



Patient Safety Incident Response Framework Policy

Purpose:

This policy supports the requirements of the NHS England Patient Safety Incident Response Framework (PSIRF) and sets out Step One Charity'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.

The PSIRF advocates a co-ordinated 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

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Owner:	Head of Operations		
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Change History			
Version	Date	Summary of Change	Reviewer
1.0	31/07/2024	New Policy - replacing Investigating Incidents and Complaints Policy	Head of Operations Governance & Assurance Manager

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Scope

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

Responses under this policy follow a systems-based approach. This recognises that patient safety is an emergent property of the health and social care 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 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.

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.

Definitions

- PSIRF – Patient Safety Incident Response Framework
- PSP's – Patient Safety Partners
- PSII – Patient Safety Incident Investigation
- PSMG – Patient Safety Management Group
- HSE – Health & Safety Executive
- RIDDOR – Reporting of injuries, diseases and dangerous occurrences regulations
- MHRA – Medicines and healthcare products regulatory agency
- LFPSE – Learning From Patient Safety Events
- PSIRP – Patient Safety Incident Response Plan

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- Patient – A patient is any individual that Step One provides a service to that is commissioned through Health or Social Care Bodies (Cypress, DMHA, Supported Living and Community Enabling).
- Patient Safety Incidents - are incidents that could have or did harm one or more patients.

Roles and Responsibilities

PSIRF is reliant on all colleagues recognising their individual responsibility to ensure that their practice, role, and environment is patient safety aware. Colleagues must contribute and participate in patient safety training and safety improvement work. Colleagues must raise patient safety incidents, and near misses to ensure learning.

Patient Safety Plans are the business of all colleagues and ensure that our practice is based on learning from past incidents and that we undertake proactive planning to avoid and/or reduce the likelihood of similar incidents recurring.

PSIRF is a mandatory part of our practice and is applicable across all our NHS commissioned services. Key functions:

- The Step One board has oversight and final accountability for all patients/residents' safety.
- Quality Assurance and Improvement Committee acting as subcommittee of the board to be assured of the effective use of PSIRF.
- Operational Governance and Assurance Committee will receive initial assurance from the PSMG of Patient Safety Incident Investigations.
- Patient Safety Management Group (PSMG) – responsible for overseeing the implementation of the PSIRF on an operational level and monitoring the implementation of any agreed safety actions.
- Investigators – We have identified 6 colleagues to undertake investigator training – they will undertake a PSIRF leadership role to support the review of incidents and to conduct an investigation response when agreed.
- Head of Operations has executive leadership for PSIRF across the charity to ensure patient safety and Chairs the Patient Safety Management Group.
- Governance and Assurance Manager has an oversight role for learning responses and internal reporting and assists with Patient Safety Incident Investigations.
- Service Managers must ensure effective patient safety procedures and practice within the requirements of the PSIRF policy.
- All colleagues have a responsibility to ensure patient safety.

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Patient Safety Culture

Step One Charity promotes a just culture approach as laid out within the NHS Just Culture Guide (Appendix 2). Step One Charity recognises an open and transparent culture enables colleagues to feel able to report incidents and raise concerns without fear of repercussions.

Supporting colleagues to be open about mistakes allows valuable lessons to be learnt so the same errors can be prevented from being repeated.

The Just Culture guide should only be used when there is already suspicion that a colleague requires some support or management to work safely, or as part of an individual practitioner performance/case investigation.

Step One encourages and supports incident reporting where any colleague feels something has happened, or may happen, which has led to, or may lead to, harm to patients (or colleagues). Please refer to the Incident Management Policy for more information on how incidents are reported and managed in an open and transparent manner to focus on learning without blame.

Patient Safety Partners

Step One recognises that individuals with lived experience have an important role to play in ensuring patient safety. Patient Safety Partners will have an important role in supporting our Patient Safety Management Group providing a patient perspective to developments and innovations to drive continuous improvement. Our Patient Safety Partners will be involved in the designing of safer services at all levels in the organisation. This means maximising the things that go right and minimising the things that go wrong for patients when they are receiving services from us.

