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Complete List of Authors:	de Wet, Carl; Griffith University, School of Medicine Bowie, Paul; NHS Scotland, O'Donnell, Catherine; University of Glasgow, General Practice & Primary Care
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Facilitators and barriers to safer care in general practice: a qualitative study of the implementation of the trigger review method using Normalisation Process Theory

Carl de Wet[1,2,3], Paul Bowie[1,2] and Catherine A O'Donnell[2]

[1]Medical Directorate, NHS Education for Scotland, Glasgow, UK
[2] General Practice and Primary Care, Institute of Health and Wellbeing, University of Glasgow, UK
[3]School of Medicine, Griffith University, Gold Coast, Australia

Address for correspondence:
Associate Professor Carl de Wet
Level 8, School of Medicine, Griffith University, Southport, Gold Coast, Australia
Email: mailto:carl_dewet@yahoo.co.uk
Tel: (+61) 0450277315

e-Mail addresses of co-authors:
Dr Paul Bowie: paul.bowie@nes.scot.nhs.uk
Prof Catherine O'Donnell: kate.o'donnell@glasgow.ac.uk

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ABSTRACT

Objectives

Patient safety is a key concern of modern health systems, with numerous approaches to support safety. One, the Trigger Review Method (TRM), is promoted nationally in Scotland as an approach to improve the safety of care in general medical practice. However, it remains unclear which factors are facilitating or hindering its implementation. The aim of this study was to identify the important factors that facilitate or hinder the implementation of the TRM in this setting.

Methods

We conducted 28 semi-structured interviews with general practitioners (n=12), practice nurses (n=11) and practice managers (n=5) in Scotland. Data analysis was theoretically informed using normalization process theory (NPT).

Results

We identified four important factors that facilitated or hindered implementation: (1) the amount of time and allocated resources; (2) integration of the TRM into existing initiatives and frameworks facilitated implementation and justified participants' involvement; (3) the characteristics of the reviewers – implementation was facilitated by experienced, reflective clinicians with leadership roles in their teams; (4) the degree to which participants perceived the TRM as acceptable, feasible and useful.

Conclusions

This study is the first known attempt to investigate how the TRM is implemented and perceived by general practice clinicians and staff. The four main factors that facilitated TRM implementation are comparable with the wider implementation science literature, suggesting that a small number of specific factors determine the success of most, if not all, complex healthcare interventions. These factors can be identified, described and understood through theoretical frameworks such as NPT and are amenable to intervention. Researchers and policy makers should pro-actively identify and address these factors.

Introduction

Patient safety is a key concern of modern health care systems (1). The importance of patient safety first emerged in the hospital setting, due to the possibility of errors leading to patient death and disability (2, 3). However, patient safety is increasingly an area of concern in primary care (4, 5). In the UK, patient safety incidents (PSIs) have been defined as 'any unintended or unexpected incident which could have or did lead to harm for one of more patients receiving National Health Service care' (6). There is, however, a recognised difficulty in identifying and measuring PSIs and many remain undetected (7). This has led to variation in the estimation of PSIs in primary care, ranging from <1 to 24 PSIs per 100 consultations (4). While this may be lower than that reported for hospital care, the volume of consultations that take place in primary care (e.g. over 340 million general practice consultations in England in 2013) equates to the opportunity for substantial harm for approximately 300 000 patients each year (8). This has increased the urgency and effort with which policy makers, health care leaders, clinicians and researchers have responded (9). Programs, initiatives and interventions aiming to identify safety threats, reliably reduce ameliorable risks and measurably improve health care performance have proliferated, including in the National Health Service (NHS) of the United Kingdom (UK). Examples include the Health Foundation's Safer Patients Initiative and Safer Patients Network and the Department of Health's Patient Safety Research Portfolio (10-12).

In Scotland, a national Patient Safety Program (SPSP) was launched in 2008 with the ambitious aims of significantly reducing secondary care mortality and harm (13). As the programme became established in hospitals, it was expanded into primary care (SPSP-PC), beginning with general medical practice (14). The SPSP-PC aimed to measurably improve the safety of care provided in participating practices through three different strategies that were specifically developed or adapted for this purpose (15). They were: (i) detecting, learning from and reducing PSIs by applying the Trigger Review Method (TRM) (16, 17); (ii) measuring and building a strong and positive safety culture (18); and (iii) improving chronic disease and medication management by using a care bundle approach (19). All three methods have been the focus of research in different international health care settings, which have increased our understanding of their potential usefulness as interventions to improve patient safety (20-24). However, much remains unknown, including which factors are associated with their successful implementation or lack thereof.

The TRM is essentially an adaptation of clinical record review (CRR) or 'case note audit', providing a structured way to rapidly screen samples of random electronic patient records for undetected PSIs. CRR is a well-established approach of detecting and quantifying sub-optimal care issues and is considered the gold standard in epidemiological type patient safety research (25). The key strength of CRR compared with other approaches is that it detects a significantly greater proportion of all PSIs (26). This is why the original landmark studies about the prevalence of adverse events in hospitals in the USA (27), UK (2), Australia (28), Canada (29) and New Zealand (30) all used some form of CRR adapted to their settings and purposes (26).

Development of the TRM commenced in 2007 in Scottish general practice, with subsequent testing in The Health Foundation-funded Safety and Improvement in Primary Care (SIPC) programme (15, 16). In 2013, the TRM was added to the Quality and Outcomes Framework of the UK General Medical Services contract (QOF, described in Box 1) with the expectation that it would be implemented nationally by Scottish general practices (c1000). A subsequent study of the implementation of the TRM found that most clinicians uncovered important patient safety concerns in their individual practices and took specific actions to improve the related care systems and processes (20). A description of the intended application of the TRM and a clinical example of its potential value are provided in Boxes 2 and 3 respectively.

Developing a potentially useful, complex healthcare intervention like the TRM is challenging. However, successfully implementing that intervention, sustaining its use and embedding it into routine practice are arguably even greater challenges (31, 32). Understanding the implementation of such interventions, including a clear explication of the barriers and facilitators to implementation, could prevent considerable amounts of time, effort and resources from being squandered. Despite the TRM being promoted and implemented in general practice nationally across Scotland, it remains unclear which factors are facilitating or hindering the success or otherwise of this process, and their relative importance in determining whether, or to what degree, this intervention can be integrated into routine practice. The aim of this study, therefore, was to identify the important contextual, organisational and resource factors that facilitated or hindered the implementation of the trigger review method (TRM) in Scottish general medical practice. A theoretical framework was used to underpin the data collection, analysis and interpretation of the findings.

Use of theory to understand the implementation of patient safety initiatives

It is now accepted that the application of a theoretical lens can greatly enhance our understanding of the organisational and contextual factors which influence the implementation of quality improvement and patient safety initiatives (33-35). The Medical Research Council (MRC) guidelines recommend the explicit application of theory from the earliest stages of designing and implementing complex healthcare interventions, such as the TRM, to reduce the likelihood that important factors will be overlooked (36, 37). There are two reasons for this. First, complex interventions such as the TRM are often a 'black box', with a lack of clarity about which elements are implemented well, and why (34). Secondly, such complex interventions are implemented in a dynamic and on-going social context, shaped by the actors using them and by the wider organisational and socio-cultural structures into which the intervention – in this case the TRM – is placed (38, 39).

Selecting the most suitable theory from the large, complex and diverse range of options can then be informed by the specific requirements of the study and researchers (40, 41). As this study was principally concerned with the 'work' that practitioners had to do to implement the TRM, both as individuals and collectively in practices, and how that interacted with their work-based context, we selected Normalisation Process Theory (NPT) as our theoretical framework. NPT is a socio-technical, middle-range theory about the 'work' people do collectively and as individuals to implement and sustain an intervention. It has been successfully used in multiple studies and international health care settings and is particularly useful for describing, understanding and evaluating complex health care interventions such as the TRM (42-44).

The NPT framework consists of four main 'constructs' (45). They are:

- Coherence - the work implementers do to understand an intervention;
- Cognitive participation - the relational work to build a community of practice around an intervention;
- Collective action - the operational work of enacting an intervention; and
- Reflexive monitoring - the work of assessing and reconfiguring an intervention.

Each construct is divided further into four components, which promotes a nuanced understanding of the implementation process. The NPT constructs and components and how they relate to the TRM are described in Table 1.

Methods

Study design

Qualitative study employing semi-structured interviews with general practitioners (GP), practice nurses (PN) and practice managers (PM). We used the Standards for Reporting Qualitative Research (SRQR) checklist for the study and manuscript (46).

Setting and sample

In Scotland, the organisational structure of the publicly-funded NHS consists of 14 regional 'Boards' who are responsible for the delivery of frontline health services and improving the health of the populations resident in their respective geographical areas (47). This study was undertaken in the West of Scotland in two of the Boards: one covering a large, urban setting with 262 general practices (designated Health Board A); the other covering a mixed urban-rural setting, with 56 practices (Health Board B). In April 2012, all practice managers in each Board area were sent written information via e-mail about the proposed study and an invitation for the PM and at least one GP and a PN to receive TRM training (Box 2) and participate. Due to resource constraints, recruitment stopped when 12 practices had agreed to participate. A convenience sample of GP practices was constructed designed to reflect the relative numerical distribution: 10 practices from Board A and 2 from Board B.

Patient and public involvement

Patients and the public were not involved in this study.

Data collection

The interview schedule was derived from the NPT framework and agreed by the authors (Supplementary file, Appendix 1). The interviews were conducted in the practice premises of participants at a time convenient to them. Informed consent was obtained from study participants prior to the interviews being conducted and after the purpose of the interview had been explained and anonymity assured. All interviews were conducted by the same investigator (CdW) who introduced himself as a GP and a researcher. Interviews were conducted between January 2013 and July 2013 and lasted approximately 45 minutes. They were digitally recorded and supplemented with contemporaneous field notes.

Data analysis

All interviews were transcribed verbatim to preserve colloquialisms, repetition and other non-verbal communication that could aid data interpretation but were not reviewed by participants. Transcripts were anonymised and the twelve participating practices assigned a unique identifier. This identifier was applied to every participant within a given practice. Participants from the same practice were differentiated by adding a further, unique identifier as a prefix, derived from their professional role: general practitioner – GP; practice nurse – PN; and practice manager – PM.

Data coding was led by CdW and COD and was informed by a framework approach using a coding frame informed by NPT (48). First, data were coded broadly to one of the four main NPT constructs. Following this, data were coded in greater detail to the specific NPT components of each construct; for example, data pertaining to understanding of the TRM (coherence) were then re-read and further coded to the sub-constructs of differentiation, communal or individual specification, and internalisation. Data could be double-coded to more than one sub-construct. The codes were then analysed in conjunction with the related, reflective memos to interpret the emerging views and themes and compare the perceptions of the different staff groups. The codes and themes were mapped and displayed using NVivo version 9.2.81.0. All authors met regularly to discuss the findings, ensure consistency and agree and verify data interpretations.

Care was taken, however, to ensure that the analysis was emergent and exploratory, and that data were not 'shoe-horned' into the NPT framework. Data that fell out with the NPT framework were assigned stand-alone codes and analysed separately to this study. The authors recognised, for example, that some data described *how* the TRM influenced participants and outcomes, rather than the 'work' of implementation, and therefore assigned different codes such as 'patient safety mindset' and 'learning moments' (unpublished - available on request from the corresponding author).

Results

Demographic data from the participating practices are summarized in Table 2. A total of 28 interviews were conducted with GPs (n=12), PNs (n=11) and PMs (n=5). One practice did not have a nurse during the study period, two PMs had to withdraw from the study due to unexpected personal reasons and another practice had a practice nurse (PN01) with the dual role of PM. The PMs of the remaining four practices were

willing to be interviewed but were excluded because concurrent data analysis indicated that data saturation was achieved as no new data or insights were obtained from the last few interviews.

Coherence – the work individuals and teams did to understand the TRM (Table 3)

Many participants explained their understanding of the TRM by comparing it with other quality improvement (QI) methods they were already familiar with through QOF, such as clinical audit and significant event analysis (SEA). However, despite the similarities between the TRM and other QI methods, participants also recognized sufficient differences for it to be perceived as a 'new' method.

Most participants initially expressed concerns that implementing the TRM would increase their workload and require additional resources and time. This perception was moderated as their understanding of the TRM increased by implementing it and they realised that the actual workload and time requirements were lower than they initially expected. For example, GP02 described getting '*bogged down'* during the first trigger review but learnt from this experience and was able to apply the method more efficiently the second time. Most reviewers found the second trigger reviews quicker and easier, even though this did not necessarily mean the findings were more important or helpful.

Cognitive participation – establishing a community of practice around the TRM (Table 4)

The initial work that was required to implement the TRM in practices was mainly done by GPs. They were motivated to undertake the work because of expressed interests in the quality of care they deliver and a desire to proactively identify and reduce potential safety threats. These 'champions' subsequently enrolled other members of their practice team to conduct TRMs using one of two strategies. The first and most common strategy was to assign specific responsibilities or tasks to individual team members. Most of the practice nurses, managers and administrative staff were recruited in this way. The second strategy was to recruit team members opportunistically when they expressed an interest in participation, which is how most GP colleagues within participating practices were recruited. Perhaps unsurprisingly then, GPs were more motivated to implement the TRM compared with practice nurses – at least initially.

GP trainees, inexperienced practice nurses and some salaried GPs were able to detect and learn from PSIs but their attempts to improve care were typically aimed at individual or small groups of patients. In contrast, GP partners and experienced practice nurses were able to disseminate learning points and act to improve care at practice and regional levels through their leadership roles and because of their ability to positively influence the rest of their team. However, a few participants were opposed to sharing the trigger review findings with anyone outside their practice team because of concerns that the data may be misinterpreted.

Factors that helped to legitimise the TRM facilitated its successful implementation. Participants felt justified in allocating additional time and resources to implement the TRM because of its inclusion in the QOF. They also perceived it as an acceptable professional activity because of its QI relevance to medical appraisal and GP specialty training. In addition, the endorsement of the TRM by their peers and professional organisations, such as the Royal College of General Practitioners (RCGP), helped to justify their participation and increased their willingness to continue using the TRM.

Collective action – the work of enacting the TRM and integrating it with existing practices and contexts (Table 5)

Implementation of the TRM was facilitated when reviewers detected PSIs quickly and the PSIs were unambiguous and perceived as serious, preventable and originating in primary care. The small minority of reviewers who were unable to detect a single PSI or only detected a few PSIs of low severity typically perceived this as an important barrier to the TRM's use. However, some reviewers alternatively interpreted 'finding nothing' as evidence for safe, high quality care in the clinical area being scrutinised.

