National standards for patient safety investigation

Guiding principles and standards for a local, systems approach to patient safety investigation in NHS-funded care

March 2020

NHS England and NHS Improvement

Contents

1. Guiding principles

The guiding principles for a local systems approach[1] to **patient safety investigations** in NHS-funded care are:

- strategic
- preventative
- collaborative
- fair and just
- expert/credible
- people focused.

Note

These national standards are designed for use by those with the skills, understanding and experience of safety investigation to:

- plan, design and commission patient safety incident response services
- plan, design and commission patient safety incident investigation services
- identify corporate (not individual) training needs and inform training plans
- provide an adjunct to the necessary training skills and experience required to conduct effective patient safety investigations.

They are **not** to be used as:

- a short-cut to or a replacement for training and expertise of investigators and those involved in investigation report oversight
- a post-investigation/investigation report compliance checklist
- a tool for local adaptation
- a means to develop performance management metrics (eg % compliance)
- standards for ‘reviews’, ‘audits’, ‘enquiries’ or investigations which have different aims or terms of reference from those specifically related to patient safety incident investigation.

[1] The approach is broken down into units to make it easier to understand the complexity, interactive nature and interdependence of the various external and internal factors.

2. Overview of standards for local systems-based patient safety investigations in NHS-funded care

1.0 STRATEGIC 1.1 Board-level oversight and governance 1.2 Proactive planning of each patient safety investigation 1.3 Focus on quality over quantity 1.4 Timely and responsive 1.5 Objective 1.6 Resourced 1.7 Monitored
2.0 PREVENTATIVE 2.1 Identify and act on deep-seated contributory or causal factors to prevent or measurably and sustainably reduce recurrence 2.2 Maintain a patient safety remit (not seeking to identify avoidability; blame; competence; cause of death)
3.0 COLLABORATIVE 3.1 Support cross-system patient safety incident investigation (cross-pathway/boundary issues) 3.2 Enable information sharing and action across systems 3.3 Facilitate development of improvement plans based on more than one similar patient safety incident investigation wherever availability allows
4.0 FAIR AND JUST 4.1 Fair and just 4.2 Open, honest and transparent
5.0 PEOPLE FOCUSED 5.1 Patients, families and carers are active and supported participants 5.2 Staff are active and supported participants
6.0 EXPERT/CREDIBLE 6.1 Systematic, systems-based and systemic 6.2 Trustworthy 6.3 Credible and adept

2.1 Aim

2.1.1 These standards are designed to support improvement in the quality of local patient safety investigation in NHS-funded care.

- The primary aim of a good quality patient safety incident investigation is to accurately and thoroughly identify what happened (problems arising) and why (contributory and causal factors); and recommend strong/effective systems-based improvements to prevent or significantly reduce the risk of a repeat incident.
- Although an investigation report is an indicator of a good quality investigation, a well-written report is not the primary aim, outcome or measure of a quality investigation.

2.1.2 Many specialist skills and practices are required to deliver a good quality systems-based patient safety investigation. As a result:

- These standards have been developed as an adjunct to the training, skills and experience required to conduct effective patient safety investigations.
- This document is not sufficient to replace or short-cut training and expertise for investigators and those involved in investigation report oversight.
- As with investigation itself, the value of these standards depends on the investigation skills, understanding and experience of the user.

2.2 Scope

2.2.1 This document specifies the basic requirements for local quality patient safety investigation in NHS-funded care.

2.2.2 This document should not be used to arbitrarily set, measure or assign percentage compliance.

2.3 Benefits

2.3.1 The value of defining standards in support of local patient safety investigations has been endorsed in a 2019 publication commissioned by the General Medical Council: *Independent review of gross negligence, manslaughter and culpable homicide*.

2.3.2 This independent review promotes the importance of “working together for a just culture”.

2.3.3 Recommendation 15 of this independent review states: “Improvements in patient safety are most likely to come through local investigations into patient safety incidents which are focused on learning not blame. We strongly endorse recent developments in the frameworks for investigations. These emphasise the need for the investigation team to have the time and the appropriate experience, skills and competence (including understanding of human factors) to undertake investigations, and the necessary degree of externality to command confidence in the process. We also stress the need to involve and support families and staff”.