Step One has not defined a total number of Patient Safety Partners that we wish to engage with but accepts that creating the opportunity for multiple voices to input our PSIRF is key. Step One will seek to recruit Patient Safety Partners in line with the [NHSE guidance: Framework for involving patients in patient safety](#).

Addressing Health Inequalities

Step One is an independent provider of NHS services and as such 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. However, most of the fundamental factors driving inequalities in health are beyond the responsibility of the health care system,

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for example our education system; economic and community development in our most deprived neighbourhoods; employment levels; pay and conditions; and availability and quality of housing.

Step One recognises the need for robust data analysis to aid with Patient Safety. When constructing our safety actions in response to any incident we will consider inequalities, and this will be inbuilt into our documentation and governance processes.

Our engagement with patients, families and carers following a patient safety investigation will recognise diverse needs and ensure inclusivity for all. Any potential inclusivity or diversity issues will be identified through the investigation process and engagement with patients and families, for example, during the duty of candour / being open process.

Engaging and involving Patients, Families and Colleagues 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 colleagues). 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.

We are committed to continuously improving the care and services we provide. 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.

Openness and honesty not only reassures the patient, their families and colleagues that the incident has been recognised and their concerns acknowledged, but also helps to prevent such events becoming formal complaints and litigation claims that can only add to the upset and distress to all involved. Our Being Open & Duty of Candour Policy provides information on Step One's standards and expectations in relation to the Duty of Candour.

Patient Safety Incident Response Planning

PSIRF enables Step One 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. We manage incidents that have nationally set requirements and can also explore patient safety incidents relevant to their context and the populations they serve rather than only those that meet a certain defined threshold.

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Step One ensures the focus of response to patient safety incidents is on maximising improvement. Step One’s Patient Safety Incident Response Plan supports proactive allocation of patient safety incident response resources, but there will always need to be a reactive element in responding to incidents.

Our Patient Safety Incident Response Plan reflects these standards and will be published alongside this overarching policy framework.

Resources and Training

Step One are ensuring that we fully embed PSIRF and meet the NHS England nationally set requirements. We have therefore used the NHS England patient safety response standards (2022) to frame the resources and training required to allow for this to happen.

PSIRF recognises that resources and capacity to investigate and learn effectively from patient safety incidents is finite. It is therefore essential that as an organisation we evaluate our capacity and resources to deliver our plan. The PSIRP provides specific details.

The charity has assembled a team of trained Patient Safety Incident Investigators (PSII) who can undertake PSII investigations, the majority have a substantive clinical or governance role, so they will have allocated time to complete investigations. PSIRP details which incidents will require a PSII.

Step One has identified different level of patient safety training required for employees and trustees. This patient safety training plan will form part of Step One’s central training matrix and is mandatory to complete during induction for all new employees and trustees.

Level One – Health Education England patient safety Essentials for Patient Safety Module
All staff involved directly in patient care will complete

Level Two – Health Education England patient safety Access to Practice Module
All Patient Safety Incident Investigators will complete

Level Three - Patient Safety Level One for Boards and Senior Leadership
All SLT and Trustees will complete

Step One recognises that patient safety incidents can cause distress to those involved. Employees affected by patient safety incidents will be afforded the necessary managerial support and be given time to participate in learning responses. Employees will have access to support via the Thrive Mental Wellbeing App and the Employee Assistance Programme. It may also be appropriate for a team debrief or reflective practice session to be arranged for

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learning and to improve patient safety processes. This will be facilitated by our psychologist, or a suitable alternative if required.

Our Patient Safety Incident Response Plan

Our plan details how Step One Charity intends to respond to patient safety incidents over a period of 12 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, as well as the plan.

Our plan is based on the analysis of themes and trends from all incidents, complaints and concerns, learning and recommendations from Serious Incidents (conducted under the previous framework), mortality reviews, risks and risk registers and feedback from employees, commissioners and patients during the past 24 months.