Implementation of the TRM was facilitated when practices allocated adequate resources and sufficient time for clinicians to conduct trigger reviews without interruptions. While most practices allocated at least some protected time for TRM work, it was seldom adequate or uninterrupted. As a result, some reviewers reported that they conducted the reviews during their leisure time or in-between other tasks. Most reviews were interrupted because of urgent clinical tasks. Some reviewers were aware of a constant feeling of other tasks '*piling up'* and a compulsion to check their workload, which distracted them from completing the trigger reviews.

The personal and professional characteristics of the clinician reviewers strongly influenced the implementation of the TRM. Experienced, enthusiastic clinicians who

were motivated and able to critically reflect on the review process and how the detected PSIs may impact on care delivery and practice systems were more likely to report successfully implementing the TRM. They explained that applying the TRM in a 'tick box' manner reduced its effectiveness. While this was not considered an issue for the practice teams in this study, the participants were concerned that a substantial minority of other practices might adopt this approach in practice. Therefore, while most participants thought that incentivizing the TRM through its inclusion in QOF was the key factor determining its uptake in the wider general practice community, they also expressed concern that a superficial, 'tick box' approach would reduce its potential usefulness.

A substantial minority of practices nurses were initially uncertain whether they would be able to apply the TRM successfully. Some clinicians also lacked confidence in the validity of their early findings or the findings of other reviewers. Despite these misgivings, most practice nurses were able to detect PSIs, share the findings with their teams and recommend or make specific improvements within their practices. The confidence of all the participants in the TRM and their own skills and findings increased with time and experience, which helped facilitate its successful implementation.

Reflexive monitoring – the work of adapting and evaluating the TRM (Table 6)

Many participants identified the flexibility of the TRM, adapting it according to specific practice or reviewer requirements, as an important facilitating factor for its successful implementation. However, only a tiny minority of clinicians modified the method, the changes were minor and did not affect the outcomes.

Most participants perceived the TRM as a useful approach to improve the care they delivered to their patients, and for general practice in its wider sense. They also recognized its potential for identifying learning needs and points, encouraging reflection and raising awareness of potential safety threats. For these reasons, the TRM was considered to have equal or more value than existing quality improvement methods. However, while the TRM's perceived usefulness was identified as an important facilitator for its implementation and was felt to increase the likelihood of it being used again in the future, all respondents were clear that evidence of its usefulness would not be sufficient to ensure normalization into routine practice.

Discussion

We identified four main factors that facilitated or hindered the implementation of the TRM in Scottish general practices. The first factor was whether the amount of time and resources allocated to conduct trigger reviews were sufficient to enable implementation. The second factor was integration of the TRM in an established, national initiative (the QOF). This was a particularly important enabler, as it provided a financial incentive and professional justification for clinicians to implement the TRM. The third factor was the characteristics of the clinician reviewers. Implementation was facilitated by experienced clinicians with leadership roles in their practice teams. The fourth factor was the perceptions of the participants of the TRM, informed by their own practical experiences of using it. Implementation was facilitated if they understood it as acceptable, feasible and useful.

Practical implications and comparison with existing literature

Devlin et al recently identified three key areas for researchers and policy makers to pro-actively consider for future, large-scale improvement initiatives if they are to be successfully implemented and normalised (49). They are: time; what the authors refer to as 'readiness', which is the product of resources and clinician engagement; and information technology (IT). An earlier systematic literature review about the influence of context on quality improvement in healthcare identified a slightly larger number of important 'success' factors: senior leadership; organisational culture; information systems; previous experience of quality improvement; clinician engagement; and resources (50). Braithwaite et al identified eight comparable factors that determine implementation outcomes: preparing for change; capacity for implementation - setting; capacity for implementation – people; types of implementation; resources; leverage; sustainability; and desirable implementation enabling features (51).

This study identified essentially the *same* factors as important determinants of successful implementation, even though it used a different theoretical framework and terminology compared with the three examples. The implication seems to be that, irrespective of differences in the methodologies, taxonomies, or the clinical settings or nature of improvement-type studies, a small number of similar, specific factors can be identified as important facilitators or barriers to implementation and normalisation.

Some factors are more likely to be important than others, though. Providing frontline clinicians and staff with validated improvement methods and tools, education and

training and 'expert' support are examples of important factors that are often included in improvement initiatives. However, they are insufficient to reliably improve care or change systems without the visible support of senior leaders and allocation of adequate resources and time (42, 49, 52, 53). This helps to explain why implementation of the TRM was greatly facilitated by its inclusion in an established, national Framework – it clearly demonstrated senior leadership support and provided additional resources through financial incentives. While the need for allocating sufficient resources may seem self-evident, many improvement interventions receive no funding or funding for the implementation stage only, and even then the initial investments may be inadequate (42). It is therefore unsurprising than many interventions fail to become normalised despite evidence of their usefulness.

Strengths and limitations of this study

A unique strength of this study is that it is the first known attempt to investigate how the TRM is implemented in primary care by exploring the perceptions of clinicians and their general practice teams. A second strength is the use of a validated theoretical framework, which is recommended for research in the discipline of implementation science (37). A third strength is that the perceptions and experiences of the three different staff groups that were critical to the successful implementation of the TRM were considered. Because practices nurses also performed trigger reviews, the 'nursing' and 'medical' experiences and views could be compared. However, we found that the perceptions of the participations were highly congruent and independent of their roles and experience.

The study has at least two limitations. The sampling strategy was a pragmatic choice and this group of volunteers may therefore not be representative of general practices in Scotland or other countries in the UK. However, thematic saturation was achieved and, in our opinion, more interviews would not have materially strengthened the main findings. Applying a theoretical framework to data raises potential concerns that researchers may be constrained by theory and miss important findings, or alternatively may 'shoe horn' data into existing themes. However, our experiences were similar to those of other researchers, which is that very little data fell outside the NPT framework, and the data that did were either too diffuse to be meaningful or did not directly relate to the main study aims (44, 54).

Next steps

Patient safety remains a high priority in primary care worldwide. The National Quality Strategy specifies six health care priorities for the United States of America (USA), of which the first is to 'make care safer' (55). One the main levers they use to achieve this aim is 'learning and technical assistance', i.e. offering training and improvement tools.

In Scotland, GPs can submit trigger review findings as part of the mandatory QI Activity evidence required for appraisal purposes (56). The 'National Framework for Quality and GP Clusters' (see Box 1) identified a role for the TRM and recommends '*structured review of high risk patient records*' as one of nine validated safety improvement tools to the new Clusters (57). The RCGP has included the method in their patient safety toolkit as a potential evidence source for supporting medical revalidation of GPs in the UK (58). In England, Clinical Commissioning Groups (CCGs) were established in 2013 with two important but distinct roles: to commission secondary and community care services for their populations; and to support quality improvement in general practice (59). While the first role has received most attention to date, the second role is equally important and a legal duty that will require greater clinical engagement and validated tools, such as the TRM (60, 61).

The Australian Commission on Safety and Quality in Healthcare started a consultation in October 2017 as a first step in developing a national approach to support improvements in patient safety and quality in primary care (62). Although the consultation is ongoing, it seems reasonable to assume that any approach will have to include the 31 Primary Health Networks (PHNs) that were established in 2015 to better integrate care and to ensure that all Australian patients '*receive the right care in the right place at the right time'* (63). The approach will also require a cohesive implementation strategy, validated tools such as the TRM and allocation of adequate resources. The 'medical homes' initiative provides a practical example of how existing funding arrangements can be adapted at the federal level to encourage a more flexible approach to health care (64).

All these examples demonstrate a need for validated tools. However, it is unclear whether any organisation has fully considered or comprehensively addressed the main factors that are known to facilitate or hinder the effective, routine use of improvement methods. The pressing questions are therefore whether and to what extent the use of improvement tools like the TRM will become normalised in specific healthcare settings like general practice, and how this process can best be supported.

Conclusion

We identified four important factors that facilitated the implementation of the TRM in Scottish general practice. The factors are comparable with the wider implementation science literature, suggesting that a small number of specific factors are instrumental in facilitating or hindering the implementation of most, if not all, complex healthcare interventions. These factors can be identified, described and understood through theoretical frameworks such as NPT and are amenable to intervention. This may allow researchers and policy makers to pro-actively identify and address the main factors that are known to facilitate or hinder the implementation and normalisation of improvement initiatives. Normalisation of the TRM therefore seems likely if the following factors could be guaranteed: clinicians have the necessary knowledge and skills to apply the TRM effectively; there is senior leadership support for the TRM at practice and national levels; adequate resources and time are provided to conduct trigger reviews; and it is formally integrated into existing professional activities, government policies and national improvement initiatives.

Footnotes

Ethical approval and consent to participate

The study was submitted to and approved by the Glasgow University's College of Medicine, Veterinary & Life Science's Ethical Committee, reference number 2012054. All participants provided written, informed consent before the interviews were conducted.

Consent for publication

The authors have read and accept the terms and conditions of Implementation Science and provide consent for publication.

Availability of data and material and authors' information

CdW worked as a general practitioner in the West of Scotland in an area outside Health Boards A and B from 2007 to 2014 and was a part-time PhD student with Glasgow University from 2011 to 2017. PB and COD both have extensive experience of primary care research and education and were CdW's educational supervisors. CdW had met a small number of the participants in passing prior to the study while attending different educational events, but there had been no significant previous social or professional interactions. The data and material are available on request from the corresponding author.

Study funding

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Competing interests

The authors declare that they have no competing interests.

Author contributions

CW: concept, study design, data analysis, co-development and critical review of manuscript. COD: data analysis. PB and COD: concept, study design, co-development and critical review of manuscript, study guarantors.

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Box 1. Summary of the Quality and Outcomes (QOF) Framework

The QOF was a major component of the General Medical Services (GMS) contract between UK general practices and the NHS (65). It was introduced in April 2004 to help address longstanding variation in the quality of primary care provision (66). The QOF was the largest pay-for-performance scheme in international healthcare and one of the most important, influential but also controversial initiatives ever to be implemented in UK general practice. The QOF measured participating practices' performances annually against a range of evidence-based or pre-agreed 'point-in-time' indicators. Practices 'earned' points according to their level of achievement for each indicator, with payment starting at a minimum threshold (usually 40%) rising to a maximum (usually 90%). Points were weighted according to the practice list size and were worth from tens to hundreds of pounds each. Participation in the QOF was voluntary, but the reality was that most practices would not have been viable business concerns if they had opted out. Consequently, virtually all Scottish general practices with GMS contracts participated in the QOF as it was one of their main potential sources of income. QOF was decommissioned in Scotland in April 2016 (67) and replaced, in part, with GP clusters – groups of 6-8 practices with Practice Quality Leads and a Cluster Quality Lead who are responsible for assessing, managing and improving care quality (57).

Box 2. Practical application of the Trigger Review Method (TRM) in general practice

The TRM allows clinicians, e.g. GPs, GP registrars and practice nurses, to screen samples of patient records (n=±25) from their own practice for previously undetected patient safety incidents (PSI) in a structured, focused, rapid and active manner:

- Structured - each of the five sections of a primary care record are screened in turn. The five sections are: clinical encounters; medication; clinical codes; correspondence; and investigations.
- Focused – reviewers search for pre-defined 'triggers'. Triggers are prompts, sentinel phrases or 'signs' in the record that *may* indicate the occurrence of PSIs.
- Rapid - a maximum of 20 minutes is allocated per record and only a pre-specified period in each record is reviewed (three calendar months.
- Active **–** clinicians are encouraged to reconstruct each patient journey and probe, analyse and critically appraise the record for evidence of PSIs and latent risks hidden in it.

Clinicians record their findings, reflections and actions on a '*Trigger Review Summary Sheet'* (SS). The SS is a double-sided template for collecting and summarizing data on the number of detected triggers, the details of any PSIs uncovered, any learning needs identified and actions that were or should be taken because of the review process. Clinicians are encouraged to share the findings from the trigger reviews with their practice team and to involve them in subsequent improvement actions.

The TRM has three consecutive steps: (1) Planning and preparation; (2) Review of records; and (3) Reflection and action. Practice managers and non-clinical staff are involved in steps 1 and 3 but do not perform trigger reviews (step 2). In our experience, clinical reviewers require on average 2-3 hours of protected time to apply the method and perform a 'trigger review' effectively. Two trigger reviews per year seems to be generally acceptable and feasible. Clinicians should receive 1-2 hours of training individually or in groups before they apply the TRM for the first time. Training is flexible but included as a minimum: a short presentation about the TRM; opportunities to practice trigger reviews using simulated patient records with facilitation and real-time feedback and provision of an educational support package.

Box 3. Example of the potential value of the TRM

While screening a sample of patient records (n=25), GP03 identified an elderly patient with established chronic kidney disease (CKD) who had not been added to the practice register and had not been offered the recommended ACE/ARB treatment. She recorded the PSI (suboptimal treatment of a patient with CKD) on the trigger review SS and rated it as low severity and high preventability. GP03 expressed surprised at detecting this PSI because the patient had consulted with her on several previous occasions in the preceding months. She described how her first actions had been to add him to the relevant chronic disease register, request a repeat eGFR blood test to check his renal function and that she arranged a review appointment to monitor his blood pressure and discuss potential further treatment. While reflecting on this incident, she identified a professional learning need about the management of CKD and subsequently addressed it. The incident was also discussed during a practice meeting and the team decided to update the practice protocol for the management of CKD and to perform a clinical audit to measure and improve the management of their patients with CKD.

