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Participatory design of a preliminary safety checklist for general practice

Abstract

Background
The use of checklists to minimise errors is well established in high reliability, safety-critical industries. In health care there is growing interest in checklists to standardise checking processes and ensure task completion, and so provide further systemic defences against error and patient harm. However, in UK general practice there is limited experience of safety checklist use.

Aim
To identify workplace hazards that impact on safety, health and wellbeing, and performance, and codesign a standardised checklist process.

Design and setting
Application of mixed methods to identify system hazards in Scottish general practices and develop a safety checklist based on human factors design principles.

Method
A multiprofessional 'expert' group ($n = 7$) and experienced front-line GPs, nurses, and practice managers ($n = 18$) identified system hazards and developed and validated a preliminary checklist using a combination of literature review, documentation review, consensus building workshops using a mini-Delphi process, and completion of content validity index exercise.

Results
A prototype safety checklist was developed and validated consisting of six safety domains (for example, medicines management), 22 sub-categories (for example, emergency drug supplies) and 78 related items (for example, stock balancing, secure drug storage, and cold chain temperature recording).

Conclusion
Hazards in the general practice work system were prioritised that can potentially impact on the safety, health and wellbeing of patients, GP team members, and practice performance, and a necessary safety checklist prototype was designed. However, checklist efficacy in improving safety processes and outcomes is dependent on user commitment, and support from leaders and promotional champions. Although further usability development and testing is necessary, the concept should be of interest in the UK and internationally.

Keywords
checklists; general practice; human factors; participatory design, patient safety.

INTRODUCTION

A recent evidence scan estimated that 1–2% of patient consultations with primary care clinicians may involve adverse events.[1] This is potentially significant given that there are around 1 million consultations daily in the UK.[2] However, it is well established that the nature, scale, and organisation of patient care in general medical practice are characterised by an inherent complexity and uncertainty, making the reliable delivery of safe and effective clinical management particularly problematic.[3]

Additionally the design quality of systems, technology, and related checking processes to support patient safety in general practice can be variable, unsafe, and ineffective.[1,4–13] Clinicians and staff often struggle to cope with daily workloads while also attempting to manage a range of other human factors interaction issues (Box 1) that may further compromise performance and safety, for example: sub-optimal work system designs (such as usability of IT systems); organisational constraints (such as responding to contractual incentives and increasing patient demand); limited resource availability (such as real-term decreases in allocated funding); and external political pressures (such as meeting targets for patient access).

In this type of high-intensity and complex working environment it is inevitable, therefore, that 'human error' will occur and that patients are sometimes, avoidably, harmed as a result.[14–15] Safety incidents may have clear and obvious physical and psychological effects on the health, wellbeing, and trust of patients and relatives. But they can also impact negatively on the physical health (for example, sharps injury or infection) and emotional wellbeing of clinicians and staff (for example, stress and anxiety related to the 'second victim syndrome'), while also affecting individual and team performance.[16,4–6]

As part of the evolving patient safety agenda[1] there is growing interest in human factors-based interventions such as 'checklists' to standardise necessary checking processes and act as cognitive aids to ensure task completion by care teams.[17] The expectation is that this will support workforce safety performance and provide further systemic defences against error and preventable harm to patients.[18–19]

The limited evidence in general practice suggests that inconsistent and unreliable

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How this fits in

Checklists are commonly used in high reliability industries and in many secondary care settings to improve safety systems and processes. The lack of standardised, timely, and consistent checking processes are known to be contributory factors in significant events. However, there is limited experience of taking a systems-based approach to checking safety issues of importance and improving related reliability in general practice. This study identified safety hazards across the general practice work system, and codesigned a prototype checklist based on published evidence, practitioner experience, and human factors principles. A safety checklist provides a method to engage front-line staff in the timely and consistent checking of important issues that can impact on the safety, health, and wellbeing of people and practice performance. The preliminary checklist has potential as an intervention to measure, monitor, and improve elements of general practice safety and performance.

checking processes can compromise care quality and safety, and are cited as contributory factors in significant events.[1,4–13] Examples include the unsafe management of controlled drugs (such as correlation of recorded and actual stock levels is lacking), emergency equipment maintenance (such as the practice oxygen supply is at insufficient levels) and medication storage (such as drugs are stored at incorrect temperatures or are outwith expiry dates).

This study focused on integrating and improving the design and timely adherence to checking processes of direct relevance to the safety and wellbeing of patients and visitors, the GP team, and overall practice performance. Adopting a consistent, methodical, and measurable approach to checking processes may lead to the standardisation and high reliability of task performance and the safety systems concerned across the working environment.[20–21] The aims, therefore, were to:

- identify and prioritise workplace hazards that are known to impact on the safety, health, and wellbeing of patients, visitors, and GP team members, and organisational performance using a human factors work system model;[22–23] and
- codesign and validate a standardised, integrated checklist process for general practices which reflects system-wide safety hazards and risks.

METHOD

Study design

A mixed methods study was undertaken which included literature and practice policy document reviews; formation of an 'expert' steering group; consensus generating workshop meetings with GPs, practice managers and nurses; and a content validity index exercise.[24]

Conceptual influences

A participatory design approach[25–26] to identifying hazards and codeveloping the safety checklist was adopted. This is a user-centred method that seeks to actively involve front-line groups with the greatest subject matter expertise in a codesign process. In this way they can inform design issues so the outcome meets their needs and usability concerns are addressed iteratively prior to implementation.

