Patient safety incident response policy

Effective date: 01.04.24

Estimated refresh date: 01.04.25

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Purpose

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

The PSIRF replaces the Serious Incident Framework (SIF), (2015) and makes no distinction between "patient safety incidents" and "serious incidents". It removes the "serious incidents" classification and the threshold for it. Instead, the PSIRF promotes a proportionate approach to responding to patient safety events by ensuring resources allocated to learning are balanced with those needed to deliver improvement. The new framework is not a different way of describing what came before; it fundamentally changes how NHS health care providers respond to patient safety events for learning and improvement.

The PSIRF advocates a co-ordinated and data-driven response to patient safety incidents. It embeds patient safety incident response within a wider system of improvement and prompts a significant cultural shift towards systematic patient safety management.

This policy supports development and maintenance of an effective patient safety incident response system that integrates the four key aims of the PSIRF:

- compassionate engagement and involvement of those affected by patient safety incidents
- application of a range of system-based approaches to learning from patient safety incidents
- considered and proportionate responses to patient safety incidents and safety issues
- supportive oversight focused on strengthening response system functioning and improvement.

This policy should be read in conjunction with our current patient safety incident response plan and is based on national guidance NHS England's Patient Safety Incident Response Framework (PSIRF).

Scope

This policy relates to responses to patient safety incidents that are solely for the purpose of learning and improvement. Any response that seeks to find liability, accountability or causality is beyond the scope of this policy.

Response types that are outside the scope of this patient safety incident response plan:

Patient safety incident response policy

- complaints
- human resources investigations
- professional standards investigations
- coronial inquests
- criminal investigations
- claims management
- financial investigations and audits
- safeguarding concerns
- information governance concerns
- estates and facilities issues

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across **all services provided by Totally.**

Responses under this policy follow a systems-based approach. This recognises 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 claims handling, human resources investigations into employment concerns, professional standards investigations, coronial inquests 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.

Note: 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.

Our patient safety culture

PSIRF preparation guide

A culture of open reporting of incidents (including near misses and 'errors') is positively encouraged by Totally as an opportunity to learn and to improve safety, systems and services. To reinforce this, we have shared across the organisation the NHSE guide 'A just culture guide' NHS_0932_JC_Guide_A3 (england.nhs.uk), which aims to promote fair and consistent staff treatment within and between healthcare organisations.

The Just Culture guide does not replace the need for patient safety investigation and will not be used as a routine or integral part of a patient safety investigation. This is because the aim of those investigations is system learning and improvement. As a result, decisions on avoidability, blame, or the management of individual staff are excluded from safety investigations to limit the adverse effect this can have on opportunities for system learning and improvement.

In order for an effective patient safety culture to operate, employees must be supported to report incidents that have occurred due to human error. Totally will not sanction or take disciplinary action against staff that freely report mistakes related to human error, staff can also raise concerns via our Freedom to Speak Up Guardians.

We ask staff to report all incidents and near misses should on our risk and compliance system by completing a Datix, we regularly remind staff of this requirement and the benefits of such reporting.

To support the culture of learning and improvement we have developed our governance framework to allow for shared learning and understanding from sites, across the organisation and up to the board. This includes:

- Frequent (daily/ weekly) **Safety Huddles** are undertaken at site level with incidents, complaints and feedback reviewed by the site leadership team and a member of the Governance Team. This encourages swift action or escalation where required.

- Weekly '**incident lookbacks'** are undertaken by the Governance Team to review themes, trends and learning which can then be shared across the organisation.

- We share learning and good practice across the organisation using the '**Clinical Learning' pages** on the intranet and via a bimonthly **Clinical Learning Forum**.

- The monthly **Clinical Assurance Group** (chaired by the Group Medical Director or Director of Nursing) reviews all safety action plans from learning responses and themes/trends from the sources described above. They also have oversight of any **Incident Review Meeting** outcomes to ensure learning responses are proportionate, resourced and lead to improvement.

