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Foreword

“To err is human, to cover up is unforgivable and to fail to learn is inexcusable”
Liam Donaldson (2004)

General practice and primary care have not traditionally been regarded as fertile ground for innovations in patient safety, with most interest and attention generally focused on developments relating to care in the acute sector. However, with Significant Event Analysis (SEA), general practice can be proud to claim that the introduction and development of this technique arose from work by two GPs, Mike Pringle and Colin Bradley.

Moreover, the publication of their pioneering work, in the form of a Royal College of General Practitioners (RCGP) Occasional Paper, dates from the 1990s, well in advance of many of the seminal works that have facilitated the global spread of the patient safety movement. Since then, I am proud to say that NHS Education for Scotland (NES) has been arguably the leading light in further developing and investigating the application of the SEA technique in primary care and beyond. In doing so, NES research has made a major contribution to the international evidence base on the use of SEA by healthcare teams and its impact on learning, safety and improvement.

This publication is the result of partnership working between a number of individuals and organisations across the United Kingdom and should mark a new phase in the development of SEA. This is no longer an exercise conducted occasionally, in a small number of practices, but a mainstream activity that all practices engage in regularly, with identifiable benefits for patients and the healthcare team. It is integral to the demonstration of reflective practice for the Quality & Outcomes framework and annual GP appraisal, and it will be important evidence for revalidation. It is also an activity where genuine multidisciplinary engagement can be demonstrated, as befits professionals working together in primary care teams. Importantly, SEA will play a key role in supporting the primary care goals of the Scottish Patient Safety Programme and the recently published Quality Strategy.

Primary care teams can use this guidance to consider:

- whether they can do more to improve the effectiveness of the SEAs they undertake
- the clear benefits to be gained from adopting a more in-depth analytical approach when using SEA.

It may also be time for local NHS Boards and primary care teams to consider whether others could learn from the vast numbers of SEAs carried out. Sharing the learning from these events more broadly would be a significant step for patient safety improvement efforts given our limited knowledge of what can go wrong and why, and how we can resolve many of these issues.

I wholeheartedly commend this educational guidance to all GPs and primary care teams in NHSScotland.

Professor T S Murray
National GP Director
NHS Education for Scotland
Purpose and background

Purpose
This guidance will enable you and your team to conduct an effective Significant Event Analysis (SEA) with the aim of improving health care and the patient experience.

Effective SEAs allow you and your team to highlight and learn from both strengths and weaknesses in the care you provide.\textsuperscript{1,2,3}

The aim of this document is to provide you with guidance on how to develop a structured and effective SEA process that can be embedded as an improvement tool within your practice. We do this by defining the process, outlining effective practices and demonstrating what can be achieved through real life examples.

Background
Improving the quality and safety of patient care is a key clinical governance priority in primary healthcare. SEA has an important role to play in contributing to this aim and this is reflected in its inclusion as part of the Quality and Outcomes Framework (QOF), GP Appraisal and proposals for revalidation being developed by the Royal College of General Practitioners (RCGP). The National Patient Safety Agency (NPSA) in \textit{Seven steps to patient safety for primary care} (\url{www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/7steps/}) strongly recommends that SEAs should be routinely undertaken by primary care teams. By doing so, patients, carers and the public can be reassured that care is being quality assured and, where appropriate, lessons are being learnt and improvements are implemented.

Most primary care teams have, traditionally, not been good at learning effectively from when things go wrong or when not so good practices are highlighted. Taking part in SEAs offers the care team a chance to hold regular structured meetings and to reflect on individual events that are identified as being ‘significant’ to them. Importantly, the opportunity for reflection, discussion and analysis helps the team (and individual healthcare professionals) to identify learning needs and share good practices. Another major advantage of doing an SEA well is that it can enhance team-working and morale, and improve communication between team members and others.
A quick guide to conducting a Significant Event Analysis

The seven stages of Significant Event Analysis

Stage 1  Awareness and prioritisation of a significant event
Staff should be confident in their ability to identify and prioritise a significant event when it happens.

The Practice should be fully committed to the routine and regular analysis of significant events.

Stage 2  Information gathering
Collect and collate as much factual information on the event as possible from personal testimonies, written records and other healthcare documentation. For more complex events, an in-depth analysis will be required to fully understand causal factors.

Stage 3  The facilitated team-based meeting
The team should appoint a facilitator who will structure the meeting, maintain basic ground rules and help with the analysis of each event. The team should meet regularly to discuss, investigate and analyse events. These meetings are often the key function in co-ordinating the SEA process and they should be held in a fair, open, honest and non-threatening atmosphere.

Agree any ground rules before the meeting starts to reinforce the educational spirit of the SEA and ensure opinions are respected and individuals are not ‘blamed’.

Minutes of the meeting should be taken and action points noted. These should be sent to all staff, including those unable to attend the meeting.

An effective SEA should involve detailed discussion of each event, demonstration of insightful analysis, the identification of learning needs and agreement on any action to be taken.
Stage 4  Analysis of the significant event

The analysis of a significant event can be guided by answering four questions:

1. What happened?
2. Why did it happen?
3. What has been learned?
4. What has been changed or actioned?

The possible outcomes may include:

- no action required;
- a celebration of excellent care;
- identification of a learning need;
- a conventional audit is required;
- immediate action is required;
- a further investigation is needed;
- sharing the learning.

Stage 5  Agree, implement and monitor change

Any agreed action should be implemented by staff designated to co-ordinate and monitor change in the same way the practice would act on the results of ‘traditional’ audits.

Progress with the implementation of necessary change should always be monitored by placing it on the agenda for future team or significant event meetings.

Where appropriate, the effective implementation and review of change is vital to the SEA process. To test how well the SEA process has gone, practices should ask themselves ‘What is the chance of this event happening again?’.

Stage 6  Write it up

It is important to keep a comprehensive, anonymised, written record of every SEA, as external bodies will require evidence that the SEA was undertaken to a satisfactory standard. The SEA report is also a written record of how effectively the significant event was analysed.

Stage 7  Report, share and review

Reporting when things go wrong is essential in general practice, but rarely happens. The practice should look to formally report and notify (via the local primary care organisation) those events where patient safety has, or could have been, compromised.

Where a mechanism exists, practices should share knowledge of important significant events with local clinical governance leaders so that others may learn from these.
A full guide to an effective Significant Event Analysis

What is a significant event?
A common question often posed by primary care teams is: ‘What exactly is a significant event?’ The original definition by Pringle and colleagues (see box below) is very broad. It is important to remember that a significant event offers an important opportunity for reflection and learning. More often than not it will highlight a negative experience for patients, relatives, clinicians and others. However, we can learn as much from good practice as from bad practice.

Examples could range from a serious patient safety incident (e.g. a medication error leading to death), to a moderate level error (e.g. failure to act on laboratory findings resulting in a four-week delay in a diagnosis), to an event which demonstrates excellent care provision (e.g. rapid diagnosis of unexpected malignancy in a fit young man), to one of a seemingly trivial nature which has serious administrative consequences (e.g. failing to change a recorded message on a Bank Holiday weekend).

Definition of a significant event
Any event thought by anyone in the team to be significant in the care of patients or the conduct of the practice.

The interchangeable use of safety-related terminology (critical incident, error, near miss, adverse event and so on) by health professionals can cause confusion. All are ‘significant events’. In one sense, because the definition of a significant event is all-embracing, this can make it easier for us to identify those issues where there are important learning opportunities for the team.