The identification of safety hazards was informed by the Systems Engineering Initiative for Patient Safety (SEIPS) work system model.[22–23] The SEIPS model seeks to explain work system designs from a human factors and patient safety perspective by adopting a 'whole system' approach that focuses on the interactions and interdependencies of five related components (people, tasks, tools and technologies, physical environment, and organisational conditions), and how these impact on 'outcomes' such as safety, performance and health and wellbeing. To illustrate the systems-centred SEIPS approach a summary of a checking-process related significant event analysis is outlined in Box 1.

Recruitment of study participants

Convenience samples of study participants were recruited by email from three professional networking groups (with an interest in patient safety) based in NHS Scotland during May 2014. Groups 1 and 2 were the national networking and learning groups for GP managers and nurses respectively, with both comprising 15 members and each member representing a territorial NHS board region. The third group was the west of Scotland GP Audit Development Group ($n = 14$), a well established group involved in educationally assessing quality improvement activities undertaken by GPs.

Review of checking process-related practice documentation

Those indicating an interest in study participation were requested to voluntarily send (in confidence), examples of safety-

related policies, protocols, and procedures (Appendix 1) to help inform the study purpose, scope, and potential checklist development. The documentation was jointly reviewed by two authors to identify safety-critical checking processes of interest.

Initial draft of checklist content

A core 'expert' steering group was formed to oversee the hazard identification and checklist design, and validation. The group included three GPs with educational roles related to patient safety, a national practice manager education lead, a national general practice nurse education lead, a patient safety scientist, and a health psychologist with safety research experience. The initial draft checklist content (of nine main themes, 32 subcategories and 40 related safety-critical issues) was developed iteratively by the group from a combination of issues raised in the literature, checking processes identified from the aforementioned policy

Box 1. Example of a patient safety incident related to checking processes and relevant sociotechnical interactions informed by the SEIPS model

Brief safety incident description: a tall, overweight 55-year-old male patient collapsed in the waiting room at 4.45pm while attending the surgery with a family member. The practice team responded to the incident as per the emergency protocol. However, the CPR defibrillator battery was not usable because it was not charged and the adrenaline was out-of-date. A lack of timely checking processes was found to be a major contributory factor. The patient survived but a formal complaint was received by the practice

People (Patient, clinician, manager, administrator; team; physical, cognitive, and psychosocial characteristics)	**Task(s)** (Variety, content, complexity, physical and psychological demands)	**Tools and Technology** (Medical devices, drugs, information technology, other tools and technologies)	**Physical environment** (Physical layout; workstation design; noise, lighting, temperature)	**Organisation** (Formal and informal organisation; safety climate; policies, protocols, and procedures; organisation structure and management)	**External environment** (Contractual, accreditation and regulatory demands; political and health authority decision making)	**OUTCOMES**	
						People (Safety, performance, health and wellbeing, care, and job satisfaction	**Organisation** (Performance, productivity, and business reputation
• Physically large adult male patient collapsed in surgery waiting room area • Very emotional and anxious family member in attendance • Clinicians with relevant experience, training, and knowledge • Administrators trained in emergency response • Clinicians fatigued after long day and without a break or lunch • Waiting room full of attending patients	• Emergency alarm activated by receptionist • Relevant team members responded rapidly • Administrator phoned emergency ambulance • GP retrieved emergency equipment • Infrequent, complicated, stressful, and physically demanding task • Practice nurse cared for family member • Administrators moved older, sick patients to linked corridor	• Functioning emergency alarm system and speed dial to ambulance service • Defibrillator unusable because ageing battery did not charge • Usability issues with defibrillator caused minor confusion • Design of blood pressure monitor is limited for emergencies • Stock of adrenaline available but out-of-date	• Small waiting room area made it difficult for team to interact effectively with patient and equipment • Layout/design contributed to a lack of privacy and dignity • Noise from other waiting patients are a distraction	• Good levels of team working and communication demonstrated • CPR retraining for two attending team members was overdue • Ad hoc and informal checking process for emergency equipment maintenance and relevant drugs, and CPR training • Prevailing safety climate did not prioritise related checking processes • Previous checking process significant events, but limited collective learning by practice team • Organisational clarity required regarding checking of safety-related processes and issues	• Main practice quality and safety focus was on meeting contractual demands and maximising access to meet increasing patient demand • Real-term decreases in practice income led to delayed decision on replacement defibrillator equipment • Heavy workload demands impacted on delayed CPR training attendance and available time for routine emergency equipment and/or drugs checking processes	**Patient** **Received manual CPR and adrenaline until ambulance paramedics arrived to stabilise and transfer to hospital care; recovered and discharged** **Team members** **Feelings of guilt and embarrassment; apportioning individual blame; worsening interpersonal relationships; added work stress and anxiety; individual on related sick leave**	**Practice** **Formal complaint received from patient's family; adverse media publicity and in local community; deterioration in practice family relations**

documentation review and professional experience in the workplace.

