



Reporting and learning from patient safety incidents in general practice

A practical guide

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Purpose of guide

The purpose of this guide is to:

- maximise opportunities to learn from patient safety incidents in your practice, and to share learning via organisational or national reporting systems
- outline a process for learning from patient safety incidents in your practice.

Where appropriate, this guide will signpost existing well-written resources and does not seek to replicate their content.

Introduction

Providing safe, high-quality care for patients in the community is the aim of every GP. More than two decades of research highlights that patients can be inadvertently harmed as a result of an event or circumstance which occurs during their care. Best estimates suggest that between 2-3% of consultations result in a **patient safety incident defined as “any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare”**.

One in 25 patient safety incidents will result in severe harm, including shortening of life expectancy, permanent injury, major loss of function or death.^[1] A GP working six sessions a week with 25 interactions per session (a conservative estimate) could be involved in seven to eight severe harm incidents a year.

One in 25 patient safety incidents will result in severe harm





What is a patient safety incident?

Unsafe healthcare has variously been described as a ‘medical error’, an ‘adverse event’, or a ‘serious untoward incident’. Internationally, the favoured term is now **patient safety incident**. An analysis of 13,699 patient safety incident reports from general practices in England and Wales revealed a diverse range of incidents that can occur (see Table 1 for a summary of incident types identified).^[2]

Communication with patients

- Miscommunication e.g. inadequate safety netting advice
- Difficulties accessing clinical services e.g. telephone triage, message handling, appointments
- Parent-held records unavailable

Communication between professionals

- Unavailable or inaccurate medical records e.g. paper notes from previous practice
- Delayed referrals e.g. erroneously completed referral, delayed decision to refer
- Information transfer between care providers e.g. delayed discharge summary or clinic letter

Diagnosis and assessment

- Missed or delayed diagnosis
- Delayed assessment of care
- Delayed assessing of patients with serious mental health conditions
- Not identifying patients at risk of deterioration

Medication and vaccine

- Errors in prescribing, dispensing and administering medicines and vaccines
- Complications with therapeutic drug monitoring processes

Investigations

- Ordering inappropriate investigations to inform differential diagnosis
- Incorrect collection, or transfer, of specimens
- Administrative failures leading to delays, wrong results or failure to receive results
- Incorrectly interpreted results e.g. blood tests, imaging, other investigations

Treatment and equipment

- Complications of procedures
- Malfunctioning and unavailability of care equipment e.g. pressure mattresses, oxygen, walking aids.

Table 1. Summary of patient safety incidents reported from general practice in England and Wales^[2]





Why report patient safety incidents?

Reporting a patient safety incident can allow:

- Reflection on the incident by the reporter and enhanced professional development (individual level)
- Identification of opportunities to undertake SEAs (practice level)
- Collated reports at a Health Board or CCG to highlight local systems issues for change (system level)
- Collated reports to help identify rare issues (national level).

GPs already dedicate resources to undertake Significant Event Analyses (SEAs), also called Significant Event Review or Audits, and these are often used for appraisal processes. SEAs inform improvement efforts in practice.

Not all incidents need a SEA

Busy GPs and practice teams should write patient safety incident reports about incidents that have not been subject to an in-house SEA. This includes incidents where the patient came to no harm, or where an intervention occurred before harm could reach the patient (so called 'near misses'). These incidents allow teams to identify and understand what processes are working well, and which could be improved.

Sharing SEAs for regional and national learning

Practices should consider sharing SEAs for regional or national learning because it represents an opportunity for the NHS to learn how to improve the quality and safety of primary care.

Incident reporting systems have been established at a national level to gather reports together to facilitate learning about what led to patient safety incidents. However, of the 14 million reports submitted from healthcare organisations in England and Wales in over a decade, general practice has contributed less than 0.5% of those reports.^[2]





What can be learnt following a patient safety incident?

Patient safety improvement efforts are predicated on understanding the work conditions and processes that contributed to a patient safety incident (so called 'contributory factors'). This aids the design of interventions which would be more likely to be effective in the context in which the incident occurred.

When writing a patient safety incident report, healthcare professionals should describe what happened in terms of the key steps resulting in an unsafe outcome for a patient, and the perceived contributory factors. For example, in Case Study One, the reporter has provided a brief and informative narrative.

CASE STUDY ONE: **Extra vaccine administered to a child**

A patient safety report written by the GP practice nurse read:

“Child had been placed with **adoptive parents** and adopted mum had been **advised by a social worker** to attend GP surgery to complete primary vaccinations. (Foster) Mum attended surgery with parental held record, **no other record on system or child health medical records available**. Only **two immunisations** had been **recorded** in the red book, remaining immunisations given with consent. Later informed by social services that child has **already completed** her primary immunisations.”

Breaking the incident down (Figure 1), the child is known to be in social care (contributory factor) and therefore the foster mum may not be able to provide the child's full health background (contributory factor). The child is new to the GP practice (contributory factor) and it is therefore not possible to corroborate what is recorded in the parent held record with her old medical records (incident). The child is given an additional vaccine (incident), and we can presume the patient is only distressed by the injection (low harm outcome) since no other outcome is explicitly stated.



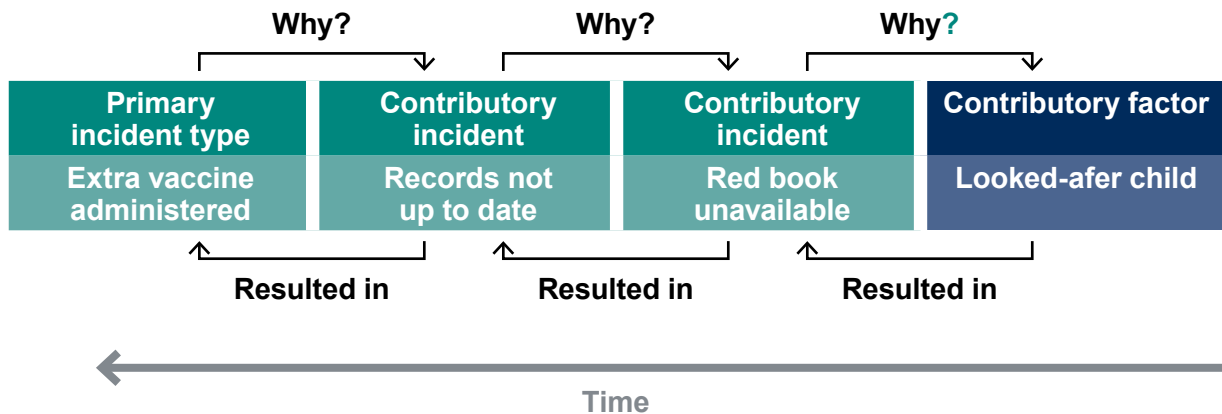


Figure 1. Example trajectory of a patient safety incident

Considering the contributory factors present within the report, several opportunities for improvement could be developed and tested by this practice team and their social care colleagues:

- Mandate all practice nurses use the electronic medical record as the definitive reference when administering vaccinations
- Create an automated alert on the medical record when a patient is new and a record is incomplete
- Social workers to enhance their handover documentation e.g. develop and test feasibility of adding 'ensure transfer of child's medical records to new GP practice within five working days' to a checklist of essential tasks to be completed before a child can be placed in an adoptive home.

Reported contributory factors to patient safety incidents

Incident reports provide an opportunity to direct improvement initiatives by summarising the weaknesses in the system that lead to incidents and harm experienced by patients.

The discipline of patient safety is predicated on the theory that harm is caused by a multifactorial chain of related incidents.^[3]

The underlying assumption is that if the working conditions and processes to delivery care can be optimised, then patient safety incidents would be less likely to occur.





CASE STUDY TWO: Seeking multiple perspectives to understand safety

The following incident report was written by a written by a general practice registrar:

“Administered IM depo-medrone instead of depo-provera. Busy clinic. Patient usually sees nurse but slotted in with me. **Never previously given this depot injection** but I have observed the procedure a number of times. Felt competent to give the injection. However, **similarly named drugs were kept adjacent to each other** in drugs cupboard and I selected wrong drug in error despite satisfying myself it was in date. Informed Dr X [trainer] and practice manager. Called patient to apologise and to return for review in the afternoon; side effects advised should patient develop these to return. For discussion at practice team meeting next week.”