Table 1. The NPT framework in relation to the TRM

Constructs	Components	Description
Coherence		The work to understand the TRM
	Differentiation	The work participants do to understand the differences and similarities between the TRM and other QI methods
	Communal Specification	The work required to understand the purpose and potential benefits of the TRM
	Individual Specification	Understanding the effort required to implement the TRM. Is the TRM perceived as feasible and a priority?
	Internalization	the work individuals and teams did to understand how the TRM 'fits in' with their culture and existing work. Is it acceptable?
Cognitive Participation		The relational work required to build and sustain a community of practice around the TRM
	Initiation	The work of ensuring that staff and clinicians are willing and able to use the TRM
	Enrolment	The work of identifying and recruiting the necessary people and ensuring the remain engaged in the process
	Activation	The continuing support work that is necessary to disseminate trigger review findings, create opportunities for improvement and sustain the use of the TRM
	Legitimation	The work individuals and teams do to justify their involvement with the TRM to themselves and others
Collective Action		The operational work required to enact the TRM. It requires participants to invest effort
	Interactional workability	The work of applying the TRM, the time and effort this required and the outcomes, i.e. whether and what type of PSIs they detected and the subsequent improvement actions they took
	Relational integration	The work of building confidence in the TRM, their own and colleagues' abilities to effectively apply it and trust that the findings are accurate
	Skill-set workability	The work of dividing tasks, allocating resources and assessing the skills of the available team members
	Contextual integration	The work of integrating the TRM into existing structures, contexts and policies. It includes allocation of adequate resources and leadership support of the TRM

Reflexive Monitoring		The work of assessing and appraising the individual and communal worth of the TRM
	Systemisation	The work of collecting and analysing data about the TRM
	Individual appraisal	The work of evaluating the value (usefulness, worth) of the TRM for the clinician reviewer, her practice and patients
	Communal appraisal	The work of evaluating the value of the TRM for other practices and their patients
	Reconfiguration	The work of adapting the TRM, team or contexts

Table 2. Demographic data of the participating practices

Practice no	Patient list size*	GPs (n)		Area	Training practice (Yes/No)
		Partners	Other		
1	2100	1	-	Semi-rural	No
2	4300	3	1 salaried	Urban	Yes
3	3200	1	1 salaried 1 long-term locum	Urban	No
4	4100	3	1 Retainer	Urban	Yes
5	11000	8	-	Semi-rural	Yes
6	5900	4	1 Salaried	Urban	Yes
7	8200	7	-	Urban	Yes
8	6800	3	2 Salaried	Urban	Yes
9	6400	3	1 Salaried	Urban	No
10	9900	6	1 Retainer	Urban	Yes
11	3000	4	1 Retainer	Urban	Yes
12	7500	6	1 Salaried	Urban	Yes

*Rounded to the nearest hundred at the beginning of the study period

Table 3. Coherence factors that facilitated or hindered TRM implementation

NPT components	Factors	Selected verbatim quotes
Differentiation	Implementation was facilitated when respondents understood the TRM was a new QI approach, but complementary to existing methods such as clinical audit.	[The TRM] is essentially looking to pick up an SEA I suppose. That's the way that you could look at it - if you need an SEA that's a good way to find one' (GP07)
Communal specification	When participants understood the TRM's intended aims and potential benefits they were more likely to use it and achieve positive outcomes	'I think it's useful as a learning tool to learn about your own systems and a way of trying to improve those systems and a way of learning as a team with the results' (GP05)
Individual specification	All participants were concerned that the available time and resources would be insufficient to implement the TRM. However, the vast majority found the TRM to be feasible, which then facilitated its further use	I think the first time doing the first couple of patients was a bit slow and because it's different and you're not quite sure where you're at. So it took a wee while, a couple of patients really to get into the swing of it. I did it again just last week and found it very quick and very easy to go through (GP02)
Internalization	Most participants perceived the TRM as acceptable and fitting with their culture, which facilitated its implementation.	You have to have systems in place that make a safe journey for the patient. So I guess that's why we think we should be doing [the TRM], whether it's a project or an incentive or not, because that's what we're all about really, bottom line (PM08)

Table 4. Cognitive participation factors that facilitated or hindered TRM implementation

NPT components	Factors	Selected verbatim quotes
Initiation	Training sessions and access to expert support facilitated implementation. However, training had to be flexible and fit with the practices' needs	'I've been trying to start the ground level approach of saying 'this is how it should be used', you know, used formatively and using it to look at your systems as well, and things like that' (GP05)
Enrolment	Initial recruitment of volunteers facilitated implementation. However, most practice nurses were assigned the TRM, which initially reduced the motivation of some	Sometimes you know that, although they're asking you [pause] it's going to come your way anyway (PN09)
Activation	The TRM was facilitated when findings were disseminated, and reviewers had sufficient autonomy and opportunity to enact change	I wasn't involved at all (PM10) I held a practice meeting afterwards to highlight that perhaps we aren't always that good (GP06)
Legitimation	Implementation of the TRM was facilitated when individuals and practice teams were able to justify investing time and resources in its application.	'I'm not sure if I'd have gone back to [the TRM] if it had disappeared off the horizon... you have to justify the time in order to make it happen' (GP06) I feel I always have to justify every single working minute I have in here (PN10)

Table 5. Collective action factors that facilitated or hindered TRM implementation

NPT components	Factors	Selected verbatim quotes
Interactional workability	Implementation was facilitated when PSIs were detected quickly and PSIs were unambiguous, serious, preventable and originated in primary care. A small minority of reviewers found no PSIs, which was a barrier to its future use	There's safe and there's safe. I mean there's life threatening and there's a slight error on certain things (PM03)
Relational integration	Participants had confidence in the TRM but felt unsure whether all other practices would apply it correctly. A minority of clinicians were concerned that the findings may be inappropriately interpreted or used.	You can do it properly or you can have a quick scamper through it and not find anything (GP04)
Skill-set workability	Implementation was hindered when practices didn't allocate adequate resources and time, or when time was allocated but not protected. The vast majority of clinician reviewers had the necessary skills and experience to perform trigger reviews	Time's the biggest killer. I think every practice could open twenty-four hours a day and still not have time. Every single thing that comes out: 'we'll get the practice nurse to do it' but just how thin do you get spread? (PN08)
Contextual integration	Inclusion of the TRM in existing GP contexts, such as the QOF, facilitated implementation	In my experience as an appraiser, I could see a lot of people doing this (GP05) I plan personally to use it with our trainees now (GP12)

Table 6. Reflexive monitoring factors that facilitated or hindered TRM implementation

NPT components	Factors	Selected verbatim quotes
Systematisation	The simple, one-page data collection template facilitated implementation by providing a clear, structured format and electronic data collection.	The form's helpful although it's perhaps a reporting tool. It forces you down the route of making you think (GP04)
Reconfiguration	The TRM was intentionally designed to be flexible, which facilitated its implementation.	We used the same list but I don't think we used the same patient's records (GP02)
Individual appraisal	The vast majority of respondents perceived the TRM as a useful approach to improve the safety of care and to identify learning needs and points	[We] got some really good outcomes from it: a couple of SEAs and an audit... There's learning for the system in there, so worthwhile, definitely worthwhile (GP04) I like this [the TRM] as a kind of start. Here's something we can do regularly that can actually show us how good we are or how bad we are or areas that we need to work at or where we need to go (PM03)
Communal appraisal	Most respondents perceived the TRM as a useful approach to further improve the quality and safety the care in the general practice setting	I think it's more valuable than QOF QP to be honest. I think it is looking internally you know - I think it has a value… it's just kind of embedding a culture within a practice (GP08)

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Supplementary file, Appendix 1. Interview schedule for general practitioners, practice managers and practice nurses

Introduction

- Hello...
- Thank you for agreeing to meet with me today. Please take a few minutes to read through the consent form. Feel free to discuss any concerns or ask for clarification before signing.
- The aim of this interview is to discuss your experience with the trigger review method (TRM).

General

This section will only be used for those respondents that did not participate in interview one.

Main question	*Additional question*	*Clarifying question*
What is your role in your practice?	How long have you been in this practice? How long have you worked in any primary care role?	

1. Coherence (i.e. 'meaning and sense making' by interviewees)

Main question	*Additional question*	*Clarifying question*
What are the benefits of the trigger review method (TRM)?	Who are likely to benefit? Is it clearly distinct from other interventions?	Patients? Staff? Are they likely to value the benefits?
Which findings or aspects of the TRM were unexpected?		

2. Cognitive participation (i.e. 'commitment and engagement')

Main question	*Additional question*	*Clarifying question*
What changes did you make as a result of the review findings?	If none, why?	It may be helpful to consider different levels, i.e. patient, practitioner, practice, primary care.
Who else could use the TRM?	Will they understand the rationale for the method? Will they be prepared to invest time and work in it?	

3. Collective action (i.e. 'work participants do' to make TRM 'function'

Main question	*Additional question*	*Clarifying question*
What did you think of the training session?	Was the training adequate? How could the training be improved?	What was your experience of the provided learning resources, venue, presenter and presenting style?
How compatible is the TRM with your existing work?	What (if any) impact does it have on different professional groups?	Consider: division of labour, resources, power, responsibility.
How does the TRM fit with the overall ethos of general practice?		How does it fit the wider organisational goals?
Who did you share the findings with?	If no one, why?	

4. Reflexive monitoring ('reflect on and appraise' the TRM)

Main question	*Additional question*	*Clarifying question*
How can the TRM be adapted or improved?		
What would help ensure that you continue using it?	Does the TRM have a role in appraisal, revalidation, education and training?	

Thank you for your time and participation.

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

	Reporting Item	Page Number
#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
#2	Summary of the key elements of the study using the abstract format of the intended publication; typically	2

		includes background, purpose, methods, results and conclusions	
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3-4
Purpose or research question	#4	Purpose of the study and specific objectives or questions	4
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	5
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	15

Context	#7	Setting / site and salient contextual factors; rationale	6
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	6
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	6, 15
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	6
Data collection instruments and technologies	#11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	6
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	7, 21
Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and	6,7

		security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	
Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	7,15
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	7
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	8-10
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	22-25
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	10-11
Limitations	#19	Trustworthiness and limitations of findings	12
Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were	12

		managed	
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	15

BMJ Open

Facilitators and barriers to safer care in general practice: a qualitative study of the implementation of the trigger review method using Normalisation Process Theory

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Facilitators and barriers to safer care in general practice: a qualitative study of the implementation of the trigger review method using Normalisation Process Theory

Carl de Wet[1,2,3], Paul Bowie[1,2] and Catherine A O'Donnell[2]

[1]Medical Directorate, NHS Education for Scotland, Glasgow, UK
[2] General Practice and Primary Care, Institute of Health and Wellbeing, University of Glasgow, UK
[3]School of Medicine, Griffith University, Gold Coast, Australia

Address for correspondence:
Associate Professor Carl de Wet
Level 8, School of Medicine, Griffith University, Southport, Gold Coast, Australia
Email: mailto:carl_dewet@yahoo.co.uk
Tel: (+61) 0450277315

e-Mail addresses of co-authors:
Dr Paul Bowie: paul.bowie@nes.scot.nhs.uk
Prof Catherine O'Donnell: kate.o'donnell@glasgow.ac.uk

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Word count: 4570

ABSTRACT

Objectives

Patient safety is a key concern of modern health systems, with numerous approaches to support safety. One, the Trigger Review Method (TRM), is promoted nationally in Scotland as an approach to improve the safety of care in general medical practice. However, it remains unclear which factors are facilitating or hindering its implementation. The aim of this study was to identify the important factors that facilitate or hinder the implementation of the TRM in this setting.

Methods

We conducted 28 semi-structured interviews with general practitioners (n=12), practice nurses (n=11) and practice managers (n=5) in Scotland. Data analysis was theoretically informed using normalization process theory (NPT).

Results

We identified four important factors that facilitated or hindered implementation: (1) the amount of time and allocated resources; (2) integration of the TRM into existing initiatives and frameworks facilitated implementation and justified participants' involvement; (3) the characteristics of the reviewers – implementation was facilitated by experienced, reflective clinicians with leadership roles in their teams; (4) the degree to which participants perceived the TRM as acceptable, feasible and useful.

Conclusions

This study is the first known attempt to investigate how the TRM is implemented and perceived by general practice clinicians and staff. The four main factors that facilitated TRM implementation are comparable with the wider implementation science literature, suggesting that a small number of specific factors determine the success of most, if not all, complex healthcare interventions. These factors can be identified, described and understood through theoretical frameworks such as NPT and are amenable to intervention. Researchers and policy makers should pro-actively identify and address these factors.

Strengths and limitations

- The convenience sample was a pragmatic choice and may not be representative of general practice in Scotland or the UK;
- The TRM were considered from the perspective of GPs, practice managers and nurses – the three staff groups that were critical to its successful implementation;
- A validated theoretical framework was used to analyse the data;
- Analysis was emergent and exploratory, and data were not 'shoe-horned' into the NPT framework;
- Thematic saturation was achieved

Introduction

Patient safety is a key concern of modern health care systems (1). The importance of patient safety first emerged in the hospital setting, due to the possibility of errors leading to patient death and disability (2, 3). However, patient safety is increasingly an area of concern in primary care (4, 5). In the UK, patient safety incidents (PSIs) have been defined as 'any unintended or unexpected incident which could have or did lead to harm for one of more patients receiving National Health Service care' (6). There is, however, a recognised difficulty in identifying and measuring PSIs and many remain undetected (7). This has led to variation in the estimation of PSIs in primary care, ranging from <1 to 24 PSIs per 100 consultations (4). While this may be lower than that reported for hospital care, the volume of consultations that take place in primary care (e.g. over 340 million general practice consultations in England in 2013) equates to the opportunity for substantial harm for approximately 300 000 patients each year (8). This has increased the urgency and effort with which policy makers, health care leaders, clinicians and researchers have responded (9). Programs, initiatives and interventions aiming to identify safety threats, reliably reduce ameliorable risks and measurably improve health care performance have proliferated, including in the National Health Service (NHS) of the United Kingdom (UK). Examples include the Department of Health's Patient Safety Research Portfolio and the Safer Patients Initiative and Safer Patients Network of the Health Foundation, a large and independent charity committed to bringing about better health in the UK(10-12).

In Scotland, a national Patient Safety Program (SPSP) was launched in 2008 with the ambitious aims of significantly reducing secondary care mortality and harm (13). As the programme became established in hospitals, it was expanded into primary care (SPSP-PC), beginning with general medical practice (14). The SPSP-PC aimed to measurably improve the safety of care provided in participating practices through three different strategies that were specifically developed or adapted for this purpose (15). They were: (i) detecting, learning from and reducing PSIs by applying the Trigger Review Method (TRM) (16, 17); (ii) measuring and building a strong and positive safety culture (18); and (iii) improving chronic disease and medication management by using a care bundle approach (19). All three methods have been the focus of research in different international health care settings, which have increased our understanding of their potential usefulness as interventions to improve patient safety (20-24). However, much

remains unknown, including which factors are associated with their successful implementation or lack thereof.

The TRM is essentially an adaptation of clinical record review (CRR) or 'case note audit', providing a structured way to rapidly screen samples of random electronic patient records for undetected PSIs. CRR is a well-established approach of detecting and quantifying sub-optimal care issues and is considered the gold standard in epidemiological type patient safety research (25). The key strength of CRR compared with other approaches is that it detects a significantly greater proportion of all PSIs (26). This is why the original landmark studies about the prevalence of adverse events in hospitals in the USA (27), UK (2), Australia (28), Canada (29) and New Zealand (30) all used some form of CRR adapted to their settings and purposes (26).

Development of the TRM commenced in 2007 in Scottish general practice, with subsequent testing in The Health Foundation-funded Safety and Improvement in Primary Care (SIPC) programme (15, 16). In 2013, the TRM was added to the Quality and Outcomes Framework of the UK General Medical Services contract (QOF, described in Box 1) with the expectation that it would be implemented nationally by Scottish general practices (c1000). A subsequent study of the implementation of the TRM found that most clinicians uncovered important patient safety concerns in their individual practices and took specific actions to improve the related care systems and processes (20). A description of the intended application of the TRM and a clinical example of its potential value are provided in Boxes 2 and 3 respectively.