Consensus building workshops

Consensus building in face-to-face workshop meetings and the use of follow-up email and telephone discussions was informed by adapting the Delphi technique — an iterative method for structuring a communication process involving expert or informed groups to achieve a particular goal — which when used in face-to-face meetings is known as a mini-Delphi.[27] The identification and potential impact of safety hazards, generation, and refinement of the checklist content on an iterative basis (including suggested frequency of checklist use and how items should be checked) was achieved by in-depth critical discussion, debate, and consensus agreement during two 4-hour workshops with study participants. During this process, the early draft checklist version and examples of related hazards were used as prompts to facilitate open discussions and small group work 'reflect and feedback' sessions. The workshop moderator took contemporaneous field notes throughout and retained all flip chart data generated by participants for subsequent analysis. After each meeting, the steering group members jointly reviewed and agreed checklist content by merging, amending, reducing, editing and, where necessary, deleting main themes, subcategories, and related issues to further enhance relevance and clarity of all items based on the feedback and consensus of the intended users. Post-workshop discussions and clarifications also took place via email and telephone between the moderator and all participants. From this a preliminary safety checklist consisting of six main safety-critical themes, 22 subcategories and 78 related items were generated.

Content Validity Index (CVI) exercise

A CVI exercise to quantify the strength of agreement on all aspects of the checklist content and further enhance relevance and clarity was undertaken by the 18 workshop participants. The relevance and clarity of each retained checklist theme, subcategory, and related item were assessed by asking participants to rate them using a validated 4-point ordinal scale: (1 = not relevant, 2 = somewhat relevant, 3 = quite relevant and 4 = very relevant). A minimum 80% agreement (15 out of 18) was required to endorse each theme, subcategory, and item for checklist inclusion by assigning a rating of at least 3 out of 4, to establish content validity beyond the 0.05 level of significance.[28] Participants were also asked to suggest other possible issues for checklist inclusion. Due to space limitations only the CVI rating scores for the core checklist themes and subcategories are reported.

Preliminary checklist design and usability principles

Checklist design and usability is made more effective and may improve human perception and interaction by paying close attention to the legibility, organisation, and comprehension of information displayed.[28–29] Basic usability guiding principles,[29–31] were followed to enhance checklist design (for example, a long checklist should be 'catalogued' in multiple pages; content should be validated with intended users; and a landscape layout style should be used with room for comments and/or actions and/or review date).

RESULTS

Personal, professional, and practice characteristics of study participants

Eighteen general practice clinicians and managers participated in the study, which equates to an overall response rate of 41% (18 out of 44). Of the professional groups approached, 10 practice managers (66%), five practice nurses (33%) and three GPs agreed to participate (21%). The majority were female (*n* = 13, 72.2%), in the age groups 45–54 and ≥55 years, and based in training practices (*n* = 13, 72.2%). Their professional details and practice characteristics are outlined in Table 1.

Table 1. Personal and professional characteristics of study participants and demographics of participating general practices (*n* = 18)

	n
Sex	
Female	13
Male	5
Age group, years	
25–34	1
35–44	3
45–54	8
≥55	6
Professional group	
Practice management	10
Practice nursing	5
Medical doctor	3
Participating health boards	
NHS Ayrshire and Arran	4
NHS Greater Glasgow and Clyde	5
NHS Highland	3
NHS Lanarkshire	4
NHS Fife	1
NHS Borders	1
Training practice accreditation	
Yes	13
No	5
Type of practice	
Remote and rural	2
Semi-rural	7
Urban	7
Inner city	2
Size of practice population	
≤5000	4
5001–10 000	13
>10 000	1

Safety hazards identified across the general practice work system

A range of hazards was identified and themed as six different safety domains (for example, medication management and information systems) by participants, which reflected the breadth of the general practice work system and informed checklist development. Identified hazards were known threats to the health and wellbeing of patients (for example, lack of available adrenaline in an emergency situation), practice visitors (for example, accidental injury from loose carpets or tiles) and GP team members (for example, infection as a result of cross-contamination from bodily fluids). Similarly, hazards were also identified that could impact on the safe performance and productivity of GP team members and the practice organisation (for example, malfunctioning emergency medical equipment and an out-of-date business continuity plan). Selected

Box 2. Selected examples of identified potential hazards in the general practice environment using the SEIPS work system model to inform checklist content development