Training

To support staff to understand the importance of reporting patient safety incidents we are rolling out training as recommended in the PSIRF standards:

Staff group	Training	Content
All staff, including bank and agency staff	Patient Safety Syllabus Training – eLfH platform **Level 1 Essentials of Patient Safety E-learning Training**	• listening to patients and raising concerns • the systems approach to safety, where instead of focusing on the performance of individual members of staff, we try to improve the way we work • avoiding inappropriate blame when things do not go well • creating a just culture that prioritises safety and is open to learning about risk and safety
Board and Senior Leadership Teams	Patient Safety Syllabus Training – eLfH platform **Level 1 Essentials of Patient Safety for Boards and Senior Leadership Teams**	• introduces patient safety measurement, monitoring, and governance for patient safety for Boards and Senior Leaders. • Board opportunities and responsibilities in patient safety, human and financial costs, and safety aspects.
Learning response and engagement leads	Patient Safety Syllabus Training – eLfH platform **Level 2 – Access to Practice (1 and 2)**	Introduction to the key elements of safety science. These elements underpin all domains of the syllabus, and are: systems thinking, risk expertise, human factors and safety culture
	HSSIB: **A systems approach to investigating and learning from patient safety incidents**	• An introduction to complex systems, systems thinking and human factors. • Investigation practice such as interviewing, using SEIPS framework and report writing. • Developing effective safety actions and recommendations.

Learning From Patient Safety Events

Our safety culture will further mature with the adoption of the new Learning from Patient Safety Events (LFPSE) system when we migrate from the previous National Reporting and Learning System to the new LFPSE system, a new national NHS system for the recording and analysis of patient safety events. This system enables Totally to share patient safety events with the national Patient Safety Team to inform system wide learning.

Patient safety partners

Framework for involving patients in patient safety guidance

Totally recognises that Patient Safety Partners (PSPs) can support effective safety governance at all levels in the organisation. The benefits of PSP involvement include:

- Promoting openness and transparency
- Supporting the organisation to consider how processes appear and feel to patients
- Helping the organisation know what is important to patients
- Helping the organisation identify risk by hearing what feels unsafe to patients
- Supporting the prioritisation of risks that need to be addressed and subsequent improvement programmes
- Supporting the organisation in developing an action plan following an investigation so that actions address the needs of patients
- Helping the organisation to produce patient information that patients understand and can access.

The role of PSPs in Totally is currently under development. The long-term aim is to have a pool of PSPs representative of the community we serve. PSPs will be involved in:

- Development of the organisation's PSI Response policy, profile and plan going forward
- Development of incident response processes including improved patient engagement and involvement
- Membership of quality and governance meetings whose responsibilities include the review and analysis of safety data
- Patient safety improvement projects
- Working with our board to consider how to improve safety
- Staff patient safety training
- PSI investigation oversight and review

Our ambition is to recruit two PSPs in 2024/35, one with a UTC focus and one with an OOH focus, this will be submitted as a business case in Q1 2024.

Addressing health inequalities

Totally as an independent provider of NHS services has a core role to play in reducing inequalities in health by improving access to services and tailoring those services around the needs of our patients in an inclusive way.

We will use data intelligently to assess for any disproportionate patient safety risk, to patients from across the range of protected characteristics.

At all opportunities we will assess and address if there are any particular features of an incident which indicate health inequalities may have contributed to harm or demonstrate a risk to a particular population group, including all protected characteristics.

Engagement of patient, families and staff following a patient safety incident is critical to the review of patient safety incidents and their response. We will ensure that we use available tools such as easy read, translation and interpretation services and other methods as appropriate to meet the needs of those concerned and maximise their potential to be involved in our patient safety incident response.

In addition to retrospective incident reviews, we are working to ensure we capture information relating to health inequalities and service users' protected characteristics, this can then be used to inform learning and improvement. Through the gathering of more demographic data, we will be able to assist our understanding of service users in terms of groups who access our services more or less frequently and develop improvement plans accordingly.

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

The PSIRF recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. It supports the development of an effective patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents (including patients, families and staff). 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.

