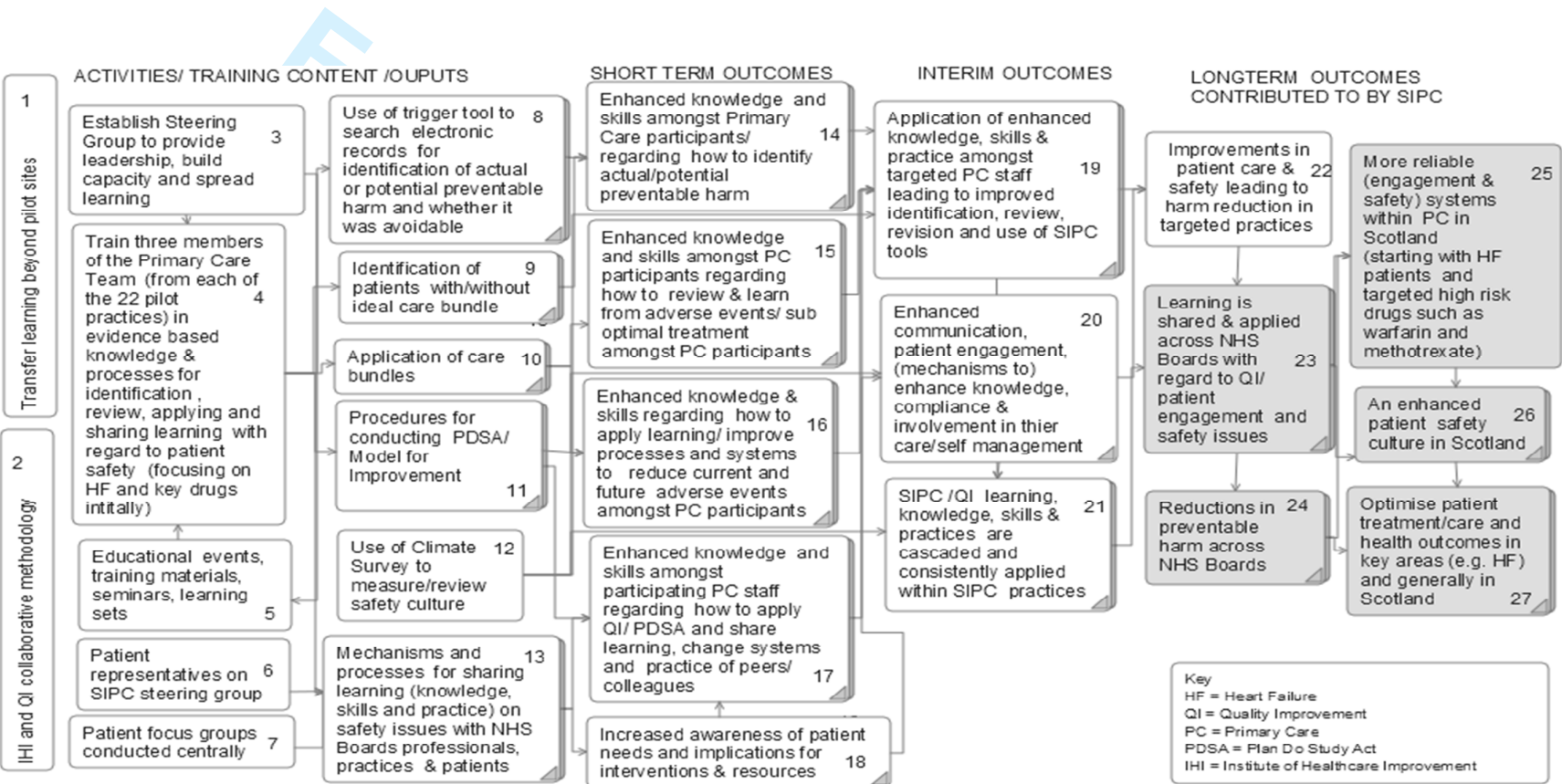
What do you find to be effective about the programme? Why was that?

What do you think did not go well about the programme. Why was that?

What programme aspects have the practice embraced? Why? How will you continue with these?

Any concerns about this type of programme approach and why?

Appendix 1 - Logic Model of the theories inherent in the SIPC pilot programme



BMJ Open

A qualitative evaluation of the safety and improvement in primary care (SIPC) pilot collaborative in Scotland: perceptions and experiences of participating care teams

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A qualitative evaluation of the safety and improvement in primary care (SIPC) pilot collaborative in Scotland: perceptions and experiences of participating care teams

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ABSTRACT

Objectives

To explore GP team perceptions and experiences of participating in a large-scale safety and improvement pilot programme to develop and test a range of interventions that were largely new to this setting.

Design

Qualitative study utilising semi-structured interviews. Data were analysed thematically.

Subjects and setting

Purposive sample of multi-professional study participants from 11 GP teams based in three Scottish NHS Boards.

Results

27 participants were interviewed. Three themes were generated: 1. Programme experiences and benefits e.g. a majority of participants referred to gaining new theoretical and experiential safety knowledge (such as how unreliable evidence based care can be) and skills (such as how to search electronic records for undetected risks) related to the programme interventions; 2. Improvements to patient care systems e.g. improvements in care systems reliability using care bundles were reported by many, but this was an evolving process strongly dependent on closer working arrangements between clinical and administrative staff; 3. The utility of the programme improvement interventions e.g. mixed views and experiences of participating in the safety climate survey and meeting to reflect on the feedback report provided were apparent. Initial theories on the utilisation and potential impact of some interventions were refined based on evidence.

Conclusion

The pilot was positively received with many practices reporting improvements in safety systems, teamworking and communications with colleagues and patients. Barriers and facilitators were identified related to how interventions were utilised as the programme

evolved, while other challenges around spreading implementation beyond this pilot were highlighted.