Safety domains (*n* = 6) and subcategories (*n* = 22)	Potential hazards: patient, GP team members and practice organisational outcomes (for example, quality, safety, health, wellbeing, performance)
Medication management (controlled drugs; emergency drugs and equipment; prescriptions and pads; vaccinations; all other drugs)	• Lack of in-date stock may lead to inability to treat acutely ill patient • Lack of necessary emergency drugs, or out-of-date emergency drugs can lead to patient safety being compromised, for example, adrenaline for anaphylaxis • Protects these prescription-related items from potential theft which can lead to unauthorised prescriptions of high risk drugs being dispensed to vulnerable patients or members of the public who may harm themselves as a result • Safe and secure keeping is necessary to prevent theft and misuse which could harm patients and members of the public • Lack of in-date stock may lead to inability to provide timely disease prevention treatments to patients • Patients, including children, ingesting non-prescribed medications and suffering related harms
Housekeeping (infection control; stocking of clinical rooms; confidential waste; clinical equipment maintenance)	• Staff and patients, including children, obtaining a needle stick injury from overfilled 'sharps' bins • Patients at risk of infection from spilled hazardous waste on clinical surfaces and/or equipment • Patients and staff at risk of cross-contamination from blood and/or bodily fluids • Risk of cross-infections from, for example, people, equipment, and clinical surface areas • Breaches of patient confidentiality can impact on patient safety via patients' suffering psychological harm from knowing their medical history has been disclosed publicly • Malfunctioning equipment (for example defibrillator or blood pressure monitoring equipment) can impact on the safety of patient care by providing un-calibrated readings that may result in false reassurance of clinical condition and erroneously affect decision making
Information systems (business continuity plan is up-to-date; verifiable back-up of all IT systems; data protection; record keeping)	• Can impact on how safe patient care is delivered in an emergency situation; for example electrical outage to the practice affecting IT systems and how to manage and deliver care in such a situation
Practice team (registration checks; CPR and anaphylaxis training; induction processes; access to patient safety-related training)	• Ensure all clinicians are registered with professional regulators. Patient safety-critical checks that protect the local patient population and the practice as an organisation
Patient access and identification (access information for patients; standardised patient ID verification)	• Numerous significant events in general practice are related to mix-ups over patient identification leading to patient's being subjected to unnecessary treatments, hospital visits, and investigations, and breaches of confidentiality which can cause avoidable physical and emotional harm
Health and safety (building safety and insurance; environmental awareness; staff health and wellbeing)	• Although a medical establishment, a first aid arrangement is still a safety requirement similar to any other place of work • Hazards in the workplace which are not identified and attended to can lead to harm (for example, a patient sustaining a head injury from walking into a low lying light) • Staff can be subject to abuse, anger, threatening behaviour, and violence and should be trained to manage these situations to protect the safety and wellbeing of themselves and patients.

examples of these hazards are described in detail in Box 2 (see Appendix 2 for a detailed listing).

Safety checklist development, validation, and frequency of use

A preliminary safety checklist was developed and validated (Appendix 3) which consists of six domains (for example, medicines management), 22 subcategories (for example, controlled drugs) and 78 related items (for example, monthly stock reconciliation undertaken). The contents were judged by participants to be safety issues of priority across the general practice work system that required routine checks to minimise the risks of hazards to people and organisational practice performance.

Participants unanimously agreed that the checklist should be consistently applied at least three times per calendar year (that is once every 4 months) in order to ensure necessary checking of identified safety issues within acceptable timescales. It was further agreed that common-sense judgements should be applied to those items that, for example, need to be checked annually or may not be applicable to all practices (for example, stocking of controlled drugs). The important issue is the implementation of a reliable, consistent but contextualised and flexible checking system. Methods for checking each safety issue were also suggested, such as documentation review, observations, and spot checks.

Content validity index (CVI) exercise

Checklist domains, subcategories, and related issues were endorsed by a minimum of 15 out of 18 participants who rated each item ≥3 on the 4-point scale (Table 2). The overall CVI ratio for the preliminary checklist was 0.92. A range of suggestions from participants on enhancing the relevance, clarity, and usability of the checklist content was also captured and reviewed by the project steering group and incorporated, where judged appropriate.

DISCUSSION

Summary

The project aims were achieved in terms of identifying hazards across the wider work system that may threaten patient safety and those that can impact on the health, safety, and wellbeing of relatives, visitors, GP team members, and also practice organisational performance. A preliminary safety checklist process was then codesigned and validated by intended users as a means to serially monitor safety performance and potentially drive system improvements, where necessary. The checklist has a dual purpose in terms of acting as a traditional 'one-off' checklist aid

Table 2. Levels of agreement: number of raters' (*n* = 18) rating each checklist domain and sub-category ≥3 (on a 4-point ordinal scale) and calculated content validity index (CVI) ratio

Safety checklist domain	Raters ≥3	CVI[a]
Medicines management	**18**	**1.0**
1. Controlled drugs	18	1.0
2. Emergency drugs and equipment	18	0.94
3. Prescriptions and pads	18	0.94
4. Vaccinations	17	0.83
5. All other drugs on premises	18	0.83
Housekeeping	**18**	**0.83**
6. Infection control	18	1.0
7. Stocking of clinical rooms	17	0.94
8. Confidential waste	18	0.94
9. Clinical equipment maintenance	17	0.94
Information systems	**18**	**0.94**
10. The practice business continuity plan is up-to-date?	16	0.89
11. The back-up of all significant IT systems can be verified?	18	1.0
12. Data protection	18	0.94
13. Record keeping	18	0.94
Practice team	18	0.89
14. Registration checks	**18**	**1.0**
15. CPR and anaphylaxis training	18	0.89
16. Induction processes	15	0.77[b]
17. All staff have access to ongoing patient safety-related training opportunities	18	0.94
Patient access and identification	**18**	**0.94**
18. Information for patients on how to access the practice urgently or in an emergency is widely available in different formats	18	0.94
19. Standardised patient identification verification	17	0.89
Health and safety	**18**	**0.89**
20. Building safety and insurance	17	0.89
21. Environmental awareness	18	0.89
22. Staff health and wellbeing	18	0.89

CVI = content validity index. [a]A CVI ratio of ≥0.8 is necessary to minimise the possibilities of chance agreement on content validity and merit item inclusion in the checklist content. The proportion of expert raters in agreement (when there are six or more raters scoring 3 or 4 on the 4-point ordinal scale) establishes content validity beyond the 0.05 level of significance. The number of raters needed and the proportion that must be in agreement to establish item content validity is decided by application of the standard error of the proportion. [b]Amended and moved to practice team domain.