Examples of incidents that could trigger a Significant Event Analysis

<table>
<thead>
<tr>
<th>Diagnoses</th>
<th>Events</th>
<th>Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>New diagnoses of cancer, Ischaemic Heart Disease (IHD) or stroke (for prevention, acute care and follow-up)</td>
<td>Unplanned pregnancies (for contraceptive advice)</td>
<td>Positive cervical smears</td>
</tr>
<tr>
<td>Meningitis, measles, mumps, rubella, pertussis, bacteria gastro-enteritis (for prevention)</td>
<td>Unexpected deaths</td>
<td>Positive mammography</td>
</tr>
<tr>
<td>Acute asthma, epileptic fits and parasuicide (for prior care)</td>
<td>Palliative and terminal care</td>
<td></td>
</tr>
<tr>
<td>Low impact fractures</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Prescribing errors
- Wrong drug prescribed
- Wrong drug dose
- Drug interaction
- Inadequate drug monitoring

### Communication
- Appointment letter sent to wrong address
- Wrong information given over telephone
- Important message not acted on
- Misinterpretation of a handwritten prescription

### Investigations and results
- Urgent referral not done
- Result mis-filed
- Result not acted on
- Investigation request not sent

### Appointments and surgeries
- Unannounced extra
- Emergency line engaged/rang out
- Registrar on alone
- Limited GP cover

### Acute cases, emergencies and harm
- Acute asthma
- Suspected meningitis
- Non-accidental injury
- Sudden unexpected death

### Patient and family
- Patient expelled from practice
- Termination request
- Domestic abuse issues
- Angry or upset

### General administration
- Equipment failure
- Computer data loss
- Target payment failure
- Complaint about premises

### Disease diagnosis and management
- Poor control of International Normalised Ratio (INR)
- Failure to follow-up
- Delayed diagnosis
- Wrong treatment given

### Home visits and external care
- Visit request not done
- Mix-up over request urgency
- Wrong address of patient
- Out-of-hours issue
Examples of interesting, complex and good practice events

<table>
<thead>
<tr>
<th>Reflection</th>
<th>Reflection</th>
<th>Reflection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>interesting case</strong></td>
<td><strong>terminal illness</strong></td>
<td><strong>complex case</strong></td>
</tr>
<tr>
<td>A review of a patient who had multiple investigations and referrals and who turned out to have a phaeochromocytoma.</td>
<td>Review of a patient with a prolonged terminal illness with bowel cancer highlighted the difficulties in managing vomiting and pain control.</td>
<td>A ‘heart-sink’ patient with multiple non-organic problems who also developed IHD.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reflection</th>
<th>Reflection</th>
<th>Reflection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>successful cardio-pulmonary resuscitation in the surgery</strong></td>
<td><strong>early unexpected diagnosis of cancer</strong></td>
<td><strong>appreciation</strong></td>
</tr>
<tr>
<td>A practice team reviews the successful cardio-pulmonary resuscitation of a middle-aged man who collapsed in the surgery waiting area.</td>
<td>A middle-aged female who had presented with a vague history of lower abdominal pains. Referred for a ‘soon’ ultrasound which identified an early stage ovarian cancer.</td>
<td>A thank you letter to all of the surgery staff from the family of a patient who had died.</td>
</tr>
</tbody>
</table>

Learn more about what can go wrong in primary care

A summary of selected studies and their findings which provides some insights into what can go wrong in general practice is outlined in Appendix 1.

Also see Appendix 2 for case scenarios of significant events.
What is a Significant Event Analysis?

Put simply, an SEA is a ‘qualitative’ method of clinical audit. In this respect it differs from the ‘traditional’ process of audit which most primary care teams will be familiar with: for example, when reviewing and improving care in the management of diabetes, asthma, IHD, or hypertension. These audits tend to deal with larger-scale ‘quantifiable’ patient data sets and involve defining criteria and setting standards which can be measured and compared against. However, SEA should involve a systematic attempt to investigate, review and learn from a single event that is deemed to be ‘significant’ by the healthcare team.

Often, these types of ‘significant events’ will not be highlighted through ‘normal’ audit, but they still offer the primary care team valuable opportunities to improve the quality and safety of healthcare. An SEA provides us with a structured framework which can guide the primary care team when discussing and investigating a chosen significant event.

Pringle’s SEA definition:
A process in which individual episodes (when there has been a significant occurrence either beneficial or deleterious) are analysed in a systematic and detailed way to ascertain what can be learnt about the overall quality of care, and to indicate any changes that might lead to future improvements.¹

The seven stages of Significant Event Analysis

In preparing and planning SEAs, the GP team should follow seven different stages (see following pages) in identifying, investigating and analysing a significant event. Closely adhering to each stage of the process helps to ensure that the team undertakes a more in-depth and enjoyable SEA experience.
Stage 1: Awareness and prioritisation of a significant event

Staff should be confident in their ability to identify a significant event when it happens, and the practice should be fully committed to the routine audit of significant events, either through dedicated meetings or as an agenda item at other practice meetings.

The practice should have a simple computer or paper-based system for logging all significant events identified by clinicians and staff.

Designated practice staff can be consulted by others and are able to make a judgement on whether a specific significant event should be formally analysed immediately, at the next routine meeting, or can be dealt with in a simpler way. Alternatively, all possible events are listed and the prioritisation, if required, takes place at the start of the routine SEA meeting.

In primary care, most incidents or events which result in either no harm to the patient or low to moderate harm should be reviewed using an SEA.

Guidance on topic selection for an SEA and team participation

- Prioritise significant events for audit based on their consequences (actual or potential) for the quality and safety of patient care. The opportunity for learning and improvement, where required, should also be clearly apparent. Not all significant events need to be formally audited. A decision on whether a significant event should be formally audited should be made after discussion with colleagues.

- Events which are concerned with under-performance, contractual or personal issues should be dealt with through existing practice procedures, rather than by an SEA.

- Some events, particularly clinical examples, will undoubtedly be highly sensitive and GPs may not be prepared to highlight these to the whole practice team, especially if team-based input is not necessarily relevant or required. This is fine as long as the SEA process is still applied in conjunction with close clinical colleagues and that insight, learning and necessary change are demonstrated. In the past, analysis of these events may have been avoided and taken off the SEA agenda. However, in the current climate where learning from patient safety incidents is paramount, these types of events can no longer be ignored.

- Events selected for audit may be heavily clinical in nature, which tends to alienate non-clinical staff. Be flexible – there is nothing to stop administrative staff meeting as a group occasionally to audit administrative significant events and reporting the outcomes at future, full, team-based meetings.

- Ultimately, it is for each team to decide who is invited. While the doctors, nurses (practice and community) and senior managers are normally invited, receptionists and administrators might also be present. There has to be a balance between those who can contribute to an honest discussion, and creating such a large group that discussion of sensitive issues, such as clinical errors, is inhibited.
Stage 2 Information gathering

The information gathering process can begin immediately after the event, just prior to the routine SEA meeting, or it can happen during the meeting. Where time permits, the team should attempt to determine exactly what happened, how it happened and why it happened for each event before the routine meeting. This may be particularly important for serious or complicated events in order to allocate greater time at the meeting to understanding the causes of these events and agreeing action points. The individual(s) involved, directly or indirectly, in the event may be best placed to lead the investigation, but others can also be delegated this task.

Collect and collate as much factual information on the actual event as possible, from medical records, personal accounts and other clinical documentation. This is necessary in order to build a timeline of the key factors which contributed to the significant event. Personal accounts will be gathered through the thoughts, opinions and impressions of those directly and indirectly involved, including (where relevant) patients and relatives or health professionals who are not part of the immediate team.

Occasionally, when an event is discussed at a team meeting, it may become obvious that it is too complex to be immediately understood and resolved. The outcome of such a meeting is a recommendation that a more in-depth investigation is therefore required (see Stage 4).

Common information sources:

- Case records, laboratory reports, letters of complaint, practice protocols and other relevant documentation.
- Personal testimony from patients, relatives, healthcare staff and individuals from other agencies.
**Stage 3 The facilitated team-based meeting**

An SEA normally involves a routine meeting of all relevant team members to discuss, investigate and analyse the significant event(s). The team-based meeting is the key function in co-ordinating the SEA process. This is where most of the learning and change will take place.

These meetings should be held regularly, for example, a dedicated monthly get-together over lunchtime or as part of another practice team meeting. Set aside at least one hour for the meeting. Some minor significant events with obvious solutions can often be dealt with quickly without much detailed analysis. Others will be much more challenging. Team members should select a facilitator from within the practice team, although it has been known for an external facilitator to be appointed in some instances.

The key to an effective SEA is that detailed discussion of each event takes place, insightful analysis is demonstrated and, where appropriate, learning needs are identified. Relevant action should be agreed based on this analysis. The meeting should be conducted in an open, fair, honest and non-threatening atmosphere – this is the core essence and spirit of the SEA. Failure to do so will hamper the entire SEA process. Where there is a fear of blame or punishment, team members will become reluctant to engage in the process and will be more likely to withhold important information about events. The greatest resource in terms of knowledge, understanding, skills, innovation and effectiveness is the team itself. The SEA thrives on this. Without these inputs from the team the SEA will be less effective.

Minutes of the meeting – outlining agreed learning points and actions to be taken by individual staff – should always be taken and circulated afterwards to all staff, including those not able to attend.

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**Role of the facilitator**

Before the meeting gets underway the facilitator should explain their role to the team, which is:

- to explain the aims and process of the discussion;
- to structure the discussion – keep to time, encourage contributions from all participants and clarify and summarise frequently;
- to maintain basic ground rules, for example, keep things civil, maintain confidentiality and allow uninterrupted discussion;
- to facilitate the investigation and analysis of the event (Stage 4), and encourage participants to accept responsibility for initiating change;
- to recognise emotion within the discussion, to acknowledge it and to allow appropriate expression within the group;
- where practicable, to remain ‘external’ to the team and to avoid giving unwarranted opinions or colluding with the group during discussions.
Good practice for team-based SEA meetings

- An SEA can be undertaken at dedicated monthly meetings or as part of regular team-based meetings. Protected time should be set aside to allow detailed discussion and in-depth investigation of events. More serious events should be discussed at specially convened meetings as soon as possible after they happen.