For peer review only

Strengths and limitations

- This study used qualitative methods to uncover the social and technical issues of relevance in the testing of multiple and novel safety improvement interventions by general practice teams as part of a large-scale pilot collaborative programme. This approach provided some evidence of the potentially transferability and utility of most interventions after adaptation to this setting (e.g. safety climate assessment and clinical care bundles), although engagement with PDSA change cycles was problematic.
- With hindsight some programme aims, data collection and improvement measures were arguably over-ambitious and unrealistic in the short timeframe available, while related learning and improvement was self-reported. The study was likely biased by involvement of volunteer 'early adopters' who over-represented the general practice training environment.
- Although many findings are promising, further testing with larger groups of representative GP teams is necessary to more fully inform the ambitions of this type of programme, the utility of related interventions and their impacts on professional and organisational learning, and making care systems safer for patients.

Keywords: patient safety, quality improvement, primary care, collaboratives, general practice

INTRODUCTION

A review of evidence in 2011 estimated that approximately 1-2% of consultations in primary care may involve an ‘error’ which could lead to potential or actual physical or psychological harm to patients [1]. In the United Kingdom (UK), for example, around one million patients consult with primary care services on a daily basis [1] which provides a guide to the possible scale of patient safety incidents - although many have minor to moderate impacts on health and wellbeing, or are mitigated before harm actually occurs [2-5].

Evidence around the types and sources of avoidable harms in primary care is largely focused on clinical diagnoses, medicines management and wider systems issues such as test results handling and communications at care interfaces [1,5-10]. For example, prescribed medicines have inherent risks that are associated with unwanted side effects, inappropriate or incorrect usage and unsafe systems of monitoring [11]. Additionally medicine-related adverse events are reported to cause between 5–17% of hospital admissions, most of which are related to prescribing, monitoring and adherence problems with many considered preventable [12]. While in general practice, prescribing or monitoring errors and harms are often associated with high risk drugs that require careful monitoring such as Warfarin and Methotrexate [13].

Efforts at the multi-organisational level to improve the safety of patient care are more advanced in acute hospital settings (where historically most of the related policy focus and resource is concentrated) compared with primary care [14]. The reasoning for this imbalance may be explained partly by the prevailing policy view internationally that primary care is a comparatively low-technology environment where patient safety is not perceived as a major issue [15]. However, recent commitments by, for example, the Scottish Government [16], European Union [17] and World Health Organisation [18] demonstrates a shift in prioritisation and formal recognition that patient safety is a problem in primary care which requires necessary action to address these concerns.

Evidence of large-scale collaborative initiatives to improve patient safety in primary care settings is limited [14, 19]. However, central to these efforts is the need to agree a shared

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3 strategic vision of the safety issues to be prioritised, develop the necessary expert
4 leadership support and invest in infrastructure that can provide valid, timely data to
5 measure and monitor care improvement at the local, organisational and national levels [20-
6 21]. Building workforce capacity and capability through delivery of training in quality
7 improvement concepts, skills and methods, and to acquire knowledge of theory-based
8 change models, is recognised as another vital element for success [21-22].
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15 This study reports the findings of the qualitative evaluation of the pilot Safety and
16 Improvement in Primary Care (SIPC) collaborative programme. The SIPC pilot programme
17 aimed to apply a collaborative learning method to improve the safety of care for patients
18 with heart failure or taking high risk medications such as Methotrexate or Warfarin (where
19 high levels of avoidable morbidity and harm is well established known to occur). This was to
20 be achieved by building quality improvement knowledge, skills and behaviours in
21 participating GP teams during protected learning time. Participants then applied this
22 learning during 'action periods' to enhance the practice safety culture by prioritising the
23 identification and measurement of risks and safety incidents, and re-designing systems and
24 processes to reduce avoidable harm. Given that many of the safety improvement concepts
25 and methods were new to the great majority of participants, the pilot study offered a
26 perfect opportunity to develop, contextualise and test the usefulness of the programme
27 interventions in this care setting. The background context underpinning how the SIPC
28 programme was delivered is described briefly in Box 1.
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42 Against this background, the main evaluation aim was to explore the perceptions and
43 experiences of those participating in the pilot programme and identify the facilitators and
44 barriers associated with the range of novel improvement concepts and methods being
45 applied to this setting, mostly for the first time. In this way, evidence of their overall utility
46 could inform decision-making to further refine and spread the implementation of the
47 programme at scale on a national basis.
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53 54 55 **METHODS** 56 57 58 59 60

A qualitative study was undertaken using open-ended semi-structured interviews [23] with key programme participants: general practitioners (GPs; family doctors), practice nurses, and practice managers.

Programme theory

The programme aims were broadly informed by a theory driven approach [24-25] to assist programme leaders to gather evidence related to predicted theories of change and inform future planning. In the early stages of the evaluation the programme plans were reviewed and key elements of the theories inherent in these were identified. The theories were further refined with input from the programme leadership (NH and JG) and subsequently illustrated in a basic Logic Model to describe how the interventions were initially understood and what results they were expected to achieve (Appendix 1).

Setting and participants

The SIPC pilot programme was undertaken in two phases over a 24-month period from March 2012 in 45 (initially 22 in Wave 1) general practices across six (initially three in Wave 1) National Health Service (NHS) Board regional areas in Scotland. The practices were of varied sizes, location and socioeconomic status with some providing care to small rural community populations of around 1,100 and others being large urban practices with over 14,000 patients. Study participants were the members of the core GP teams (GPs, practice nurses and practice managers) in each of the three Wave 1 participating NHS Boards. Wave 1 participants were selected for interview based on the pragmatic decision that they had potentially the greatest programme experience and insights, as well as for availability of evaluation resource reasons. Purposive sampling was employed in an attempt to represent a wide range of views and reflect fundamental characteristics of interest to the evaluation such as NHS Board setting, professional grouping and programme withdrawal.

Programme interventions

A multi-intervention strategy was employed by the programme steering group based on related evidence of driving learning and improvement using similar methods in secondary care settings [22], and informed by professional consensus and experiences in frontline practice. The main interventions comprised: delivery of a quality improvement

collaborative based on the IHI Breakthrough Series [22]: application of the 'model for improvement' (MFI) [26], trigger review method (TRM) [27], clinical care bundles [28], safety climate assessment survey [29], infrastructure/advisory support from local NHS Boards, and formation of a multi-professional programme steering group to co-ordinate activities (Box 2).