(for example, checking that all clinicians are registered with regulators), while also having a 'global check' monitoring role (for example, checking that daily cold chain temperature recording was undertaken).

Safety checklist validation was strong with the vast majority of content being retained immediately, and with a significant minority of items being enhanced to improve readability, clarity, and understanding; this may be a reflection of the participatory approach adopted and a developing sense of relevance and ownership of the checklist process. This is important because while effective safety checklists should be focused on the critical priorities that need to be checked, they should be designed to support and augment the professional judgements of the users rather than to replace these.[32]

Comparison with existing literature

The six main checklist domains (for example, medicines management) are mostly addressed to some extent by existing high level quality indicators and standards developed for general practice in Australia,[33] Canada,[34] England,[35] and New Zealand,[36] although the latter all have a broader remit than 'safety'. On the overlapping issues, compared to the proposed checklist, these lack specific detail on the precise safety issues to be actually checked, the necessary frequency of checking and guidance on how to do this in order to minimise risks. Furthermore the checklist is intended to be implemented as part of a continuous improvement process to help monitor and enhance safety as part of routine practice rather than, for example, conducting checking processes just before an external inspection visit is due. From a safety perspective, the proposed checklist is arguably more comprehensive in scope, scale, and detail and may therefore assist practices to prepare for external inspection visits and measure improvement performance routinely.

Strengths and limitations

Checklists are not a panacea in fully resolving the issues that are identified as being amenable to checklist use. From a human factors perspective a checklist is an 'additional interface' between the user and the system,[17] but users need to view it as having a high level of importance in overcoming recognised front-line problems and which enables them to apply 'common-sense' judgements,[32] otherwise it will be considered an irritation and remain unused. An externally imposed checklist process that lacks the flexibility, adaptability, and autonomy to contextualise it to suit local circumstances may struggle to be fully accepted and implemented effectively.[17,37] The related development process should also be dynamic and flexible and continuously incorporate feedback from users, experts, and the latest research evidence in order to enhance its front-line relevance, feasibility, and impact.[38–42]

Similarly, when implemented as a single intervention, checklists are often inadequate 'technical fixes' to what is in effect a sociocultural safety problem that is related, among other factors, to how seriously the issue of checking processes is taken within a team or organisation, particularly in complex working environments.[32,42–43] Intended

users may also resist or feel threatened by checklists because they are perceived to replace their expertise or decision making, or oversimplify the complexity of the working environment.[37–44] Allied to user commitment and the support of healthcare leaders and promotional champions, checklist success is therefore more likely where structured step-by-step instructions for comparatively simple or straightforward technical tasks are necessary, variations in related performance already exists, and reliance on human memory is a known problem.[17,32]

A study limitation was the potential for bias as is evident through the pragmatic use of convenience samples of volunteer participants who over-represented specialty training practices, which are arguably more likely to be interested in learning and safety activities than non-training practices. Only three GPs were recruited for workshops and participated in follow-up correspondence, although a further three GPs were represented on the study steering group. A larger study with purposive or representative samples of intended users would have minimised this type of bias. Although the codesign and validation approach taken was robust, more substantial usability testing with a wider range of users across the UK is necessary and greater evidence of the acceptability, feasibility, and safety impact of the checklist is clearly required.

Implications for research and practice

Additional usability testing is clearly necessary alongside a broader 'implementation package' that may include, for example, a short training intervention, educational guidance on managing sociocultural barriers to checklist use, development of a possible comparative audit and feedback system, and human factors advice on improving practice system designs.

Full-scale checklist implementation in UK general practices is not imminently likely and would also require some form of local or national incentivisation. At a fundamental level, however, the prototype checklist may be voluntarily used immediately by GP managers and nurses to update existing checking processes, or help inform the development of a new system of checks as another mechanism for proactively engaging with the nascent patient safety agenda.[1] In this way, it can help provide reassurance by ensuring that some of the most safety-critical organisational tasks are actually carried out efficiently, on a timely basis and without ambiguity.

A further possibility is linking checklist implementation to the leadership, patient safety, and staff health and wellbeing responsibilities of practice managers via their annual appraisal and personal development plans, particularly as it brings together a range of safety-critical tasks that fall largely within their organisational job role and remit. Also, in light of the recent Francis report[45] and Berwick review,[46] there is potential to explore how this approach may contribute to Vincent *et al*'s published framework for guiding healthcare organisations and care teams to measure and monitor safety and review progress against related objectives.[47]

The study adopted a robust, user-centred, and systems-based methodological approach to taking the first steps in the development of a necessary safety checklist prototype for the general practice work system. Usability testing is the necessary next stage before implementation issues in UK general practice can be considered more fully, while the concept should be of interest internationally. However, there are highly important sociocultural implementation issues that may need to be contained if future checklist use is to be effective and successful.