A popular way of thinking about how incidents occur is through the Swiss Cheese model which uses the analogy of serial slices of Swiss cheese where each hole represents either an incident (an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient) or contributory factor (circumstances, actions or influences, that initiate or increase the risk of an incident).^[4]

The report, above, offers a one-sided account of what happened and perceived reasons why. However, it was the starting point for discussion at the practice team meeting a week later. Through discussion it became apparent all staff (administrators, partners, and nurses) were having a particularly difficult time on that day. On review of appointments lists, all the GPs were running between 30 to 40 minutes behind due to additional slots being created due to staff sickness. Further, the receptionist shared that she felt unclear about what procedures to book in with the GP registrar if the patient’s usual GP or nurse was not available at short notice. Several GPs and nurses shared their longstanding concerns that they would also select the wrong drug from the cupboard eventually because some members of the team needed to stretch up to reach some drugs.

Their discussion is summarised using the Swiss Cheese model concept in Figure 2.



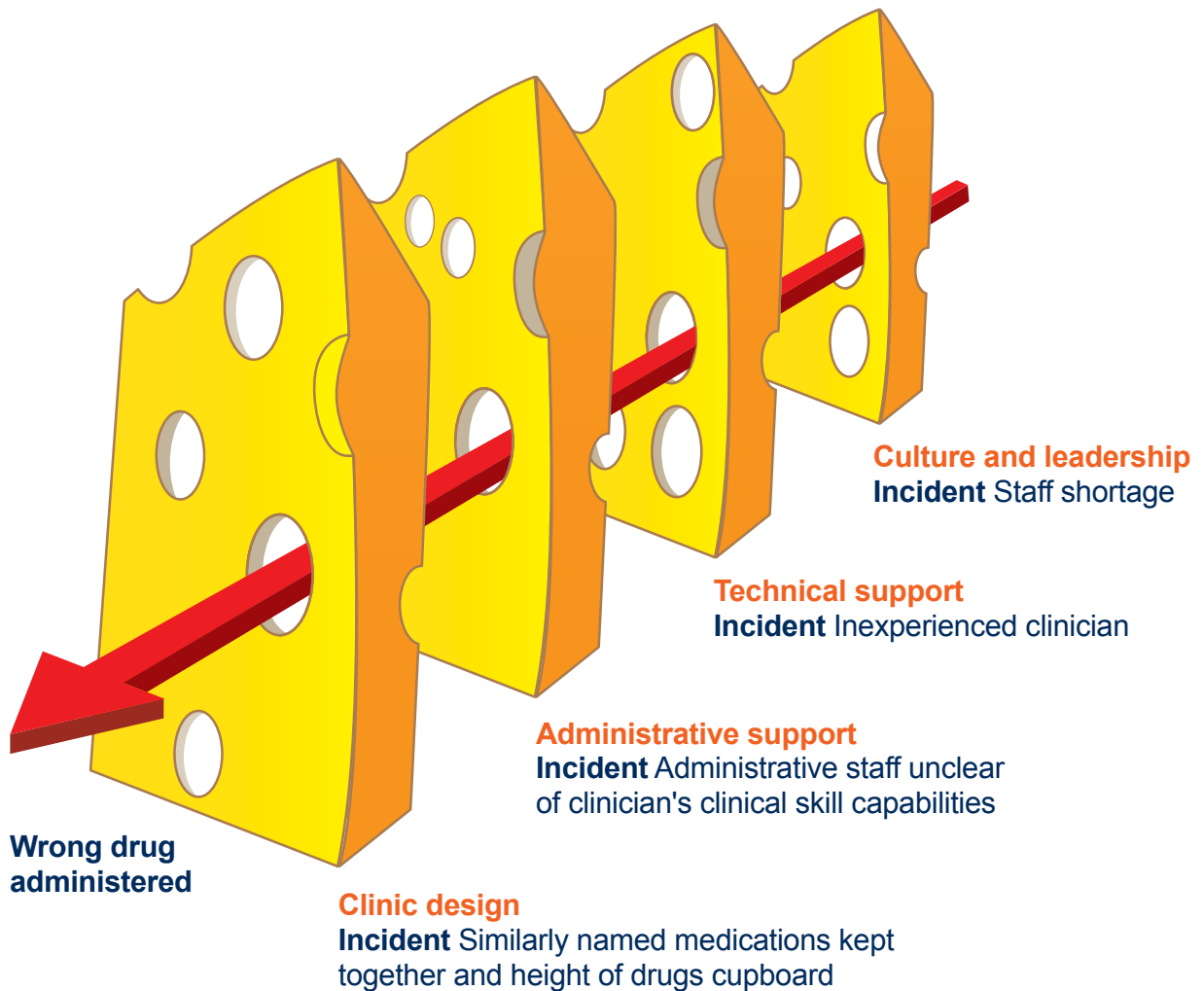


Figure 2. Swiss Cheese model applied to a clinical incident

Many different contributory factors can coexist at any one time to result in an incident. They can be diverse in nature, and thought of in terms of human factors, for example staff or patient related, as well as system factors such as organisational, financial or equipment related issues.

The ability to identify contributory factors when an incident occurs represents an opportunity to understand how healthcare systems and processes can be improved, to minimise weaknesses and strengthen defences. **This study of human factors as a field of specialist inquiry is described as “enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture, organisation on human behaviour and abilities, and application of that knowledge in clinical settings.”** [5]



The practice team recognised several opportunities to improve care for their patients. This was summarised by the practice manager as follows:

- **Teamwork** – we will trial identifying a ‘go to doctor’ for the GP registrar for each session.
- **Workspace** – we will group drugs together according to their purpose (not alphabetical order) and move where these are kept so they are visible and reachable from standing height.
- **Task allocation** – admin staff to discuss with duty doctor if they are unclear about the competency of the registrar. If duty doctor not available, to offer patient an alternative appointment.
- **Culture** – Dr X [GP trainer] will more explicitly inquire at weekly tutorials about whether GP registrar feels able to call upon help and guidance from other staff.
- **Organisation** – to have clear contingency plans for re-allocating appointments for when key members of staff are unavoidably absent.
- **Knowledge** – we all feel the priority issues for improvement have emerged from our discussion today. A more detailed Significant Event Analysis is not required.

An aggregation of incident reports (at a regional and national level) can reveal issues for systems improvement that would be missed or overlooked at a local level. It also permits collation of a large volume of similarly themed reports. In the next case study, the benefits of nationally aggregated data are considered.

CASE STUDY THREE: **Using contributory factors to redesign care**

An analysis of paediatric vaccine-related incident reports demonstrated a diverse range of incidents and contributory factors that resulted in the development of 1745 vaccine-related incidents involving children in England and Wales between 2002 and 2013. [6,7] Contributory factors were identified in the free text narratives by researchers trained in Human Factors, with an interest in designing improvement interventions based on the nature of the described contributory factors.





	Freq.
Patient / parent factors	
Patient/parent behaviour the way in which patients or parents act or conduct themselves e.g. non-compliance, non-disclosure	74
Patient/parent geography e.g. patient new to the area	64
Patient health factors relating to the patient's physical and mental well being (e.g. allergy, disability, immunocompromised, pregnant)	37
Patient/parent knowledge insufficient knowledge or inadequate application of knowledge	48
Out-of-home care children not in the care of their parents e.g. in foster care	18
Patient/parent language barrier patient or parent unable to communicate in English	5
Staff factors	
Mistake cognitive lapses	240
Similar vaccine appearances vaccines with similar names or appearances	45
Distraction influence to prevent concentration on a task	22
Misreading to judge or interpret incorrectly	18
Inattention failure to carefully think, list, or observe	10
Similar patient names confusion arising from patients with similar names	9
Failure to follow protocol not adhering to organisational guidelines	186
Knowledge insufficient knowledge or inadequate application of knowledge	19
Fatigue/stress extreme tiredness, mental or emotional strain	5
Equipment / vaccine factors	
Failure of equipment/vaccine the equipment or vaccine is faulty	36
Equipment/vaccine packaging the packaging is impractical, inadequate or faulty	25
Equipment/vaccine storage inadequate impractical storage	25
Poor equipment/vaccine design the design is impractical, inadequate or faulty	3
Organisational factors	
Working Conditions factors relating to the work environment	52
Continuity of care issues with the coordination of services	48
Education and training insufficient education and training of staff	36
Inadequate guidelines or protocols existing guidelines not fit for purpose	27

Table 2. Frequency of described contributory factors in 1745 paediatric vaccine-related incidents from Rees et al. 2015 [6]





Table 2 provides an overview of the factors described and their definitions.