- Remember to rotate meetings so that part-time staff can also participate.

- The ground rules for meetings should be agreed and made explicit to team members beforehand, in particular that opinions will be respected, ‘blame’ not apportioned and the purpose of the meeting will be reflection, quality improvement and education. Teams need to be assured (perhaps regularly) that the SEA process is not about allocating blame, but is about gaining a full understanding of why events occur and learning from them. More often than not it will be practice systems and procedures which are deficient – with unfortunate individuals caught up in the process. Where fear of being open and honest about events is apparent, because of potential embarrassment and reprisal, the less effective the SEA will be.

- Success is heavily reliant on positive team dynamics and interaction. A well-established, strong and cohesive team displaying a high degree of maturity, trust and openness will be well placed to apply the SEA technique effectively. Confidence that frank discussion will not exacerbate interpersonal problems is required.

- Participants should always refrain from direct personal blame or criticism. Participants need to be clear that discussion and individual feedback should always be positive, fair, constructive and sensitive.

- Enthusiastic, well-respected and (preferably) trained individuals should be used to promote, co-ordinate and facilitate SEA meetings at the outset.

- Strong leadership/facilitation is important in running meetings to time, gaining co-operation and agreement, encouraging participation by all members of the team, exposing hidden agendas and in ensuring meetings are not always dominated by a few individuals, particularly medical staff. Employed staff may feel low in the hierarchy, find it difficult to act confidently as equals and feel vulnerable when speaking out.

- Once the team meetings are well established and team members become more confident and at ease with the process, it may be helpful to rotate the facilitator.
Stage 4: Analysis of the significant event

The entire process for analysing a significant event should be guided by answering the following four key questions:

1. **What happened?** (also see Stage 2)
   - Establish what, how and where the event happened in detailed, chronological order.
   - Focus on collecting as much factual information as possible from:
     - written and computer records;
     - personal testimony from those team members directly and indirectly involved, patients, relatives and colleagues from NHS bodies and other agencies.
   - Determine what the impact was or could have been (both positive and negative), for example, clinically and/or emotionally for the patient, the professionalism of individuals or the team, or the liability of the organisation.

2. **Why did it happen?**
   - Establish the **main** and **underlying** reasons – positive and negative – contributing to why the event happened. Identify the problems in administrative, care and systems processes that led to the incident. For example, these may include, for whatever reasons, things that should have happened but did not, or did happen as intended, but something else unexpected interfered with the process.
   - The majority of significant incidents can often be attributed to a combination of errors, system deficiencies and other contributory factors. However, many event investigations are limited by a superficial examination of the underlying causes of the incident, often focusing exclusively on the role of individual health care workers. Failing to identify the role of healthcare systems and processes as key causal factors can result in lost opportunities for learning, improvement and potential recurrence.
   - There are a number of formal problem solving tools that could help you and your team to analyze the causes of incidents in a more structured, thorough and effective manner. The 'five whys' (box 1) and 'fishbone diagrams' (box 2) are commonly used methods, which require very little additional training and are straightforward to apply with practise. The use of both approaches is also illustrated in the SEA examples outlined in the Appendices.
The five whys

The five whys technique starts with a clearly defined problem (in our case: What Happened?). The aim is to attempt to uncover the ‘root’ cause(s) of the problem by repeatedly asking the question ‘why’. By convention the question is asked five times, but there is no maximum or minimum. As you continually ask ‘why’ imagine that you are peeling away causal layers until you reach the underlying processes. The practical steps are illustrated in the clinical example outlined below:

The technique has limitations: for example, identified causes can be influenced by the specific questions being posed and who is asking them; additionally this approach may detect only some of the important contributing factors. If the final answer does not feel intuitive or ‘obviously right’ consider a more sophisticated technique such as the fishbone diagram.
The fishbone diagram

The fishbone diagram is a graphic illustration of the relationship between an incident and its potential causes. It is used to identify, explore, sort, display and analyze factors underlying problems. The completed diagram resembles the skeleton of a fish. It can be drawn by following a few simple steps:

**Step 1:** Place the identified incident in a box on one side of a page in the ‘head’ of the fish. Draw the backbone of the fish as a horizontal line from this box across the page.

**Step 2:** Identify and label the primary causal factors (categories), each represented as a ‘rib’. Any number and type or pre-existing categories may be used.

**Step 3:** Identify secondary and further level causes, indicated by smaller ‘bones’ linked to each other and the ribs. Individual and group brainstorming may increase detected causes.

**Step 4:** Analyze the diagram and attempt to prioritize the causes

The four steps are combined and illustrated through a clinical example below:
3. What has been learned?

- Based on the reasons established as to why the event happened, outline the learning needs identified, if any, from the event.
- Demonstrate that reflection and learning have taken place on an individual or team basis and that relevant team members have been involved in the analysis of the event.
- Consider, for instance:
  - a lack of knowledge and training;
  - the need to follow systems or procedures;
  - the vital importance of team working or effective communication.

4. What has been changed or actioned?

- Based on the understanding of why the event happened and the identification of learning needs, outline the action(s) agreed and implemented (where this is relevant or feasible).
- Action is not always necessary – particularly for positive and purely reflective events – but should always be considered and justifiably ruled out if not necessary.
- Consider, for instance, if a protocol has been amended, updated or introduced, how was this done and who was involved, and how will this change be monitored. It is also good practice to attach any documentary evidence of change to the subsequent SEA report, for example, a letter of apology to a patient or a new protocol.
- Consider also how this SEA could be shared and if the event should be formally reported to a local incident reporting system managed by the NHS Board.
**Possible outcomes of a significant event meeting**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Celebration</strong></td>
<td>Often the care and service provided are shown to be exemplary. For example, the team-based effort in successfully resuscitating an elderly man who collapsed in the surgery waiting room.</td>
</tr>
<tr>
<td><strong>No action</strong></td>
<td>The event is part of everyday practice or is so unlikely to ever happen again that it would not be an effective use of time and resources putting preventative measures in place.</td>
</tr>
<tr>
<td><strong>A learning need</strong></td>
<td>A patient’s sudden collapse in the surgery revealed that the nurse and doctor who attended needed refresher training in cardio-pulmonary resuscitation (CPR). Other team members agreed they needed it too and a session was arranged.</td>
</tr>
<tr>
<td><strong>A learning point</strong></td>
<td>A discharge summary was received in the practice, but the prescriptions on the practice computer were not changed. An out-of-hours doctor had to sort out the problem and the patient complained. The doctors agreed to be more careful in responding to new discharge summaries.</td>
</tr>
<tr>
<td><strong>A conventional audit is required</strong></td>
<td>A problem is revealed, but the team is unsure how common it is. For example, a 49 year-old overweight patient and smoker is admitted to the local hospital with a myocardial infarction (MI). Review of his records shows that he was at risk, but was not on appropriate medication.</td>
</tr>
<tr>
<td><strong>Immediate change</strong></td>
<td>A child was given an out-of-date vaccination prompting a complaint from the parents. The practice had an ad-hoc arrangement for monitoring vaccinations. A formal protocol was introduced immediately to ensure regular checking of vaccinations and refrigerator temperatures by designated staff.</td>
</tr>
<tr>
<td><strong>Further investigation: in-depth SEA required</strong></td>
<td>The team discussed an apparent missing blood test result which had been ordered for an elderly man who was subsequently hospitalised with anaemia. It was unclear why this had happened. The GP who ordered the test and the practice manager would jointly undertake an SEA to fully investigate.</td>
</tr>
<tr>
<td><strong>Sharing the learning</strong></td>
<td>As well as sharing the SEA among colleagues in the immediate practice, consideration should also be given to sharing both the circumstances surrounding the anonymised event and the associated learning gained from the analysis with any local forums (for example, GP Trainers’ Groups, the local health centre, CPD and Protected Learning Time meetings, Patient Safety Action Teams based in local healthcare organisations).</td>
</tr>
</tbody>
</table>
Stage 5  Agree, implement and monitor change

All SEA meetings should start by looking at agreed actions in the minutes of the last or previous meetings. Action that is agreed as part of an SEA should be implemented by those staff designated to co-ordinate and monitor change, in the same way the practice would act on the results of the ‘traditional’ audit process. A timescale for change should always be built in to the process.

Progress with the implementation of change should always be monitored by placing it on the agenda for future team or significant event meetings. In this way, confirmation that the change has been implemented can be made or any difficulties in this area can be discussed and overcome with the help of the team.