Guidance on engaging patients, family and staff can be found at, Engaging and involving patients, families and staff following a patient safety incidents guidance, patient safety incident response standards and the PSIRF preparation guide

We want to learn from any incident where care does not go as planned or expected by our patients, their families, or carers to prevent recurrence. As well as meeting our regulatory and professional requirements for Duty of Candour, we want to be open and transparent with our patients, families,

and carers because it is the right thing to do. This is regardless of the level of harm caused by an incident.

We will be open with those affected, explaining what has happened, listening to any questions and/or concerns, and explaining what will happen next. The requirement to comply with Duty of Candour regulations is unchanged in that all providers must inform the patient, family or carers of any notifiable patient safety incident and follow all the requirements of the Duty of Candour.

The following standards are endorsed for all learning responses but they must be upheld where a patient safety incident investigation is undertaken. Those affected by patient safety incidents should be:

- Provided with a named main contact within Totally to liaise with about any learning response and support.
- Communicated with in a way that takes account of their needs.
- Fully informed about what happened.
- Given the opportunity to provide their perspective on what happened.
- Given an opportunity to raise questions about what happened and to have these answered openly and honestly.
- Helped to access support if needed eg advocacy services
- Allowed to bring a friend, family member or advocate of their choice with them to any meeting that is part of the learning response process they are involved in.
- Given the opportunity to agree a realistic timeframe for any investigation.
- Informed in a timely fashion of any delays with the investigation and the reasons for them.
- Updated at specific milestones in the investigation should they wish to be.
- Given the opportunity to review the learning report with a member of the investigation team while it is still in draft and there is a realistic possibility that their suggestions may lead to amendments. *Note this does not mean that their suggestions must be incorporated but any decision not to incorporate their suggestions must be explained to them.*
- Invited to contribute to the development of safety actions resulting from the learning report.
- Given the opportunity to feedback on their experience of the learning response and report (e.g. timeliness, fairness, and transparency)

Where a Patient Safety Incident Investigation (PSII) has taken place the team/s should be supported to collaborate in the development of learning action and a debrief and learning event should be held within the staff team/s to share the findings of the investigation and to enable reflection and learning to be undertaken.

Patient safety incident response planning

Guide to responding proportionately to patient safety incidents, patient safety incident response standards and the PSIRF preparation guide

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. Beyond nationally set requirements, organisations can explore 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

Totally is fully committed to ensuring that PSIRF is embedded and that staff feel confident to manage patient safety issues. Staff affected by patient safety events will be given the necessary managerial support required and time to participate in learning responses.

When necessary, Totally will utilise subject matter experts (internal and external) who have relevant knowledge and skills to support the learning response and provide expertise, and advice.

Training

Totally recognises that meaningful leaning and improvement following a patient safety event can only be achieved if supportive systems and processes are in place. Therefore, appropriate training and education will be provided to staff to ensure safety events are investigated in line with PSIRF guidance (see page 6 for details).

Our patient safety incident response plan

Guide to responding proportionately to patient safety incidents

Our PSIRF plan sets out how Totally intends to respond to patient safety incidents over a period of 12 to 18 months. The plan is not a permanent set of rules that cannot be changed. We will remain flexible and consider the specific circumstances in which each patient safety incident occurred and the needs of those affected.

Reviewing our patient safety incident response policy and plan

Our patient safety incident response plan is a 'living document' that will be appropriately amended and updated as we use it to respond to patient safety incidents. We will review the plan 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.

Updated plans will be published on our website, replacing the previous version.

A rigorous planning exercise will be undertaken every four years and more frequently if appropriate (as agreed with our lead integrated care board (ICB)) to ensure efforts continue to be balanced between learning and improvement. This more in-depth review will include reviewing our response capacity, mapping our services, a wide review of organisational data (for example, patient safety incident investigation (PSII) reports, improvement plans, complaints, claims, staff survey results, inequalities data, and reporting data) and wider stakeholder engagement.