Developing a potentially useful, complex healthcare intervention like the TRM is challenging. However, successfully implementing that intervention, sustaining its use and embedding it into routine practice are arguably even greater challenges (31, 32). Understanding the implementation of such interventions, including a clear explication of the barriers and facilitators to implementation, could prevent considerable amounts of time, effort and resources from being squandered. Despite the TRM being promoted and implemented in general practice nationally across Scotland, it remains unclear which factors are facilitating or hindering the success or otherwise of this process, and their relative importance in determining whether, or to what degree, this intervention can be integrated into routine practice. The aim of this study, therefore, was to identify the important contextual, organisational and resource factors that facilitated or hindered the implementation of the trigger review method (TRM) in Scottish general medical practice.

A theoretical framework was used to underpin the data collection, analysis and interpretation of the findings.

Use of theory to understand the implementation of patient safety initiatives

It is now accepted that the application of a theoretical lens can greatly enhance our understanding of the organisational and contextual factors which influence the implementation of quality improvement and patient safety initiatives (33-35). The Medical Research Council (MRC) guidelines recommend the explicit application of theory from the earliest stages of designing and implementing complex healthcare interventions, such as the TRM, to reduce the likelihood that important factors will be overlooked (36, 37). There are two reasons for this. First, complex interventions such as the TRM are often a 'black box', with a lack of clarity about which elements are implemented well, and why (34). Secondly, such complex interventions are implemented in a dynamic and on-going social context, shaped by the actors using them and by the wider organisational and socio-cultural structures into which the intervention – in this case the TRM – is placed (38, 39).

Selecting the most suitable theory from the large, complex and diverse range of options can then be informed by the specific requirements of the study and researchers (40, 41). As this study was principally concerned with the 'work' that practitioners had to do to implement the TRM, both as individuals and collectively in practices, and how that interacted with their work-based context, we selected Normalisation Process Theory (NPT) as our theoretical framework. NPT is a socio-technical, middle-range theory about the 'work' people do collectively and as individuals to implement and sustain an intervention. It has been successfully used in multiple studies and international health care settings and is particularly useful for describing, understanding and evaluating complex health care interventions such as the TRM (42-44).

The NPT framework consists of four main 'constructs' (45). They are:

- Coherence - the work implementers do to understand an intervention;
- Cognitive participation - the relational work to build a community of practice around an intervention;
- Collective action - the operational work of enacting an intervention; and
- Reflexive monitoring - the work of assessing and reconfiguring an intervention.

Each construct is divided further into four components, which promotes a nuanced understanding of the implementation process. The NPT constructs and components and how they relate to the TRM are described in Table 1.

Methods

Study design

Qualitative study employing semi-structured interviews with general practitioners (GP), practice nurses (PN) and practice managers (PM). A range of different types of general practice staff was included in the study to allow exploration and comparison of the perceptions of clinicians and non-clinicians and practice owners or partners and salaried employees. We used the Standards for Reporting Qualitative Research (SRQR) checklist for the study and manuscript (46).

Setting and sample

In Scotland, the organisational structure of the publicly-funded NHS consists of 14 regional 'Boards' who are responsible for the delivery of frontline health services and improving the health of the populations resident in their respective geographical areas (47). This study was undertaken in the West of Scotland in two of the Boards: one covering a large, urban setting with 262 general practices (designated Health Board A); the other covering a mixed urban-rural setting, with 56 practices (Health Board B). In April 2012, all practice managers in each Board area were sent written information via e-mail about the proposed study and an invitation for the PM and at least one GP and a PN to receive TRM training (Box 2) and participate. Due to resource constraints, recruitment stopped when 12 practices had agreed to participate. A convenience sample of GP practices was constructed to reflect the relative numerical distribution: 10 practices from Board A and 2 from Board B.

Patient and public involvement

Patients and the public were not involved in the design or planning of this study..

Data collection

The interview schedule was derived from the NPT framework and agreed by the authors (Supplementary file, Appendix 1). The interviews were conducted in the practice premises of participants at a time convenient to them. Informed consent was obtained from study participants prior to the interviews being conducted and after the purpose of the interview had been explained and anonymity assured. All interviews were conducted by the same investigator (CdW) who introduced himself as a GP and a researcher and explained that the interviews were confidential, candid and participants had no obligation to report 'successes' with the TRM or the implementation process. Interviews were conducted between January 2013 and July 2013 and lasted

approximately 45 minutes. They were digitally recorded and supplemented with contemporaneous field notes.

Data analysis

All interviews were transcribed verbatim to preserve colloquialisms, repetition and other non-verbal communication that could aid data interpretation but were not reviewed by participants. Transcripts were anonymised and the twelve participating practices assigned a unique identifier. This identifier was applied to every participant within a given practice. Participants from the same practice were differentiated by adding a further, unique identifier as a prefix, derived from their professional role: general practitioner – GP; practice nurse – PN; and practice manager – PM.

Data coding was led by CdW and COD and was informed by a framework approach using a coding frame informed by NPT (48). First, data were coded broadly to one of the four main NPT constructs. Following this, data were coded in greater detail to the specific NPT components of each construct; for example, data pertaining to understanding of the TRM (coherence) were then re-read and further coded to the sub-constructs of differentiation, communal or individual specification, and internalisation. Data could be double-coded to more than one sub-construct. The codes were then analysed in conjunction with the related, reflective memos to interpret the emerging views and themes and compare the perceptions of the different staff groups. The codes and themes were mapped and displayed using NVivo version 9.2.81.0. All authors met regularly to discuss the findings, ensure consistency and agree and verify data interpretations.

Care was taken, however, to ensure that the analysis was emergent and exploratory, and that data were not 'shoe-horned' into the NPT framework. Data that fell out with the NPT framework were assigned stand-alone codes and analysed separately to this study. The authors recognised, for example, that some data described *how* the TRM influenced participants and outcomes, rather than the 'work' of implementation, and therefore assigned different codes such as 'patient safety mindset' and 'learning moments' (unpublished - available on request from the corresponding author).

Results

Demographic data from the participating practices are summarized in Table 2. A total of 28 interviews were conducted with GPs (n=12), PNs (n=11) and PMs (n=5). One practice did not have a nurse during the study period, two PMs had to withdraw from the study due to unexpected personal reasons and another practice had a practice nurse (PN01) with the dual role of PM. The PMs of the remaining four practices were willing to be interviewed but were excluded because concurrent data analysis indicated that data saturation was achieved as no new data or insights were obtained from the last few interviews.

The results section is structured according to the four main constructs of the NPT framework. The study findings relating to each construct is described in the text and summarised as a Table with selected, verbatim quotes. The four NPT constructs are: Coherence (Table 3), Cognitive Participation (Table 4), Collective Action (Table 5) and Reflexive Monitoring (Table 6).

Coherence – the work individuals and teams did to understand the TRM (Table 3)

Many participants explained their understanding of the TRM by comparing it with other quality improvement (QI) methods they were already familiar with through QOF, such as clinical audit and significant event analysis (SEA). However, despite the similarities between the TRM and other QI methods, participants also recognized sufficient differences for it to be perceived as a 'new' method.

Most participants initially expressed concerns that implementing the TRM would increase their workload and require additional resources and time. This perception was moderated as their understanding of the TRM increased by implementing it and they realised that the actual workload and time requirements were lower than they initially expected. For example, GP02 described getting '*bogged down'* during the first trigger review but learnt from this experience and was able to apply the method more efficiently the second time. Most reviewers found the second trigger reviews quicker and easier, even though this did not necessarily mean the findings were more important or helpful.

Cognitive participation – establishing a community of practice around the TRM (Table 4)

The initial work that was required to implement the TRM in practices was mainly done by GPs. They were motivated to undertake the work because of expressed interests in the quality of care they deliver and a desire to proactively identify and reduce potential safety threats. These 'champions' subsequently enrolled other members of their practice team to conduct TRMs using one of two strategies. The first and most common strategy was to assign specific responsibilities or tasks to individual team members. Most of the practice nurses, managers and administrative staff were recruited in this way. The second strategy was to recruit team members opportunistically when they expressed an interest in participation, which is how most GP colleagues within participating practices were recruited. Perhaps unsurprisingly then, GPs were more motivated to implement the TRM compared with practice nurses – at least initially.

GP trainees, inexperienced practice nurses and some salaried GPs were able to detect and learn from PSIs but their attempts to improve care were typically aimed at individual or small groups of patients. In contrast, GP partners and experienced practice nurses were able to disseminate learning points and act to improve care at practice and regional levels through their leadership roles and because of their ability to positively influence the rest of their team. However, a few participants were opposed to sharing the trigger review findings with anyone outside their practice team because of concerns that the data may be misinterpreted.

Factors that helped to legitimise the TRM facilitated its successful implementation. Participants felt justified in allocating additional time and resources to implement the TRM because of its inclusion in the QOF. They also perceived it as an acceptable professional activity because of its QI relevance to medical appraisal and GP specialty training. In addition, the endorsement of the TRM by their peers and professional organisations, such as the Royal College of General Practitioners (RCGP), helped to justify their participation and increased their willingness to continue using the TRM.

Collective action – the work of enacting the TRM and integrating it with existing practices and contexts (Table 5)

Implementation of the TRM was facilitated when reviewers detected PSIs quickly and the PSIs were unambiguous and perceived as serious, preventable and originating in primary care. The small minority of reviewers who were unable to detect a single PSI or

only detected a few PSIs of low severity typically perceived this as an important barrier to the TRM's use. However, some reviewers alternatively interpreted 'finding nothing' as evidence for safe, high quality care in the clinical area being scrutinised.

Implementation of the TRM was facilitated when practices allocated adequate resources and sufficient time for clinicians to conduct trigger reviews without interruptions. While most practices allocated at least some protected time for TRM work, it was seldom adequate or uninterrupted. As a result, some reviewers reported that they conducted the reviews during their leisure time or in-between other tasks. Most reviews were interrupted because of urgent clinical tasks. Some reviewers were aware of a constant feeling of other tasks '*piling up'* and a compulsion to check their workload, which distracted them from completing the trigger reviews.

The personal and professional characteristics of the clinician reviewers strongly influenced the implementation of the TRM. Experienced, enthusiastic clinicians who were motivated and able to critically reflect on the review process and how the detected PSIs may impact on care delivery and practice systems were more likely to report successfully implementing the TRM. They explained that applying the TRM in a 'tick box' manner reduced its effectiveness. While this was not considered an issue for the practice teams in this study, the participants were concerned that a substantial minority of other practices might adopt this approach in practice. Therefore, while most participants thought that incentivizing the TRM through its inclusion in QOF was the key factor determining its uptake in the wider general practice community, they also expressed concern that a superficial, 'tick box' approach would reduce its potential usefulness.

A substantial minority of practices nurses were initially uncertain whether they would be able to apply the TRM successfully. Some clinicians also lacked confidence in the validity of their early findings or the findings of other reviewers. Despite these misgivings, most practice nurses were able to detect PSIs, share the findings with their teams and recommend or make specific improvements within their practices. The confidence of all the participants in the TRM and their own skills and findings increased with time and experience, which helped facilitate its successful implementation.

Reflexive monitoring – the work of adapting and evaluating the TRM (Table 6)

Many participants identified the flexibility of the TRM, adapting it according to specific practice or reviewer requirements, as an important facilitating factor for its successful

implementation. However, only two clinicians modified the method, the changes were minor and did not affect the outcomes.

Most participants perceived the TRM as a useful approach to improve the care they delivered to their patients, and for general practice in its wider sense. They also recognized its potential for identifying learning needs and points, encouraging reflection and raising awareness of potential safety threats. For these reasons, the TRM was considered to have equal or more value than existing quality improvement methods. However, while the TRM's perceived usefulness was identified as an important facilitator for its implementation and was felt to increase the likelihood of it being used again in the future, all respondents were clear that evidence of its usefulness, while important, was insufficient in itself to ensure normalization into routine practice. Successful normalisation would also require contextual integration, adequate protected time and additional resources.

Discussion

We identified four main factors that facilitated or hindered the implementation of the TRM in Scottish general practice. The first factor was whether the amount of time and resources allocated to conduct trigger reviews were sufficient to enable implementation. The second factor was integration of the TRM in an established, national initiative (the QOF). This was a particularly important enabler, as it provided a financial incentive and professional justification for clinicians to implement the TRM. The third factor was the characteristics of the clinician reviewers. Implementation was facilitated by experienced clinicians with leadership roles in their practice teams. The fourth factor was the perceptions of the participants of the TRM, informed by their own practical experiences of using it. Implementation was facilitated if they understood it as acceptable, feasible and useful.

Practical implications and comparison with existing literature

Devlin et al recently identified three key areas for researchers and policy makers to pro-actively consider for future, large-scale improvement initiatives if they are to be successfully implemented and normalised (49). They are: time; what the authors refer to as 'readiness', which is the product of resources and clinician engagement; and information technology (IT). An earlier systematic literature review about the influence of context on quality improvement in healthcare identified a slightly larger number of important 'success' factors: senior leadership; organisational culture; information

systems; previous experience of quality improvement; clinician engagement; and resources (50). Braithwaite et al identified eight comparable factors that determine implementation outcomes: preparing for change; capacity for implementation - setting; capacity for implementation – people; types of implementation; resources; leverage; sustainability; and desirable implementation enabling features (51).

The evidence from this study and the wider implementation science literature therefore suggest that a small number of specific factors are instrumental in facilitating or hindering the implementation of most, if not all, complex healthcare interventions. These factors can be identified, described and understood and are amenable to intervention. It is important for policy makers, health care professionals and researchers to proactively consider these factors when they are designing, implementing and evaluating new initiatives.

Providing frontline clinicians and staff with validated improvement methods and tools, education and training and 'expert' support are examples of important factors that are often included in improvement initiatives. However, they are insufficient to reliably improve care or change systems without the visible support of senior leaders and allocation of adequate resources and time (42, 49, 52, 53). This helps to explain why implementation of the TRM was greatly facilitated by its inclusion in an established, national Framework – it clearly demonstrated senior leadership support and provided additional resources through financial incentives. While the need for allocating sufficient resources may seem self-evident, many improvement interventions receive no funding or funding for the implementation stage only, and even then the initial investments may be inadequate (42). It is therefore unsurprising than many interventions fail to become normalised despite evidence of their usefulness.

Strengths and limitations of this study

A unique strength of this study is that it is the first known attempt to investigate how the TRM is implemented in primary care by exploring the perceptions of clinicians and their general practice teams. A second strength is the use of a validated theoretical framework, which is recommended for research in the discipline of implementation science (37). A third strength is that the perceptions and experiences of the three different staff groups that were critical to the successful implementation of the TRM were considered. Because practices nurses also performed trigger reviews, the 'nursing' and 'medical' experiences and views could be compared. However, we found that the perceptions of the participants were highly congruent and independent of their

roles and experience. A fourth strength is the different characteristics of participating practices, i.e. training and non-training; semi-rural to urban locations and small to large patient populations.