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Ethical approval

A study protocol was reviewed by the West of Scotland Research Ethics Committee but judged to be service development and evaluation.

Provenance

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Competing interests

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Appendix 1. Examples of written policies, protocols and procedures with an explicit safety focus submitted by participants to inform study development

Controlled drugs policy

- Controlled drugs policy
- Hand hygiene policy
- Cleaning of premises policy
- Cleaning of equipment policy
- Cleaning materials policy
- General waste disposal policy
- Clinical waste disposal policy
- Sharps policy
- Needle stick injury policy
- Specimen handling protocol
- Business continuity plan
- Data protection registration
- New staff induction policy
- Locum doctor induction pack
- Staff equal opportunities policy
- Significant event policy
- Health & safety policy
- Fire safety policy
- Electrical safety policy
- Disability access policy
- Public liability insurance
- Employer's liability insurance
- Laboratory test result handling protocol
- MMR vaccination protocol

Appendix 2. Example list of hazards in general medical practice identified by study participants for each checklist subcategory (*n* = 22) and how the safety, health and wellbeing of patients, GP team members, and practice organisation performance can be impacted

1. **Controlled drugs**	• Safe and secure keeping is necessary to prevent theft and misuse which could harm patients and members of the public • Lack of in-date stock may lead to inability to treat acutely ill patient
2. **Emergency drugs and equipment**	• Lack of necessary emergency drugs or out-of-date emergency drugs can lead to patient safety being compromised, for example, adrenaline for anaphylaxis • Similarly, malfunctioning emergency equipment, such as defibrillator with a 'dead' battery, may lead to an inability to resuscitate a collapsed patient
3. **Prescriptions and pads**	• Protects these items from potential theft which can lead to unauthorised prescriptions of high-risk drugs being dispensed to vulnerable patients or members of the public who may harm themselves as a result
4. **Vaccinations**	• Poor re-ordering system may affect drug availability while lack of monitoring may lead to expiry of drug dates • Safe and secure keeping is necessary to prevent theft and misuse which could harm patients and members of the public • Lack of in-date stock may lead to inability to provide timely disease prevention treatments to patients
5. **All other drugs on premises**	• Patients, including children, ingesting non-prescribed medications and suffering related harms • Stolen drugs with the potential to cause harm without medical monitoring being used 'on the street' • Efficacy and safety of medications being given if out-of-date
6. **Infection control**	• Healthcare acquired infection is a major source of patient safety incidents across all health sectors. • Staff and patients, including children, obtaining a needle stick injury from overfilled 'sharps' bins • Patients at risk of infection from spilled hazardous waste on clinical surfaces/equipment • Patients at risk of infection from non-immunised staff members
7. **Stocking of clinical rooms**	• Patients and staff at risk of cross-contamination from blood/bodily fluids • Risk of cross-infections from, for example, people, equipment, and clinical surface areas • Efficient stock management is a good system design issue to minimise time wasted locating these items
8. **Confidential waste**	• Breaches of patient confidentiality can impact on patient safety via patients' suffering psychological harm from knowing their medical history has been disclosed publicly
9. **Clinical equipment maintenance**	• Malfunctioning equipment (for example, defibrillator or blood pressure monitoring equipment) can impact on the safety of patient care by providing un-calibrated readings which may result in false reassurance of clinical condition and erroneously affect decision making, for example inappropriate treatment with antihypertensive drugs due to poor condition of blood pressure monitor
10. **The practice business continuity plan is up-to-date?**	• Can impact on how safe patient care is delivered in an emergency situation; for example, electrical outage to the practice affecting IT systems and how to manage and deliver care in such a situation
11. **The back-up of all significant IT systems can be verified?**	• Loss of, or limited access to, timely patient, medical, and prescribing data can lead to poorly informed clinical decision making
12. **Data protection**	• Impacts on how evidence-based care is delivered potentially affecting the safety and efficacy of care provision because latest evidence and options are not available • May lead to inappropriate access to patient records
13. **Record keeping**	• Poor data coding can lead to inappropriate/poor follow-up care • Administration of drugs that cause avoidable side-effects (for example, allergic reactions)
14. **Registration checks**	• All are patient safety-critical checks which protect the local patient population and the practice as an organisation
15. **CPR and anaphylaxis training**	• Although rare the practice teams should be trained to deal with these types of acute medical emergencies
16. **Induction processes**	• Staff or locum staff who are unfamiliar with safety-critical operations in the practice (for example, the test results handling system, where emergency equipment is stored, how to gain access to GP in an emergency) may not follow correct procedures thereby potentially endangering patients
17. **All staff have access to ongoing patient safety-related training opportunities** (for example, needle stick injury, health and safety/fire safety, coding data)	• Errors in coding can lead to poor or wrong medical care being provided as it is also shared with other health care sectors (for example, acute hospitals) • Staff are aware of the risks of injury to themselves and patients and how to manage related accidents
18. **Information for patients on how to access the practice urgently or in an emergency is widely available in different formats** (for example, posters, leaflets, booklet, website)	• Patients not fully understanding how to access the practice for urgent or emergency care can further prolong illness, delays in treatment, and lead to unnecessary visits to other health services
19. **Standardised patient identification (ID) verification**	• Numerous significant events in general practice are related to mix-ups over patient identification leading to patient's being subjected to unnecessary treatments, hospital visits, and investigations, and breaches of confidentiality which can cause avoidable physical and emotional harm