Responding to patient safety incidents

Patient safety incident reporting arrangements

See guidance: NHS England » Report a patient safety incident

Guide to responding proportionately to patient safety incidents

All staff are responsible for reporting any potential or actual patient safety incident on the Datix reporting system and should record the level of harm they know has been experienced by the person affected.

Services have frequent (daily or weekly) Safety Huddles to review incidents, feedback and complaints. This forum allows for a prompt review of incidents to ensure that patient safety incidents can be responded to proportionately and in a timely fashion. Appropriate learning responses should be considered at this point eg utilising a SWARM, MDT review, or arranging a Incident Review Meeting. Most incidents will only require local review within the service, however for some, where it is felt that the opportunity for learning and improvement is significant, these should be escalated via the Incident Review Meeting.

All incidents which form one of our key themes (or could generate learning and improvement) are reviewed at the weekly lookback meeting, and learning and actions are shared across the organisation as required.

An Incident Review Meeting brings together senior representatives to review an incident and agree appropriate learning response eg whether to commission a PSII, thematic review etc. This group should include consideration of whether Duty of Candour applies.

The Clinical Assurance Group will have oversight of all outcomes from the Incident Review Meetings to ensure a proportionate response to incidents. They will also ensure learning has been shared appropriately across the organisation.

Patient safety incident response decision-making

National Event Response Requirements- **Events requiring a specific type of response as set out in policies or regulations**

Event	Action required	Lead body for the response
Deaths thought more likely than not due to problems in care (incidents meeting the learning from deaths criteria for PSII)[5]	Locally-led PSII	The organisation in which the event occurred
Deaths of patients detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies, where there is reason to think that the death may be linked to problems in care (incidents meeting the learning from deaths criteria)	Locally-led PSII	The organisation in which the event occurred
Incidents meeting the Never Events criteria 2018, or its replacement.	Locally-led PSII	The organisation in which the Never Event occurred

Event	Action required	Lead body for the response
Mental health-related homicides	Referred to the NHS England Regional Independent Investigation Team (RIIT) for consideration for an independent PSII Locally-led PSII may be required	As decided by the RIIT
Maternity and neonatal incidents meeting Healthcare Safety Investigation Branch (HSIB) criteria or Special Healthcare Authority (SpHA) criteria when in place	Refer to HSIB or SpHA for independent PSII See also Appendix B	HSIB (or SpHA)
Child deaths	Refer for Child Death Overview Panel review Locally-led PSII (or other response) may be required alongside the panel review – organisations should liaise with the panel	Child Death Overview Panel
Deaths of persons with learning disabilities	Refer for Learning Disability Mortality Review (LeDeR) Locally-led PSII (or other response) may be required alongside the LeDeR – organisations should liaise with this	LeDeR programme
Safeguarding incidents in which: • babies, children, or young people are on a child protection plan; looked after plan or a victim of wilful neglect or domestic abuse/violence	Refer to local authority safeguarding lead Healthcare organisations must contribute towards domestic independent inquiries, joint targeted area inspections, child safeguarding practice reviews, domestic homicide reviews and any other safeguarding reviews (and inquiries) as required to do so by the local safeguarding partnership (for children) and local safeguarding adults boards	Refer to your local designated professionals for child and adult safeguarding

• adults (over 18 years old) are in receipt of care and support needs from their local authority • the incident relates to FGM, Prevent (radicalisation to terrorism), modern slavery and human trafficking or domestic abuse/violence		
Incidents in NHS screening programmes	Refer to local screening quality assurance service for consideration of locally-led learning response See: Guidance for managing incidents in NHS screening programmes	The organisation in which the event occurred
Deaths in custody (eg police custody, in prison, etc) where health provision is delivered by the NHS	Any death in prison or police custody will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the Independent Office for Police Conduct (IOPC) to carry out the relevant investigations Healthcare organisations must fully support these investigations where required to do so	PPO or IOPC
Domestic homicide	A domestic homicide is identified by the police usually in partnership with the community safety partnership (CSP) with whom the overall responsibility lies for establishing a review of the case	CSP
	Where the CSP considers that the criteria for a domestic homicide review (DHR) are met, it uses local contacts and requests the establishment of a DHR panel The Domestic Violence, Crime and Victims Act 2004 sets out the statutory obligations and requirements of organisations and commissioners of health services in relation to DHRs	

If the patient safety event does not have a specific type of response required our daily/weekly Safety Huddles can identify various options to ensure we are responding proportionately and in a timely manner, these options include escalating to an Incident Review Meeting to consider an appropriate and proportionate learning response.