The study has at least three limitations. The sampling strategy was a pragmatic choice and this group of volunteers may therefore not be representative of general practices in Scotland or other countries in the UK. However, thematic saturation was achieved and, in our opinion, more interviews would not have materially strengthened the main findings. Applying a theoretical framework to data raises potential concerns that researchers may be constrained by theory and miss important findings, or alternatively may 'shoe horn' data into existing themes. However, our experiences were similar to those of other researchers, which is that very little data fell outside the NPT framework, and the data that did were either too diffuse to be meaningful or did not directly relate to the main study aims (44, 54). The third limitation is potential researcher bias. The analysis of qualitative data is inevitably influenced by the previous experiences and other characteristics of the researchers. A concerted effort was made to account for subjectivity through a combination of reflection, rigorous application of a transparent analysis process and by evaluating the veracity of the results against the international literature.

Next steps

Patient safety remains a high priority in primary care worldwide. The National Quality Strategy specifies six health care priorities for the United States of America (USA), of which the first is to 'make care safer' (55). One the main levers they use to achieve this aim is 'learning and technical assistance', i.e. offering training and improvement tools.

In Scotland, GPs can submit trigger review findings as part of the mandatory QI Activity evidence required for appraisal purposes (56). The 'National Framework for Quality and GP Clusters' (see Box 1) identified a role for the TRM and recommends '*structured review of high risk patient records*' as one of nine validated safety improvement tools to the new Clusters (57). The RCGP has included the method in their patient safety toolkit as a potential evidence source for supporting medical revalidation of GPs in the UK (58). In England, Clinical Commissioning Groups (CCGs) were established in 2013 with two important but distinct roles: to commission secondary and community care services for their populations; and to support quality improvement in general practice (59). While the first role has received most attention to date, the second role is equally important

and a legal duty that will require greater clinical engagement and validated tools, such as the TRM (60, 61).

The Australian Commission on Safety and Quality in Healthcare started a consultation in October 2017 as a first step in developing a national approach to support improvements in patient safety and quality in primary care (62). Although the consultation is ongoing, it seems reasonable to assume that any approach will have to include the 31 Primary Health Networks (PHNs) that were established in 2015 to better integrate care and to ensure that all Australian patients '*receive the right care in the right place at the right time'* (63). The approach will also require a cohesive implementation strategy, validated tools such as the TRM and allocation of adequate resources. The 'medical homes' initiative provides a practical example of how existing funding arrangements can be adapted at the federal level to encourage a more flexible approach to health care (64).

All these examples demonstrate a need for validated tools. However, it is unclear whether any organisation has fully considered or comprehensively addressed the main factors that are known to facilitate or hinder the effective, routine use of improvement methods. The pressing questions are therefore whether and to what extent the use of improvement tools like the TRM will become normalised in specific healthcare settings like general practice, and how this process can best be supported.

Conclusion

We identified four important factors that facilitated the implementation of the TRM in Scottish general practice. The factors are comparable with the wider implementation science literature, suggesting that a small number of specific factors are instrumental in facilitating or hindering the implementation of most, if not all, complex healthcare interventions. These factors can be identified, described and understood through theoretical frameworks such as NPT and are amenable to intervention. This may allow researchers and policy makers to pro-actively identify and address the main factors that are known to facilitate or hinder the implementation and normalisation of improvement initiatives. Normalisation of the TRM therefore seems likely if the following factors could be guaranteed: clinicians have the necessary knowledge and skills to apply the TRM effectively; there is senior leadership support for the TRM at practice and national levels; adequate resources and time are provided to conduct trigger reviews; and it is formally integrated into existing professional activities, government policies and national improvement initiatives.

Footnotes

Ethical approval and consent to participate

The study was submitted to and approved by the Glasgow University's College of Medicine, Veterinary & Life Science's Ethical Committee, reference number 2012054. All participants provided written, informed consent before the interviews were conducted.

Consent for publication

The authors have read and accept the terms and conditions of Implementation Science and provide consent for publication.

Availability of data and material and authors' information

CdW worked as a general practitioner in the West of Scotland in an area outside Health Boards A and B from 2007 to 2014 and was a part-time PhD student with Glasgow University from 2011 to 2017. PB and COD both have extensive experience of primary care research and education and were CdW's educational supervisors. CdW had met a small number of the participants in passing prior to the study while attending different educational events, but there had been no significant previous social or professional interactions. The data and material are available on request from the corresponding author.

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Competing interests

The authors declare that they have no competing interests.

Author contributions

CW: concept, study design, data analysis, co-development and critical review of manuscript. COD: data analysis. PB and COD: concept, study design, co-development and critical review of manuscript, study guarantors.

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Box 1. Summary of the Quality and Outcomes (QOF) Framework

The QOF was a major component of the General Medical Services (GMS) contract between UK general practices and the NHS (65). It was introduced in April 2004 to help address longstanding variation in the quality of primary care provision (66). The QOF was the largest pay-for-performance scheme in international healthcare and one of the most important, influential but also controversial initiatives ever to be implemented in UK general practice. The QOF measured participating practices' performances annually against a range of evidence-based or pre-agreed 'point-in-time' indicators. Practices 'earned' points according to their level of achievement for each indicator, with payment starting at a minimum threshold (usually 40%) rising to a maximum (usually 90%). Points were weighted according to the practice list size and were worth from tens to hundreds of pounds each. Participation in the QOF was voluntary, but the reality was that most practices would not have been viable business concerns if they had opted out. Consequently, virtually all Scottish general practices with GMS contracts participated in the QOF as it was one of their main potential sources of income. QOF was decommissioned in Scotland in April 2016 (67) and replaced, in part, with GP clusters – groups of 6-8 practices with Practice Quality Leads and a Cluster Quality Lead who are responsible for assessing, managing and improving care quality (57).

Box 2. Practical application of the Trigger Review Method (TRM) in general practice

The TRM allows clinicians, e.g. GPs, GP registrars and practice nurses, to screen samples of patient records (n=±25) from their own practice for previously undetected patient safety incidents (PSI) in a structured, focused, rapid and active manner:

- Structured - each of the five sections of a primary care record are screened in turn. The five sections are: clinical encounters; medication; clinical codes; correspondence; and investigations.
- Focused – reviewers search for pre-defined 'triggers'. Triggers are prompts, sentinel phrases or 'signs' in the record that *may* indicate the occurrence of PSIs.
- Rapid - a maximum of 20 minutes is allocated per record and only a pre-specified period in each record is reviewed (three calendar months).
- Active **–** clinicians are encouraged to reconstruct each patient journey and probe, analyse and critically appraise the record for evidence of PSIs and latent risks hidden in it.

Clinicians record their findings, reflections and actions on a '*Trigger Review Summary Sheet'* (SS). The SS is a double-sided template for collecting and summarizing data on the number of detected triggers, the details of any PSIs uncovered, any learning needs identified and actions that were or should be taken because of the review process. Clinicians are encouraged to share the findings from the trigger reviews with their practice team and to involve them in subsequent improvement actions.

The TRM has three consecutive steps: (1) Planning and preparation; (2) Review of records; and (3) Reflection and action. Practice managers and non-clinical staff are involved in steps 1 and 3 but do not perform trigger reviews (step 2). In our experience, clinical reviewers require on average 2-3 hours of protected time to apply the method and perform a 'trigger review' effectively. Two trigger reviews per year seems to be generally acceptable and feasible. Clinicians should receive 1-2 hours of training individually or in groups before they apply the TRM for the first time. Training is flexible but included as a minimum: a short presentation about the TRM; opportunities to practice trigger reviews using simulated patient records with facilitation and real-time feedback and provision of an educational support package.

Box 3. Example of the potential value of the TRM

While screening a sample of patient records (n=25), GP03 identified an elderly patient with established chronic kidney disease (CKD) who had not been added to the practice register and had not been offered the recommended ACE/ARB treatment. She recorded the PSI (suboptimal treatment of a patient with CKD) on the trigger review SS and rated it as low severity and high preventability. GP03 expressed surprise at detecting this PSI because the patient had consulted with her on several previous occasions in the preceding months. She described how her first actions had been to add him to the relevant chronic disease register, request a repeat eGFR blood test to check his renal function and that she arranged a review appointment to monitor his blood pressure and discuss potential further treatment. While reflecting on this incident, she identified a professional learning need about the management of CKD and subsequently addressed it. The incident was also discussed during a practice meeting and the team decided to update the practice protocol for the management of CKD and to perform a clinical audit to measure and improve the management of their patients with CKD.

Table 1. The NPT framework in relation to the TRM

Constructs	Components	Description
Coherence		The work to understand the TRM
	Differentiation	The work participants do to understand the differences and similarities between the TRM and other QI methods
	Communal Specification	The work required to understand the purpose and potential benefits of the TRM
	Individual Specification	Understanding the effort required to implement the TRM. Is the TRM perceived as feasible and a priority?
	Internalization	The work individuals and teams did to understand how the TRM 'fits in' with their culture and existing work. Is it acceptable?
Cognitive Participation		The relational work required to build and sustain a community of practice around the TRM
	Initiation	The work of ensuring that staff and clinicians are willing and able to use the TRM
	Enrolment	The work of identifying and recruiting the necessary people and ensuring the remain engaged in the process
	Activation	The continuing support work that is necessary to disseminate trigger review findings, create opportunities for improvement and sustain the use of the TRM
	Legitimation	The work individuals and teams do to justify their involvement with the TRM to themselves and others
Collective Action		The operational work required to enact the TRM. It requires participants to invest effort
	Interactional Workability	The work of applying the TRM, the time and effort this required and the outcomes, i.e. whether and what type of PSIs they detected and the subsequent improvement actions they took
	Relational Integration	The work of building confidence in the TRM, their own and colleagues' abilities to effectively apply it and trust that the findings are accurate
	Skill-set Workability	The work of dividing tasks, allocating resources and assessing the skills of the available team members
	Contextual Integration	The work of integrating the TRM into existing structures, contexts and policies. It includes allocation of adequate resources and leadership support of the TRM

Reflexive Monitoring		The work of assessing and appraising the individual and communal worth of the TRM
	Systemisation	The work of collecting and analysing data about the TRM
	Individual appraisal	The work of evaluating the value (usefulness, worth) of the TRM for the clinician reviewer, her practice and patients
	Communal appraisal	The work of evaluating the value of the TRM for other practices and their patients
	Reconfiguration	The work of adapting the TRM, team or contexts

Table 2. Demographic data of the participating practices

Practice no	Patient list size*	GPs (n)		Area	Training practice (Yes/No)
		Partners	Other		
1	2100	1	-	Semi-rural	No
2	4300	3	1 salaried	Urban	Yes
3	3200	1	1 salaried 1 long-term locum	Urban	No
4	4100	3	1 Retainer	Urban	Yes
5	11000	8	-	Semi-rural	Yes
6	5900	4	1 Salaried	Urban	Yes
7	8200	7	-	Urban	Yes
8	6800	3	2 Salaried	Urban	Yes
9	6400	3	1 Salaried	Urban	No
10	9900	6	1 Retainer	Urban	Yes
11	3000	4	1 Retainer	Urban	Yes
12	7500	6	1 Salaried	Urban	Yes

*Rounded to the nearest hundred at the beginning of the study period

Table 3. Coherence factors that facilitated or hindered TRM implementation

NPT components	Factors	Selected verbatim quotes
Differentiation	Implementation was facilitated when respondents understood the TRM was a new QI approach, but complementary to existing methods such as clinical audit or significant event analysis (SEA).	[The TRM] is essentially looking to pick up an SEA I suppose. That's the way that you could look at it - if you need an SEA that's a good way to find one' (GP07)
Communal specification	When participants understood the TRM's intended aims and potential benefits they were more likely to use it and achieve positive outcomes	'I think it's useful as a learning tool to learn about your own systems and a way of trying to improve those systems and a way of learning as a team with the results' (GP05)
Individual specification	All participants were concerned that the available time and resources would be insufficient to implement the TRM. However, the vast majority found the TRM to be feasible, which then facilitated its further use	I think the first time doing the first couple of patients was a bit slow and because it's different and you're not quite sure where you're at. So it took a wee while, a couple of patients really to get into the swing of it. I did it again just last week and found it very quick and very easy to go through (GP02)
Internalization	Most participants perceived the TRM as acceptable and fitting with their culture, which facilitated its implementation.	You have to have systems in place that make a safe journey for the patient. So I guess that's why we think we should be doing [the TRM], whether it's a project or an incentive or not, because that's what we're all about really, bottom line (PM08)

Table 4. Cognitive participation factors that facilitated or hindered TRM implementation

NPT components	Factors	Selected verbatim quotes
Initiation	Training sessions and access to expert support facilitated implementation. However, training had to be flexible and fit with the practices' needs	'I've been trying to start the ground level approach of saying 'this is how it should be used', you know, used formatively and using it to look at your systems as well, and things like that' (GP05)
Enrolment	Initial recruitment of volunteers facilitated implementation. However, most practice nurses were assigned the TRM, which initially reduced the motivation of some	Sometimes you know that, although they're asking you [pause] it's going to come your way anyway (PN09)
Activation	The TRM was facilitated when findings were disseminated, and reviewers had sufficient autonomy and opportunity to enact change	I wasn't involved at all (PM10) I held a practice meeting afterwards to highlight that perhaps we aren't always that good (GP06)
Legitimation	Implementation of the TRM was facilitated when individuals and practice teams were able to justify investing time and resources in its application.	'I'm not sure if I'd have gone back to [the TRM] if it had disappeared off the horizon... you have to justify the time in order to make it happen' (GP06) I feel I always have to justify every single working minute I have in here (PN10)

Table 5. Collective action factors that facilitated or hindered TRM implementation

NPT components	Factors	Selected verbatim quotes
Interactional workability	Implementation was facilitated when PSIs were detected quickly and PSIs were unambiguous, serious, preventable and originated in primary care. A small minority of reviewers found no PSIs, which was a barrier to its future use	There's safe and there's safe. I mean there's life threatening and there's a slight error on certain things (PM03)
Relational integration	Participants had confidence in the TRM but felt unsure whether all other practices would apply it correctly. A minority of clinicians were concerned that the findings may be inappropriately interpreted or used.	You can do it properly or you can have a quick scamper through it and not find anything (GP04)
Skill-set workability	Implementation was hindered when practices didn't allocate adequate resources and time, or when time was allocated but not protected. The vast majority of clinician reviewers had the necessary skills and experience to perform trigger reviews	Time's the biggest killer. I think every practice could open twenty-four hours a day and still not have time. Every single thing that comes out: 'we'll get the practice nurse to do it' but just how thin do you get spread? (PN08)
Contextual integration	Inclusion of the TRM in existing GP contexts, such as the QOF, facilitated implementation	In my experience as an appraiser, I could see a lot of people doing this (GP05) I plan personally to use it with our trainees now (GP12)

Table 6. Reflexive monitoring factors that facilitated or hindered TRM implementation

NPT components	Factors	Selected verbatim quotes
Systematisation	The simple, one-page data collection template facilitated implementation by providing a clear, structured format and electronic data collection.	The form's helpful although it's perhaps a reporting tool. It forces you down the route of making you think (GP04)
Reconfiguration	The TRM was intentionally designed to be flexible, which facilitated its implementation.	So I changed it [the TRM trigger order] to: High Priority, New Allergy, Investigations and then the Consultations and the Docman [correspondence] ehm Repeat medication at the very end. I found that was the quickest way for me to get through the triggers (PN01)
Individual appraisal	The vast majority of respondents perceived the TRM as a useful approach to improve the safety of care and to identify learning needs and points	[We] got some really good outcomes from it: a couple of SEAs and an audit... There's learning for the system in there, so worthwhile, definitely worthwhile (GP04) I like this [the TRM] as a kind of start. Here's something we can do regularly that can actually show us how good we are or how bad we are or areas that we need to work at or where we need to go (PM03)
Communal appraisal	Most respondents perceived the TRM as a useful approach to further improve the quality and safety the care in the general practice setting	I think it's more valuable than QOF QP to be honest. I think it is looking internally you know - I think it has a value… it's just kind of embedding a culture within a practice (GP08)

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Supplementary file, Appendix 1. Interview schedule for general practitioners, practice managers and practice nurses

Introduction

- Hello...
- Thank you for agreeing to meet with me today. Please take a few minutes to read through the consent form. Feel free to discuss any concerns or ask for clarification before signing.
- The aim of this interview is to discuss your experience with the trigger review method (TRM).