2.4 Limitations

2.4.1 This document is designed as a standard national NHS tool and is not approved for local adaptation.

2.4.2 It is not possible or appropriate to specify all the criteria that comprise a good quality patient safety investigation in a single document.

2.4.3 Suggestions for its improvement should be made to the NHS England and NHS Improvement national patient safety team: patientsafety.enquiries@nhs.net

2.4.4 These standards do not apply to reviews, enquiries or investigations with different aims or terms of reference from those specifically related to safety investigation.

2.5 Acronyms

PSII	Patient safety incident investigation
PSIRF	Patient Safety Incident Response Framework (2019)
PSIRP	Patient safety incident response plan
SIF	Serious Incident Framework (2015)
ToR	Terms of reference

2.6 Definitions

Patient safety incident	Any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving healthcare. [NPSA]
Safety investigation	A process conducted for the purpose of accident prevention which includes the gathering and analysis of information, the drawing of conclusions, including the determination of causes, and, when appropriate, the making of safety recommendations. [Skybrary]
Safety investigation	To improve aviation safety globally by determining the causes of air accidents and serious incidents and making safety recommendations intended to prevent recurrence. It is not to apportion blame or liability. [AAIB[2]]

2 Nixon J, Braithwaite G (2018) What do aircraft accident investigators do and what makes them good at it? *Safety Sci* 103: 153–61.

3. Patient safety investigation standards – for commissioners and boards

PRINCIPLES for systems-based patient safety investigation (PSII)	Ref no	STANDARDS for BOARDS and COMMISSIONERS on systems-based PSII related to:
1.0 STRATEGIC	**A1.0**	**1.0 STRATEGIC** – boards and commissioners ensure that:
1.1 BOARD OVERSIGHT and GOVERNANCE	A1.1a	An environment of just culture,[3] learning and continuous improvement from patient safety incidents is encouraged by supporting and promoting these principles and standards.
	A1.1b	Time and resources are invested to support PSIIs and subsequent delivery of improvement actions.
	A1.1c	Development of information governance agreements which allow patient safety information sharing between local organisations.
1.2 PROACTIVE PLANNING of each investigation	A1.2a	All PSIIs are planned and have specified terms of reference (ToR) which align with national policy.
1.3 FOCUS ON QUALITY OVER QUANTITY	A1.3a	A patient safety incident response plan (PSIRP) identifies the approach for PSIIs and reviews over a designated period.
	A1.3b	The local PSIRP describes how PSIIs will be conducted on a range of incident severity outcomes, selected on the basis of risk and learning potential (following intelligence gathering and triangulation of safety data/metrics and links to the Learning from Deaths programme).

[3] A culture in which people are not punished for actions, omissions or decisions commensurate with their experience and training, but where gross negligence, wilful violations and destructive acts are not tolerated. Eurocontrol (2019) Just culture.

	A1.3c	The local PSIRP identifies the top 3–10 patient safety incident areas of concern – using past reported data and selected based on level of risk and learning potential – and sets out plans to pool findings from 5–10 full, good quality investigations into incidents arising in each category.
	A1.3d	The local PSIRP includes the use of other more appropriate methods of managing incident reports than investigation.
	A1.3e	The local PSIRP requires application of the national standard investigation methodology and templates (both to PSIIs and patient safety incident-related complaint investigations).
	A1.3f	The local PSIRP describes the mechanism of accountability of the board, the investigator and the commissioner/allocator of the investigation in upholding PSII values and standards.
	A1.3g	The local PSIRP includes information about appeal and complaint processes related to PSIIs.
1.4 TIMELY and RESPONSIVE	A1.4a	The local PSIRP describes the timescale for the start of PSIIs and for their completion. The aim is that PSIIs start as soon as possible after the incident is identified. PSIIs should be completed within 1–3 months, in consultation with the patient/family. No local PSII should take longer than 6 months.
1.5 OBJECTIVE	A1.5a	PSIIs are not conducted by people involved in the incident or by those directly managing the staff involved. (In some cases, external oversight or external investigation will be required. ToRs should outline the degree of independence required and any competing interests of those undertaking the investigations should also be declared.
	A1.5b	The core PSII team consists of more than one person (in addition to any panels) to provide multiple perspectives.
1.6 RESOURCED	A1.6a	All PSIIs are led, chaired or overseen by those with seniority equivalent to Band 8a or above.
	A1.6b	All PSIIs are led or chaired only by those with at least two days' formal training and skills development in a 'systems approach' to PSII.
	A1.6c	All PSII oversight is led/conducted only by those with at least two days' formal training and skills development in a 'systems approach' to PSII plus one day's training in PSII oversight.