As seen in Table 2, contributory factors can be thought of in terms of patient or parent factors, staff factors (e.g. staff shortage, inexperienced clinician, receptionist unclear of clinician's competency), equipment and vaccine factors (e.g. storage of similar named drugs), and organisational factors (e.g. allocating supervision to training doctor).

The contributory factors in Table 2 are intuitive and often easily identifiable in everyday life when they occur in isolation. Having large volumes of similar reports can permit the modelling of the relationship between processes in care such as vaccine delivery, and the salient contributory factors described (see Figure 3). Opportunities for intervention can be considered by administrators, healthcare professionals and even manufacturers.

Starting at 'Parent makes appointment', follow the patient's journey throughout the vaccination delivery process. Multiple processes are required in order for a child to receive the correct vaccination. At each process, there is potential for variation in practice as a result of staff, patient, organisational and equipment and vaccine-related factors.

In Figure 4, such contributory factors can be used as the basis of generating improvement ideas to mitigate future incidents. This level of in-depth insight has emerged from a research study. This is not the level of detail that can be expected to occur in general practices because the volume of vaccine reports will probably be small. These illustrations are included, however, to highlight issues that can be solved at a local level (e.g. prepare vaccines for one child at a time, store similar vaccines separately) whilst others might require escalation to regional representative bodies and sometimes Government (e.g. no sudden changes in vaccine brand / formulation).

Review of these vaccine-related incident reports describing unsafe care to children has enhanced knowledge about what happened (incidents) and why (contributory factors). When combined, they can inform a working theory of change to improve the vaccine delivery process for children in general practice.





Weaknesses in the process of childhood vaccination delivery

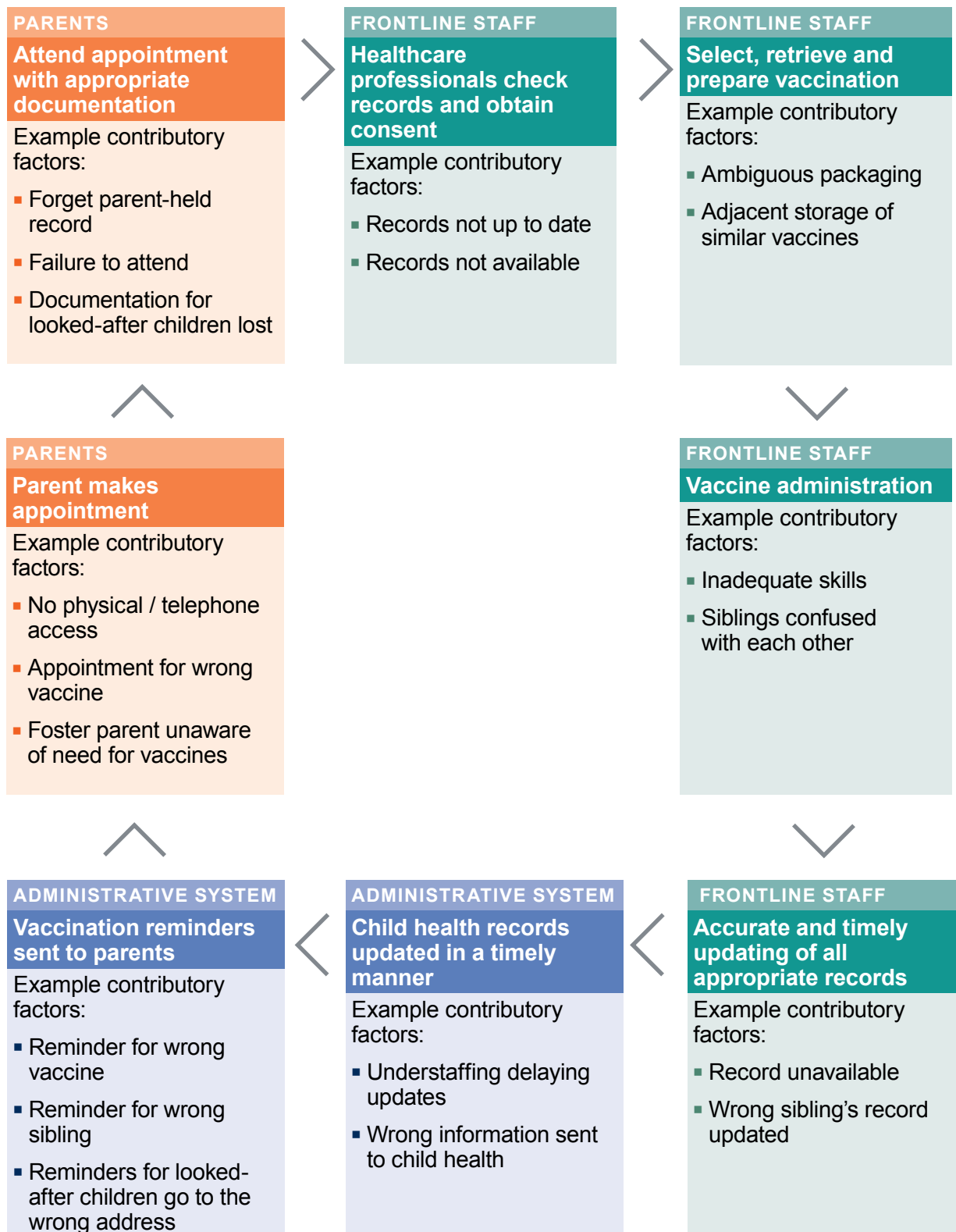


Figure 3. Weakness in the process of childhood vaccination delivery



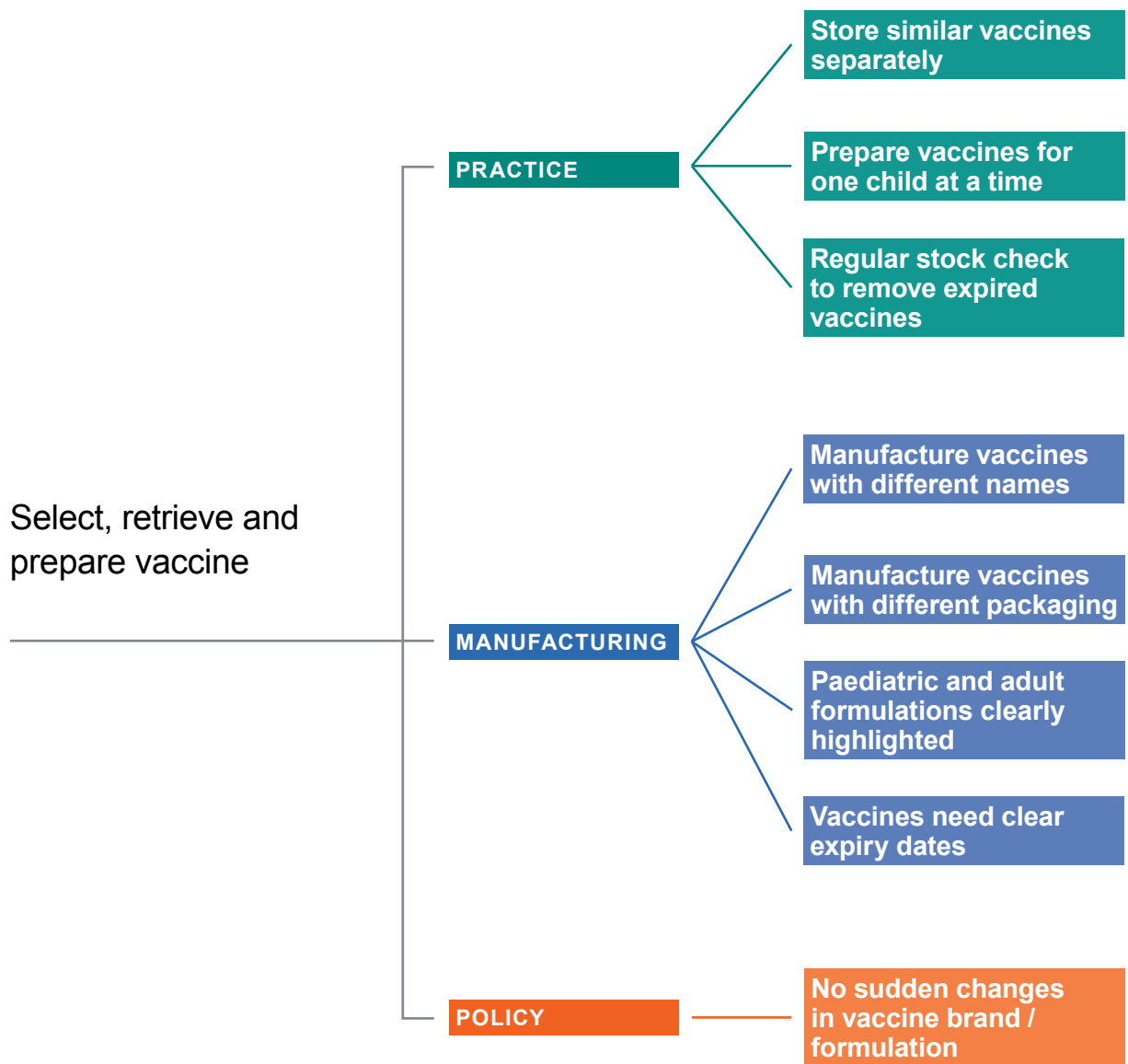


Figure 4. Improvement ideas to mitigate incidents involving selection, retrieval and preparation of vaccines

