Patient Safety Incident Response Policy

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This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out LEAD's approach to developing and maintaining effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety.

This policy embraces the aims of PSIRF to be compassionate as we engage with those affected by patient safety incidents as well as to be considered and proportionate in our responses to patient safety incidents and safety issues. We will use system-based approaches to learn from patient safety incidents with supportive oversight.

1 Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across LEAD.

We recognise that patient safety is an emergent property of the healthcare system: that is, safety is provided by interactions between components and not from a single component. Responses do not take a 'person-focused' approach where the actions or inactions of people, or 'human error', are stated as the cause of an incident. There is no remit to apportion blame or determine liability, preventability or cause of death in a response conducted for the purpose of learning and improvement. Other processes, such as professional standards investigations and criminal investigations, exist for that purpose. The principle aims of each of these responses differ from those of a patient safety response and are outside the scope of this policy. Information from a patient safety response process can be shared with those leading other types of responses, but other processes should not influence the remit of a patient safety incident response.

2 Our Patient Safety Culture

LEAD is committed to patient safety by ensuring that there is an embedded culture where reporting of, and learning from, all incidents, is both encouraged and welcomed. We have a number of policies that oversee this including our incident, safeguarding and complaints policies. We encourage the reporting of incidents by having an incident form which is available for staff, patients, and the public to record patient safety-related issues, concerns and incidents.

The benefit of reporting incidents is to identify patterns and trends of when things go wrong, to undertake timely investigations, to pre-empt complaints and litigation, to target resources more effectively and to share learning within the organisation. In doing so LEAD is committed to developing a culture which promotes openness and honesty, that supports staff to have the confidence to report incidents, and one which focuses on improving practice and patient and staff safety, not on deficiencies and blame. LEAD adopts a culture where the focus is balanced towards "how and why, rather than who".

Learning from what goes wrong in healthcare is crucial to addressing identified risks and reducing and preventing future harm. It requires a culture of openness and honesty to ensure staff, patients, families and

carers feel supported to speak up in a constructive way. We support the notion of the national guardian that 'speaking up should be business as usual'. https://nationalguardian.org.uk/ . Staff should feel able to speak up about any matters of concern.

We also encourage feedback from patients and their families. Any concerns raised as a feedback comment are reviewed by the manager and may lead to further investigation or action if deemed necessary.

Any reports made should be submitted to the Manager who will oversee the response and feedback to those who have submitted the report. LEAD is committed to ensure each and every issue raised is followed up in a timely and confidential way.

There are also external organisations which can provide support when raising a concern, such as Protect (telephone: 020 3117 2520 email: whistle@protect-advice.org.uk). Protect provide free expert advice to whistleblowers. They can provide help to decide how best to raise a concern, give advice on what protection one is entitled to and what can be done if things go wrong. Staff may also consider discussing concerns with their trade union.

Staff induction includes reference to LEAD's policies which has further advice for reporting expectations for non-patient safety incidents (eg information governance incidents).

3 Patient Safety Partners

LEAD has and will continue to engage with stakeholders to develop and review our patient safety policy and procedures. Our stakeholders include (but are not limited to); patients, carers, staff, NHS organisations and others who purchase our services.

We also understand the importance of engaging with stakeholders appropriately after a patient safety incident and involving them in any subsequent investigation.

4 Engaging and involving patients, families and staff following a patient safety incident

Engaging with those directly affected by a patient safety incident substantially improves our understanding of what happened, and potentially how to prevent a similar incident in future. Patients, their family members, and carers may be the only people with insight into what occurred at every stage of a person's journey through the healthcare system. Not including those insights could mean an incomplete picture of what happened is created. PSIRF recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. This involves working with those affected by patient safety incidents to understand and answer any questions they have in relation to the incident and signpost them to support as required.

Similarly, staff have important contributions to make about their experience of the incident and the working environment at the time and should be supported to share their account.

LEAD will also engage with key partners when an incident is reported concerning a commissioning ICB and will discuss with the appropriate safety lead within the ICB concerned.