General

This section will only be used for those respondents that did not participate in interview one.

Main question	*Additional question*	*Clarifying question*
What is your role in your practice?	How long have you been in this practice? How long have you worked in any primary care role?	

1. Coherence (i.e. 'meaning and sense making' by interviewees)

Main question	*Additional question*	*Clarifying question*
What are the benefits of the trigger review method (TRM)?	Who are likely to benefit? Is it clearly distinct from other interventions?	Patients? Staff? Are they likely to value the benefits?
Which findings or aspects of the TRM were unexpected?		

2. Cognitive participation (i.e. 'commitment and engagement')

Main question	*Additional question*	*Clarifying question*
What changes did you make as a result of the review findings?	If none, why?	It may be helpful to consider different levels, i.e. patient, practitioner, practice, primary care.
Who else could use the TRM?	Will they understand the rationale for the method? Will they be prepared to invest time and work in it?	

3. Collective action (i.e. 'work participants do' to make TRM 'function'

Main question	*Additional question*	*Clarifying question*
What did you think of the training session?	Was the training adequate? How could the training be improved?	What was your experience of the provided learning resources, venue, presenter and presenting style?
How compatible is the TRM with your existing work?	What (if any) impact does it have on different professional groups?	Consider: division of labour, resources, power, responsibility.
How does the TRM fit with the overall ethos of general practice?		How does it fit the wider organisational goals?
Who did you share the findings with?	If no one, why?	

4. Reflexive monitoring ('reflect on and appraise' the TRM)

Main question	*Additional question*	*Clarifying question*
How can the TRM be adapted or improved?		
What would help ensure that you continue using it?	Does the TRM have a role in appraisal, revalidation, education and training?	

Thank you for your time and participation.

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

	Reporting Item	Page Number
#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
#2	Summary of the key elements of the study using the abstract format of the intended publication; typically	2

		includes background, purpose, methods, results and conclusions	
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3-4
Purpose or research question	#4	Purpose of the study and specific objectives or questions	4
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	5
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	15

Context	#7	Setting / site and salient contextual factors; rationale	6
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	6
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	6, 15
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	6
Data collection instruments and technologies	#11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	6
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	7, 21
Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and	6,7

		security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	
Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	7,15
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	7
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	8-10
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	22-25
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	10-11
Limitations	#19	Trustworthiness and limitations of findings	12
Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were	12

		managed	
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	15

BMJ Open

Facilitators and barriers to safer care in Scottish general practice: a qualitative study of the implementation of the trigger review method using Normalisation Process Theory

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Facilitators and barriers to safer care in Scottish general practice: a qualitative study of the implementation of the trigger review method using Normalisation Process Theory

Carl de Wet[1,2,3], Paul Bowie[1,2] and Catherine A O'Donnell[2]

[1]Medical Directorate, NHS Education for Scotland, Glasgow, UK
[2] General Practice and Primary Care, Institute of Health and Wellbeing, University of Glasgow, UK
[3]School of Medicine, Griffith University, Gold Coast, Australia

Address for correspondence:
Associate Professor Carl de Wet
Level 8, School of Medicine, Griffith University, Southport, Gold Coast, Australia
Email: mailto:carl_dewet@yahoo.co.uk
Tel: (+61) 0450277315

e-Mail addresses of co-authors:
Dr Paul Bowie: paul.bowie@nes.scot.nhs.uk
Prof Catherine O'Donnell: kate.o'donnell@glasgow.ac.uk

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ABSTRACT

Objectives

Patient safety is a key concern of modern health systems, with numerous approaches to support safety. One, the Trigger Review Method (TRM), is promoted nationally in Scotland as an approach to improve the safety of care in general medical practice. However, it remains unclear which factors are facilitating or hindering its implementation. The aim of this study was to identify the important factors that facilitate or hinder the implementation of the TRM in this setting.

Design

Qualitative study employing semi-structured interviews. Data analysis was theoretically informed using normalization process theory (NPT).

Setting

Scottish general practice

Participants

We conducted 28 semi-structured interviews with general practitioners (n=12), practice nurses (n=11) and practice managers (n=5) in Scotland.

Results

We identified four important factors that facilitated or hindered implementation: (1) the amount of time and allocated resources; (2) integration of the TRM into existing initiatives and frameworks facilitated implementation and justified participants' involvement; (3) the characteristics of the reviewers – implementation was facilitated by experienced, reflective clinicians with leadership roles in their teams; (4) the degree to which participants perceived the TRM as acceptable, feasible and useful.

Conclusions

This study is the first known attempt to investigate how the TRM is implemented and perceived by general practice clinicians and staff. The four main factors that facilitated TRM implementation are comparable with the wider implementation science literature, suggesting that a small number of specific factors determine the success of most, if not all, complex healthcare interventions. These factors can be identified, described and understood through theoretical frameworks such as NPT and are amenable to

intervention. Researchers and policy makers should pro-actively identify and address these factors.

Strengths and limitations

- The convenience sample was a pragmatic choice and may not be representative of general practice in Scotland or the UK;
- The TRM were considered from the perspective of GPs, practice managers and nurses – the three staff groups that were critical to its successful implementation;
- A validated theoretical framework was used to analyse the data;
- Analysis was emergent and exploratory, and data were not 'shoe-horned' into the NPT framework;
- Thematic saturation was achieved

Introduction

Patient safety is a key concern of modern health care systems (1). The importance of patient safety first emerged in the hospital setting, due to the possibility of errors leading to patient death and disability (2, 3). However, patient safety is increasingly an area of concern in primary care (4, 5). In the UK, patient safety incidents (PSIs) have been defined as 'any unintended or unexpected incident which could have or did lead to harm for one of more patients receiving National Health Service care' (6). There is, however, a recognised difficulty in identifying and measuring PSIs and many remain undetected (7). This has led to variation in the estimation of PSIs in primary care, ranging from <1 to 24 PSIs per 100 consultations (4). While this may be lower than that reported for hospital care, the volume of consultations that take place in primary care (e.g. over 340 million general practice consultations in England in 2013) equates to the opportunity for substantial harm for approximately 300 000 patients each year (8). This has increased the urgency and effort with which policy makers, health care leaders, clinicians and researchers have responded (9). Programs, initiatives and interventions aiming to identify safety threats, reliably reduce ameliorable risks and measurably improve health care performance have proliferated, including in the National Health Service (NHS) of the United Kingdom (UK). Examples include the Department of Health's Patient Safety Research Portfolio and the Safer Patients Initiative and Safer Patients Network of the Health Foundation, a large and independent charity committed to bringing about better health in the UK(10-12).

In Scotland, a national Patient Safety Program (SPSP) was launched in 2008 with the ambitious aims of significantly reducing secondary care mortality and harm (13). As the programme became established in hospitals, it was expanded into primary care (SPSP-PC), beginning with general medical practice (14). The SPSP-PC aimed to measurably improve the safety of care provided in participating practices through three different strategies that were specifically developed or adapted for this purpose (15). They were: (i) detecting, learning from and reducing PSIs by applying the Trigger Review Method (TRM) (16, 17); (ii) measuring and building a strong and positive safety culture (18); and (iii) improving chronic disease and medication management by using a care bundle approach (19). All three methods have been the focus of research in different international health care settings, which have increased our understanding of their potential usefulness as interventions to improve patient safety (20-24). However, much

remains unknown, including which factors are associated with their successful implementation or lack thereof.

The TRM is essentially an adaptation of clinical record review (CRR) or 'case note audit', providing a structured way to rapidly screen samples of random electronic patient records for undetected PSIs. CRR is a well-established approach of detecting and quantifying sub-optimal care issues and is considered the gold standard in epidemiological type patient safety research (25). The key strength of CRR compared with other approaches is that it detects a significantly greater proportion of all PSIs (26). This is why the original landmark studies about the prevalence of adverse events in hospitals in the USA (27), UK (2), Australia (28), Canada (29) and New Zealand (30) all used some form of CRR adapted to their settings and purposes (26).

Development of the TRM commenced in 2007 in Scottish general practice, with subsequent testing in The Health Foundation-funded Safety and Improvement in Primary Care (SIPC) programme (15, 16). In 2013, the TRM was added to the Quality and Outcomes Framework of the UK General Medical Services contract (QOF, described in Box 1) with the expectation that it would be implemented nationally by Scottish general practices (c1000). A subsequent study of the implementation of the TRM found that most clinicians uncovered important patient safety concerns in their individual practices and took specific actions to improve the related care systems and processes (20). A description of the intended application of the TRM and a clinical example of its potential value are provided in Boxes 2 and 3 respectively.

Developing a potentially useful, complex healthcare intervention like the TRM is challenging. However, successfully implementing that intervention, sustaining its use and embedding it into routine practice are arguably even greater challenges (31, 32). Understanding the implementation of such interventions, including a clear explication of the barriers and facilitators to implementation, could prevent considerable amounts of time, effort and resources from being squandered. Despite the TRM being promoted and implemented in general practice nationally across Scotland, it remains unclear which factors are facilitating or hindering the success or otherwise of this process, and their relative importance in determining whether, or to what degree, this intervention can be integrated into routine practice. The aim of this study, therefore, was to identify the important contextual, organisational and resource factors that facilitated or hindered the implementation of the trigger review method (TRM) in Scottish general medical practice.

A theoretical framework was used to underpin the data collection, analysis and interpretation of the findings.

Use of theory to understand the implementation of patient safety initiatives

It is now accepted that the application of a theoretical lens can greatly enhance our understanding of the organisational and contextual factors which influence the implementation of quality improvement and patient safety initiatives (33-35). The Medical Research Council (MRC) guidelines recommend the explicit application of theory from the earliest stages of designing and implementing complex healthcare interventions, such as the TRM, to reduce the likelihood that important factors will be overlooked (36, 37). There are two reasons for this. First, complex interventions such as the TRM are often a 'black box', with a lack of clarity about which elements are implemented well, and why (34). Secondly, such complex interventions are implemented in a dynamic and on-going social context, shaped by the actors using them and by the wider organisational and socio-cultural structures into which the intervention – in this case the TRM – is placed (38, 39).

Selecting the most suitable theory from the large, complex and diverse range of options can then be informed by the specific requirements of the study and researchers (40, 41). As this study was principally concerned with the 'work' that practitioners had to do to implement the TRM, both as individuals and collectively in practices, and how that interacted with their work-based context, we selected Normalisation Process Theory (NPT) as our theoretical framework. NPT is a socio-technical, middle-range theory about the 'work' people do collectively and as individuals to implement and sustain an intervention. It has been successfully used in multiple studies and international health care settings and is particularly useful for describing, understanding and evaluating complex health care interventions such as the TRM (42-44).

The NPT framework consists of four main 'constructs' (45). They are:

- Coherence - the work implementers do to understand an intervention;
- Cognitive participation - the relational work to build a community of practice around an intervention;
- Collective action - the operational work of enacting an intervention; and
- Reflexive monitoring - the work of assessing and reconfiguring an intervention.

Each construct is divided further into four components, which promotes a nuanced understanding of the implementation process. The NPT constructs and components and how they relate to the TRM are described in Table 1.

Methods

Study design

Qualitative study employing semi-structured interviews with general practitioners (GP), practice nurses (PN) and practice managers (PM). A range of different types of general practice staff was included in the study to allow exploration and comparison of the perceptions of clinicians and non-clinicians and practice owners or partners and salaried employees. We used the Standards for Reporting Qualitative Research (SRQR) checklist for the study and manuscript (46).

Setting and sample

In Scotland, the organisational structure of the publicly-funded NHS consists of 14 regional 'Boards' who are responsible for the delivery of frontline health services and improving the health of the populations resident in their respective geographical areas (47). This study was undertaken in the West of Scotland in two of the Boards: one covering a large, urban setting with 262 general practices (designated Health Board A); the other covering a mixed urban-rural setting, with 56 practices (Health Board B). In April 2012, all practice managers in each Board area were sent written information via e-mail about the proposed study and an invitation for the PM and at least one GP and a PN to receive TRM training (Box 2) and participate. Due to resource constraints, recruitment stopped when 12 practices had agreed to participate. A convenience sample of GP practices was constructed to reflect the relative numerical distribution: 10 practices from Board A and 2 from Board B.

Patient and public involvement

Patients and the public were not involved in the design or planning of this study..

Data collection

The interview schedule was derived from the NPT framework and agreed by the authors (Supplementary file, Appendix 1). The interviews were conducted in the practice premises of participants at a time convenient to them. Informed consent was obtained from study participants prior to the interviews being conducted and after the purpose of the interview had been explained and anonymity assured. All interviews were conducted by the same investigator (CdW) who introduced himself as a GP and a researcher and explained that the interviews were confidential, candid and participants had no obligation to report 'successes' with the TRM or the implementation process. Interviews were conducted between January 2013 and July 2013 and lasted

approximately 45 minutes. They were digitally recorded and supplemented with contemporaneous field notes.