In Figure 5, the driver diagram contains the following details:

- **Outcome** covers the aim(s) of the project or the impact to be made.
- **Primary drivers** are high-level factors/areas that need to be addressed or influenced in order to achieve the outcome.
- **Secondary drivers** contribute to at least one primary driver and cover areas in which to take action and plan for change.

The driver diagram is described in more detail in the *RCGP QI Guide for General Practice*, page 31.^[8]

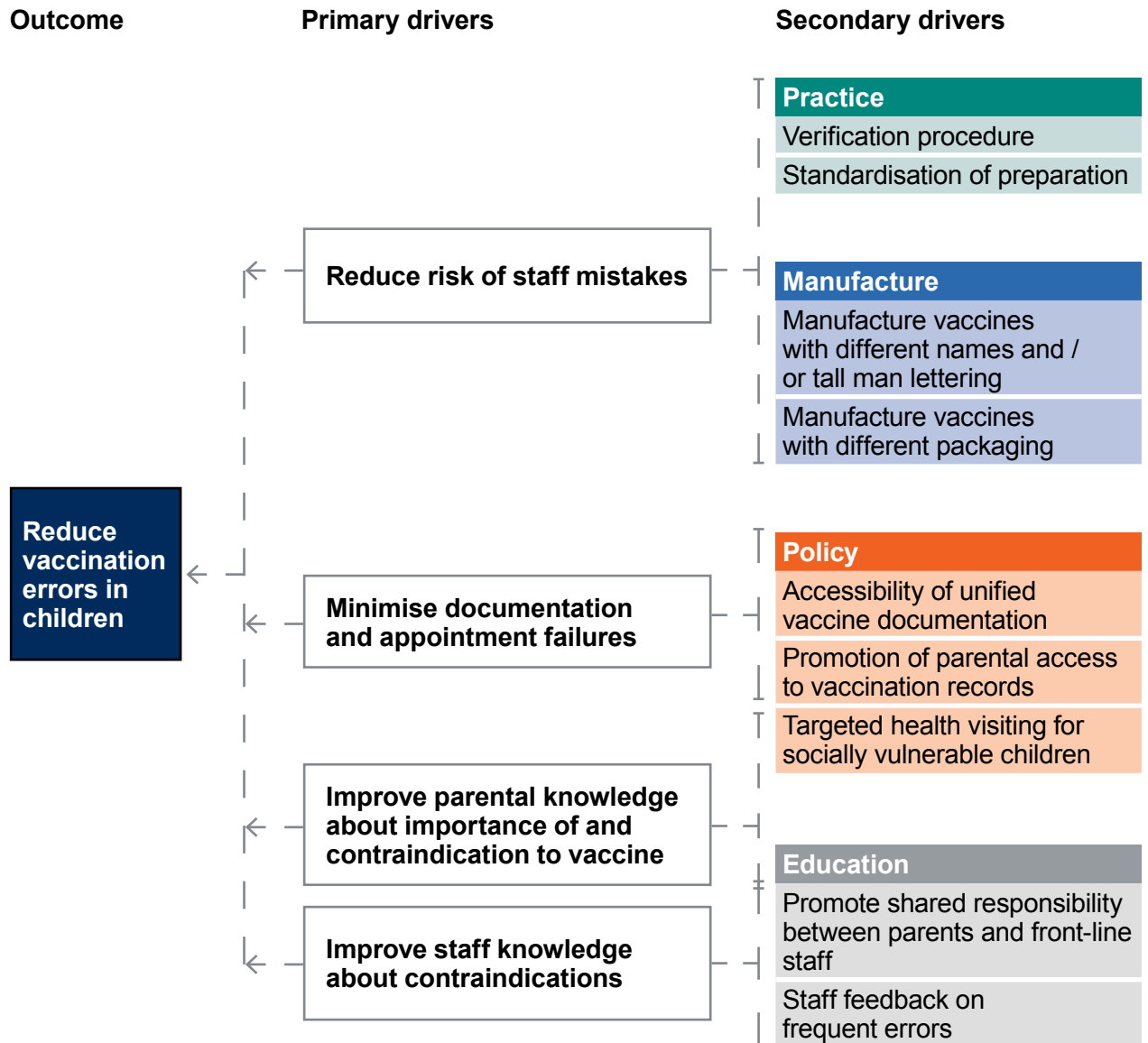


Figure 5. Driver diagram to reduce vaccination errors in children from Rees et al. 2015 [6]

For those interested in improving vaccine delivery safety in their practices, perhaps as a result of an incident that prompted a SEA, this driver diagram could be a starting point for considering where in your practice you could begin to target your improvement efforts. Essentially, it is a first draft of ideas about where to intervene (rather than starting with a blank sheet of paper).





Mechanism for generating learning in practice

Given the volume of incidents occurring in primary care on a daily basis, each practice should have a process for generating learning from incidents that have occurred, and have a mechanism for sharing those reports in accordance with their local, regional (and in England and Wales, national) agreements with incident reporting systems.

The Primary Care Patient Safety (PISA) Learning for Care Improvement model is suggested below. You could use this model as a starting point for discussion as a practice team to consider what your practice currently does at each stage of this learning process.

Involving patients and their families

Providing information to patients, families and their carers is of paramount importance throughout the learning process. Acknowledging a patient safety incident has occurred is the first important step to take. Practices should consider how they will communicate with patients that a patient safety incident has occurred and to advise patients on the actions that will be taken to prevent future occurrences.

Not acknowledging an incident has occurred is a major source of distress and upset for patients. Determining how to best communicate a patient safety incident in different contexts is key. For example, your approach for advising a patient that their referral to see a cancer specialist has been delayed because of an administrative error, might differ to advising they need to re-attend for a repeat blood pressure reading because it has been identified the sphygmomanometer was faulty on their last visit. Such judgements are usually influenced by the severity of harm outcome (see following section Stage 3: Risk Assessment.)

In the interests of transparency, in the first instance inform the patient about the incident, what this means and what intervention or follow up is needed. Once the outcome of a team-based discussion and / or SEA is clear, feed back to the patient what has been learnt. Your approach for providing this feedback should be developed per the severity of the outcome, your awareness of the patient's expectations and their circumstances.