We recognise that those affected by a patient safety incident may have a range of needs (including clinical needs) as a result and these must be met where possible. This is part of our duty of care. Meeting people's needs not only helps alleviate the harm experienced, but also helps avoid compounding that harm. While we cannot change the fact that an incident has happened, it is always within our gift to compassionately engage with those affected, listen to, and answer their questions and try to meet their needs.

Our obligations with regards to Duty of Candour means that we must: tell those affected by a patient safety incident when something has gone wrong, apologise to them and offer an appropriate remedy or support to put matters right (if possible).

Engagement principles:
We follow the PSIRF nine principles of engagement.

1. Apologies are meaningful

Apologies need to demonstrate understanding of the potential impact of the incident on those involved, and a commitment to address their questions and concerns. Ideally, an apology communicates a sense of accountability for the harm experienced, but not responsibility for it ahead of investigation. Getting an apology right is important – it sets the tone for everything that follows. Apologising is also a crucial part of the Duty of Candour.

2. Approach is individualised

Engagement and involvement should be flexible enough to adapt to changing needs and the individual. These needs could be practical, physical, or emotional. Engagement leads (usually the manager but may be delegated to a clinician) should recognise that every response might need to be different, based on an understanding of the different needs and circumstances of those affected by an incident.

3. Timing is sensitive

Some people can feel they are being engaged and involved too slowly or too quickly, or at insensitive times. Engagement leads need to talk to those affected about the timing and structure of engagement and involvement, and any key dates to avoid (eg birthdays, funeral dates, anniversaries), particularly where someone has lost a loved one.

4. Those affected are treated with respect and compassion

Everyone involved in a learning response should be treated respectfully. There should be a duty of care to everyone involved in the patient safety incident and subsequent response, and opportunities provided for open communication and support through the process. Overlooking the relational elements of a learning response can lead to a breakdown of trust between those involved (including patients, families, and healthcare staff) and the organisation.

5. Guidance and clarity are provided

Patients, families, and healthcare staff can find the processes that follow a patient safety incident confusing. Those outside the health service, and even some within it, may not know what a patient safety incident is, why the incident they were involved in is being investigated or what the learning response entails. Patients, families, and healthcare staff can feel powerless and ill-equipped for the processes following a patient safety incident. Therefore, all communications and materials need to clearly describe the process and its purpose, and not assume any prior understanding.

6. Those affected are ‘heard’

Everyone affected by a patient safety incident should have the opportunity to be listened to and share their experience. They will all have their individual perspective on what happened and each one is valid in building a comprehensive picture to support learning. Importantly, the opportunity to be listened to is also part of restoring trust and repairing relationships between organisations and staff, patients, and families.

7. Approach is collaborative and open

An investigation process that is collaborative and open with information, and provides answers, can reduce the chance that litigation will be used as a route for being heard. The decision to litigate is a difficult one. Organisations must not assume that litigation is always about establishing blame – some feel it is the only way to get answers to their questions.

8. Subjectivity is accepted

Everyone will experience the same incident in different ways. Engagement leads should ensure that patients, families, and healthcare staff are all viewed as credible sources of information in response to a patient safety incident.

9. Strive for equity

The opportunity for learning should be weighed against the needs of those affected by the incident. Engagement leads need to understand and seek information on the impact of how they choose response types on those affected by incidents and be aware of the risk of introducing inequity into the process of safety responses.

5 Patient safety incident response planning

PSIRF supports organisations to respond to incidents and safety issues in a way that maximises learning and improvement, rather than basing responses on arbitrary and subjective definitions of harm. This means exploring patient safety incidents relevant to their context and the populations they serve rather than only those that meet a certain defined threshold.

Resources and training to support patient safety incident response

We encourage staff to complete training using e-learning for health modules for PSIRF (Patient safety syllabus training). Most members of staff are also employed within the NHS and undertake training as part of their work within the NHS.

Patient safety incident reporting arrangements

Patient safety incidents are any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare. Reporting them helps us learn from mistakes and to take action to keep patients safe.
Both healthcare staff and the general public are encouraged to report any incidents, whether they result in harm or not.