Data collection

Semi-structured interviews were conducted face-to-face in a location of convenience to study participants and lasted between 50 and 85 minutes. They were undertaken by an experienced qualitative researcher and health psychologist (LH) over the final 9-month period of the SIPC programme during 2012/13 and informed by a brief topic guide (Box 3) designed to explore participant perceptions and experiences and reported barriers and facilitators related to the programme interventions. Interviews were tape-recorded with consent from participants and then digitally transcribed.

Data analysis and interpretation

Data were coded and categorised on an iterative basis by LH immediately post-interview to inform further interviews and then subjected to a simple thematic analysis [30] by LH and PB independently. Both researchers met regularly to compare analyses and further co-develop and refine data categories to generate themes with any disagreements being resolved by consensus. From the outset the stated evaluation aim explicitly shaped how data were analysed and provided a basic framework to present the evolving themes that were generated. The findings were shared iteratively with the programme steering group leading to mid-programme activity corrections and refinement of related theories, and as a means of providing supporting evidence for learning outcomes and future implementation efforts at scale.

RESULTS

A total of 27 participants from 11 general practice teams took part in open-ended semi-structured, face-to-face interviews (Table 1). Three main themes emerged:

- Programme perceptions, experiences and benefits;

- Improvements to patient care systems; and
- Utility of programme interventions.

1. Programme perceptions, experiences and benefits

Most participants believed that the programme had benefited their organisations, patient care and professional work performance. The programme was reported as well organised and providing an explicit focus for patient safety issues to be examined while also encouraging broader team working. The learning set sessions were generally well received and valued because they provided opportunity for participants to reflect on current practices, network with peer practices, discuss concerns, feed back on their progress, keep staff focused on the programme goals, and provide opportunities to share learning and improvement successes across practice teams as these evolved during the programme.

“...it was a good opportunity to systematically review how we do look after these patients and that was all very positive” [Practice Nurse 4]

“...they [learning sets] were thought provoking and change stimulating as well as informative and hard hitting” [GP2]

“I think it has been very positive, it has been a good way for me to work with other people, we have all kind of come together” [GP1]

“...listening to other practices doing other things has also been a benefit...it was good to meet with the other practices, good to share...you really do learn from others” [GP3]

A majority of participants referred to gaining new theoretical and experiential safety knowledge (e.g. how unreliable evidence based care can be) and skills (e.g. how to search electronic records for undetected clinical risks) related to the programme interventions. Some also reported improvements in aspects of their clinical knowledge with regard to specific drugs and their interactions, and the importance of educating patients taking high risk medications. A much greater awareness of improvement concepts, systems thinking, the potential for avoidable harm, the importance of safety culture, and the need to proactively manage risk was reported by most participants as positive programme outcomes.

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3 *"...in terms of the project globally I think it has been very well organised with*
4 *structured learning days and the support we have had from designated people in the*
5 *practice" [GP3]*
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8 *"I welcome the concept of identifying potential harm and preventing it rather than*
9 *waiting until it occurs" [GP7]*
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12 *"...it has certainly increased my knowledge so hopefully we may have an increased*
13 *knowledge I am delivering better patient care...[and]...made the doctors think a bit*
14 *more on how they see their patients, how they read their patient's records and what*
15 *action they take" [Practice Nurse 2]*
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19 Multiple competing workload priorities, time demands, difficulties in communicating with
20 and engaging colleagues, and managing the necessary change processes were highlighted
21 as major challenges due to heavy workload constraints. Participants described problems in
22 physically getting team members together in a meeting room to feed back and reflect on
23 programme learning and agree improvement steps from the learning sets. Some practice
24 managers and nurses believed they could have offered much greater support to the
25 programme, but felt largely excluded because their delegated roles were very limited or
26 even diminished by the decision-making of medical hierarchies. Others reported a lack of
27 medical involvement and support, and the shifting of much of the programme workload and
28 responsibility onto practice nurses and managers.
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38 Many participants reported a significant mismatch between the comparatively low level of
39 backfill funding received and the time and resources actually committed to the workload
40 demands of the programme. For some these were the key factors informing their decisions
41 to withdraw from the programme, while others gave serious consideration to future
42 participation due to similar financial concerns. Three practices disengaged from the
43 programme citing lack of time-out for staff, staff stress due to workloads and time with
44 patients potentially being compromised.
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53 *"...the work has basically fallen to myself and the practice nurse, the doctors haven't*
54 *really engaged with it...the first [GP partner] who came with me she was very cynical and*
55 *very critical and I found that challenging because I wasn't want to carry the sole*
56 *responsibility, that was a struggle to the practice to begin with to have, we brought the*
57 *wrong one [GP partner] along [Practice Manager 3]*
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5 *"...the main challenge was keeping the rest of the team inspired, pulling the team on*
6 *board was difficult...if it is going to fail it's going to fail because we just can't all get*
7 *together, that is just not achievable"* [Practice Manager 2]
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10 *"...feeding back things from learning events to the rest of the team, feeding that back to*
11 *the wider practice group...coming back to a busy practice back into all the time*
12 *constraints and all the demands on your time to then try and pass on that energy is*
13 *extremely difficult, that's where a lot of it falters, it is actually very, very difficult to pass*
14 *that onto the wider group"* [GP 4]
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17 *"...the amount of money given to us to pay for back fill didn't pay for a quarter of the*
18 *back fill, and it costs money to take people out to have meetings, it would have been*
19 *easier to release time if I had more money to put in locum provision"* [Practice Manager
20 4]
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26 **2. Improvements to patient care systems**

27 Improvements in care bundle data collection methods and the reliability of related systems
28 were reported by most practices over the course of the programme (see Appendix 2 for
29 examples), but this was an evolving process that was strongly dependent on closer working
30 arrangements between clinical and administrative staff. These changes reportedly led to a
31 number of improvements, including: enhanced systematic monitoring of patients (e.g. blood
32 tests and side-effects) and documentation; greater personal vigilance when, for example,
33 handling repeat medication prescriptions and the prescribing of antibiotics; developing
34 more robust systems for managing laboratory tests results for patients; and more proactive
35 patient contact, education and involvement in their care, including checking understanding
36 of medication regimes and how to seek further support.
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46 A majority of practices reported that they were now gradually providing safer, more reliable
47 care for patients with Heart Failure or Left Ventricular Systolic Dysfunction. They indicated
48 that programme participation had enabled them to identify sub-optimal care in these areas
49 and take action such as: clean up related patient registers and improve identification of
50 LVSD patients; optimise Heart Failure management through specialist clinics leading to
51 **reported** improvements in, for example, NYHA [New York Heart Association] recording and
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increased Pneumococcal Vaccinations; implement more robust monitoring of medications and improved patient contacts and care education.