Learning responses:

Patient Safety Incident Investigations (PSII)	A PSII offers an in-depth review of a single patient safety event or cluster of safety events to understand what happened and how. These will be undertaken using Systems Engineering Initiative for Patient Safety (SEIPS) methodology.
SWARM	The swarm huddle is designed to be initiated as soon as possible after an event and involves an MDT discussion. Staff 'swarm' to the site to gather information about what happened and why it happened as quickly as possible and (together with insight gathered from other sources wherever possible) decide what needs to be done to reduce the risk of the same thing happening in future.
Multidisciplinary (MDT) Team Review	An MDT review supports health and social care teams to learn from patient safety events that occurred in the significant past and/or where it is more difficult to collect staff recollections of events either because of the passage of time or staff availability. The aim is, through open discussion (and 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.

After Action Review (AAR)	AAR is a structured facilitated discussion of an event, the outcome of which gives individuals involved in the event understanding of why the outcome differed from that expected and the learning to assist improvement. AAR generates insight from the various perspectives of the MDT and can be used to discuss both positive outcomes as well as safety events. It is based around four questions: • What was the expected outcome/expected to happen? • What was the actual outcome/what actually happened? • What was the difference between the expected outcome and the event? • What is the learning?
Thematic Review	A thematic review can identify patterns in data to help answer questions, show links or identify issues. Thematic reviews typically use qualitative (I.e., Incident reports, Complaint's data etc.) rather than quantitative data to identify safety themes and issues. Thematic Reviews can be used for multiple purposes, including: • Developing or revising our Safety Improvement Profile • Aggregating information from many diverse sources of safety intelligence datasets. • Gathering insight about gaps / safety issues across a pathway or as part of an overarching safety theme to direct further analysis • Aggregating findings from multiple incident responses to identify interlinked contributory factors to inform / direct improvement efforts. • Presenting summary data to show the impact of ongoing safety improvement work.

Responding to cross-system incidents/issues

Totally is committed to taking a system wide approach to learning from patient safety events and this, on occasion, may involve working closely with other organisations.

If a patient safety incident requires a cross -system review Totally will contact the relevant organisation(s) required to support this. We will also work collaboratively wherever necessary when other organisations ask us to support cross-system reviews.

Timeframes for learning responses

Guide to responding proportionately to patient safety incidents

We will undertake a learning response as soon as possible after the incident is identified in line with the processes described.

We will agree learning response timeframes in discussion with those affected, particularly the patient(s) and/or their families/carer(s), where they wish to be involved in such discussions.

PSIIs should take no longer than 6 months and not exceed timeframes agreed with those affected. If these are exceeded processes must be reviewed to understand how timeliness can be improved.

In exceptional circumstances (e.g., when a partner organisation requests an investigation is paused), a longer timeframe may be needed to respond to an event. In this case, any extension should be agreed with those affected (patient, family, carers and staff).

The time needed to conduct a response must be balanced against the impact of long timescales on those affected by the event. This should also consider 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.

Where external bodies (or those affected by patient safety events) 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. The response may be revisited later, should new information indicate the need for further investigative activity.

Safety action development and monitoring improvement

Safety action development guide

After identifying and agreeing those aspects of the system where change could reduce risk and potential for harm, safety actions to reduce risk will be generated in relation to each defined area for improvement. Following this, measures to monitor safety actions will be defined. The term ‘areas for improvement’ should be used instead of ‘recommendations’ to reduce the likelihood of alighting on a solution at an early stage of the safety action development process.