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 months to ensure our focus remains up to date. It is recognised that 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 months. Due to the implementation timing of PSIRF with Step One, the initial Patient Safety Incident Response Plan will be reviewed after 18 months, allowing for future 12 monthly planning in line with the financial year and other Step One governance cycles.

A rigorous planning exercise will be undertaken every four years and more frequently if appropriate (as agreed with our 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, staff survey results, and reporting data) and wider stakeholder engagement.

Responding to Patient Safety Incidents

Patient Safety Incident Reporting Arrangements

All colleagues are responsible for reporting any potential or actual patient safety incidents.

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Patient safety incident reporting will remain in line with the Step One’s Incident Management Policy. It is recognised that colleagues must continue to feel supported and able to report any incidents, or concerns in relation to patient safety, to promote a system of continuous improvement and a just and open culture. One of the most important factors in ensuring timeliness of a learning response is thorough, complete and accurate incident reporting when the circumstances are fresh in the minds of the incident reporter and the wider team.

All patient safety incidents will be reviewed by the Governance and Assurance Manager, who will ensure a responsive approach to managing any actions required and ensure learning is shared. Certain incidents will require external reporting to national bodies such as CQC, Charity Commission, HSE, RIDDOR and MHRA. The Governance and Assurance Manager will coordinate any external reporting required and is responsible for ensuring all patient safety incidents are reported via LFPSE (excluding near misses).

Patient Safety Incident Response decision-making

Reporting of incidents will continue in line with Step One’s Incident Management Policy. Step One has governance and assurance systems in place to ensure oversight of incidents at an operational level, executive level and board level. The Governance and Assurance Manager reviews all incidents and will escalate patient safety incidents as required, as defined within Appendix 1.

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The Patient Safety Management Group (PSMG) will have delegated responsibility for the oversight of the outcomes of such reviews to ensure that recommendations are founded on a systems-based approach and safety actions are valid and contribute to existing safety improvement plans or the establishment of such plans where they are required.

The Quality Assurance and Improvement Committee will have overall oversight of such processes and will challenge decision making of the PSMG to ensure that the Board can be assured that the true intent of PSIRF is being implemented within Step One and we are meeting the national patient safety incident response standards.

Patient safety incidents that require escalating for Patient Safety Incident Investigation :

- Any safety incident that has required the individual to be escalated to acute hospital.
- Any safety incident that could potentially result in staff disciplinary action
- Any safety incident that the police are asked to respond to / a 999 call made.
- Missing service user
- Any safeguarding incident going to a Section 42 England; Section 47 Children.
- Any incident that triggers Duty of Candour
- Mental Health Act breach leading to illegal detention.
- Any incident that compromises the safety of a service
- Any safety incident that has media interest or is likely to.
- All deaths
- In addition - all incidents that are not included in the above where the service, region, network, or the board chooses to have a discretionary PSII.

An initial review must be completed within 72 hours of the incident to determine any further investigation or escalation required. The principles of proportionality and a focus on incidents that provide the greatest opportunity for learning will be central to this decision making under PSIRP. This may often mean no further investigation is required, especially where the incident falls within one of the improvement themes identified in the PSIRP.

Timeframes for learning responses

Learning responses must balance the need for timeliness and capture of information as close to the event as possible, with thoroughness and a sufficient level of investigation to identify the key contributory factors and associated learning for improvement.

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Where a PSII for learning is indicated, the investigation must be started as soon as possible after the patient safety incident is identified and should ordinarily be completed within one to three months of their start date. No local PSII should take longer than six months.

The time frame for completion of a PSII will be agreed with those affected by the incident, as part of the setting of terms of reference, provided they are willing and able to be involved in that decision. A balance must be drawn between conducting a thorough PSII, the impact that extended timescales can have on those involved in the incident, and the risk that delayed findings may adversely affect safety or require further checks to ensure they remain relevant.

In exceptional circumstances, a longer time frame may be required for completion of the PSII. In this case, any extended time frame should be agreed between Step One and those affected.