A small minority of participants highlighted the perceived positive impact heart failure clinics and education had, for example, on patients' awareness, knowledge and self-management of their conditions. This had reportedly led to some patients feeling more in control in terms of self management and having a greater understanding of their illness and with respect to high risk medications.

"...[Patients are now] weighing themselves every day.....and they have got it written down, they have never done that before...they are also now fully aware of what side effects to look out for from the outset". [Practice Nurse 4]

"We have drafted information cards for the patients on methotrexate and isothyoprine, we have had positive feedback, they have actually participated and helped us revise the cards" {Practice Nurse 4}

"We have tidied up our DMARD programme, we have got the new guidelines, our safety has improved with regards to the DMARDS...and we have put together a pre-initiation check list which is working really, really well, everyone in the practice is aware of that..." [GP 1]

3. Utility of programme interventions

Clinical Care Bundles

Most participants favoured the care bundle intervention as having potentially the greatest positive impact in improving patient care safety and reliability. They considered the visual nature of the 'run charts' related to care bundle data measurement as important for encouraging and motivating staff and driving improvement. The care bundle approach was reported to be effective in highlighting unreliable practice and participants believed that this led to improved care systems, and enhanced patient education and involvement in self-management of illness.

However adapting, re-designing and gaining consensus on the content of the care bundles was perceived as problematic by many of those involved in the process. For some, the care

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3 bundles that were locally developed (e.g. related to heart failure care) were viewed as
4 having a limited evidence base and relevance, and were difficult to interpret and challenging
5 in terms of achieving high reliability in the areas of patient care delivery being targeted.
6 Practice teams also reported further struggles with patient non-compliance with some
7 aspects of recommended care related to the bundles which 'skewed' their data. They also
8 reported issues with interpreting statistical relevance related to care bundle compliance
9 data. Additional technical problems with information technology for related data collection,
10 storage and access were felt by some to often hinder effective implementation of the care
11 bundle approach.
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21 *"...you can see week by week, month by month, whether or not you are showing any*
22 *improvement, we seem to be improving and that's good because we are able to see*
23 *our graphs and what not and how we were doing with that" [GP3]*
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25 *"...the [Care] Bundle is the thing that forces you to make changes everything else is*
26 *driven by that...they are straight forward, it is not too complicated" [GP1]*
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30 *Model for Improvement (MFI)/PDSA Change Cycles*

31 Although there were some reported successes, multiple barriers were apparent for many
32 participants related to the everyday implementation of MFI/PDSA Cycles as a method to
33 facilitate small tests of change and drive rapid care improvements. Participants indicated
34 that time constraints and competing work priorities meant that they quickly lost momentum
35 and motivation after initially implementing the PDSA cycle process to test changes in care
36 practices. They also reported some confusion with fully grasping the concept and its
37 relevance to the general practice setting and how the PDSA cycle process actually aligned
38 with 'data measurement' and 'improvement'. Others indicated that they found the method
39 to be a little 'contrived' and 'unnecessary' for everyday work. Many participants reported
40 that they felt it was unnecessary to always formally document records of PDSA cycles
41 undertaken, as many viewed it as an 'instinctive' or 'mental' thought process that was
42 routinely done 'automatically' when making small scale adjustments to ways of working.
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54 *"In some ways it feels almost it's quite contrived what you are doing with it because*
55 *you have got to do each individual step rather than just say this is how I think we*
56 *should deal with it...you just tend to make changes and just roll with it, maybe why it*
57 *is a bit more difficult for us to try and sort of implement it in the way we work" [GP 7]*
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"I would say they are a bit of a pain...probably about 50% of the [improvement] work that we have done has not been recorded by a PDSA...just breaking it down and recording it is time consuming and a bit of a faff...too many paper exercises for us as practitioners" [Practice Nurse 3]

"...it's a good way to implement change, how to make your systems better you can make changes quickly you know it doesn't need to be as cumbersome as, you know, audit..." [GP 2]

Safety climate assessment survey

Participants reported mixed views and experiences of participating in the safety climate survey intervention and holding related team-based meetings to discuss and reflect upon the feedback report of survey findings that was provided as part of the programme. In the early stage of programme, many participants reported multiple issues related to survey participation mainly to do with the online technology used but also in interpreting the relevance of their survey findings, particularly in comparison to other GP teams. This caused confusion, raised concerns around statistical meaningfulness and fomented negativity about this activity for some participants who reported very limited learning and improvement from survey participation. This prompted a review of how the climate survey was designed and delivered by the programme leadership, resulting in a number of technical and educational support refinements during the programme, with later programme participants reporting increasingly positive feedback on the usefulness and impact of the climate survey.

For those participants who reportedly engaged well with the climate survey at the outset this activity was perceived to lead to valuable, if occasionally difficult, team discussions on patient safety systems, internal and external communication problems, and practice leadership issues. Participants also indicated that survey participation provided welcome reassurance on safety performance; highlighted misplaced perceptions of how safe the practice was thought to be; teased out why there were marked differences in clinical and non-clinical responses to the survey; and identified areas for improvement within practices.