Stages of the Primary Care Patient Safety (PISA) Learning for Care Improvement Model

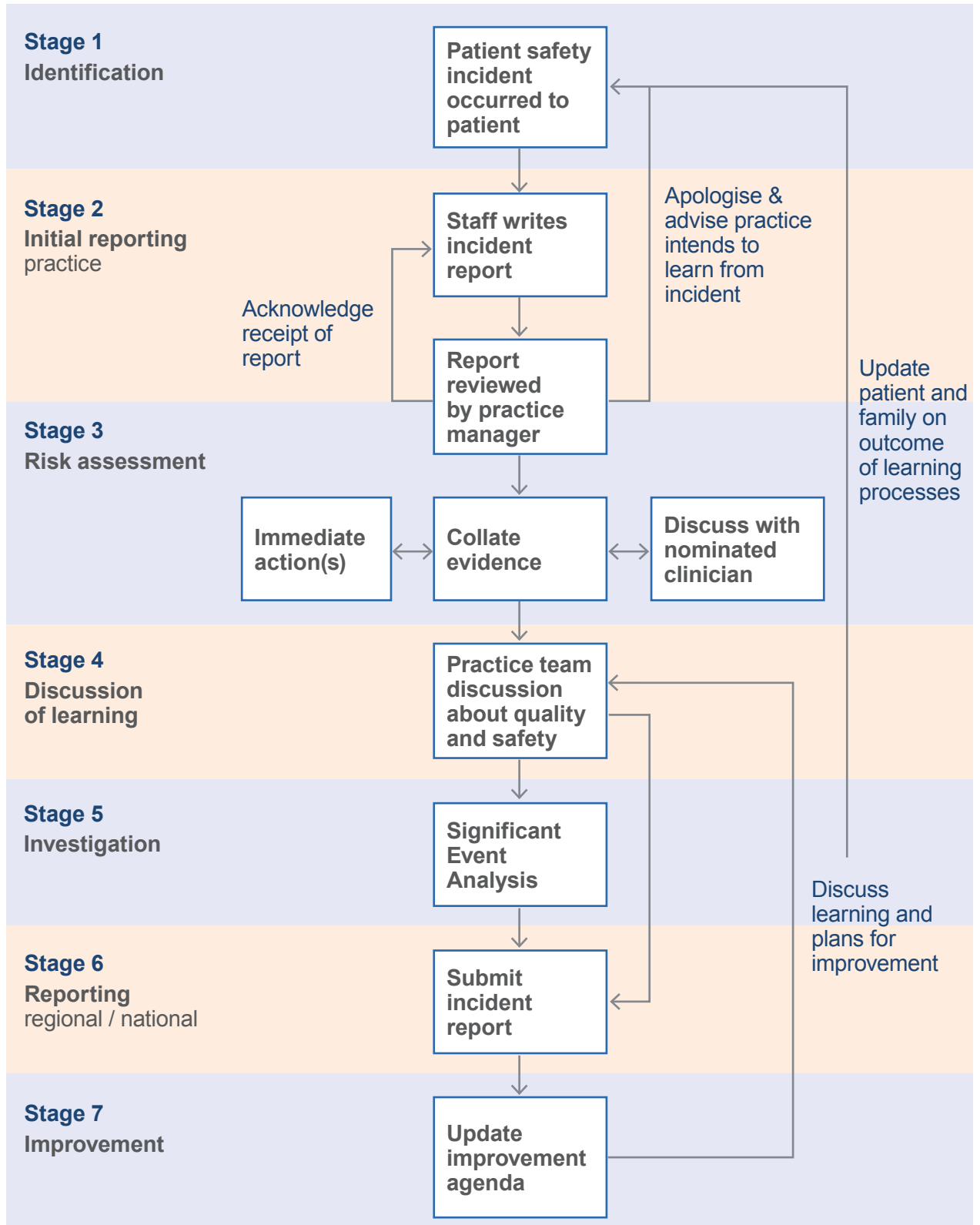


Figure 6. Stages of the Primary Care Patient Safety (PISA) Learning for Care Improvement Model





This contact might range from a telephone call to a face to face meeting, and your first contact with the patient might help guide how they want to be kept updated.

The key stages of the 'PISA Learning for Care Improvement' model will now be considered in more detail.

Stage 1: Identification

Staff should understand what a patient safety incident is. Incidents may be identified through direct observation, discussion with colleagues, staff meeting discussions, complaints, reviewing patient's notes.

Table 1 could be used to begin a group discussion about the range of incidents that have occurred in general practice in England and Wales. You might use the following questions to guide those discussions:

- "How many of these incidents have occurred in our practice in the past month?"
- "What did we do when they occurred?"
- "How are we learning to prevent them?"
- "What changes can we make to ensure everyone can learn from patient safety incidents?"

Stage 2: Initial reporting (practice)

GPs, all healthcare professionals, administrative staff and the practice manager can submit an incident report directly to the National Reporting and Learning System (NRLS) in NHS England. The other UK countries have their own arrangements for reporting incidents to either regional or national learning repositories (see Stage 6: Submitting an incident report, from page 26). To ensure the practice can learn in the first instance, a mechanism is needed for capturing all incident reports before forwarding them on for wider NHS learning.

All members of the practice team should know how to report a patient safety incident. Staff should feel confident to report an incident without fear of reprimand. The emphasis of reporting should be to identify ways to improve the practice's processes for achieving its daily work rather than blaming an individual.





From an analysis of thousands of incident reports submitted to the England and Wales National Report and Learning system, a team of GPs at Cardiff University identified essential questions that should be answered in an incident report (Figure 7).

The criteria align with the World Health Organization's Minimal Information Model for Incident Reporting.^[10]

Appendix 1 shows an example of a patient safety incident report already used in general practice. We recommend that practices develop their own local reporting forms to capture all relevant information.

Who

- 1.1 Who is reporting the incident?
- 1.2 Which members of staff were involved?
- 1.3 Were people in that situation aware that there was a problem?

What

- 2.1 What happened, or what was the problem?
- 2.2 What was the outcome for the patient in this incident?
- 2.3 Was there a risk inherent to the clinical situation? e.g. medical adverse event?
- 2.4 Is this an isolated incident or is it a wider problem?

Where /when

- 3.1 In which area of healthcare did something go wrong?

Why

- 4.1 Is there an identifiable cause to the problem?
- 4.2 Could this harm have been predicted?

Preventing recurrence

- 5.1 How could the harm have been prevented?
- 5.2 Has anything been learned from the situation?
- 5.3 Have measures been put in place to prevent reoccurrence?

Figure 7. Criteria for an incident report [9]





Stage 3: Risk assessment

The incident report should provide essential information about what happened. It is often the case that the practice manager (and designated partner for quality and safety) will begin an informal inquiry to identify additional details such as the severity of harm outcome, to consider the risk of a similar incident recurring in the practice, and determine whether any immediate action is needed for the patient and their family.

An initial review of the incident report should be made by the practice manager who will decide whether the report also requires review by the nominated quality and safety lead partner. Practices should agree on rules for escalating an incident report to the nominated partner. Some incidents will come to light which have been generated by actions outside the practice such as in hospitals. For example, a patient may have developed advanced stage cancer because a radiology report went missing or was misinterpreted in the hospital; however, the error is only detected when the patient attends for consultation with obvious signs or symptoms of cancer or has an investigation repeated a few months later. In these circumstances, whilst the practice will need to review the incident, the appropriate action would be to draw the matter to the attention of the medical director of the hospital as well as reporting the incident to the NRLS (in England and Wales).

The practice manager (and/or nominated partner) should decide whether the facts about the incident have been sufficiently determined and will be suitable for group discussion at the next quality and safety meeting, will require a Significant Event Audit, or both. If the incident is complex, it may benefit from a more structured investigation like a SEA. For example, a facilitated team-based discussion may be needed if the incident resulted from care received over multiple episodes by multiple GPs or the patient has a complex medical and social background. Similarly, for issues where input from representatives from secondary or tertiary services (e.g. opinion from Consultant Neurologist) would be beneficial, this might benefit from a SEA.

Tools are suggested to help structure this process by considering the severity of harm (Table 3) and risk of recurrence (Table 4).





Severity of harm

The Primary Care Patient Safety (PISA) team at Cardiff University have developed a system for classifying the different levels of harm experienced by patients and their family because of patient safety incidents in primary care. The definitions in Table 3 range from no harm to death, and are aligned with the WHO International Classification for Patient Safety. These definitions can be used to think about the physical, social and psychological implications for your patients and their families during discussion of incidents during team-based discussions and SEAs.





Severity	Definition
No harm	An incident occurred but no harm was experienced by the patient.
No harm outcome due to mitigating action	Any incident that had the potential to cause harm to a patient but this was prevented, resulting in no harm.
Mild harm	Patient was harmed with mild and short term impact on physical, mental or social functioning. This includes requiring: minimal intervention/treatment e.g. antiemetic, oral antibiotic. Repeat of a minor procedure such as vaccination or insertion of contraceptive implant. The patient or their loved ones experiencing transient emotional distress but no long-term consequences.
Moderate harm	Patient was harmed causing a medium term impact on physical, mental or social functioning. This includes requiring: medical intervention in the form of treatment e.g. intravenous fluids or antibiotics. Short term hospitalisation for assessment and/or minor treatment in either A&E or a hospital ward. The patient or their loved ones experiencing psychological difficulty of a more longstanding nature but not requiring formal treatment e.g. evidence of more longstanding anxiety, insomnia, or low mood.
Severe harm	Patient was harmed causing a major long term or permanent impact on physical, mental or social function or shortening of life-expectancy. This includes requiring: major medical or surgical intervention (most often delivered in a hospital setting) e.g. thrombolysis, cardioversion, any major surgery. Prolonged hospitalisation or admission to HDU/CCU/ITU. The patient or their loved ones experiencing enduring psychological difficulty that requires specialist treatment e.g. evidence of chronic anxiety or depression or psychosis.
Death	On the balance of probabilities, death was caused or brought forward in the short term by the incident.