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Appendix 2 continued. Example list of hazards in general medical practice identified by study participants for each checklist subcategory (*n* = 22) and how the safety, health and wellbeing of patients, GP team members, and practice organisation performance can be impacted

20. Building safety and insurance	• All are legally required and are there to protect the health, safety, and wellbeing of staff, patients, and visitors • Notification of workplace accidents to the Health & Safety Executive is required by law where an individual is required to take ≥3 days off work as a consequence • Although a medical establishment, a first aid arrangement is still a safety requirement similar to any other place of work
21. Environmental awareness	• Hazards in the workplace which are not identified and attended to can lead to harm; for example, a patient sustaining a head injury from walking into a low lying light • Lack of thermal comfort can act as a distraction and make staff uncomfortable, thereby impacting on physical and mental health and increasing risk of error and poor performance
22. Staff health and wellbeing	• Disorganisation of work and lack of clarity of roles and tasks can cause confusion, impact on mental health, and raise the risk of poor performance and error which could compromise patient safety • Staff can be subject to abuse, anger, threatening behaviour, and violence and should be trained to manage these situations to protect the safety and wellbeing of themselves and patients • Inadequate work station design, poor display screen and equipment training and practice, and lack of knowledge of manual handling guidance can impact on the physical (musculoskeletal injury) and mental health (for example, increased stress levels) and wellbeing of staff (for example, job satisfaction, and motivation), affecting performance levels and increasing the risks of errors being made (for example, attention levels when confirming patient ID on a computerised system or coding safety-critical patient data)

Appendix 3. Preliminary safety checklist for general practice [NHS Education for Scotland (draft version)]

Why do we need such a checklist?

- Practice processes for checking priority safety issues that can impact on the health and wellbeing of patients and GP team members are highly variable and can be inconsistently applied which often contributes to why significant events happen.
- When combined with everyday complex workloads and stresses our memory spans and attention to detail are affected. This means we can often forget to undertake necessary checks of important safety tasks as planned — this can lead to errors being made, sometimes this has no real consequences but on other occasions it impacts negatively on patients, staff, and the practice.
- Checklists are used routinely in high risk industries such as aviation, nuclear power, and many hospitals to help staff remember critical tasks to be undertaken to ensure mistakes are not made and help make patients and the workplace safer.
- The purpose of this checklist is to help ensure that tasks that are considered to be important from a safety perspective are actually checked on a routine basis and action is taken where needed to improve overall compliance. It aims to combine some existing checking processes into a single checking system which is undertaken every four months to ensure that the necessary checks are completed on a timely basis.

About the checklist

- The preliminary checklist was developed based on a combination of what we know can go wrong when things that should be checked routinely in practice are not, and the knowledge and expertise of a large group of practice managers, practice nurses, and GPs who contributed to its design and content over several workshops and surveys.
- It is important to note that it is not mandatory — but is a flexible guide, you will not necessarily agree with all of the content nor may it always be relevant to your practice. Use your own judgement and apply your own common sense. In these cases simply tick Yes for being fully compliant.
- As far as possible the development process was informed by human factors/systems thinking and guidance to make the checklist content relevant and understandable and to cover all aspects of the general practice workplace.
- If the checklist is not an improvement on existing checking processes then it is unlikely to be used, although bear in mind that some practices do this inconsistently and infrequently compared with others. The prevailing safety culture within a practice will also influence how seriously the checklist and checking processes are taken, that is: the checklist itself will not make the practice processes safer, like any improvement activity this is always down to the leadership, team-working and commitment of the GP team.

How to use the checklist

- Simply work your way through the checklist (it has been sub-divided to make it easier to follow and complete) and use a combination of checking and your own professional judgement to determine whether you are fully compliant with each of the issues outlined.

1. Medication Management • Core safety issues to be checked	**How to check?**	**Fully Compliant? Yes (•)**	**Fully Compliant? No (•)**	**If No, please outline Action Plan and Date of Review**	**Review Date**
1. Controlled drugs • Securely stored • Up-to-date register exists • Stock balances are undertaken at appropriate time intervals based on practice usage • Any out-of-date stock is appropriately disposed	Document review and spot check				
2. Emergency drugs & equipment • Your usual supplies are available in sufficient quantities • Evidence of monthly stock check and expiry date rotation • Evidence of monthly equipment check (for example, nebuliser, defibrillator, airways, anaphylaxis)	Document review and spot check				
3. Prescriptions & pads • Securely stored • Serial numbers are for prescription pads are recorded and stored	Spot check				
4. Vaccinations • Cold chain temperature recording at least once daily • Storage facility is locked and alarmed • Your usual supplies are available in sufficient quantities • Evidence of expiry date rotation	Document review and spot check				
5. All other drugs on premises • Storage facility is secure • Your usual supplies are available in sufficient quantities • Evidence of expiry date rotation • Where a process exists for drugs to be returned to the practice, they are disposed of safely	Document review and spot check				

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Appendix 3 continued. Preliminary safety checklist for general practice [NHS Education for Scotland (draft version)]