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3 *"..the whole area round the climate survey was disappointing, I would say that was the*
4 *failure point of the programme for us...the way it is done just now just hasn't worked in*
5 *this practice" [Practice Nurse 1]*
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8 *"I felt that we didn't get enough input prior to completing it, it was just e-mailed, asked*
9 *to complete it but we didn't know what it was about...we felt we didn't have enough*
10 *explanation" [Practice Manager 3]*
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13 *"Many of us in the practice doctors and staff hadn't really made the link that us failing*
14 *to communicate in some other ways was a threat to patient safety so we opened that*
15 *up for discussion, we had a lot of really good stuff came out of it, a lot of very open*
16 *discussion" [GP7]*
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19 *Trigger Review Method (TRM)*

20 Mixed views were reported on the perceived purpose and usefulness of TRM, with some
21 participants finding this intervention daunting and threatening. It was immediately clear from
22 early evaluation feedback that 'reliable measurement' of harm rates in the electronic
23 records of specific patient groups was not being attempted by most participants. Problems
24 were being reported by participants related to how they perceived and interpreted the
25 'harm measurement' element of TRM. Many participants indicated that they struggled to
26 identify enough harm cases to be able to calculate a 'reliable measure of harm' for the
27 specific patient group being reviewed by TRM. Instead those who engaged well with the
28 tool reported an alternative application in actually identifying previously unknown
29 incidences of patient harm in electronic records related to, for example, the altering of
30 medications, inadequate recording of adverse drug reactions and drug allergies, and lack of
31 clinical follow-up of patients. This was reported to have prompted greater scrutiny in
32 medication-prescribing and monitoring systems, as well as improved coding of adverse
33 events as a means to manage clinical risks and potentially reduce avoidable harm to patients
34 in future.
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49 Based on these early programme experiences the purpose and application of the TRM was
50 adapted to a method of 'flagging up' previously undetected patient safety incidents (e.g.
51 'latent risks', 'near miss events' and 'adverse events') in specific high risk patient groups
52 (e.g. those taking Warfarin). In this regard the TRM purpose was altered by these
53 participants to a method for *identifying* patient safety-related learning needs though
54 highlighting sub-optimal processes and general quality of care issues. A clear facilitating
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factor was the provision of one-to-one training by a medical doctor experienced in the method, which was associated with its perceived successful application by participants.

"[we] discovered quite a few people whose haemoglobin was quite low for no obvious reason, we've now built in a regular haemoglobin review into patients on Warfarin therapy". [GP2]

"...occasionally trends in blood counts rather than absolute values had been missed, we have definitely now got procedures in place that pick those up". [GP4]

"[The TRM] identified near misses that would never have otherwise been unveiled to anybody ever but had very significant learning". [GP1]

DISCUSSION

The pilot collaborative programme largely achieved its objective of capturing key perceptions and experiences of participants, and identifying the facilitators and barriers associated with the range of novel improvement interventions being tested. Encouragingly most participants valued the educational benefits of being involved such as learning about safety and improvement theory and methods, having protected time for team-based reflection, and participating in peer-to-peer learning. The findings confirmed and refuted some aspects of the initial programme theories, which enabled us to refine initial assumptions about how some of the interventions were working (or otherwise) and why, and make mid- or end of programme corrections to their purpose and delivery. This evidence has since informed decision-making to further refine and spread the implementation of the programme at scale on a national basis.

While the Breakthrough Series collaborative concept was well received, similar to previous research [19], the overall approach also provided some evidence of the potential transferability and utility of most interventions after adaptation to the Scottish primary care context (particularly clinical care bundles, but also safety climate assessment and TRM). However, engagement with MFI/PDSA change cycles was more problematic and is perhaps worthy of future research exploration, particularly given the findings of a recent systematic review [31] which also found issues with the understanding, application and reporting of this method.

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3 Additionally clear challenges were identified around protected time to participate,
4 competing workload priorities and wider engagement of GP teams beyond core programme
5 participants. Further work is also necessary to ensure data collection and monitoring
6 systems are improved, that there is greater realism around what can be achieved, and the
7 unintended consequences of participation in such programmes are considered – all are well
8 established improvement challenges [32-34]. The main theory-related learning suggests the
9 following refinements:
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- 15 • High system reliability appears difficult to achieve in some circumstances with care
16 bundles as success can be strongly dependent on patient compliance issues.
- 17 • Care bundle content should be based on strong evidence to be professionally
18 acceptable, while larger patient sample sizes are needed to demonstrate system
19 improvements and clinical impacts.
- 20 • The TRM does not appear feasible as a tool for *measuring* harms and was reportedly
21 more useful for *identifying* learning and improvement opportunities related to
22 (previously undetected) patient safety incidents.
- 23 • TRM training was associated with enhancing the success of implementation, while
24 the method appeared to have greater utility when used with specific ‘high risk’
25 patient populations, rather than random samples of the GP patient population.
- 26 • Feedback related to safety climate measures and performance needs to be simplified
27 and illustrated by graphs, with minimal use of even basic statistical concepts as these
28 may not be well understood by many and can cause confusion. Careful
29 consideration should be given to introducing the concept, explaining its purpose, the
30 formatting of feedback reports and the need for basic guidance for participants.
- 31 • PDSA cycles were not generally well utilised as these were frequently viewed as
32 unnecessary for rapid improvements, while related documentation processes were
33 also thought unnecessary and cumbersome.

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53 *Study limitations*

54 Caution must be exercised when interpreting the findings, largely due to potential bias
55 because of the comparatively small number of mainly enthusiastic volunteer participants
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(early adopters) who over-represented general practices in the speciality training community. The programme was primarily a feasibility pilot and relatively short-term which resulted in a lack of objective, longer term outcome measures being collated at the national level around whether harm was actually reduced or care process reliability increased – participants reported examples from their locally held data to evaluators but these could not be verified and so overall programme success was difficult to gauge. With hindsight if participants had greater knowledge and experience of the interventions being tested and all of the socio-cultural and technical issues uncovered during the pilot had previously been resolved to a large extent, then achieving some of the patient-safety related programme aims may have been more achievable (and measureable). The evaluation process was largely descriptive and would have benefited from a greater analytical focus, which is perhaps a reflection of the over-ambitious programme goals and the broad evaluation approach employed for this type of feasibility pilot. Future study of these specific improvement interventions (and related evaluation) will require much greater clarity about the social, technical and behavioural processes that need to be measured and altered to achieve the desired impacts on frontline practice [34].