Where required, the implementation, monitoring and review of change are vital to the success of the SEA. Like traditional audits, failure to consider change that is necessary and implement it effectively is a common barrier to successful SEAs in general practice. As a litmus test to how well an SEA is undertaken, practices should ask themselves: ‘What is the chance of this event happening again?’
Stage 6 Write it up

Keep a written record of every SEA undertaken using a well established standardised report format. These report formats have been widely used for appraisal purposes by doctors in training and by other clinical professions as a reflective educational tool. The written report should be separate from the minutes of meetings, as these notes often lack the depth of detail that is necessary when keeping a record of an SEA. Remember to update the report as actions are carried out, or outcomes are achieved, so that the report records the whole process.

The written SEA report

A comprehensive SEA report needs to be written as soon as possible after the analysis is completed. When writing a report, bear in mind that it needs to be a sufficiently detailed account of the entire investigation process, which should cover the following four key areas:

1. What happened?
2. Why did it happen?
3. What was learned?
4. What was changed? (where appropriate).

The written report is a window on the entire SEA process. It acts as a permanent record of the event and is evidence of identified learning needs and action taken, if necessary. If it does not reflect the necessary depth of analysis the event merited, then it is entirely possible that Quality and Outcomes Framework (QOF) Reviewers, GP Appraisers or Educators will raise concerns with the standard of the SEA. Regardless of whether a different report format is in use, detailed information on the four key areas shown above should be included. It is good practice to avoid using any identifying information for the patients, members of staff or agencies involved in the event; that is, don’t use first or second names – instead use codenames such as ‘Patient X,’ ‘Dr A’ or ‘Nurse Y’.

Stakeholders who may expect to see anonymised SEA reports include:

- Patients and carers;
- Educational peer reviewers;
- QOF Assessors/Reviewers;
- GP Appraisers;
- RCGP Quality Practice Awards Assessors/RCGP Practice Accreditation;
- Clinical governance committees;
- Community Health Partnerships;
- Vocational Training Scheme for Practice Managers;
- GP Educational Supervisors;
- In time, the General Medical Council (GMC) in revalidation.
Stage 7 Report, share and review

Report and share the learning from significant events

Reporting when things go wrong is essential in general practice, but rarely happens. The practice should look to formally report and notify (via the local primary care organisation) those events where patient safety has, or could have been, compromised.

Also, where such a mechanism exists, confidential SEA reports should be passed to local clinical governance leads so there may be an opportunity for lessons learned to be shared with others.

For staff and primary care contractors to feel comfortable reporting significant events or incidents, they must have confidence in the culture: that it is open and fair, and that staff can feel able to speak up when they have concerns, and where they know they will be treated fairly if they do so. Creating, nurturing and sustaining that culture is a responsibility of each and every one of us; as is the responsibility to report significant events and patient safety incidents.

Nominate a lead to complete a report. Also, share the learning with others. In some cases the primary care organisation is required to report significant events to external organisations.

External organisations that might require a report include:

- Community Health Partnerships (CHPs)
- Medicines and Healthcare products Regulatory Agency (MHRA);
- Health and Safety Executive through Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR);
- NHS Boards (NHSScotland).

Which events should be reported?

The NPSA encourages the confidential and anonymous reporting of incidents that caused no harm to patients, or where harm was averted, as well as events with a serious outcome which are more likely to be flagged up in existing clinical governance and reporting systems. It is these prevented patient safety incidents (known as near misses) that can provide the most valuable learning for the NHS because they can highlight problem areas where there is the potential for things to go wrong in the future. They can also highlight ways in which staff have prevented the incident harming the patient (or have minimised the actual harm caused to the patient), and the NPSA is looking to learn from these actions to encourage the spread of best practice.

All NHS organisations in the UK should have local arrangements in place to enable primary care staff to report patient safety incidents.
Quick pointers to writing up SEA reports and examples

<table>
<thead>
<tr>
<th>Standardised SEA Report templates</th>
</tr>
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<tbody>
<tr>
<td>• Standard report formats are strongly recommended for GP Appraisal in the UK and these should be used to record the details and outcomes of SEA attempts by practices (see Examples 1-4).</td>
</tr>
<tr>
<td>• The lack of standardisation makes it difficult and time-consuming for QOF visitors, GP Appraisers, primary care organisations and others to analyse and review the information they contain.</td>
</tr>
<tr>
<td>• Using a standard report format encourages consistency of approach and an appropriately detailed SEA account by the practice.</td>
</tr>
<tr>
<td>• Reports should be typed. Avoid handwriting reports for obvious reasons of legibility.</td>
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<table>
<thead>
<tr>
<th>Length of SEA reports</th>
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<tbody>
<tr>
<td>• There is no standard length of report. However, in most cases, shorter reports (less than one page) are more prone to have important details missing.</td>
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<thead>
<tr>
<th>Basic information</th>
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<tr>
<td>• A number of significant event reports omit important basic information, such as date of event, date of the SEA meeting and the forum where this took place.</td>
</tr>
<tr>
<td>• This information is important because it would be expected that dates relating to an event would be provided at third party request (for example, a clinical governance lead or reporting and learning system). Dates are also important in assisting teams with action planning and follow-up.</td>
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<thead>
<tr>
<th>Reflection, learning and change</th>
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<tr>
<td>• The content of SEA reports often focuses largely on what happened.</td>
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<tr>
<td>• Reports should also demonstrate clearly that practices have determined how and why an event occurred.</td>
</tr>
<tr>
<td>• The learning needs arising from the analysis and the changes agreed and implemented by the team should also be stated clearly and in sufficient detail.</td>
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<tr>
<th>‘Negative’ and ‘positive’ significant events</th>
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<tbody>
<tr>
<td>• Most practices focus on auditing ‘negative’ significant events, that is, where things have gone wrong or where care could have been better.</td>
</tr>
<tr>
<td>• ‘Positive’ significant events, that is, those where care has been excellent or could be shared so others can learn from them, are equally welcome for QOF or appraisal purposes.</td>
</tr>
<tr>
<td>• Learning from near misses.</td>
</tr>
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<tr>
<th>Multi-professional involvement</th>
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<tr>
<td>• Avoid carrying out an SEA in isolation or with only a small number of staff, particularly with events that are relevant to the whole team.</td>
</tr>
<tr>
<td>• Significant events often identify problems between organisations (for example, hospitals, police, ambulance service, nursing home) which need to be highlighted and addressed. The SEA process should focus on these events as well as those on ‘internal’ practice affairs.</td>
</tr>
</tbody>
</table>
Example 1

Inappropriate immunization SEA report and educational feedback provided

Wrongly administered MMR vaccination

1. What happened?

(Describe what actually happened in detail. Consider, for instance, how it happened, where it happened, who was involved and what the impact or potential impact was on the patient, the team, organisation and/or others).

A three-month-old child attended the combined Child Health Surveillance/Immunisations Clinic to receive her second booster of primary immunisation. The health visitor informed the duty doctor that instead of giving the DTP/Hib vaccine she had wrongly administered an MMR vaccine quite ‘accidentally’. The GP explained to the parents that this was an honest and genuine human error. Understandably the parents were rather alarmed that such an error was made, especially in the wake of media attention and heightened public anxiety about MMR. The GP also contacted the local hospital paediatric consultant who confirmed that there was no real danger to the health of the three-month-old child. The parents needed much reassurance that their child was going to be alright. The GP visited the parents’ house later that evening to check on the child and to see how the parents were coping under the circumstances, and to deal with any other concerns they had regarding the wrong vaccine being administered. This event could have led to a complaint and/or litigation and adverse publicity for the practice, while there was a small chance of a clinical impact on the child. Our HV and PN were upset about the event.

2. Why did it happen?

(Describe the main and underlying reasons – both positive and negative – contributing to why the event happened. Consider, for instance, the professionalism of the team, the lack of a system or a failing in a system, lack of knowledge or the complexity and uncertainty associated with the event).

- Child immunisation had previously been performed by our practice nurse, but due to ever-increasing workloads in other areas of primary care, especially management of chronic diseases, our practice, after discussion with all team members, decided that our health visitor would be trained to take up childhood immunisations.
- The health visitor attended a course in childhood immunisations and commenced immunisation in the practice around six months ago, but always under the supervision of another qualified health visitor, who has great experience in administering childhood vaccinations in our practice.
- Both the health visitors’ account of the event was that Ms X had drawn up the solution from the vial. Only after she had administered it and was checking with Ms Y, so that the batch number and expiry date of the vaccine could be recorded in the patient’s case records, did they both discover the now empty vial was actually MMR and they realised that Ms X must have administered MMR to the child instead of the second DTP/Hib booster she was due.
- Ms X under some distress left the clinic and Ms Y advised the parents of the child to take a seat as she needed to speak to the GP right away.
Alternative analysis of the event using the ‘five whys’ method

The significant incident
A health visitor administered an MMR rather than DTP/Hib vaccine to a three-month old patient.