Table 3. PISA Harm Severity Classification





Risk of recurrence

A severity assessment code (SAC) matrix, developed by the Veteran's Health Administration, can be used to consider the urgency of the action needed to be taken based on the severity of the harm outcome and the probability of it reoccurring.

Deciding on the probability of an incident reoccurring can be based on your professional experience of previous similar incidents and judgement based on your awareness of known underlying contributory factors. This might involve looking for similar cases in the practice or seeking an informal opinion from the nominated patient safety lead or member of the clinical or administration team with most expertise in this area.

Probability categories	Definition
Frequent	Is expected to occur again in our practice either immediately or within a short period (likely to occur most weeks or months).
Likely to occur in other practices	Will probably occur in most other practices in similar circumstances (several times a year).
Possible	Might possibly recur in our practice and in other practices – might occur at some time (may happen every 1 to 2 years).
Unlikely	Possibly will recur – could occur at some time in 2 to 5 years.
Rare	Unlikely to recur – may occur only in exceptional circumstances (may happen every 5 to 30 years).

Table 4. Probability of recurrence (developed from the SAC Matrix system developed by the Veteran's Health Administration)

Using the outcome (Table 3) and probability (Table 4) variables, a SAC matrix score can be generated to guide the level and urgency of investigation required (Table 5).





Probability as per table 4	Harm severity as per Table 3				
	Death	Severe Harm	Moderate Harm	Mild Harm	No Harm
Frequent	4	4	3	2	2
Likely	4	4	3	2	2
Possible	4	3	3	2	1
Unlikely	4	3	2	1	1
Rare	3	2	2	1	1

Table 5. SAC Matrix (developed from VHA) ^[11]

Each SAC matrix score from one to four has defined actions. Examples are provided here for illustration purposes and these must be amended for your own context, particularly agreed within your own practice and with your relevant commissioning body.

- **4 = Extreme risk:** Immediate action required – Clinical Director of Primary Care / Clinical Governance Leads must be informed. Investigation must be commenced across primary and secondary care. Significant Event Analysis to be undertaken in practice. Incident report to be sent to national database. Learning to be shared via agreed mechanisms with other GP and healthcare professional colleagues via local or regional groups (e.g. Clusters, CCG), and/or third sector providers.
- **3 = High risk:** Notification to Clinical Director of Primary Care / Clinical Governance Leads. Significant Event Analysis (and where relevant a Root Cause Analysis) involving relevant primary care team members and respective department staff. Incident report to be sent to national database. Learning to be shared via agreed mechanisms with other local / regional GPs.
- **2 = Medium risk:** Practice manager to aggregate data and Significant Event Analysis to be undertaken to inform an improvement project. Incident report to be sent to national database. Learning to be shared via agreed mechanisms with other local / regional GPs.
- **1 = Low risk:** Practice manager to aggregate data. To be discussed at team-based meeting and decision needed about whether Significant Event Analysis will be undertaken to inform practice improvement. Incident report to be sent to national database. Learning to be shared via agreed mechanisms with other local / regional GPs.





Stage 4: Discussion of learning

Discuss patient safety incident reports as a standing agenda item at partner meetings.

Efforts to explore how to involve the wider practice in those discussions on a regular basis will be valuable since issues for discussion will benefit from their knowledge and expertise about administration and operations in the practice.

Discussing safety incident reports with a representative from each staff group on a regular basis should allow you to discuss new incidents, celebrate successful improvements and identify further items to tackle on your improvement agenda.

A range of options exist for involving patients in team discussions. This can include inviting patient representatives to SEA discussions, reading out a thank you letter at the beginning of the meeting, and / or asking patient representatives to comment on the minutes of the team meetings.

Consider the following agenda at the meeting which includes discussing positive feedback letters from patients and families, examples of excellent practice and patient safety incidents:

Agenda

Date: _____

Items of Discussion (suggestions only):

- 1. Previous Minutes**
- 2. Thank you letters from patients / families**
- 3. Improvement project progress**
 - a. New gout template launched
 - b. Development of patient and public involvement group
 - c. Medication non-adherence
- 4. Review of excellence and patient safety incidents**
 - a. What new areas for improvement can we identify?
 - b. What changes can we make that will lead to improvement?
 - c. How will we know that a change is an improvement?
- 5. AOB**
- 6. Next meeting: (Date)**





Discussions about incidents can be structured using QI tools such as process mapping which is an activity to create a visual representation of all the steps in a process. This tool can help identify bottlenecks in processes that are creating needless extra work for staff. A 'how to guide' describing how to use process mapping and other techniques is included in the RCGP *Quality Improvement Guide*.^[8]

Stage 5: Investigation

Significant Event Analysis (SEAs) is an established process in general practices for investigating “any event thought by anyone in the team to be significant in the care of patients or the conduct of the practice.”^[12] It is a team-based approach to gather information, identify changes that could result in safer, better quality care, and plan to implement those in practice. Quality improvement tools like process mapping are helpful for the multi-disciplinary team to identify which care processes could be improved. A step-by-step guide for undertaking SEAs in primary care teams has been prepared by NHS Education for Scotland which outlines a seven-stage method as follows:^[13]

- **Stage 1:** Awareness and prioritisation of a significant event
- **Stage 2:** Information gathering
- **Stage 3:** The facilitated team-based discussion
- **Stage 4:** Analysis of the significant event
- **Stage 5:** Agree, implement and monitor change
- **Stage 6:** Write it up
- **Stage 7:** Report, share and review.

The RCGP Patient Safety Toolkit contains a structured form for capturing learning from the SEA process.^[14]

www.rcgp.org.uk/clinical-and-research/toolkits/patient-safety.aspx ↗

Stage 6: Submitting an incident report

The National Reporting and Learning System (NRLS) is a central repository of incident reports from healthcare organisations in England and Wales. There are currently 15 million reports in the NRLS. Analysis of similar reports (e.g. all reports about vaccine-related incidents involving children





General Practice Patient Safety Incident Report Form



National Reporting and Learning System

This form is designed for use by general practitioners, practice nurses and general practice staff to report patient safety incidents to the National Reporting and Learning System. This includes near misses and incidents where there is a beneficial outcome, for example where systems and processes have successfully prevented an untoward incident. Submitted reports are analysed for themes and trends to support national learning and sharing of good practice.

If the incident that you are reporting relates to safeguarding, whistleblowing or other incident type where separate policies for notification exist, these must be followed in addition to completing this form.

If you are reporting a Serious Incident requiring notification to the NHS England Sub Region (previously the Area Team), please include your practice ODS code and this report will be automatically shared with your NHS England Sub Region.

Please do not include any person identifiable information in your report.

Incident details

* Mandatory | Help

Q1 Please enter your ODS practice code ?

[Click here to verify code](#)

Q2 Please describe what happened? * ?

Do not include patient or person identifiable information

Q3 Please enter the date on which the event occurred * ?

Q4 Please enter the location in which the incident occurred * ?

Within the GP Practice Outside the GP Practice

Q5 Please categorise the Patient Safety Incident from the following choices * ?

Q6 Was this incident a never event? ?

Yes No Unsure

Q7 Was the incident shared or discussed with the patient, carer and/or family? ?

Yes No Unknown

Q8 Using the following grading, please indicate the degree of harm to the patient * ?

No Harm Low Harm Moderate Harm Severe Harm Death

Q9 Please use only one of the following options to add the age of the patient at the time the incident occurred * ?

Date of birth

or Age

or Unknown

Figure 8. NHS England General Practice Incident Report Form



Previous


Next





in general practice) permits identification of where in the care delivery process incidents are occurring, and an understanding about how to intervene.