While improvement collaboratives, including the Breakthrough Series approach [22], are well-established in many acute hospital settings, there is limited evidence of their implementation in primary care. Several studies have, however, been undertaken and reported mixed findings in improving COPD [35], diabetes care [36-39], advanced patient access [40-41], pressure ulcer care in nursing homes [42], chronic heart failure [43] and prehospital care for acute myocardial infarction and stroke [44]. The common thread amongst these studies is that they focused improvement efforts entirely on a specific, well-defined disease or patient group using a standard collaborative approach. In contrast, the approach adopted in this pilot study was arguably unorthodox and, with hindsight, over-ambitious. Efforts were focused on multiple interventions and patient safety issues simultaneously. This included testing the feasibility of the Breakthrough series collaborative approach at scale, piloting nascent improvement methods which hitherto had largely never been applied in this setting in Scotland and internationally, and challenging participants to reduce harm incidents or increase care delivery reliability.

The study findings are informing the (re)design and delivery of a planned future safety and improvement programme to be implemented nationally in Scottish general practices, before spreading to other primary care professional groups. Further testing and refinement of the programme interventions are ongoing with more representative groups of GP teams, with some having demonstrated promise in their reported potential to improve the reliability of clinical safety systems [45] and identify previously undetected patient safety concerns [46]. The potential for some of the tools to support QI evidence requirements for GP specialty training and medical appraisal and revalidation is also apparent [45-48].

There is growing evidence of the impact of interventions to improve the safety and reliability of specific aspects of specialist hospital care - such as through the successful implementation of surgical checklists [49-50] and clinical care bundles [51] to reduce avoidable harms. However there are still question marks over the effectiveness of such initiatives - and also large-scale collaborative programmes - in achieving and sustaining the desired improvements in the quality and safety of patient care [52-54]. Overall the evidence of what interventions work to enhance safety in primary care is less well developed [15], with related evaluations being predominantly observational, conducted in single sites and of variable quality [25, 33-34]. This evaluation provides some evidence of the transferability and utility of specific safety improvement methods in primary care, and sheds some light on related implementation issues that can arise.

CONCLUSIONS

The delivery of the SIPC pilot programme was positively received by the great majority of participants, with many reporting improvements in practice safety systems, teamworking and communications with colleagues and patients. However, some practices struggled with understanding the concepts, relevance and application of many of the improvement interventions tested. The evaluation provided valuable insights into how the interventions were utilised and adapted and contextualised as the programme evolved, which has already led to further refinements and improvements in application. A number of social and technical implementation challenges (e.g. appropriate use of financial incentives, IT support and availability of data, and workload demands) were also identified that need to be taken into consideration when spreading this approach at larger scale. To achieve this, policy and

organisational levers will be necessary to implement the programme interventions on a formal basis at the national level in general practice. However this will require significant resources to support the design of infrastructure to enable the routine collection of data for improvement (both narrative and numerical) and the requirement to systematically build capacity and capability in improvement skills amongst the primary care workforce.

FOOTNOTES:

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Contributors

PB was principal investigator, co-designed the study, assisted with data analysis and interpretation and co-wrote the initial manuscript. LH co-designed the study, conducted interviews and analysed and interpreted data, and co-wrote the paper. AB provided advice on study design and theory, data analysis and interpretation and contributed to the writing and critical appraisal of the manuscript. NH and JG designed and led the programme intervention, contributed to evaluation data interpretation and to the critical evaluation and writing of the manuscript. All authors approved the final version of the manuscript.

Competing interests

No, there are no competing interests.

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Ethical review

The study and evalaution protocols were pre-screened by the west of Scotland Research Ethics Committee, but it was judged to be a service development which did not require ethical approval.

Data Sharing

No additional data available.

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Table 1. Characteristics of SIPC programme evaluation participants (n=27)

Factor	n
Gender:	
Female	19
Male	8
Professional Group:	
General Practitioner	9
Practice Nurse	7
Practice Manager	11
NHS Board Area:	
Forth Valley	11
Lothian	9
Tayside	7
Specialty Training Practice Accreditation:	
Yes	15
No	12

Box 1. A brief summary of how the SIPC Pilot Programme was delivered and guided by the IHI Breakthrough Series Collaborative Method

- The programme was implemented over a 24-month period through adherence to the IHI's Breakthrough Series Collaborative Method i.e. A combination of Learning Events for multi-disciplinary practice teams followed by Action Periods to measure and improve the safety and reliability of care.
 - Participant attended three 1-day Learning Events intersped with 3-month Action Periods in frontline clinical practice to deliver on programme aims (with local leadership, advice and support provided in each NHS Board area, and the programme being managed centrally by a core leadership and advisory team)
 - The SIPC project steering team delivered the 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 Model for Improvement (incorporating PDSA cycles) was taught to participants as a method for them to test its usefulness in facilitating rapid improvements in care processes and systems
 - The Trigger Review Method for primary care was taught to participants (in groups sessions and face-to-face) to test its usefulness in serially measuring undetected harm events in electronic patient records and identify areas for improvement
 - The principles of Clinical Care Bundles were taught to participants who developed and tested these locally to assess their potential for improving the reliability of patient care delivery in selected clinical areas.
 - A web based online questionnaire survey was developed to assess perceptions of safety climate in participating practices and determine its usefulness for team-based reflection and acting on the quantitative feedback reports provided as a way to enhance the prevailing safety culture
- The focus of this study is the first wave of the SIPC programme which was initiated in August 2012.
- This involved three clinical and management representatives from 22 GP teams based in three regional NHS Board areas in Scotland. Participating NHS Boards and general practices were recruited on a voluntary basis.
 - Financial support for backfill costs was provided to enable core GP team representatives to attend Learning Sets and have some protected time for improvement activities.
 - Participants were supported by a local NHS Board level team consisting of a public partner; GP Clinical Lead; manager; and quality improvement facilitator.
 - The expectation was that NHS Boards would also develop their expertise in supporting practices in improving their care through collaborative working, and in co-ordinating system-wide approaches to complex patient care
 - The overall pilot programme was managed and co-ordinated by a core team from Healthcare Improvement Scotland (HIS) - the national organisation responsible for the - which consisted of a GP Clinical Lead, Programme Manager, two Project Officers and two Project Administrators. The expectation was that this team would gain insights into how to patient safety improvement might be further developed in primary care