1. Why?
The drawn-up solution and vial was not double-checked by both health visitors before administration.

2. Why?
They did not appreciate the reason and importance of double-checking before administration.

3. Why?
The practice did not have a formal immunisation programme.

4. Why?
The practice assumed that the local immunisation training would include a relevant protocol.

Alternative analysis of the event using a fishbone diagram

A health visitor administered an MMR rather than DTP/Hib vaccine to a three-month old patient.

Factors:
- Vaccines
- Supervisor: In close proximity
- Health visitor: Communication or confidence barrier
- Dismissed Individual
- Limited experience
- Parent
- Patient
- Crying
- Limited availability
- Room availability
- Staff rules changed (HV replaced HV)
- Increased workload
- Financial pressure
- No immunisation protocol
- Combined clinic, requiring different types of immunisations
- Practice size, patient demand
- Practice
- Local primary care organisation
- Training programme may be inadequate

Root Causes:
- Assumes covered by training
- Assumed covered by training
- Assumed covered by training
- Assumed covered by training
- Assumed covered by training
It appears that this event has occurred due to a number of possible explanations:

1. Ms X had, instead of drawing up DTP/Hib, unknowingly picked up the MMR that may have been placed near the other vaccines and drew from the vial.
2. Ms X may have been distracted at the time she picked up and drew from the wrong vaccine, hence did not realise that it was the wrong one.
3. There was a lack of ‘double checking’ of the vial prior to immunisation by both staff (involuntary automaticity).
4. There was a lack of communication between the two health visitors at the time and/or with the parent of the child.
5. There was no formal standard immunisation protocol in place for giving vaccinations.
6. The practice assumed (wrongly) that the local primary care organisation would have trained both health visitors in following a relevant protocol.
7. As the MMR vaccine is a live attenuated vaccine and grown/cultured in chicken egg yolk, it is vital and compulsory to ask parents of the child being immunised with MMR if the child could possibly be allergic to eggs.
8. Since Ms X had not realised she had drawn up the MMR vaccine she had obviously not asked the parents regarding any possibility of allergy to the component.

3. What has been learned?

(Demonstrate that reflection and learning have taken place on an individual or team basis and that relevant team members have been involved in the analysis of the event. Consider, for instance: a lack of education and training; the need to follow systems or procedures; the vital importance of team working or effective communication).

- The existing process of immunisation failed to properly protect the safety of a child. The team agreed that a key learning point was actually the lack of a formal, reliable and robust immunisation system.
- The practice learned that because of this system issue, it was inevitable that errors would happen.
- All persons administering vaccinations should be fully aware of the immunisation system and should refer to it frequently and especially prior to administration of each vaccination.
- There was a lack of communication between staff and between staff and parents.
- The combined clinics and volume of associated workload contributed to the error.
- The practice assumed the local primary care organisation would have organised training and developed a protocol to be followed and would be responsible for this. Responsibility and liability is also an issue for the practice.
4. What has been changed?

(Outline the action(s) agreed and implemented, where this is relevant or feasible. Consider, for instance: if a protocol has been amended, updated or introduced; how was this done and who was involved; how will this change be monitored. It is also good practice to attach any documentary evidence of change e.g. a letter of apology to a patient or a new protocol).

This event was further discussed at the next (weekly) practice meeting. It was stressed to all team members the seriousness of this type of error and possible consequences, in particular anaphylactic reactions of the child, but also litigation from the family of the child and ways to prevent this from ever occurring again. After the team investigation the following changes were put in place:

- A routine check-list for the immunisation clinic was developed and introduced (attached), which was laminated and put up at the place of immunisation. It was added to the practice protocols folder and the new staff induction pack.
- In the fridge, one designated and clearly marked shelf would hold all the childhood vaccinations.
- Work surfaces kept clean and with a good overview of different vaccines.
- Separate designated immunisation clinics were introduced to allow more time for vaccination and recording.
- The senior GP partner sent a letter of apology to the family concerned and informed them that an internal investigation had led to a new immunisation system being introduced.
- The vaccination issue will be monitored at future SEA meetings until the practice is satisfied that learning and change have taken hold and the new system is working effectively.

What was effective about this SEA?

- This was a significant event for the practice and merited further analysis.
- A clear description of the event was provided, including the roles of all individuals involved and the setting in which the event took place.
- The impact and other potential consequences of the event were clearly stated.
- A number of issues which contributed to the event were documented, which provide insights into why this event actually happened.
- The analysis of the event by the team demonstrated that clear reflection and learning had taken place which was relevant and informed what actions would have to be taken.
- The actions taken are already in place and are appropriate in the circumstances. These are an improvement on previous practices and should help to reduce the chance of a similar event occurring again.
Example 2
Delayed diagnosis SEA report and educational feedback provided

Misfiled report

1. What happened?

(Describe what actually happened in detail. Consider, for instance, how it happened, where it happened, who was involved and what the impact or potential impact was on the patient, the team, organisation and/or others).

Failed to pass complete haematology report to patient, and failure to act on blood report. Patient had attended local surgery on feeling tired and unwell. Post-viral symptoms? Full blood count was sent off by Treatment Room Sister. When the patient phoned for the result a few days later the report was not to hand, so Dr X obtained counts from the laboratory by phone. The only abnormality was a WBC of 11.59; otherwise FBC and ESR were normal. This was given to the patient as a reasonable result for a post-viral illness. Only subsequently was the printed FBC report received, with a written advice report, ‘Lymphocytes with activated forms...suggest repeat in two-three weeks’. This report was marked by Dr Y as ‘Dr will speak to patient’ and filed. Dr Y did not know that Dr X had given the patient a verbal report over the phone. The patient was not informed further as the patient thought that he already had the full report. The patient returned to surgery nearly five months later with a cough, when another local saw the report, told the patient that a repeat blood had been advised and was overdue, and repeated the FBC. This showed a persistent high WBC of 14.98 and features, which were later confirmed to be Chronic Lymphatic Leukaemia.

2. Why did it happen?

(Describe the main and underlying reasons – both positive and negative – contributing to why the event happened. Consider, for instance, the professionalism of the team, the lack of a system or a failing in a system, lack of knowledge or the complexity and uncertainty associated with the event).

The incident was discussed in detail at a weekly practice meeting. It happened because the report was given to the patient on the basis of a telephone report from the laboratory, probably with counts taken from the laboratory computer. The haematologist’s written advice was not given and was probably not available at the time the report was given by the laboratory over the phone. The report was obtained from the laboratory by our receptionist. It is possible that the written advice report would have been given if a doctor had phoned for the report. Results of blood tests initiated by a locum are more difficult to handle as there is a lack of ownership of the result. Very often, if results are abnormal, but not too drastic, we rely on the patient to phone back in to get the result. The report is marked, ‘Dr will speak to patient’.
Alternative analysis of the event using the ‘five whys’ method

The significant incident
The diagnosis of chronic lymphatic leukaemia was unnecessarily delayed

1. Why?
A FBC was not repeated within a fortnight as recommended by the haematologist

2. Why?
The patient assumed there was no need to repeat his FBC

3. Why?
DR X based his advice on an incomplete, verbal laboratory report

4. Why?
The fact that the full, printed report was not yet available was not considered, documented or discussed

5. Why?
The systems for dealing with investigation results and patient enquiries may be unsafe

Alternative analysis of the event using a fishbone diagram
3. What has been learned?

(Demonstrate that reflection and learning have taken place on an individual or team basis and that relevant team members have been involved in the analysis of the event. Consider, for instance: a lack of education and training; the need to follow systems or procedures; the vital importance of team working or effective communication).

The whole process of issuing results to patients over the phone was reviewed. We have advised extreme caution in results obtained over the phone as these may be incomplete and a receptionist may not get as full a result as a doctor. If a patient is given a result which has come verbally over the phone, the patient should be asked to phone for confirmation of the result of this when the report comes in writing. Alternatively, the doctor giving the result should be responsible for checking that the subsequent written report contains no additional items of importance. Caution also must be exercised over results of tests initiated by a locum. A new procedure is that whenever a result is marked ‘Dr will speak to patient’, the doctor must initial this. This lets the receptionist know which doctor to refer to, but also gives the doctor a sense of ownership of the result, and a sense of responsibility for transmission of the result to the patient. If a laboratory report advises a definite repeat test in a particular time interval, we now are inclined to the view that we should contact the patient by letter or phone to ensure the patient has the advice.
Example 3
Example of Safe Disposal of Sharps SEA Report and Educational Feedback Provided

Safe Disposal of Sharps

1. What happened?

(Describe what actually happened in detail. Consider, for instance, how it happened, where it happened, who was involved and what the impact or potential impact was on the patient, the team, organisation and/or others).