All safety action plans will have oversight by the monthly Clinical Assurance Group who will ensure:

- Safety action plans are progressing
- Improvement is being embedded and monitored
- Learning shared across the organisation and wider as required

Learning from safety action plans will be also be shared via the various internal processes in place eg Clinical Learning Forum, intranet, service governance meetings etc.

Safety improvement plans

Safety improvement plans bring together findings from various responses to patient safety events and issues. Totally's PSIRP has outlined the organisations' priorities for the first 12 months. These were developed due to the opportunity they offer for learning and improvement across areas where there is no existing plan or where improvement efforts have not been accompanied by reduction in risk or harm.

We will use the outcomes from Incident Review Meetings and any relevant learning responses to inform future improvement plans working across our services to ensure there is an aligned approach to development of plans and resultant improvement efforts.

The Clinical Assurance Group (CAG) will review safety action plans, improvement plans and learning responses to provide support and oversight. The Group will monitor and measure progress against agreed learning actions and outcomes to ensure effective improvements are implemented and sustained.

The CAG will ensure cross departmental support where required eg if factors relating to culture and leadership are identified, the CAG will request input from HR, Learning and Development team etc

Where appropriate, local monitoring of actions via audit should be considered when improvement plans are complete, to ensure that changes are embedded and continue to deliver the desired outcomes.

Oversight roles and responsibilities

Oversight roles and responsibilities specification and Patient safety incident response standards

Totally Executive Board

The organisation's board are responsible and accountable for effective patient safety incident management in the organisation.

This includes supporting and participating in cross-system/multi-agency responses and/or independent patient safety incident investigations where required.

Director responsibilities for Patient Safety and PSIRF Implementation

The Director of Nursing and Group Medical Director hold responsibility for quality and patient safety, with the Director of Nursing responsible for PSIRF implementation. In line with NHS England Oversight Roles and Responsibilities guidance the Director of Nursing is responsible for:

- Ensuring the organisation meets national Patient Safety Incident Response Standards
- Ensuring PSIRF is central to overarching safety governance arrangements
- Quality assuring learning response outputs

Patient safety incident response policy

Areas for development and strengthening have been highlighted throughout the implementation phase and are as follows:

- Full rollout of this policy and PSIRP will support staff to understand the roles and responsibilities in relation to patient safety incident responses.
- Mandatory training and induction will support staff to understand the PSIRF approach.
- Further training in the PSIRF approach and supporting methodologies may be required for certain roles as this approach matures.
- Business case required to support employment of Patient Safety Partners.

All other Directors/ Heads of Services

All Directors and Heads of Services have responsibility for adhering to, championing and supporting the implementation of this patient safety policy within the remits of their identified portfolios.

The Director of Nursing will delegate responsibilities as appropriate to strategic leads who will support the development and implementation of this policy. This includes:

- reviewing and defining the organisation's patient safety improvement profile
- identifying and engaging with internal and external stakeholders
- ensuring the voice of patients, families and carers is heard at all levels of the organisation
- ensuring necessary training is available in relation to PSIRF

Complaints and appeals

Totally recognises the importance of compassionate engagement and involvement of those affected by patient safety incidents (including patients, families and staff). As such, we will assign an engagement lead as part of the PSII response process.

Their role is to liaise with the patient and/or their representative, families and staff and:

- Provide those affected with clear information about the purpose of a learning response and what to expect from the process.
- Ensure those affected by a patient safety incident are signposted to relevant support services as needed.
- Adopt a flexible approach to the individual and changing needs of those affected.
- Ensure those affected are listened to, share their experience, have the opportunity to ask questions and inform the terms of reference of a learning response.

Those affected by a patient safety incident should raise any complaints or concerns regarding the PSII response process with the Engagement Lead initially where possible. However, if attempts to resolve any issues are unsuccessful or if a patient wishes to make a formal complaint, patients can do so via Totally's complaints process.