	A1.6d	PSII training is conducted by those who have attended courses in and related to PSII which amount to more than 30 days; are current in investigation best practice; have delivered high-level investigation courses; and have both conducted and reviewed many investigations – the quality of which has been peer reviewed by other national experts.
	A1.6e	Patient safety investigators attend update training and networking events with other investigators at least annually to build and maintain their skills and expertise.
	A1.6f	Patient safety investigators have dedicated time – or their role back-filled – to conduct PSIIs.
	A1.6g	PSII leads have a role wider than conducting PSIIs.
	A1.6h	PSII teams have access to administration, communications and legal support.
	A1.6i	Clinical subject matter experts have relevant knowledge and skills and are involved throughout PSIIs to provide clinical review, advice and proofreading.
1.7 MONITORED	A1.7a	All PSII recommendations/solutions/improvement plans are monitored for IMPLEMENTATION as intended (eg embedding in work systems, processes and practices).
	A1.7b	All PSII recommendations/solutions/improvement plans are monitored for EFFICACY and the application of human factors understanding as intended (that is, achievable/ measurable reduction or prevention of risk or repeat incidents).
	A1.7c	All PSII recommendations/solutions/improvement plans are monitored for SUSTAINED IMPROVEMENT as intended (that is, sustained reduction or prevention of risk or repeat incidents).
	A1.7d	Recommendations/solutions/improvements are not shared until their efficacy in delivering sustained reduction or prevention of risk or repeat incidents has been established.
	A1.7e	PSII standards can be monitored annually (for compliance – via process measures; for improvement – via outcome measures) and improvements planned and implemented.

2.0 PREVENTATIVE	**A2.0**	**PREVENTATIVE** – boards and commissioners ensure that:
2.1 SYSTEMIC, DEEP-SEATED, INTERCONNECTED, CAUSAL FACTORS are identified and acted on to sustainably prevent or measurably reduce recurrence	A2.1a	PSIIs are conducted for the sole purpose of learning and identifying improvements which prevent or significantly reduce recurrence.
2.2 PATIENT SAFETY REMIT	A2.2a	PSIIs are insulated from remits that seek to determine avoidability/preventability/ predictability; legal liability; blame; professional conduct/competence/fitness to practise; criminality; or cause of death.
	A2.2b	Once systemic, interconnected **causal factors** are robustly identified, improvements are formally resourced and championed by the board via a refocus of activity from investigation to implementation, to embed into everyday care and practice sustainable improvements that significantly reduce the risk of repeat incidents.

3.0 COLLABORATIVE	**A3.0**	**COLLABORATIVE** – boards and commissioners ensure that:
3.1 CROSS-SETTING	A3.1a	Commissioners provide the necessary support to facilitate cross-pathway/setting investigations.
	A3.1b	PSIIs involve other providers in all cross-pathway/setting incidents.
3.2 SHARED	A3.2a	Where multiple agencies need to be involved in a single PSII, the investigation is led by the agency with the greatest capacity to investigate the issues of concern.
	A3.2b	Where an incident indicates the need for both a clinical complaint investigation and a patient safety incident investigation, these are conducted as a single PSII.
	A3.2c	Learning related to causal factors and improvements should be shared only when effectiveness in significantly reducing the risk of repeat incidents is demonstrable.
3.3 AGGREGATED	A3.3a	Improvement plans are based on the findings of more than one similar PSII (see A1.3c).