Members of the public
Report any incident to a member of staff. Members of the public may also report patient safety incidents using the NRLS Patient eForm. The National Reporting and Learning System (NRLS) is due to be decommissioned and will be replaced by the *Learn from patient safety events service* (LFPSE). Members of the public may continue to use the NRLS Patient eForm until the LFPSE has developed full functionality. Please note that the NRLS does not investigate individual reports, any reports made will be used to support national learning:

Healthcare staff
Complete an incident form and send this to the LEAD manager. They can also now record patient safety events directly to the new Learn from patient safety events service (LFPSE), which is currently being rolled out to replace the existing NRLS.

- Report an incident to LFPSE

Patient safety incident response decision-making

Past experience shows a low level of Patient safety incidents at LEAD. Due to the low numbers of safety incidents a Patient Safety Incident Response Plan is not deemed necessary. However we aim to remain proactive as well as considered and proportionate in our responses to patient safety incidents. To ensure this we will use of a range of system-based

approaches to learning from patient safety incidents. As Healthcare is complex and can be highly variable, uncertain, and dynamic. A system-based approach will identify where changes need to be made and then monitored within the system to improve patient safety.

SEIPS (System Engineering Initiative for Patient Safety) is the systems-based framework endorsed by PSIRF. Please see this guide https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-SEIPS-quick-reference-and-work-system-explorer-v1-FINAL-1.pdf

SEIPS is a framework for understanding outcomes within complex systems which can be applied to support the analysis of incidents and safety issues more broadly. This identifies that a 'work system' consists of six broad elements:

- External environment
- Organisation
- Internal environment
- Tools and technology
- Tasks
- Person(s)

In turn a work system can influence processes (work done), which in turn shapes outcomes. It follows that people cannot be separated from the work system; their deliberate placement at the centre emphasises that design should support – not replace or compensate for – people.

The actual response to an incident needs to be proportionate. Some events in healthcare require a specific type of response as set out in regulations. These responses include mandatory patient safety incident investigation (PSII) in some circumstances (please refer to Appendix A in the Guide to responding proportionately to patient safety incidents).

Most incidents which do not reach the threshold for mandatory PSII will be considered using a variety of approaches, a Multidisciplinary team (MDT) review being one approach. With an MDT review the aim is, through open discussion (and use of other approaches such as observations and walk throughs undertaken in advance of the review meeting(s)), to agree the key contributory factors and system gaps that impact on safe patient care.

6 Reviewing our incidents policy

Our incident policy will be appropriately amended and updated as we use it to respond to patient safety incidents. We will review the policy every 12 to 18 months to ensure our focus remains up to date; with ongoing improvement work our patient safety incident profile is likely to change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 12 to 18 months.

7 Responding to patient safety incidents

Timeframes for learning responses

The time needed to conduct a response must be balanced against the impact of long timescales on those affected by the incident, and the risk that for as long as findings are not described, action may not be taken to improve safety or further checks will be required to ensure the recommended actions remain relevant.

A response must start as soon as possible after an incident is identified, and usually completed within one to three months.

The timeframe for completing a PSII should be agreed with those affected by the incident, as part of setting the terms of reference for the PSII, provided they are willing and able to be involved in that decision. PSIIs (and other local response) should take no longer than six months. Where external bodies (or those affected by patient safety incidents) cannot provide information, to enable completion within six months or the agreed timeframe, the local response leads should work with all the information they have to complete the response to the best of their ability; it may be revisited later, should new information indicate the need for further investigative activity.

In exceptional circumstances (eg when a partner organisation requests an investigation is paused), a longer timeframe may be needed to respond to an incident. In this case, any extension to timescales should be agreed with those affected (including the patient, family, carer, and staff).

8 Safety action development and monitoring improvement

Please also see Safety Action Development Guide which is referred to in this section

Agree Areas for Improvement

Capturing the whole teams perspective is essential for defining areas for improvement. Involving patients, carers, families, administrators, maintenance staff and managers where appropriate and available. This will capture valuable insights that may not otherwise be considered.