Last week the cleaner in our office felt a jab on her finger while tying a domestic refuse sack from our practice nurse’s room. When she looked in the bag she saw what she thought was a hypodermic needle. There was no apparent broken skin or bleeding from our cleaner’s hand. As a precaution she washed her hand in warm soapy water and then filled in the relevant section in our practice accident book and informed the practice manager. Clearly there was a potential risk to her health from this event and this caused our member of staff distress and considerable anxiety. As a practice we take very seriously our health & safety obligations towards valued members of staff and we too were extremely concerned that this incident had occurred.

2. Why did it happen?

(Describe the main and underlying reasons – both positive and negative – contributing to why the event happened. Consider, for instance, the professionalism of the team, the lack of a system or a failing in a system, lack of knowledge or the complexity and uncertainty associated with the event).

Immediately after the event the doctor spoke to the cleaner and to our practice nurse.

- It came to light that the sharps bin in the practice nurse’s room was on a shelf directly above the domestic refuse bin.
- It would seem that a needle had accidentally fallen into the domestic refuse bin while it was being placed into the sharps bin.
- It also transpired during the conversation that our cleaner had not received Hepatitis B vaccinations.
- On subsequently checking with the practice manager it was clear that we do not routinely check Hep B status with new members of staff even although this clearly part of our induction system. In this case it was wrongly assumed that because the cleaner had previously been employed in another practice that her status would be up-to-date.
- Consequently, blood was taken from our cleaner for Hep B and other blood borne infections and thankfully this returned negative.
Alternative analysis of the event using the ‘five whys’ method

The significant incident
A staff member suffered a needle-stick injury

1 Why?
The hypodermic needle was in the domestic waste

2 Why?
The needle accidentally fell from the sharps bin

3 Why?
The sharps bin was positioned directly over the bag intended for domestic waste and was too full

4 Why?
The sharps bin was not positioned or replaced appropriately

5 Why?
The practice did not perform a pro-active health and safety risk management review

Alternative analysis of the event using a fishbone diagram

A staff member suffered a needle-stick injury

Staff member
- Did not expect or see needle

Practice
- No needle-stick injury protocol
- New staff
- Location of sharps boxes
- Inadequate risk management policy

No protective clothing
- No formal Hep B vaccination check

Domestic waste uncovered
- Overfull
- Lack of time
- Unaware

Sharps bin
- Forgot
- Underestimated risk

Waste containers
- Responsible individual did not replace
3. What has been learned?

(Demonstrate that reflection and learning have taken place on an individual or team basis and that relevant team members have been involved in the analysis of the event. Consider, for instance: a lack of education and training; the need to follow systems or procedures; the vital importance of team working or effective communication).

- After the discussion with the cleaner and the practice nurse we decided to raise the topic of sharps safety at our next practice meeting. The incident was discussed without breaking confidentiality and a leaflet was distributed to all staff members reminding them of the relevant procedures on the safe disposal of sharps.
- Sharps disposal posters were posted on the walls of all rooms where sharps boxes were positioned.
- We learned of the vital importance of the safe disposal of sharps and the potential consequences this may have not to mention the distress and anxiety an incident such as this can cause. This is particularly so in front-line staff such as cleaners who can often arguably be more at risk than some other staff.

4. What has been changed?

(Outline the action(s) agreed and implemented, where this is relevant or feasible. Consider, for instance: if a protocol has been amended, updated or introduced; how was this done and who was involved; how will this change be monitored. It is also good practice to attach any documentary evidence of change e.g. a letter of apology to a patient or a new protocol).

- The cleaner has now received a course of Hep B vaccinations.
- At the practice meeting we decided that although all sharps bins should be kept out of reach above floor level but clearly the sharps bins should be moved away from domestic refuse bins to prevent an incident such as this occurring again – this has now been actioned.
- We have also drawn up a protocol for dealing with needle-stick/clinical sharps injuries which has been added to the protocol folder and placed on the practice intranet (see attached).
- In addition we have also checked that all attached staff has been vaccinated against Hep B and that they have had a response to this.
- We have adapted our Induction Procedures to highlight that all new attached staff must have their Hep B status checked prior to working regardless if they came from another health care setting.

What was effective about this SEA?

Needle-stick injury to member of staff

- A very good description of the actual event, the role of the individuals involved and the setting in which the event took place was provided.
- The impact of this event both for the staff member concerned and others was well described.
- The underlying reasons why this event happened are clearly documented.
- Reflection, insight and learning are clearly demonstrated and all relevant staff members were involved in the analysis.
- The changes implemented should certainly help reduce the chance of a similar event occurring in the future.
Example 4
Example of Prescribing Error SEA Report and Educational Feedback Provided

Prescribing Error

1. What happened?

(Describe what actually happened in detail. Consider, for instance, how it happened, where it happened, who was involved and what the impact or potential impact was on the patient, the team, organisation and/or others).

I was the on-call GP for the practice. A member of staff asked me to sign a repeat prescription for a patient unknown to me. As the patient had run out of tablets I was asked to sign the prescription as he was waiting at the reception desk. The script was for Amitriptyline but the dose appeared to be incorrect so I asked for the patient’s notes to confirm what the consultant psychiatrist had requested the patient be commenced on. It was then that I noticed that the hand written request had asked for Amisulpride to be commenced. The patient had a history of psychosis. This was confirmed by checking the consultant’s dictated letter. I therefore changed the prescription to the correct dose of Amisulpride and explained the change to the patient, who was still clinically stable. He accepted the apology after an explanation. However, it does not alter the fact that this patient had been taking the wrong medication for 2-months the potential result that there could have been a recurrence of his psychosis and all that that may have entailed.

2. Why did it happen?

(Describe the main and underlying reasons – both positive and negative – contributing to why the event happened. Consider, for instance, the professionalism of the team, the lack of a system or a failing in a system, lack of knowledge or the complexity and uncertainty associated with the event).

On investigation it transpired:

- A member of staff had misread the medication requested on the hand written note, and had therefore typed the wrong medication into the computer for the acute prescription.
- The script had been presented to the GP without the hand written request from the hospital. It had been a busy time in the practice and he had signed the script assuming it was the correct medication.
- On review of the hand written hospital request by staff involved it could be seen how the mistake had been made due to the poor quality of the doctor’s handwriting.
 Alternative analysis of the event using the ‘five whys’ method

The significant incident
Amitriptyline, rather than Amisulpride, was wrongly prescribed for a patient on more than one occasion

1. Why?
The wrong medication was entered as a repeat item

2. Why?
The receptionist dealing with the original secondary care prescription request misread the name

3. Why?
The receptionist did not have the experience or necessary training to deal with an illegible handwritten request

4. Why?
The practice’s policy for dealing with prescription requests may be inappropriate and unsafe

 Alternative analysis of the event using a fishbone diagram
3. What has been learned?

(Demonstrate that reflection and learning have taken place on an individual or team basis and that relevant team members have been involved in the analysis of the event. Consider, for instance: a lack of education and training; the need to follow systems or procedures; the vital importance of team working or effective communication).

- Unfortunately it is a normal expectation for many that the handwriting of doctors is poor, resulting in poor communication and the potential for serious errors to occur as a result. Caution must always be exercised when reading and interpreting hand-written scripts.
- It was made clear to me and the practice team that errors in prescribing can so easily occur if work pressure exists and handwriting is so poor that it can be misinterpreted, particularly by non-clinical staff.
- Safety-nets within the practice structure are needed to prevent this happening again.

4. What has been changed?

(Outline the action(s) agreed and implemented, where this is relevant or feasible. Consider, for instance: if a protocol has been amended, updated or introduced; how was this done and who was involved; how will this change be monitored. It is also good practice to attach any documentary evidence of change e.g. a letter of apology to a patient or a new protocol).

In view of the error a practice meeting was arranged to discuss the significant event. The meeting included members from all the different teams in the practice, and was conducted in a non-confrontational manner. It was made clear how the error had occurred following discussion with the team members, as described above.

Following discussion and team agreement the following changes were introduced to the prescribing procedure within the practice, which the practice manager would lead on:

1. Hand-written requests from the hospital were to be collected by the patient 48-hours after being handed in to reception, unless urgent.
2. All hand written hospital requests were to be presented to the patient’s GP, who was then to write the prescription.
3. Staff involved in prescribing were to change their work environment to a quieter room, away from distractions.
4. It was decided that all GPs should sign their prescriptions in their rooms, again away from any distractions.