England

General practices in England can submit reports directly to the NRLS. A GP-specific e-Incident report form (see Figure 8) has been developed where practices can choose to include their practice name and code, or report anonymously. The former would enable the NRLS to share information with Local Area Teams and the Clinical Commissioning Group (CCG). The NRLS analyses reported information for themes and trends to generate national learning. Examples of outputs from this process include Patient Safety Alerts which can be accessed at: england.nhs.uk/patientsafety/psa 

This e-Incident form contains enhanced features for efficient completion of the report, as well as an associated Continuing Professional Development / Significant Event Analysis reflective template for CPD, Appraisal and Revalidation purposes. NHS England has produced a guidance document for incident reporting.^[15]

Guidance from NHS England and the Care Quality Commission (CQC) is clear that a high reporting rate should not be seen as a marker of an unsafe organisation, but may represent a culture of openness and transparency, which should be encouraged for improved patient safety.^[16]

Notification to the Care Quality Commission

Regulation 20 (duty of candour) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 outlines requirements that practice must follow when an incident occurs, including informing patients about the incident, providing reasonable support, truthful information and an apology.

The duty of candour applied to patient safety requires general practices, their professionals and staff to demonstrate:

- **Openness** – a culture where incidents and complaints can be raised without fear of reprimand.
- **Transparency** – sharing of information about what happened to staff, patients, the public and regulators.





- **Candour** – any patient harmed by the provision of a healthcare service is informed, and an intervention is made where appropriate, regardless of whether a complaint has been made or questions have been raised about the safety of care.


The registered manager in practice should also notify the CQC should any of the following outcomes occur for patients:

- the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition
- an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days
- changes to the structure of the service user's body
- the service user experiencing prolonged pain or prolonged psychological harm, or the shortening of the life expectancy of the service user
- requirement for additional treatment to prevent one of the harms described above.^[17]

The CQC has developed guidance on demonstrating duty of candour at registration and during inspection.^[17]

Scotland, Northern Ireland and Wales

There is not a national patient safety incident reporting system in Scotland and Northern Ireland; however, both countries have reporting systems for patient safety incidents involving a medical device or its instruction for use.

In Scotland, Healthcare Improvement Scotland's national guidance^[18] on incident reporting advises "all adverse events should be recorded on local electronic adverse event reporting systems as soon as possible after the event has occurred." The guidance also provides an extensive list of external agencies to report specific kinds of incidents to. For example, the [Incident Reporting and Investigation Centre](#)  receives reports about patient safety incidents arising from equipment-related failures or environment-related issues. Healthcare Improvement Scotland also encourages local reporting through GP clusters to provide tailored responsive support.





In Northern Ireland, the [Northern Ireland Adverse Incident Centre](#) [↗](#) receives reports about device malfunctioning, unclear or incorrect user instructions, user practices, equipment servicing and maintenance or the conditions of use. Practices are expected to report all patient safety incidents to the Integrated Care Directorate in their local Health and Social Care Board (HSCB) office.

In Wales, whilst patient safety incident reports from general practices are submitted to the NRLS via their commissioning Health Boards, a bespoke general practice incident report form has not been developed.

An opportunity exists in these countries to utilise local and regional groups of neighbouring general practices to share incident reports and SEAs on a regular basis in the interests of identifying priority issues for improvement in local and regional services.

Stage 7: Improvement

Incident reports, and findings from SEAs, provide sources of insight that can be used to develop the improvement agenda in your practice. The processes of quality improvement and associated tools for practice are described in the RCGP Quality Improvement Guide.^[8]

Analysis of similar reports at a local (CCG), regional or national level can permit more established diagnostics to identify priority areas for wider NHS systems improvement.^[2]^[19] This has included analysis of discharge-related incidents between secondary and primary care,^[20] paediatric vaccine-related incidents,^[6] and incidents involving vulnerable and sick children.^[21, 22]

CASE STUDY FOUR:

An improvement project initiated by 15 GP practices

In 2010, primary and secondary care was brought together under Integrative Health Boards in NHS Wales. GPs in a large Health Board raised patient safety concerns about the primary and secondary care interface relating to discharge, prescribing and shared care.

The statutory representative organisation felt that concerns that had been communicated to the previous secondary care organisations had not been acted upon. There was no formal or reliable incident reporting process in place for GPs.





An incident reporting system was set up for GPs to report patient safety incidents. The reporting system received 192 reports from GPs between February 2012 to December 2013. The system was separate to the paper-based incident reporting system used in the organisation's hospitals.

Anticoagulation-related incidents were the most frequently reported issue to the reporting system. 27 separate incidents have been received, 18 of which were received over an eight month period from 15 different practices. In isolation, each report concerning anticoagulation had previously been sent to the relevant clinical directorate for investigation and action.

However, by combining the reports, the organisation could identify three major opportunities for improvement:

1. Management of patients with unstable INRs in the community needed investment for community based teams.
2. Management of stable patients and slow-loading was feasible by general practice providing fees to provide an enhanced service where available.
3. Hospital teams would support a safe discharge by providing timely discharge advice to general practice.

The themes informed the development of a driver diagram which was used to discuss the planning of an improvement project (see Figure 9).

The organisation identified 25 patients over a calendar month that had a delayed discharge whilst awaiting a stable INR which was estimated to cost £38,874 per month, with overall unnecessary hospitalisation costs to be £466,488 per annum. Estimated costs were drawn up for each of the proposed primary drivers and demonstrated a potential cost saving of around £300k. Such cost savings could be used to pay GPs to provide an enhanced service for slow-loading patients in the community and paying for additional Acute Rehabilitation Team staff members to manage patients with unstable INRs at home.



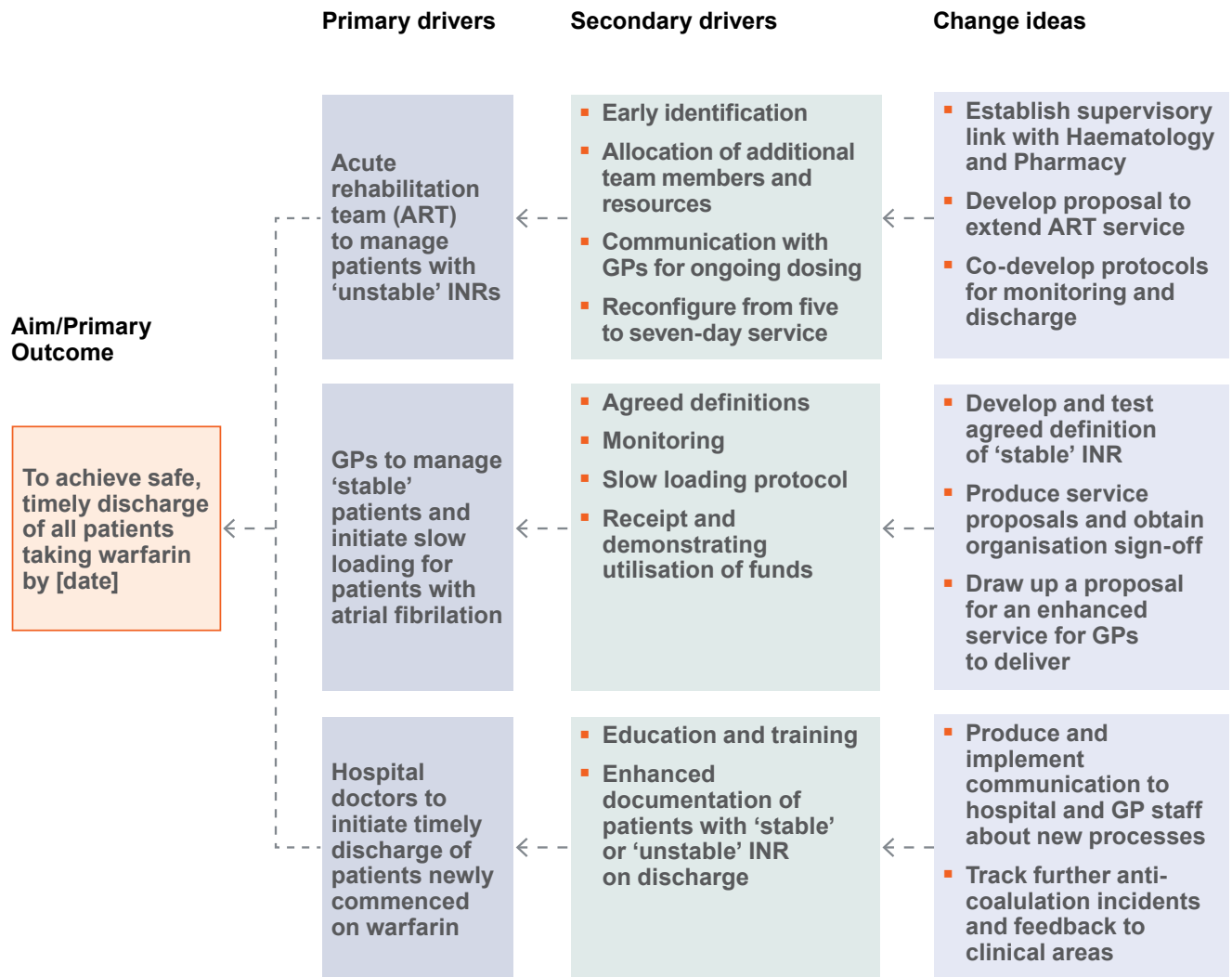


Figure 9. Driver diagram for improvement of anticoagulation services



GMC guidance for appraisal and revalidation

The GMC's appraisal and revalidation guidance recommends supporting evidence is required to demonstrate participation in activities to learn from significant events and quality improvement activities.