Outlining areas of improvement does not seek to define precise safety actions rather it sets out to identify where improvements are needed without defining how this improvement is to be achieved.

Areas for improvement must be linked to the outcomes of learning responses or findings from other related approaches such as thematic reviews and horizon scanning: the reason for change must remain clear as safety actions are developed and implemented. This will help with implementation later.

Define Context

One method to determine the context for an area of control involves marking areas according to their 'sphere of control':

Control (Local Context) -Area of improvement is within the local team's control to address on their own.

Influence (Wider Organisational Context) –The team will likely need some outside help.

Escalate –These require a lot of outside support and usually a lot of resources. They tend to use up an excessive amount of energy from the local team if that team attemps to tackle them alone.

Actions may be taken across the different layers of the system: some can be implemented quickly and reported in a learning response report (eg patient safety incident investigation (PSII) report) while others will take considerably longer to implement and produce results.

Define safety actions

Actions to reduce risk are generated in relation to each defined area for improvement.

Continue to involve the team:

Where possible, those affected by the patient safety incident should also be involved (See Engaging and involving patients, families, and staff after a patient safety incident).

Brainstorm safety actions:
It can be helpful to think about brainstorming safety actions that:

- **Expand on what's good**

Elements in your system that you want to make happen as often as possible. E.g.:standardised arrangement

- **Improve what's bad**

Elements in your system that are highly variable or are making it difficult to complete work/meet an expectation

- **Mitigate what's ugly**

Elements in your system where you have found unmitigated risk that can cause severe harm or death

Consider the sphere of control:
We want to hear the ideas of members of the team whose work is to be influenced. As these ideas are within their control to act on. Staff should feel empowered and encouraged to lead the development of improvements in their work.

Focus on the system:
The Human Factors Intervention Matrix (HFIX4) uses a series of questions to prompt thinking about how each area of improvement identified might be translated into possible safety actions to reduce risk. An adaption has been made to align HFIX with the Systems Engineering Initiative for Patient Safety (SEIPS5) work system categories. Which can be found in this guide:
https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-Safety-action-development-v1.1.pdf (Please follow link and see table 2 and Appendix A of the linked document)

Prioritise safety actions

Avoid prioritizing safety actions based on intuition or opinion alone.

Prioritise using iFACES criteria and where possible test prior to implementation

The iFACES tool can help quantify the potential value of each identified action using six criteria: inequality, feasibility, acceptability, cost/benefit, effectiveness, and sustainability. Please refer to

https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-Safety-action-development-v1.1.pdf for iFACES tool

Test safety actions:

Once the safety actions to be considered for implementation have been decided, these should then be tested where possible in 'real-life' or under simulated conditions. During testing we observe and discuss the action:

- What issues did people find? Make the necessary improvements.
- Did users behave as expected? If not, update safety action.

Continue with team involvement:

At least one follow-up conversation with the team to make sure that those who do not have action ownership are still part of the discussion.

Define Safety Measures

Before finalising a safety action, a plan is made for how it's effectiveness and progress towards specific goals will be evaluated. Meaningful measures need to be identified that can be monitored through normal processes, to ensure that the benefits of change are sustained.
Part of this plan should include when a safety action should be abandoned. This is to avoid the temptation to press on at all costs. The decision to abandon the safety action is as an opportunity to invest in better alternatives – not a wasted investment of time.

Defining safety measures is a three-step process.

Step 1: Identify measures
Consider what can be measured to increase confidence that the safety action is influencing what it was intended to.
Measures will change over time:

- The first measure acknowledges that the safety action has been introduced – it simply notes the existence of an activity, input or process

related to the safety action. Measuring the completion of an action alone (eg check added to checklist) does not sufficiently indicate whether the change is beneficial.

• The second measure checks whether the activity, input or process is taking place, eg is the tool being used as intended? You may already have collected data on this when testing your safety action. You may need to adjust your safety action at this stage.