4.0 FAIR AND JUST	**A4.0**	**FAIR AND JUST** – boards and commissioners ensure that:
4.1 FAIR AND JUST	A4.1a	Promotion of a climate that fosters a just culture.
	A4.1b	Unfair blame is avoided. Disciplinary action is only appropriate and considered for acts of wilful harm or wilful neglect. Bias and discrimination are avoided for staff with different protected characteristics (eg BAME groups) who have traditionally faced disproportionate disciplinary actions.
4.2 OPEN, HONEST and TRANSPARENT	A4.2a	Support and promotion of open, honest and transparent information to patients/families/carers and staff on incidents of moderate or more severe harm in which they are involved.
	A4.2b	Promotion of additional or professional support of patients/families/carers and staff where required to further aid recovery.

5.0 PEOPLE FOCUSED	**A5.0**	**PEOPLE FOCUSED** – boards and commissioners provide:
5.1 PATIENTS/FAMILIES/CARERS are ACTIVE and SUPPORTED PARTICIPANTS	A5.1a	Support for informing patients/families/carers of any PSII at the outset and what to expect from the process.
	A5.1d	Promotion of local support for patients/families/carers during any PSII to aid recovery.
	A5.1h	Support for the engagement of patients/families/carers in PSIIs.
5.2 STAFF are ACTIVE and SUPPORTED PARTICIPANTS	A5.2a	Support for informing staff of any PSII at the outset and what to expect from the process.
	A5.2d	Promotion of local support for staff during PSIIs.
	A5.2g	Support for the full participation of staff in PSIIs.

6.0 EXPERT/CREDIBLE	**A6.0**	**EXPERT/CREDIBLE** – boards and commissioners ensure that:
6.1 SYSTEMS-BASED, system-wide and systematic	A6.1a	The accuracy and credibility of their PSIIs.
6.2 TRUSTWORTHY	A6.2a	Support and promote the professionalisation of patient safety investigators.
6.3 ADEPT – conducted by investigation teams with deep knowledge of safety investigation, human factors, improvement science,[4] health policy and clinical practice to command the confidence of patients/families/carers, the public and staff	A6.3a	Support and promote the importance and value of expertise in PSII.

[4] Improvement science is about finding out how to improve and make changes in the most effective way. It is about systematically examining the methods and factors that best work to facilitate quality improvement. Health Foundation (2011) https://www.health.org.uk/publications/improvement-science

4. Patient safety investigation standards – for investigators

PRINCIPLES for systems-based patient safety investigation (PSII)	Ref no	STANDARDS for INVESTIGATORS on systems-based PSII related to: INVESTIGATION METHODOLOGY

1.0 STRATEGIC	**M1.0**	**1.0 STRATEGIC** – investigators ensure that:
1.2 PROACTIVE PLANNING of each investigation	M1.2a	All PSIIs are planned and have specified terms of reference (ToR) which align with national policy.
1.4 TIMELY and RESPONSIVE	A1.4a	PSIIs are started as soon as possible after the incident is identified and should be completed within 1–3 months, in consultation with the patient/family. No local PSII should take longer than 6 months.
1.5 OBJECTIVE	A1.5a	PSIIs are not conducted by people involved in the incident or by those directly managing the staff involved.
	A1.5b	The core PSII team consists of more than one person (in addition to any panels) to provide multiple perspectives.
1.6 RESOURCED	A1.6a	All PSIIs are led, chaired or overseen by those with a seniority level of Band 8a or above.
	A1.6b	All PSIIs are led or chaired only by those with at least two days' formal training and skills development in a 'systems approach' to PSII.
	A1.6e	Patient safety investigators attend update training and networking events with other investigators at least annually to build and maintain skills and expertise.
	A1.6g	PSII leads have a role wider than conducting PSIIs.