All other learning responses must be started as soon as possible after the patient safety incident is identified and should ordinarily be completed within one month of the start date. No other learning response should take longer than two months to complete. The PSMG will be responsible for oversight of all local learning responses and will need to flag any delay through the Operational Governance and Assurance Committee.

Safety action development and monitoring improvement

PSIRF moves away from the identification of 'recommendations' as this can lead to premature attempts to devise a solution. A Quality Improvement approach is valuable in this aspect of learning and improvement following a patient safety investigation.

Step One has systems and processes in place to design, implement and monitor safety actions to reduce risk and limit the potential for future harm. This process follows on from the initial findings of any form of learning response or patient safety investigation which might result in identification of aspects of agreed ways of working where change could reduce risk and potential for harm – areas for improvement. Safety Actions will be generated in relation to each of these defined areas for improvement. This is detailed within the Patient Safety Incident Response Plan (PSIRP).

Safety actions must continue to be monitored at a service level through monthly governance arrangements to ensure that any actions put in place remain impactful and sustainable. Reporting on the progress with safety actions including the outcomes of any measurements will be made to the Patient Safety Management Group and escalated via Step One's Governance process.

Safety Improvement Plans

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The PSIRP details how we will ensure patient safety incidents are investigated in a more holistic and inclusive way, to identify learning and safety actions which will reduce risk and improve safety and quality. Safety improvement plans bring together findings from various responses to patient safety incidents and issues.

Step One has outlined the range of priorities for focus of investigation under PSIRF. 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 apparent risk or harm. Step One will also use the outcomes from existing completed or ongoing patient safety incident reviews (Serious Untoward Incidents (SUI) and LeDeR reviews) to create related safety improvement plans to help to focus our improvement work.

Monitoring of progress with safety improvement plans will be overseen by the Governance and Assurance Manager and relevant Service Manager. Progress will be reported to the Patient Safety Management Group to implement and further learning process across Step One or wider systems.

Compliance and Effectiveness Monitoring

Step One believes that learning from Patient Safety Incidents will lead to improved service delivery. This can only be achieved if the processes in place are compliant with NHS England, CQC and Step One’s own internal Quality Assurance standards.

The compliance and effectiveness of these processes will be monitored by the Governance and Assurance Manager as laid out within Step One’s Quality Assurance Framework. The Governance and Assurance Manager will ensure that all Patient Safety Incident Investigations are carried out appropriately ensure that learning is shared, and safety improvement work is adequately directed.