• Finally, and most importantly, you must measure the **effectiveness** of the safety action – that is, has the safety action delivered the intended benefits? You must also consider whether there have been any unintended consequences of implementing the safety action.

When measuring effectiveness, you should avoid counting the number of reported incidents and compliance with a safety action – this loses sight of the need to manage inherent risks and can be influenced by factors unrelated to safety (eg greater awareness that there is a risk/problem). Instead, you should focus more on the change associated with the activity undertaken, eg changes in observed behaviours, improved documentation (due to paperwork redesign), faster response time.

Be aware of unintended consequences of measurement, eg measuring the number of safety briefings completed may result in a decline in briefing quality. An alternative measure could be attendee feedback or comments related to the meetings.

Step 2: Prioritise and select safety measures

Several safety measures may have been identified, but selecting one or two measures will be more practical than measuring all of them.
Before you can prioritise, you need to sufficiently define the potential measures so they will be evaluated with a common understanding of what they entail.

To prioritise safety measures, consider the practicalities and data availability. For example, are measures:

• currently collected and reported

• collected, but not reported

• available, but not collected

• not currently available.

This gives insights into the effort required to monitor the safety action. Further criteria for evaluating and identifying the best measures are given below. If the answers to these questions are predominantly ‘yes’, the

measure is more favourable than one for which the answers are predominantly 'no'.
• Will there be enough data to identify trends?
• Will the quality of the data be good enough?
• Does the measure have a clear unambiguous definition?
• Is it easy to communicate what is being measured?
• Will it provide timely warning of deterioration?
• Does it measure what is intended?
• Will changes in the measure lead to action?
• Will the measure promote the desired behaviour?
• Do the benefits of the measure outweigh the costs of collecting and monitoring the data?

Several related measures may be identified. Rather than choosing one, it may be beneficial to combine several measures. Document why each measure is considered further or rejected this provides a valuable audit trail.
If several measures appear promising, a trial could help decide which one is the most useful.

Step 3: Define measures
Once a measure has been selected, it must be clearly defined so that it is consistently recorded, reported, and understood across the organisation. This will require input from all those involved in measuring, analysing, reporting, acting on and reviewing, to ensure that the measure is clearly understood.

Write safety actions

Safety actions should be SMART (specific, measurable, achievable, relevant, time-bound). They should also:
• Be documented in a learning response report or in a safety improvement plan as applicable.
• Be directed to the correct level of the system: that is, people who have the levers to activate change (ideally this should include the person closest to the work and who has been empowered to act).
• Be succinct: any preamble about the safety action should be separate.
• Standalone: that is, readers should know exactly what it means without reading the report.
• Make it obvious why it is required.

Continue to work with those to whom the safety actions are directed to ensure they are on board and willing to implement change.

While safety actions should feature in the learning response report or safety improvement plan alongside the information that supports them, an overview of measurement and monitoring should be summarised in a table (an example table for this is provided in Appendix B of the Safety action development guide Please follow the link to view)

Monitor and review

Continue being curious: inquire about how things are working and monitor that safety actions put in place remain impactful and are sustainable.
The safety actions and associated measure(s) should be reviewed as defined in the safety action summary table to ensure they continue to provide value by being the issues of most concern.

Final thoughts
Our desire to ensure an incident does not happen again can push us to skip learning and jump to solutions. But it is important we establish the learning before we start to define areas for improvement.
We cannot always 'fix' the system so that a patient safety incident will never happen again. Healthcare is complex and 'change is the only constant'. We can reduce risk and we can strive to fail safely, but perfect fixes may not exist.
While one safety action is unlikely to resolve a defined area for improvement, it is important to ensure all safety actions are meaningful. We do not implement change for the sake of change – we must ensure improvement results from change and continue to monitor this. No action will achieve its purpose on its own, independently of others and what goes on around it. This is the reality of a complex system.

Appendix 1

INCIDENT REPORT FORM

Incident details

Date and time of incident

_____

What happened?

_____

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_____

Patient details

_____

_____

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_____

Resolution

_____

_____

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_____

Supervisor comments

Supervisor signature

Date and Time