Data analysis

All interviews were transcribed verbatim to preserve colloquialisms, repetition and other non-verbal communication that could aid data interpretation but were not reviewed by participants. Transcripts were anonymised and the twelve participating practices assigned a unique identifier. This identifier was applied to every participant within a given practice. Participants from the same practice were differentiated by adding a further, unique identifier as a prefix, derived from their professional role: general practitioner – GP; practice nurse – PN; and practice manager – PM.

Data coding was led by CdW and COD and was informed by a framework approach using a coding frame informed by NPT (48). First, data were coded broadly to one of the four main NPT constructs. Following this, data were coded in greater detail to the specific NPT components of each construct; for example, data pertaining to understanding of the TRM (coherence) were then re-read and further coded to the sub-constructs of differentiation, communal or individual specification, and internalisation. Data could be double-coded to more than one sub-construct. The codes were then analysed in conjunction with the related, reflective memos to interpret the emerging views and themes and compare the perceptions of the different staff groups. The codes and themes were mapped and displayed using NVivo version 9.2.81.0. All authors met regularly to discuss the findings, ensure consistency and agree and verify data interpretations.

Care was taken, however, to ensure that the analysis was emergent and exploratory, and that data were not 'shoe-horned' into the NPT framework. Data that fell out with the NPT framework were assigned stand-alone codes and analysed separately to this study. The authors recognised, for example, that some data described *how* the TRM influenced participants and outcomes, rather than the 'work' of implementation, and therefore assigned different codes such as 'patient safety mindset' and 'learning moments' (unpublished - available on request from the corresponding author).

Results

Demographic data from the participating practices are summarized in Table 2. A total of 28 interviews were conducted with GPs (n=12), PNs (n=11) and PMs (n=5). One practice did not have a nurse during the study period, two PMs had to withdraw from the study due to unexpected personal reasons and another practice had a practice nurse (PN01) with the dual role of PM. The PMs of the remaining four practices were willing to be interviewed but were excluded because concurrent data analysis indicated that data saturation was achieved as no new data or insights were obtained from the last few interviews.

The results section is structured according to the four main constructs of the NPT framework. The study findings relating to each construct is described in the text and summarised as a Table with selected, verbatim quotes. The four NPT constructs are: Coherence (Table 3), Cognitive Participation (Table 4), Collective Action (Table 5) and Reflexive Monitoring (Table 6).

Coherence – the work individuals and teams did to understand the TRM (Table 3)

Many participants explained their understanding of the TRM by comparing it with other quality improvement (QI) methods they were already familiar with through QOF, such as clinical audit and significant event analysis (SEA). However, despite the similarities between the TRM and other QI methods, participants also recognized sufficient differences for it to be perceived as a 'new' method.

Most participants initially expressed concerns that implementing the TRM would increase their workload and require additional resources and time. This perception was moderated as their understanding of the TRM increased by implementing it and they realised that the actual workload and time requirements were lower than they initially expected. For example, GP02 described getting '*bogged down'* during the first trigger review but learnt from this experience and was able to apply the method more efficiently the second time. Most reviewers found the second trigger reviews quicker and easier, even though this did not necessarily mean the findings were more important or helpful.

Cognitive participation – establishing a community of practice around the TRM (Table 4)

The initial work that was required to implement the TRM in practices was mainly done by GPs. They were motivated to undertake the work because of expressed interests in the quality of care they deliver and a desire to proactively identify and reduce potential safety threats. These 'champions' subsequently enrolled other members of their practice team to conduct TRMs using one of two strategies. The first and most common strategy was to assign specific responsibilities or tasks to individual team members. Most of the practice nurses, managers and administrative staff were recruited in this way. The second strategy was to recruit team members opportunistically when they expressed an interest in participation, which is how most GP colleagues within participating practices were recruited. Perhaps unsurprisingly then, GPs were more motivated to implement the TRM compared with practice nurses – at least initially.

GP trainees, inexperienced practice nurses and some salaried GPs were able to detect and learn from PSIs but their attempts to improve care were typically aimed at individual or small groups of patients. In contrast, GP partners and experienced practice nurses were able to disseminate learning points and act to improve care at practice and regional levels through their leadership roles and because of their ability to positively influence the rest of their team. However, a few participants were opposed to sharing the trigger review findings with anyone outside their practice team because of concerns that the data may be misinterpreted.

Factors that helped to legitimise the TRM facilitated its successful implementation. Participants felt justified in allocating additional time and resources to implement the TRM because of its inclusion in the QOF. They also perceived it as an acceptable professional activity because of its QI relevance to medical appraisal and GP specialty training. In addition, the endorsement of the TRM by their peers and professional organisations, such as the Royal College of General Practitioners (RCGP), helped to justify their participation and increased their willingness to continue using the TRM.

Collective action – the work of enacting the TRM and integrating it with existing practices and contexts (Table 5)

Implementation of the TRM was facilitated when reviewers detected PSIs quickly and the PSIs were unambiguous and perceived as serious, preventable and originating in primary care. The small minority of reviewers who were unable to detect a single PSI or

only detected a few PSIs of low severity typically perceived this as an important barrier to the TRM's use. However, some reviewers alternatively interpreted 'finding nothing' as evidence for safe, high quality care in the clinical area being scrutinised.

Implementation of the TRM was facilitated when practices allocated adequate resources and sufficient time for clinicians to conduct trigger reviews without interruptions. While most practices allocated at least some protected time for TRM work, it was seldom adequate or uninterrupted. As a result, some reviewers reported that they conducted the reviews during their leisure time or in-between other tasks. Most reviews were interrupted because of urgent clinical tasks. Some reviewers were aware of a constant feeling of other tasks '*piling up'* and a compulsion to check their workload, which distracted them from completing the trigger reviews.

The personal and professional characteristics of the clinician reviewers strongly influenced the implementation of the TRM. Experienced, enthusiastic clinicians who were motivated and able to critically reflect on the review process and how the detected PSIs may impact on care delivery and practice systems were more likely to report successfully implementing the TRM. They explained that applying the TRM in a 'tick box' manner reduced its effectiveness. While this was not considered an issue for the practice teams in this study, the participants were concerned that a substantial minority of other practices might adopt this approach in practice. Therefore, while most participants thought that incentivizing the TRM through its inclusion in QOF was the key factor determining its uptake in the wider general practice community, they also expressed concern that a superficial, 'tick box' approach would reduce its potential usefulness.

A substantial minority of practices nurses were initially uncertain whether they would be able to apply the TRM successfully. Some clinicians also lacked confidence in the validity of their early findings or the findings of other reviewers. Despite these misgivings, most practice nurses were able to detect PSIs, share the findings with their teams and recommend or make specific improvements within their practices. The confidence of all the participants in the TRM and their own skills and findings increased with time and experience, which helped facilitate its successful implementation.

Reflexive monitoring – the work of adapting and evaluating the TRM (Table 6)

Many participants identified the flexibility of the TRM, adapting it according to specific practice or reviewer requirements, as an important facilitating factor for its successful

implementation. However, only two clinicians modified the method, the changes were minor and did not affect the outcomes.

Most participants perceived the TRM as a useful approach to improve the care they delivered to their patients, and for general practice in its wider sense. They also recognized its potential for identifying learning needs and points, encouraging reflection and raising awareness of potential safety threats. For these reasons, the TRM was considered to have equal or more value than existing quality improvement methods. However, while the TRM's perceived usefulness was identified as an important facilitator for its implementation and was felt to increase the likelihood of it being used again in the future, all respondents were clear that evidence of its usefulness, while important, was insufficient in itself to ensure normalization into routine practice. Successful normalisation would also require contextual integration, adequate protected time and additional resources.

Discussion

We identified four main factors that facilitated or hindered the implementation of the TRM in Scottish general practice. The first factor was whether the amount of time and resources allocated to conduct trigger reviews were sufficient to enable implementation. The second factor was integration of the TRM in an established, national initiative (the QOF). This was a particularly important enabler, as it provided a financial incentive and professional justification for clinicians to implement the TRM. The third factor was the characteristics of the clinician reviewers. Implementation was facilitated by experienced clinicians with leadership roles in their practice teams. The fourth factor was the perceptions of the participants of the TRM, informed by their own practical experiences of using it. Implementation was facilitated if they understood it as acceptable, feasible and useful.

Practical implications and comparison with existing literature

Devlin et al recently identified three key areas for researchers and policy makers to pro-actively consider for future, large-scale improvement initiatives if they are to be successfully implemented and normalised (49). They are: time; what the authors refer to as 'readiness', which is the product of resources and clinician engagement; and information technology (IT). An earlier systematic literature review about the influence of context on quality improvement in healthcare identified a slightly larger number of important 'success' factors: senior leadership; organisational culture; information

systems; previous experience of quality improvement; clinician engagement; and resources (50). Braithwaite et al identified eight comparable factors that determine implementation outcomes: preparing for change; capacity for implementation - setting; capacity for implementation – people; types of implementation; resources; leverage; sustainability; and desirable implementation enabling features (51).

The evidence from this study and the wider implementation science literature therefore suggest that a small number of specific factors are instrumental in facilitating or hindering the implementation of most, if not all, complex healthcare interventions. These factors can be identified, described and understood and are amenable to intervention. It is important for policy makers, health care professionals and researchers to proactively consider these factors when they are designing, implementing and evaluating new initiatives.

Providing frontline clinicians and staff with validated improvement methods and tools, education and training and 'expert' support are examples of important factors that are often included in improvement initiatives. However, they are insufficient to reliably improve care or change systems without the visible support of senior leaders and allocation of adequate resources and time (42, 49, 52, 53). This helps to explain why implementation of the TRM was greatly facilitated by its inclusion in an established, national Framework – it clearly demonstrated senior leadership support and provided additional resources through financial incentives. While the need for allocating sufficient resources may seem self-evident, many improvement interventions receive no funding or funding for the implementation stage only, and even then the initial investments may be inadequate (42). It is therefore unsurprising than many interventions fail to become normalised despite evidence of their usefulness.

Strengths and limitations of this study

A unique strength of this study is that it is the first known attempt to investigate how the TRM is implemented in primary care by exploring the perceptions of clinicians and their general practice teams. A second strength is the use of a validated theoretical framework, which is recommended for research in the discipline of implementation science (37). A third strength is that the perceptions and experiences of the three different staff groups that were critical to the successful implementation of the TRM were considered. Because practices nurses also performed trigger reviews, the 'nursing' and 'medical' experiences and views could be compared. However, we found that the perceptions of the participants were highly congruent and independent of their

roles and experience. A fourth strength is the different characteristics of participating practices, i.e. training and non-training; semi-rural to urban locations and small to large patient populations.

The study has at least three limitations. The sampling strategy was a pragmatic choice and this group of volunteers may therefore not be representative of general practices in Scotland or other countries in the UK. However, thematic saturation was achieved and, in our opinion, more interviews would not have materially strengthened the main findings. Applying a theoretical framework to data raises potential concerns that researchers may be constrained by theory and miss important findings, or alternatively may 'shoe horn' data into existing themes. However, our experiences were similar to those of other researchers, which is that very little data fell outside the NPT framework, and the data that did were either too diffuse to be meaningful or did not directly relate to the main study aims (44, 54). The third limitation is potential researcher bias. The analysis of qualitative data is inevitably influenced by the previous experiences and other characteristics of the researchers. A concerted effort was made to account for subjectivity through a combination of reflection, rigorous application of a transparent analysis process and by evaluating the veracity of the results against the international literature.

Next steps

Patient safety remains a high priority in primary care worldwide. The National Quality Strategy specifies six health care priorities for the United States of America (USA), of which the first is to 'make care safer' (55). One the main levers they use to achieve this aim is 'learning and technical assistance', i.e. offering training and improvement tools.

In Scotland, GPs can submit trigger review findings as part of the mandatory QI Activity evidence required for appraisal purposes (56). The 'National Framework for Quality and GP Clusters' (see Box 1) identified a role for the TRM and recommends '*structured review of high risk patient records*' as one of nine validated safety improvement tools to the new Clusters (57). The RCGP has included the method in their patient safety toolkit as a potential evidence source for supporting medical revalidation of GPs in the UK (58). In England, Clinical Commissioning Groups (CCGs) were established in 2013 with two important but distinct roles: to commission secondary and community care services for their populations; and to support quality improvement in general practice (59). While the first role has received most attention to date, the second role is equally important

and a legal duty that will require greater clinical engagement and validated tools, such as the TRM (60, 61).

The Australian Commission on Safety and Quality in Healthcare started a consultation in October 2017 as a first step in developing a national approach to support improvements in patient safety and quality in primary care (62). Although the consultation is ongoing, it seems reasonable to assume that any approach will have to include the 31 Primary Health Networks (PHNs) that were established in 2015 to better integrate care and to ensure that all Australian patients '*receive the right care in the right place at the right time'* (63). The approach will also require a cohesive implementation strategy, validated tools such as the TRM and allocation of adequate resources. The 'medical homes' initiative provides a practical example of how existing funding arrangements can be adapted at the federal level to encourage a more flexible approach to health care (64).

All these examples demonstrate a need for validated tools. However, it is unclear whether any organisation has fully considered or comprehensively addressed the main factors that are known to facilitate or hinder the effective, routine use of improvement methods. The pressing questions are therefore whether and to what extent the use of improvement tools like the TRM will become normalised in specific healthcare settings like general practice, and how this process can best be supported.

Conclusion

We identified four important factors that facilitated the implementation of the TRM in Scottish general practice. The factors are comparable with the wider implementation science literature, suggesting that a small number of specific factors are instrumental in facilitating or hindering the implementation of most, if not all, complex healthcare interventions. These factors can be identified, described and understood through theoretical frameworks such as NPT and are amenable to intervention. This may allow researchers and policy makers to pro-actively identify and address the main factors that are known to facilitate or hinder the implementation and normalisation of improvement initiatives. Normalisation of the TRM therefore seems likely if the following factors could be guaranteed: clinicians have the necessary knowledge and skills to apply the TRM effectively; there is senior leadership support for the TRM at practice and national levels; adequate resources and time are provided to conduct trigger reviews; and it is formally integrated into existing professional activities, government policies and national improvement initiatives.

Footnotes

Ethical approval and consent to participate

The study was submitted to and approved by the Glasgow University's College of Medicine, Veterinary & Life Science's Ethical Committee, reference number 2012054. All participants provided written, informed consent before the interviews were conducted.

Authors' information

CdW worked as a general practitioner in the West of Scotland in an area outside Health Boards A and B from 2007 to 2014 and was a part-time PhD student with Glasgow University from 2011 to 2017. PB and COD both have extensive experience of primary care research and education and were CdW's educational supervisors. CdW had met a small number of the participants in passing prior to the study while attending different educational events, but there had been no significant previous social or professional interactions.

Data availability

The data and material are available on request from the corresponding author.

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Competing interests

The authors declare that they have no competing interests.