Box 2. Main SPIC Interventions tested and developed: Purpose and Evidence

Intervention	Description	Original Programme Purpose	Relevant evidence
Quality Improvement Collaborative	Quality improvement collaboratives involve groups of professionals coming together, either from within an organisation or across multiple organisations, to learn from and motivate each other to improve the quality of health services. Collaboratives often use a structured approach, such as setting targets and undertaking rapid cycles of change.	To apply QIC methodology to improve knowledge, change behaviours, and share learning and experiences with peers	de Silva, 2014 [19] IHI Breakthrough Series [22]
Implementation of Care Bundles	Care bundles aim to improve standards of care and patient outcomes by promoting the consistent implementation of a group of effective interventions	To measure the reliability of selected evidence based clinical care processes and direct improvement efforts	Institute for Healthcare Improvement, Innovation Series [28]
Trigger Review Method (Structured Review of Electronic Patient Records)	The use of "triggers", or clues, to identify adverse events in patient records is a method for measuring the overall level of harm from medical care in a care setting.	To facilitate periodic measurement of avoidable harm rates within general practices using a Trigger Tool	de Wet & Bowie, 2009 [3]
Model for Improvement (MFI)/PDSA Change Cycles	MFI is a tool that is applied by care practitioners to accelerate care improvement and is used in combination with Plan-Do-Study-Act (PDSA) cycles to test changes on a small scale.	To apply the Model of Improvement as the main mechanism for driving rapid change and improvements in practice	Langley et al, 2006 [26]
Safety Climate Assessment	Safety climate assessment typically employs a questionnaire tool to capture an objective measure of the safety culture - the 'way things are done' in your organisation/team when it comes to safety - as the starting point for improvement. In this study an online tool was used to capture participants' attitudes and perceptions in key areas of practice safety and improvement, while guaranteeing anonymity. The tool then generates a written graphical report, and provides guidance to help improve local safety culture.	To formatively measure perceptions of the safety climate within primary care teams at key junctures in the programme To feed back climate scores to primary care teams to help direct safety related learning and improvement and build a positive safety culture	de Wet et al, 2010 [29]

Box 3. Brief interview topic guide

Programme goals, information and improvement support

What did you understand about the programme goals
What was your experience of the Learning sets? How did you and the team benefit?
Explore sharing and spread of programme concept and practices with the wider practice team

Interventions

Explore barriers and facilitators with each intervention
What is realistic and feasible and why? If not, why is this?

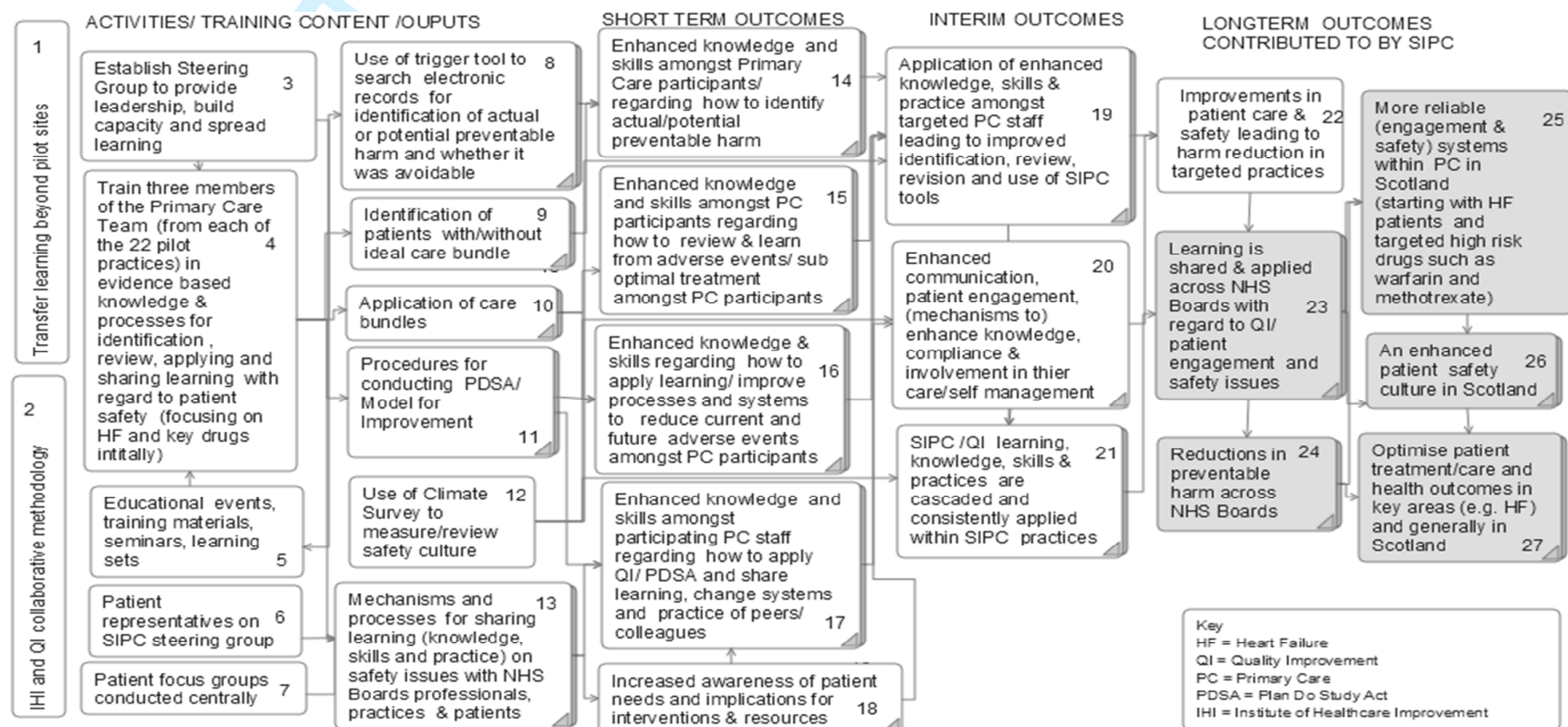
Explore programme impact at different levels:

Personal and team learning
Internal relationships
Practice safety system improvements
Direct patient care improvements
Consequences, good and not so good, for everyday practice

Overall experience of SIPC programme

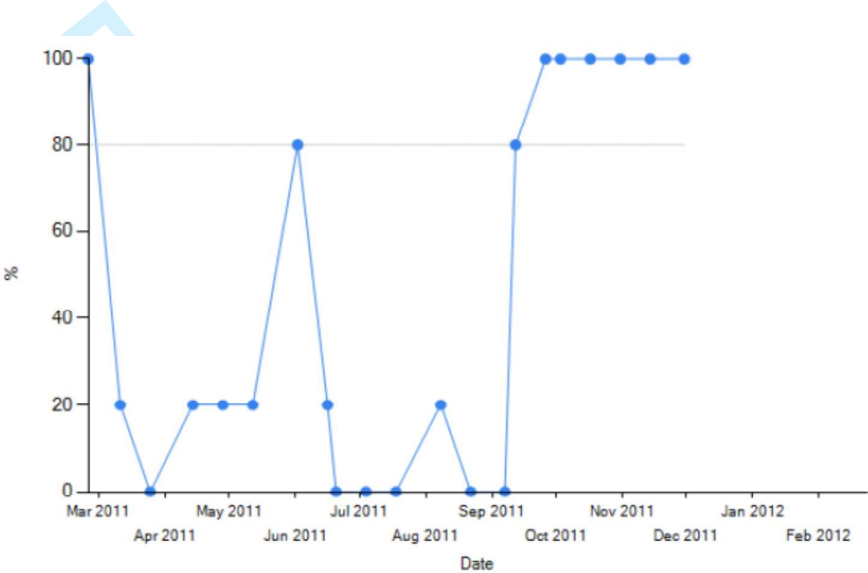
What do you find to be effective about the programme? Why was that?
What do you think did not go well about the programme. Why was that?
What programme aspects have the practice embraced? Why? How will you continue with these?
Any concerns about this type of programme approach and why?

Appendix 1 - Logic Model of the theories inherent in the SIPC pilot programme

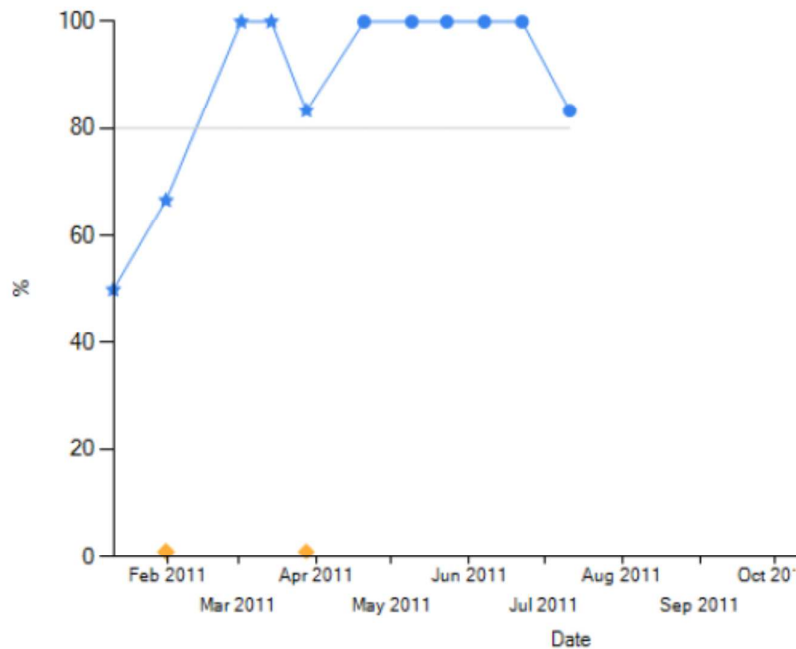


APPENDIX 2 – Examples of Data Run Charts Demonstrating Clinical Care Bundle Improvements by General Practice Teams as Part of the SIPC Pilot Programme

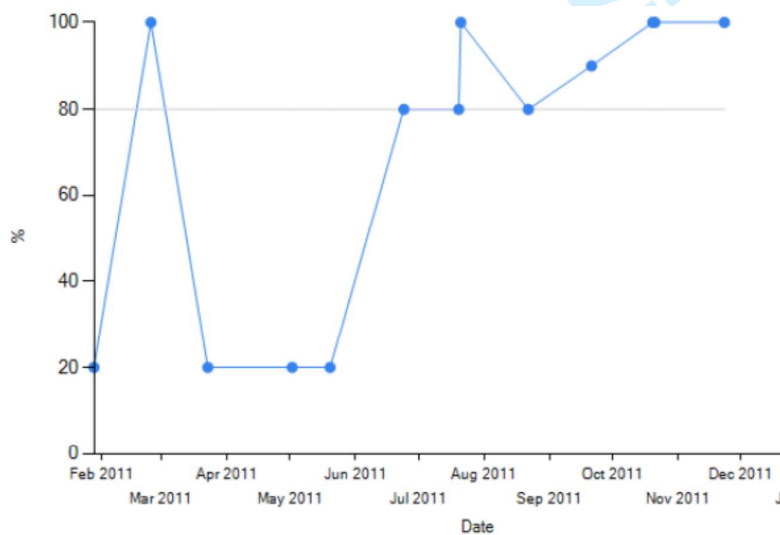
Following regular data submissions, practices began to create run charts, showing improvements of each element of the bundle, as well as the composite score. Please refer to run chart below as an example of a practice which has achieved reliability, which in the case of the SIPC work, was set at 80%.



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



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



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

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