The GMC guidance supports discussion about patient safety incidents (including those that result in no harm or were near misses) and state the purpose of the supporting information is to “illustrate events which may not have a serious outcome but highlight issues which could be handled with greater clinical effectiveness and patient safety, and from which lessons could be learnt.”

Using patient safety incidents to inform quality improvement activities creates an opportunity to demonstrate several appraisal and revalidation requirements:

- “participation in logging any incidents or events...”
*Stage 1 – Stage 2 – Initial Reporting (practice) and Stage 6 – Reporting**
- “...should be able to demonstrate that you are aware of any patterns in the types of incidents or events recorded about your practice and discuss any lessons learnt.” *Stage 3 – Risk assessment**
- “...participation in any clinical governance meetings where incidents or events and learning are discussed” *Stage 4 – Discussion of learning**
- “Discussion at appraisal should include any systematic learning from errors and events such as investigations and analysis, and the development of solutions and implementation of improvements.”
*Stage 5 – Investigation & Stage 7 – Improvement**

*PISA Learning for Care Improvement Model





Summary

Learning from patient safety incidents is an opportunity to examine the processes and work conditions in your practice to achieve safer care for patients. Sharing this learning through incident reports offers an opportunity for regional and national-level learning about systems and rare issues for improvement. Our top tips for incident reporting in general practice are:

- Learn from patient safety incidents to support the design of safer practices.
- All members of the practice team should know how to report a patient safety incident.
- Inform patients when they have been involved in a patient safety incident and keep them updated about what has been learnt in the practice.
- Not all incidents need a Significant Event Analysis but all reported incidents in the practice should be discussed by the team.
- Use patient safety incidents to inform quality improvement activities.
- Patient safety-focused quality improvement activity can be evidence for appraisal and revalidation requirements.
- All practices should know their local arrangements for sharing incident reports (e.g. to the CCG, Health Board) and know when and how to escalate safety concerns.





Glossary of terms

from World Health Organization's International Classification for Patient Safety^[4]

Ameliorating action – an action taken or circumstances altered to make better or compensate any harm after an incident.

Contributory factor – a circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.

Harm – implies impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological.

Incident – an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.

Near miss – an incident which did not reach the patient.

Patient safety – the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.

Patient safety incident – an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.

Reportable circumstance – a situation in which there was significant potential for harm, but no incident occurred.

Risk – the probability that an incident will occur.

System improvement – the result or outcome of the culture, processes, and structures that are directed toward the prevention of system failure and the improvement of safety and quality.





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Appendix 1

PISA Patient Safety Incident Reporting Form Template

Who

Patient affected:

Where/When

Location:

Person reporting incident
(including job title):

Date/time of incident:

Date/time reported to manager:

What

Incident category type (please circle):

- Medication process
- Diagnostic / clinical assessment
- Investigation process
- Communication process
- Equipment
- Other

What happened?

Why?

Was immediate action necessary? If yes please document below

Were there any contributing factors? (e.g. system, staff, patient)

What was the patient harm severity outcome?

(please circle – refer to table on next page):

- No harm
- Mild harm
- Moderate harm
- Severe harm
- Death

What is the probability of recurrence?

(please circle — refer to matrix on the next page)

- Extreme risk
- High risk
- Medium risk
- Low risk

Actions to prevent recurrence and how this incident will be investigated?





PISA Harm Severity Classification

Severity	Definition
No harm	An incident occurred but no harm was experienced by the patient.
No harm outcome due to mitigating action	Any incident that had the potential to cause harm to a patient but this was prevented, resulting in no harm.
Mild harm	<p>Patient was harmed with mild and short-term impact on physical, mental or social functioning; this includes requiring:</p> <ul style="list-style-type: none"> • minimal intervention/treatment e.g. antiemetic, oral antibiotic; or, • repeat of a minor procedure such as vaccination or insertion of contraceptive implant; or, • the patient or their loved ones experiencing transient emotional distress but no long-term consequences.
Moderate harm	<p>Patient was harmed causing a medium-term impact on physical, mental or social functioning; this includes requiring:</p> <ul style="list-style-type: none"> • medical intervention in the form of treatment e.g. intravenous fluids or antibiotics; or, • short-term hospitalisation for assessment and/or minor treatment in either A&E or a hospital ward; or, • the patient or their loved ones experiencing psychological difficulty of a more longstanding nature but not requiring formal treatment e.g. evidence of more longstanding anxiety, insomnia, or low mood.
Severe harm	<p>Patient was harmed causing a major long-term or permanent impact on physical, mental or social function or shortening of life-expectancy; this includes requiring:</p> <ul style="list-style-type: none"> • major medical or surgical intervention (most often delivered in a hospital setting) e.g. thrombolysis, cardioversion, any major surgery; or, • prolonged hospitalisation or admission to HDU/CCU/ITU; or, • the patient or their loved ones experiencing enduring psychological difficulty that requires specialist treatment e.g. evidence of chronic anxiety or depression or psychosis.
Death	On the balance of probabilities, death was caused or brought forward in the short term by the incident.

Probability as per Table 4	Harm severity as per Table 3				
	Death	Severe Harm	Moderate Harm	Mild Harm	No Harm
Frequent most weeks/months	4	4	3	2	2
Likely a few times a year	4	4	3	2	2
Possible may happen every 1—2 years	4	3	3	2	1
Unlikely possibility could occur in the next 5 years	4	3	2	1	1
Rare unlikely to reoccur	3	2	2	1	1

SAC Matrix *developed from VHA* [↗](#)

Each SAC matrix score from one to four has defined actions. Examples are provided here for illustration purposes and these must be amended for your own context, particularly agreed within your own practice and with your relevant commissioning body.

4 = Extreme risk – Immediate action required – Clinical Director of Primary Care / Clinical Governance Leads must be informed. Investigation must be commenced across primary and secondary care. Significant Event Analysis to be undertaken in practice. Incident report to be sent to national database. Learning to be shared via agreed mechanisms with other local / regional GPs.

3 = High risk – Notification to Clinical Director of Primary Care / Clinical Governance Leads. Significant Event Analysis (and where relevant a Root Cause Analysis) involving relevant primary care team members and respective department staff. Incident report to be sent to national database. Learning to be shared via agreed mechanisms with other local / regional GPs.

2 = Medium risk – Practice manager to aggregate data and Significant Event Analysis to be undertaken to inform an improvement project. Incident report to be sent to national database. Learning to be shared via agreed mechanisms with other local / regional GPs.

1 = Low risk – Practice manager to aggregate data. To be discussed at team-based meeting and decision needed about whether Significant Event Analysis will be undertaken to inform practice improvement. Incident report to be sent to national database. Learning to be shared via agreed mechanisms with other local / regional GPs.





2017

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Acknowledgements: The authors wish to express their gratitude to colleagues and collaborators at the Primary Care Patient Safety Group at Cardiff University, namely Drs Huw Williams, Alison Cooper, Jennifer Cooper, Huw Evans, Philippa Rees, Felicity Smith and Professor Adrian Edwards, for their input into development of content included in the case studies.

The guide was prepared for a Royal College of General Practitioners Spotlight Project supported by the All Wales Therapeutics and Toxicology Centre, the NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre, and the Wales Centre for Primary and Emergency Care Research.

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