Author contributions

CW: concept, study design, data analysis, co-development and critical review of manuscript. COD: data analysis. PB and COD: concept, study design, co-development and critical review of manuscript, study guarantors.

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Box 1. Summary of the Quality and Outcomes (QOF) Framework

The QOF was a major component of the General Medical Services (GMS) contract between UK general practices and the NHS (65). It was introduced in April 2004 to help address longstanding variation in the quality of primary care provision (66). The QOF was the largest pay-for-performance scheme in international healthcare and one of the most important, influential but also controversial initiatives ever to be implemented in UK general practice. The QOF measured participating practices' performances annually against a range of evidence-based or pre-agreed 'point-in-time' indicators. Practices 'earned' points according to their level of achievement for each indicator, with payment starting at a minimum threshold (usually 40%) rising to a maximum (usually 90%). Points were weighted according to the practice list size and were worth from tens to hundreds of pounds each. Participation in the QOF was voluntary, but the reality was that most practices would not have been viable business concerns if they had opted out. Consequently, virtually all Scottish general practices with GMS contracts participated in the QOF as it was one of their main potential sources of income. QOF was decommissioned in Scotland in April 2016 (67) and replaced, in part, with GP clusters – groups of 6-8 practices with Practice Quality Leads and a Cluster Quality Lead who are responsible for assessing, managing and improving care quality (57).

Box 2. Practical application of the Trigger Review Method (TRM) in general practice

The TRM allows clinicians, e.g. GPs, GP registrars and practice nurses, to screen samples of patient records (n=±25) from their own practice for previously undetected patient safety incidents (PSI) in a structured, focused, rapid and active manner:

- Structured - each of the five sections of a primary care record are screened in turn. The five sections are: clinical encounters; medication; clinical codes; correspondence; and investigations.
- Focused – reviewers search for pre-defined 'triggers'. Triggers are prompts, sentinel phrases or 'signs' in the record that *may* indicate the occurrence of PSIs.
- Rapid - a maximum of 20 minutes is allocated per record and only a pre-specified period in each record is reviewed (three calendar months).
- Active **–** clinicians are encouraged to reconstruct each patient journey and probe, analyse and critically appraise the record for evidence of PSIs and latent risks hidden in it.

Clinicians record their findings, reflections and actions on a '*Trigger Review Summary Sheet'* (SS). The SS is a double-sided template for collecting and summarizing data on the number of detected triggers, the details of any PSIs uncovered, any learning needs identified and actions that were or should be taken because of the review process. Clinicians are encouraged to share the findings from the trigger reviews with their practice team and to involve them in subsequent improvement actions.

The TRM has three consecutive steps: (1) Planning and preparation; (2) Review of records; and (3) Reflection and action. Practice managers and non-clinical staff are involved in steps 1 and 3 but do not perform trigger reviews (step 2). In our experience, clinical reviewers require on average 2-3 hours of protected time to apply the method and perform a 'trigger review' effectively. Two trigger reviews per year seems to be generally acceptable and feasible. Clinicians should receive 1-2 hours of training individually or in groups before they apply the TRM for the first time. Training is flexible but included as a minimum: a short presentation about the TRM; opportunities to practice trigger reviews using simulated patient records with facilitation and real-time feedback and provision of an educational support package.

Box 3. Example of the potential value of the TRM

While screening a sample of patient records (n=25), GP03 identified an elderly patient with established chronic kidney disease (CKD) who had not been added to the practice register and had not been offered the recommended ACE/ARB treatment. She recorded the PSI (suboptimal treatment of a patient with CKD) on the trigger review SS and rated it as low severity and high preventability. GP03 expressed surprise at detecting this PSI because the patient had consulted with her on several previous occasions in the preceding months. She described how her first actions had been to add him to the relevant chronic disease register, request a repeat eGFR blood test to check his renal function and that she arranged a review appointment to monitor his blood pressure and discuss potential further treatment. While reflecting on this incident, she identified a professional learning need about the management of CKD and subsequently addressed it. The incident was also discussed during a practice meeting and the team decided to update the practice protocol for the management of CKD and to perform a clinical audit to measure and improve the management of their patients with CKD.

Table 1. The NPT framework in relation to the TRM

Constructs	Components	Description
Coherence		The work to understand the TRM
	Differentiation	The work participants do to understand the differences and similarities between the TRM and other QI methods
	Communal Specification	The work required to understand the purpose and potential benefits of the TRM
	Individual Specification	Understanding the effort required to implement the TRM. Is the TRM perceived as feasible and a priority?
	Internalization	The work individuals and teams did to understand how the TRM 'fits in' with their culture and existing work. Is it acceptable?
Cognitive Participation		The relational work required to build and sustain a community of practice around the TRM
	Initiation	The work of ensuring that staff and clinicians are willing and able to use the TRM
	Enrolment	The work of identifying and recruiting the necessary people and ensuring the remain engaged in the process
	Activation	The continuing support work that is necessary to disseminate trigger review findings, create opportunities for improvement and sustain the use of the TRM
	Legitimation	The work individuals and teams do to justify their involvement with the TRM to themselves and others
Collective Action		The operational work required to enact the TRM. It requires participants to invest effort
	Interactional Workability	The work of applying the TRM, the time and effort this required and the outcomes, i.e. whether and what type of PSIs they detected and the subsequent improvement actions they took
	Relational Integration	The work of building confidence in the TRM, their own and colleagues' abilities to effectively apply it and trust that the findings are accurate
	Skill-set Workability	The work of dividing tasks, allocating resources and assessing the skills of the available team members
	Contextual Integration	The work of integrating the TRM into existing structures, contexts and policies. It includes allocation of adequate resources and leadership support of the TRM

Reflexive Monitoring		The work of assessing and appraising the individual and communal worth of the TRM
	Systemisation	The work of collecting and analysing data about the TRM
	Individual appraisal	The work of evaluating the value (usefulness, worth) of the TRM for the clinician reviewer, her practice and patients
	Communal appraisal	The work of evaluating the value of the TRM for other practices and their patients
	Reconfiguration	The work of adapting the TRM, team or contexts

Table 2. Demographic data of the participating practices

Practice no	Patient list size*	GPs (n)		Area	Training practice (Yes/No)
		Partners	Other		
1	2100	1	-	Semi-rural	No
2	4300	3	1 salaried	Urban	Yes
3	3200	1	1 salaried 1 long-term locum	Urban	No
4	4100	3	1 Retainer	Urban	Yes
5	11000	8	-	Semi-rural	Yes
6	5900	4	1 Salaried	Urban	Yes
7	8200	7	-	Urban	Yes
8	6800	3	2 Salaried	Urban	Yes
9	6400	3	1 Salaried	Urban	No
10	9900	6	1 Retainer	Urban	Yes
11	3000	4	1 Retainer	Urban	Yes
12	7500	6	1 Salaried	Urban	Yes

*Rounded to the nearest hundred at the beginning of the study period

Table 3. Coherence factors that facilitated or hindered TRM implementation

NPT components	Factors	Selected verbatim quotes
Differentiation	Implementation was facilitated when respondents understood the TRM was a new QI approach, but complementary to existing methods such as clinical audit or significant event analysis (SEA).	[The TRM] is essentially looking to pick up an SEA I suppose. That's the way that you could look at it - if you need an SEA that's a good way to find one' (GP07)
Communal specification	When participants understood the TRM's intended aims and potential benefits they were more likely to use it and achieve positive outcomes	'I think it's useful as a learning tool to learn about your own systems and a way of trying to improve those systems and a way of learning as a team with the results' (GP05)
Individual specification	All participants were concerned that the available time and resources would be insufficient to implement the TRM. However, the vast majority found the TRM to be feasible, which then facilitated its further use	I think the first time doing the first couple of patients was a bit slow and because it's different and you're not quite sure where you're at. So it took a wee while, a couple of patients really to get into the swing of it. I did it again just last week and found it very quick and very easy to go through (GP02)
Internalization	Most participants perceived the TRM as acceptable and fitting with their culture, which facilitated its implementation.	You have to have systems in place that make a safe journey for the patient. So I guess that's why we think we should be doing [the TRM], whether it's a project or an incentive or not, because that's what we're all about really, bottom line (PM08)

Table 4. Cognitive participation factors that facilitated or hindered TRM implementation

NPT components	Factors	Selected verbatim quotes
Initiation	Training sessions and access to expert support facilitated implementation. However, training had to be flexible and fit with the practices' needs	'I've been trying to start the ground level approach of saying 'this is how it should be used', you know, used formatively and using it to look at your systems as well, and things like that' (GP05)
Enrolment	Initial recruitment of volunteers facilitated implementation. However, most practice nurses were assigned the TRM, which initially reduced the motivation of some	Sometimes you know that, although they're asking you [pause] it's going to come your way anyway (PN09)
Activation	The TRM was facilitated when findings were disseminated, and reviewers had sufficient autonomy and opportunity to enact change	I wasn't involved at all (PM10) I held a practice meeting afterwards to highlight that perhaps we aren't always that good (GP06)
Legitimation	Implementation of the TRM was facilitated when individuals and practice teams were able to justify investing time and resources in its application.	'I'm not sure if I'd have gone back to [the TRM] if it had disappeared off the horizon... you have to justify the time in order to make it happen' (GP06) I feel I always have to justify every single working minute I have in here (PN10)

Table 5. Collective action factors that facilitated or hindered TRM implementation

NPT components	Factors	Selected verbatim quotes
Interactional workability	Implementation was facilitated when PSIs were detected quickly and PSIs were unambiguous, serious, preventable and originated in primary care. A small minority of reviewers found no PSIs, which was a barrier to its future use	There's safe and there's safe. I mean there's life threatening and there's a slight error on certain things (PM03)
Relational integration	Participants had confidence in the TRM but felt unsure whether all other practices would apply it correctly. A minority of clinicians were concerned that the findings may be inappropriately interpreted or used.	You can do it properly or you can have a quick scamper through it and not find anything (GP04)
Skill-set workability	Implementation was hindered when practices didn't allocate adequate resources and time, or when time was allocated but not protected. The vast majority of clinician reviewers had the necessary skills and experience to perform trigger reviews	Time's the biggest killer. I think every practice could open twenty-four hours a day and still not have time. Every single thing that comes out: 'we'll get the practice nurse to do it' but just how thin do you get spread? (PN08)
Contextual integration	Inclusion of the TRM in existing GP contexts, such as the QOF, facilitated implementation	In my experience as an appraiser, I could see a lot of people doing this (GP05) I plan personally to use it with our trainees now (GP12)

Table 6. Reflexive monitoring factors that facilitated or hindered TRM implementation

NPT components	Factors	Selected verbatim quotes
Systematisation	The simple, one-page data collection template facilitated implementation by providing a clear, structured format and electronic data collection.	The form's helpful although it's perhaps a reporting tool. It forces you down the route of making you think (GP04)
Reconfiguration	The TRM was intentionally designed to be flexible, which facilitated its implementation.	So I changed it [the TRM trigger order] to: High Priority, New Allergy, Investigations and then the Consultations and the Docman [correspondence] ehm Repeat medication at the very end. I found that was the quickest way for me to get through the triggers (PN01)
Individual appraisal	The vast majority of respondents perceived the TRM as a useful approach to improve the safety of care and to identify learning needs and points	[We] got some really good outcomes from it: a couple of SEAs and an audit... There's learning for the system in there, so worthwhile, definitely worthwhile (GP04) I like this [the TRM] as a kind of start. Here's something we can do regularly that can actually show us how good we are or how bad we are or areas that we need to work at or where we need to go (PM03)
Communal appraisal	Most respondents perceived the TRM as a useful approach to further improve the quality and safety the care in the general practice setting	I think it's more valuable than QOF QP to be honest. I think it is looking internally you know - I think it has a value… it's just kind of embedding a culture within a practice (GP08)

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Supplementary file, Appendix 1. Interview schedule for general practitioners, practice managers and practice nurses

Introduction

- Hello...
- Thank you for agreeing to meet with me today. Please take a few minutes to read through the consent form. Feel free to discuss any concerns or ask for clarification before signing.
- The aim of this interview is to discuss your experience with the trigger review method (TRM).

General

This section will only be used for those respondents that did not participate in interview one.

Main question	*Additional question*	*Clarifying question*
What is your role in your practice?	How long have you been in this practice? How long have you worked in any primary care role?	

1. Coherence (i.e. 'meaning and sense making' by interviewees)

Main question	*Additional question*	*Clarifying question*
What are the benefits of the trigger review method (TRM)?	Who are likely to benefit? Is it clearly distinct from other interventions?	Patients? Staff? Are they likely to value the benefits?
Which findings or aspects of the TRM were unexpected?		

2. Cognitive participation (i.e. 'commitment and engagement')

Main question	*Additional question*	*Clarifying question*
What changes did you make as a result of the review findings?	If none, why?	It may be helpful to consider different levels, i.e. patient, practitioner, practice, primary care.
Who else could use the TRM?	Will they understand the rationale for the method? Will they be prepared to invest time and work in it?	

3. Collective action (i.e. 'work participants do' to make TRM 'function'

Main question	*Additional question*	*Clarifying question*
What did you think of the training session?	Was the training adequate? How could the training be improved?	What was your experience of the provided learning resources, venue, presenter and presenting style?
How compatible is the TRM with your existing work?	What (if any) impact does it have on different professional groups?	Consider: division of labour, resources, power, responsibility.
How does the TRM fit with the overall ethos of general practice?		How does it fit the wider organisational goals?
Who did you share the findings with?	If no one, why?	

4. Reflexive monitoring ('reflect on and appraise' the TRM)

Main question	*Additional question*	*Clarifying question*
How can the TRM be adapted or improved?		
What would help ensure that you continue using it?	Does the TRM have a role in appraisal, revalidation, education and training?	

Thank you for your time and participation.

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

	Reporting Item	Page Number
#1	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	1
#2	Summary of the key elements of the study using the abstract format of the intended publication; typically	2

		includes background, purpose, methods, results and conclusions	
Problem formulation	#3	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3-4
Purpose or research question	#4	Purpose of the study and specific objectives or questions	4
Qualitative approach and research paradigm	#5	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	5
Researcher characteristics and reflexivity	#6	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	15

Context	#7	Setting / site and salient contextual factors; rationale	6
Sampling strategy	#8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	6
Ethical issues pertaining to human subjects	#9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	6, 15
Data collection methods	#10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	6
Data collection instruments and technologies	#11	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	6
Units of study	#12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	7, 21
Data processing	#13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and	6,7

		security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	
Data analysis	#14	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	7,15
Techniques to enhance trustworthiness	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	7
Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	8-10
Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	22-25
Intergration with prior work, implications, transferability and contribution(s) to the field	#18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	10-11
Limitations	#19	Trustworthiness and limitations of findings	12
Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and conclusions; how these were	12

		managed	
Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation and reporting	15