2. Housekeeping • Core safety issues to be checked	How to check?	Fully Compliant? Yes (•)	Fully Compliant? No (•)	If No, please outline Action Plan and Date of Review	Review Date
6. Infection control • All staff are trained in standard infection control precautions, including hand hygiene and sharps/bite/splash management • Practice equipment is cleaned in line with practice policy • Premises (floors, furnishings, surfaces, children's toys etc) are cleaned in line with practice policy • Clinical waste is disposed of in line with practice policy • Laboratory specimens are handled and stored in line with practice policy • All staff are offered immunisation/boosters and are up-to-date (for example, Hepatitis B, Rubella & Influenza)	Document review, spot checks & discrete observation				
7. Stocking of clinical rooms • Adequate personal protective equipment (PPE) is available • Single use only sterile and non-sterile gloves in a range of sizes (where necessary) with latex-free alternatives are available • Disposable hand and couch paper towels are available for use • Liquid soap and Alco Gel are available • Sharps containers are available, correctly assembled, out of reach of children, not filled beyond indicator mark and do not contain inappropriate waste	Spot checks				
8. Confidential waste • Identifiable patient information is disposed securely and confidentially (for example, shredded)	Spot checks and discrete observation				
9. Clinical equipment maintenance • There is a log of all significant items of clinical equipment • There is a date system for when equipment should be serviced/working status checked • All significant items of clinical equipment are calibrated or maintained in line with manufacturer's instructions/service recommendations • Equipment which is not in use/maintained is disposed of appropriately	Document review, spot checks				

3. Information systems • Core safety issues to be checked	How to check?	Fully Compliant? Yes (•)	Fully Compliant? No (•)	If No, please outline Action Plan and Date of Review	Review Date
10. The practice business continuity plan is up-to-date?	Document review				
11. The back-up of all significant IT systems can be verified?	Spot check				
12. Data protection • Latest software updates for all systems are installed (for example, formulary, EMIS, Vision)? • Password security policy is being followed (including remote access protocols	Spot checks				
13. Record keeping • Clear evidence is available of accurate and up-to-date record keeping (for example, data coding and summarising, allergy updates)	Document reviews and spot checks				

4. Practice Team • Core safety issues to be checked	How to check?	Fully Compliant? Yes (•)	Fully Compliant? No (•)	If No, please outline Action Plan and Date of Review	Review Date
14. Registration checks • All clinicians are registered with regulators • All clinicians are registered with a Defence union • Protecting Vulnerable Groups (PVG) checks are up-to-date • Doctors are on the Performer's list	Document reviews				
15. CPR and Anaphylaxis training • All staff have up-to-date CPR training • All clinical staff have up-to-date anaphylaxis training	Document reviews				
16. Induction processes • Induction process is up-to-date and any new staff are inducted appropriately for their role • Up-to-date locum doctor/nurse induction pack is available and used	Document reviews and spot check				
17. All staff have access to ongoing patient safety-related training opportunities (for example, needle-stick injury, health and safety/fire safety, coding data)	Document reviews				

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Appendix 3 continued. Preliminary safety checklist for general practice [NHS Education for Scotland (draft version)]

5. Patient access and identification • Core safety issues to be checked	How to Check?	Fully Compliant? Yes (•)	Fully Compliant? No (•)	If No, please outline Action Plan and Date of Review	Review Date
18. **Information for patients on how to access the practice urgently or in an emergency is widely available in different formats** (for example, posters, leaflets, booklet, website)	Document review and spot check				
19. **Standardised patient identification (ID) verification** • The practice has a patient ID process using **two** approved patient identifiers and the practice team can describe how it is applied. • Patient ID is always confirmed by all staff (over the telephone, face-to-face, when filing or handling records/results, writing prescriptions/referrals) using **two** of the following three characteristics: full name, date of birth and postal address (sex and CHI number if known/ available can also be used).	Document review and discrete observation				

6. Health & Safety • Core safety issues to be checked	How to Check?	Fully Compliant? Yes (•)	Fully Compliant? No (•)	If No, please outline Action Plan and Date of Review	Review Date
20. **Building safety and insurance** • Practice policies on electrical and fire safety are adhered to • Public and employer's liability insurance are up-to-date and displayed • A system for recording and notifying accidents/violent incidents/near misses is in operation • First aid arrangements are in place (a first aid box is available and all staff are aware of trained first aiders)	Document reviews				
21. **Environmental awareness** • Routine checks for hazards to staff, patients, children and visitors are undertaken internally (for example, spillages, worn flooring, low hanging or protruding objects) and externally (for example, broken glass, spillages, obstructions) • General thermal and lighting comfort (heating and cooling where necessary) is achieved within the premises	Spot checks				
22. **Staff health and wellbeing** • All partners and staff have clear work roles and designated tasks, and workloads are balanced • The practice recognises the existence of work-related stress and accepts the need to identify its symptoms and resolve or manage contributory factors • Regular team meetings are held to review practice performance, raise issues and problems and seek resolutions • Access to training in handling threatening behaviour is available to all staff. • The workstations of all display screen equipment users provide adequate space and are assessed to health and safety legal standards. • All relevant staff are trained in manual handling procedures	Document review and spot check				