How can this be prevented from happening again?

It was decided to review the situation with staff at a practice meeting within the next quarter to ensure that the changes had been successfully implemented, and that no similar errors had occurred.
**Why this SEA could have been better**

- It is unclear if the patient was given a one-month or two-month supply of the drug initially. If the former was the case then it is possible that the error may in fact have occurred twice before being noticed.

- A more detailed explanation of why the event had occurred could have been given. For example, providing a clearer picture of the normal system for dealing with handwritten hospital outpatient prescriptions would have been helpful.

- It is unusual for a non-clinician (it would have been helpful to know the occupation at this stage) to be given the responsibility of interpreting a handwritten request, the information from which is then put on the repeat prescription system – a point which is explored.

- Is there a continued risk associated with non-clinicians adding/altering prescriptions to the system?

- In terms of the actions agreed and implemented, further points could be considered:
  - Was the event discussed with the hospital specialist to bring the handwriting situation to their attention? They too have a duty of care to the patient.
  - How will the new system hold-up if the GP is on holiday?
  - What if the patient refuses to wait for 48 hours (or two working days?) or if the prescription is considered urgent – what is the practice system in this instance?
  - What system is in place to stop the computer operator inadvertently adding the wrong drug to the repeat prescribing list (that is, to pick up human error)?
Linking reflection, personal development and regulation

Reflection

At its core, the SEA is based on sound educational principles. It is one key element among a range of others in a ‘learning organisation’ and in developing an effective safety climate within the practice team. Importantly, the SEA encourages a culture of honesty in the team as well as both team-based and individual reflection. The educational agenda for individual team members, groups and for the whole practice should be fed by significant event discussions, and education should inform the discussions within the significant event meetings.

Continuing professional development

GP Appraisal became a requirement to be admitted to, and remain on, the Performers List in line with the NHS (Primary Medical Services Performers List) (Scotland) Regulations 2004.

Since the Scheme was set up there has been a major review of professional regulation. It is now clear that appraisal will have a fundamental role in the revalidation process. The foresight shown in Scotland provides a ready made infrastructure and our learning so far can usefully inform the future role of appraisal in medical revalidation.

Other healthcare professionals will, in time, find that regular appraisal changes from being a voluntary, professional activity to being mandated. The link between an SEA, personal reflection and the patient safety agenda is increasingly being made. A formative, developmental appraisal looks at professional values, importantly including reflection, personal growth, and continuing education. Taking part in an SEA provides much of the evidence required to satisfy a large part of an appraisal discussion.

Regulation and recertification

In time, doctors will experience periodic recertification, as part of revalidation. Whatever form it takes, its core purpose is to demonstrate that licensed doctors are up-to-date and fit to practise medicine. A key element of being up-to-date is likely to be the demonstration of clinical audit and reflection – one way to show those is through effective participation in an SEA. Local clinical governance processes are the NHS mechanism for assuring the quality and safety of patient care. If clinical governance is to be effective, it must examine risk management and an important aspect of that is an SEA.

Doctors in training

One way for this group to gain valuable experience of the SEA process is to let them take full ownership of an event audit at the outset – from facilitating the discussion of this at the meeting to leading on the event analysis all the way through to writing up a report and then gaining educational feedback from the GP trainer. Ideally the event chosen should be one they were involved with in some way and which can be shared with, and requires input from, other team members. In this way, the doctor is able to lead the team in group reflection and insightful analysis, identify learning needs and facilitate the implementation of change – all important skills, experience and knowledge to be gained in preparation for independent practice.
A brief history of SEAs

SEAs evolved in the mid-1990s from a marriage or synthesis of traditional case-based discussion and the critical incident technique. Although case-based discussions are encouraged educationally in healthcare, they were not accepted by the medical establishment as a form of ‘audit’ because they were invariably viewed as superficial, informal, unstructured and, therefore, lacking in rigour and reliability.

However, there was a strong counter-argument, particularly in general practice, that the value of reflecting on an individual case or event should not be lost, but used to improve the quality and safety of healthcare. Bradley argued convincingly that case-based discussion (and traditional medical anecdotes) could be injected with some scientific rigour by combining this approach with the flexible philosophy and principles which underpin the well-established critical incident technique. This type of ‘significant event analysis’ would be of benefit in terms of ensuring the healthcare team adopted a greater emphasis on a more structured, robust and factual approach to case-based discussion, thereby decreasing subjectivity and increasing rigour.

This laid the groundwork for Pringle and colleagues’ seminal study on the feasibility and acceptability of SEAs in general practice in 1994, which in turn paved the way for this new technique to evolve as a highly important clinical audit method.

What is different about SEAs?

There are important differences between SEAs and other similar retrospective methods such as root cause analysis and case-based discussion, which you may be familiar with. It is necessary to explain these so that the primary care team is not confused by these different approaches, but understands why they exist and the contexts in which they are normally applied.

Outlined below is a description of some of these techniques and their purpose:

| **Case-based discussion (or audit)** | Retrospective team-based (often uni-professional) discussion of interesting, complex or idiosyncratic clinical cases. Long tradition in medicine and other clinical professions. However, criticised as a proxy for ‘audit’ because it is informal, superficial and subjective and unlikely to lead the learning and change often envisaged.
 |
| **Random case analysis** | Retrospective educational review of case records. Applied extensively in monitoring the care of trainee doctors as part of vocational training. Typically involves the joint review by the GP trainer and doctor-in-training of a small random selection of case records of patients who consulted with the trainee.
 |
| **Critical Incident Technique (CIT)** | Developed and tested by Flanagan in military, industrial, commercial, educational and healthcare settings from the 1940s onwards. Accepted as a highly flexible and robust research method, particularly in the social sciences. ‘Critical’ means ‘crucial’ or ‘decisive’ rather than its healthcare connotation. SEAs and CITs are occasionally (and mistakenly) used interchangeably. |
Root Cause Analysis (RCA)  Originated in industry around 30 years ago. Typically involves a retrospective, external (to the immediate team) and independent investigation by trained individuals of a serious patient safety incident (most commonly in acute/mental health settings) using a standard, structured set of procedures. The purpose of RCA is to establish the root causes of an incident. The principle of searching for ‘root causes’ can also form part of an SEA, where appropriate. The one-to-one interview of those directly and indirectly involved in an incident is a key information gathering technique – highly unlikely to be feasible in close-knit, independent, contractor-led health teams like general practice.

The London protocol  Pioneered by Vincent and colleagues. The protocol takes a systems approach and outlines a process of incident investigation, analysis and recommendations for action. Like RCA, the one-to-one interview of those directly and indirectly involved in an incident is a key information gathering technique.
References


5. Standing Medical Advisory Committee for the Secretary of State for Health. The Quality of Medical Care. (1990) London. HMSO.


Further reading


McKay J, Shepherd A, Bowie P & Lough M. Acceptability and educational impact of a peer feedback model for significant event analysis. *Medical Education* 2008; 42: 1210-1217


Bowie P, McKay J, Dalgetty E, Lough M. A qualitative study of why general practitioners may participate in significant event analysis and educational peer review. *Quality & Safety in Health Care* 2005; 14: 185-189


McKay J, Shepherd A, Bowie P & Lough M. Acceptability and educational impact of a peer feedback model for significant event analysis. *Medical Education* 2008; 42: 1210-1217


Bowie P, McKay J, Dalgetty E, Lough M. A qualitative study of why general practitioners may participate in significant event analysis and educational peer review. *Quality & Safety in Health Care* 2005; 14: 185-189


Bowie P, and McKay J. *Seven steps for significant event analysis for primary care teams*. Article and Module for the BMJ Learning website: www.bmjlearning.com

## Useful web links

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<th>Organization</th>
<th>Website</th>
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<td>NHS Education for Scotland – Significant event analysis</td>
<td><a href="http://www.nes.scot.nhs.uk/sea">www.nes.scot.nhs.uk/sea</a></td>
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<td>Royal College of General Practitioners</td>
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<td>Healthcare Improvement Scotland</td>
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Appendix 1

A summary of selected studies and their findings provides some insights into what can go wrong in general practice:

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<tr>
<th>Study</th>
<th>Summary of main findings</th>
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<tr>
<td>McKay J, Bradley N, Lough M and Bowie P. A review of significant events analysed in general medical practice: implications for the quality and safety of patient care. BMC Family Practice 2009: 10.61</td>
<td>191 SEA reports were reviewed. 48 described patient harm (25.1%). A further 109 reports (57.1%) outlined circumstances that had the potential to cause patient harm. Individual ‘error’ was cited as the most common reason for event occurrence (32.5%). Learning opportunities were identified in 182 reports (95.3%) but were often non-specific professional issues not shared with the wider practice team. 154 SEA reports (80.1%) described actions taken to improve practice systems or professional behaviour. However, non-medical staff were less likely to be involved in the changes resulting from event analyses describing patient harm (p&lt;0.05). The study provides some evidence of the potential of SEA to improve healthcare quality and safety. If applied rigorously, GP teams and doctors in training can use the technique to investigate and learn from a wide variety of quality issues including those resulting in patient harm. This leads to reported change but it is unclear if such improvement is sustained.</td>
</tr>
<tr>
<td>Cox, Stephen J. and Holden, John D. A retrospective review of significant events reported in one district in 2004-2005. British Journal of General Practice 2007 57: 542; 732-736(5)</td>
<td>Three hundred and thirty-seven QOF-reported SEAs were reviewed from 32 (91%) of a total of 35 St Helens PCT practices (mean 10.5, range 4-17). Practices identified learning points in 89% of SEAs. Twenty-two of 32 (69%) practices successfully performed SEA and required no further support. Four practices identified learning points but needed further facilitation in implementing change or actions arising from SEA. Six practices had significant difficulties with SEA processes and were referred for extra SEA training locally. Ninety (26.7%) of all significant events were classified as patient-safety incidents. Of these, 22 (6.5%) were ‘serious or life threatening’ and 67 (19.9%) were ‘potentially serious’. Ninety-six (28.5%) of the significant events related to medicines management issues; and 63 (18.7%) had key learning points for partnership organisations. SEA in general practice is a valuable clinical governance and educational tool with potential patient safety benefits. Most practices performed SEA successfully but there were performance concerns and patient-safety issues were highlighted.</td>
</tr>
<tr>
<td>Pringle M., Bradley CP, Carmichael C.M., Wallis H. and Moore A. Significant Event Analysing: A study of the feasibility and potential of case-based auditing in primary medical care. Occasional Paper No.70. Royal College of General Practitioners. (1995) London. RCGP.</td>
<td>A preliminary taxonomy of significant events occurring in 10 randomly chosen urban and rural general practices in two English regions was developed. In total, 538 clinical and administrative events were identified, of which 161 were discussed at practice meetings. Clinical events were classified into groupings such as cancer and tumours; chronic diseases; infections; trauma and self-harm; secondary care problems and therapeutics. Administrative events were classified into groupings such as: complaints and comments; prescribing and dispensing; protocol or procedural breaches; communication issues; errors of omission; administration and training; and education.</td>
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<td>Study</td>
<td>Summary of main findings</td>
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<tr>
<td>Silk N. An analysis of 1,000 consecutive UK general practice negligence claims. Unpublished report from the Medical Protection Society. (2000) Leeds. Medical Protection Society.</td>
<td>Sixty-three per cent of claims were related to investigations and treatment – mainly to do with failure/delay in diagnosis or the wrong diagnosis. Cancer was the largest disease category. In prescribing, the largest category was failure to warn or recognise drug side effects, followed by medication/prescribing errors (main groups were steroids and antibiotic allergy). Administration errors and practice nurse error were present in 4.8 per cent and 3.2 per cent of claims respectively.</td>
</tr>
<tr>
<td>Sandars J. and Esmail A. The frequency and nature of medical error in primary care: understanding the diversity across studies. Family Practice. 2003; 20: 231-236</td>
<td>This literature review determined that medical error occurs between five and 80 times per 100,000 consultations. Errors are mainly related to the processes involved in diagnosis and treatment. Errors may also occur in up to 11 per cent of all prescriptions, mainly related to drug dose.</td>
</tr>
<tr>
<td>Rubin G., George A., Chinn D.J., Richardson C. Errors in general practice: development of an error classification and pilot study of a method for detecting errors. Quality and Safety in Health Care. 2003; 12: 443-447</td>
<td>In a two-week period, 940 errors were recorded in 10 UK practices and classified as follows: prescriptions (42 per cent); communication (30 per cent); equipment (16 per cent) and clinical errors (three per cent). The overall error rate was 75.6/1,000 appointments.</td>
</tr>
<tr>
<td>Makeham M. A. B., Dovey S. M. et al. An international taxonomy for errors in general practice: a pilot study, Medical Journal of Australia. 2002; 177: 68-72</td>
<td>A study involving 102 GPs from six countries including the UK. There were 171 error types identified: 79 per cent process errors (administration, investigations, treatments, communication etc), and 21 per cent knowledge and skills errors (executing a clinical task, diagnoses, treatment decisions etc).</td>
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Appendix 2

More examples of significant event case scenarios

Case 1
A patient was prescribed a drug which had the potential to interact with their current medication. This was noticed by the community pharmacist who, following a call to the practice, did not dispense the medication and informed the patient they needed to return to the GP who would prescribe another medication. This is a ‘near miss’.

Case 2
An elderly patient whose husband had COPD rang the practice to speak to a doctor at 9.10am regarding his increasing distress and breathlessness – the phone was engaged for 40 minutes and the home help also tried without success. An ambulance was eventually called and the patient died in hospital later that day. A complaint was subsequently received by the practice.

Case 3
A GP was out on a visit and received a telephone call to visit a child in the next street who was unwell and couldn’t come to the surgery. The grandmother was looking after the child and stated that the child was not allergic to anything. The GP prescribed penicillin. On return to the surgery the GP entered the information on the computer and noticed that the child was allergic to penicillin. The grandmother was contacted and, as the prescription had not been dispensed, an alternative drug was prescribed.

Case 4
The GP dictated referral letters at the end of a surgery using a hand-held dictation machine. When the typist later put the dictation tape in the machine it was blank. The wrong tape was handed over. The correct tape had been used again for another surgery, over-writing the original dictation for that surgery’s referrals.

Case 5
The practice nurse did a smear test on Mrs W and informed her that she would be notified if there were any problems with the results. The result came back abnormal and the practice tried to contact Mrs W, but there was no record of a telephone number and she was ex-directory. A letter was sent, but this was returned and it became apparent that Mrs W had moved and not notified the surgery. Meanwhile, Mrs W assumed that as she hadn’t heard then the result must be normal. Six months later Mrs W came to the surgery on a routine appointment and was informed of the result and referred.
Case 6
A patient was referred to a rheumatologist because of arthritic symptoms. The rheumatologist diagnosed rheumatoid arthritis and asked for the patient to be commenced on sulphasalazine. The patient was given a prescription for a one-month supply of the drug and told that it would be put on repeat prescription. The patient phoned in to obtain a repeat prescription three months in a row, but the repeat prescription had been entered as sulphadiazine instead of sulphasalazine. He therefore had three months of sulphadiazine in error prior to the mistake being identified.

Case 7
A patient told the nurse she would not be in on the following day because she was going out with her family. Her family would instil eye drops. The nurse forgot to pass the message onto colleagues. The visiting nurse therefore spent a lot of time tracking down the family to find out why the elderly lady was not in. The police were almost called to break in.

Case 8
The parents of a four-year-old boy were not convinced that he should have the MMR vaccination as he was a ‘poorly baby’. The doctor documented their decision. However, the automatic notification system for his pre-school immunisations generated a requirement for the boy to receive the pre-school booster, minus the whooping cough element, and to receive the MMR. The nurse gave both the pre-school booster and the MMR vaccine. It was only after the mother and child had left the clinic and when the nurse checked the boy’s notes that she discovered that the parents were refusing to let their son have the MMR vaccine.

Case 9
The distressed wife of an elderly man who was well known to the practice staff phoned to say she had received a letter inviting him to attend for a monitoring blood test. The patient had died three weeks earlier.

Case 10
An elderly man attended the flu jab clinic. In the hurley-burley of the clinic the practice nurse noticed that he appeared to be a bit short of breath. She asked him wait until the clinic was finished and then did a proper consultation. The blood test she ordered showed a haemoglobin of 9.3 with Chronic Lymphatic Leukaemia.
About NHS Education for Scotland

NHS Education for Scotland (NES) helps to provide better patient care by supplying educational solutions for workforce development. We do this by designing, commissioning, quality assuring and, where appropriate, providing education, training and lifelong learning for NHS Scotland staff.

NES is part of the Scottish Patient Safety Alliance, which for the first time, brings together all the groups developing safer health care in NHSScotland. We are committed to developing a coordinated educational strategy that will support patient safety and quality improvement initiatives across the Scottish Health Service. “NES has been instrumental in developing and embedding the SEA technique in the national education and training systems of different clinical professions and staff groups.”

NES has developed a voluntary peer review system which enables members of the primary care team in the west of Scotland to submit SEA reports for developmental feedback from trained frontline colleagues as part of their continuing professional development (www.nes.scot.nhs.uk/partnership)
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