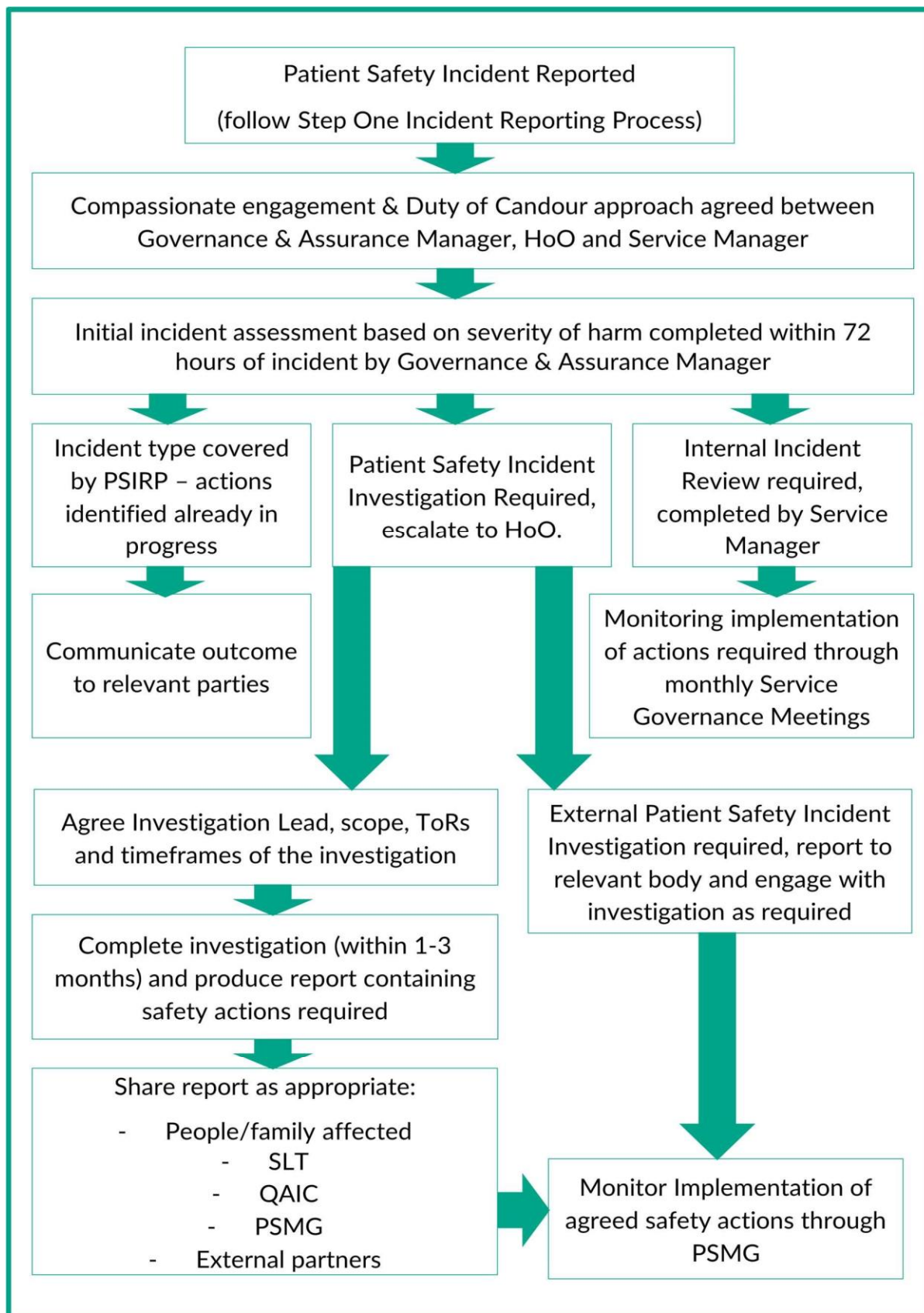
Step One’s Senior Leadership Team (SLT) receives assurance on patient safety incidents via the Operational Governance and Assurance Committee (OGAC). Step One’s Board of Trustees will receive assurance regarding the implementation of PSIRF and associated standards via existing forums such as the Quality, Assurance and Improvement Committee (QAIC). All Patient Safety Incidents will be reported to the QAIC, along with all learning and safety improvement work. [Complaints](#)

We recognise that on occasion patients, service users or carers might be dissatisfied with aspects of the care and services provided by Step One Charity. In any instance like this please follow the process detailed within Step One Charity’s Complaints Policy, information on which can be found on our website or provided to you by the relevant Service Manager.

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Appendix 1

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A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should not automatically be examined using this just culture guide, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- A just culture guide is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- A just culture guide can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- A just culture guide does not replace HR advice and should be used in conjunction with organisational policy.
- The guide can only be used to take one action for failure to act through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - Q1. deliberate harm test

1a. Was there any intention to cause harm?



Recommendation: Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual.

END HERE

No go to next question - Q2. health test

2a. Are there indications of substance abuse?



Recommendation: Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier.

END HERE

2b. Are there indications of physical ill health?



Recommendation: Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier.

END HERE

2c. Are there indications of mental ill health?

If No to all go to next question - Q3. foresight test

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?



Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

END HERE

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?

If Yes to all go to next question - Q4. substitution test

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?



Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

END HERE

4b. Was the individual missed out when relevant training was provided to their peer group?

4c. Did more senior members of the team fail to provide supervision that normally should be provided?

If No to all go to next question - Q5. mitigating circumstances

5a. Were there any significant mitigating circumstances?



Recommendation: Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

END HERE

If No

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

END HERE

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Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

Supported by:



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