	A1.6i	Clinical subject matter experts have relevant knowledge and skills and are involved throughout PSIIs to provide clinical review, advice and proofreading.

2.0 PREVENTATIVE	**M2.0**	**PREVENTATIVE** – investigators ensure that:
2.1 SYSTEMIC, DEEP-SEATED, INTERCONNECTED, CAUSAL FACTORS identified and acted on to sustainably prevent or measurably reduce recurrence	M2.1a	PSIIs are conducted for the sole purpose of learning and identifying improvements which prevent or significantly reduce recurrence.
2.2 PATIENT SAFETY REMIT	M2.2a	PSIIs are conducted entirely separately from investigations that seek to determine avoidability/ preventability/predictability; legal liability; blame; professional conduct/competence/fitness to practise; criminality; or cause of death.

3.0 COLLABORATIVE	**M3.0**	**COLLABORATIVE** – investigators ensure that:
3.1 CROSS-SETTING	M3.1b	PSIIs involve other providers in all cross-pathway/boundary incidents.

4.0 FAIR AND JUST	**M4.0**	**FAIR AND JUST** – investigators ensure that:
4.1 FAIR and JUST	M4.1a	Where investigators believe that an individual professional may be subject to criticism following a patient safety incident, the professional is referred to HR for individual management/ performance review with reference to the A just culture guide. Unfair blame is avoided.
	M4.1b	Unfair blame is avoided. Referral for individual management/performance review or disciplinary action is only appropriate for acts of wilful harm or wilful neglect. Bias and discrimination are avoided for staff with different protected characteristics (eg BAME groups) that have traditionally faced disproportionate disciplinary actions.

4.2 OPEN, HONEST and TRANSPARENT	M4.2a	Patients/families/carers and staff are informed of any incident of moderate or more severe harm in which they were involved. (For patients, families and carers this involves applying Duty of Candour where: the incident is described; a formal, meaningful, authentic apology and regret is expressed; the greatest possible degree of openness and transparency is provided – that is, not inhibited or constrained by anticipation of a PSII.)
	M4.2b	Patients/families/carers and staff are offered/signposted to professional support and advocacy services where required to further aid recovery.

5.0 PEOPLE FOCUSED	**M5.0**	**If a PSII is to be conducted, then PATIENTS/FAMILIES/CARERS are:**
5.1 PATIENTS/FAMILIES/CARERS are ACTIVE and SUPPORTED PARTICIPANTS	M5.1a	Given the opportunity to receive information at the outset on whether there will be a PSII and what to expect from the process.
	M5.1b	Given or signposted to a copy of these PSII standards and the Patient Safety Incident Response Framework (PSIRF) document.
	M5.1c	Informed who will conduct any PSII and of any changes to that arrangement.
	M5.1d	Given the opportunity to receive local support throughout a PSII to aid recovery (including that enabling meaningful understanding of what happened; agreement on ToR; and discussion of final findings, clinical issues and contributory/causal factors identified).
	M5.1e	Engaged and given the opportunity to input into: ToR including the addition of any special questions; and further meeting arrangements.
	M5.1f	Given the opportunity to agree a realistic timeframe for any PSII.
	M5.1g	Informed in a timely fashion of any delays with the PSII and the reasons for them.
	M5.1h	Given the opportunity to provide evidence (written and/or verbal) to inform/validate the timeline, analysis and improvement plan.
	M5.1i	Given the opportunity to be updated at specific milestones in the PSII (not a running commentary but to be informed about progress).

	M5.1j	Given the opportunity to review the PSII report with a member of the investigation team while it is still in draft.
	M5.1k	Given the opportunity to comment on the PSII report before its completion/publication.
	M5.1l	Given the opportunity to feedback on their experience of the PSII (level of satisfaction with the process, eg timeliness, fairness and transparency of the PSII and report).
		If a PSII is to be conducted, then STAFF involved or with an interest/expertise in the field are:
5.2 STAFF are ACTIVE and SUPPORTED PARTICIPANTS	M5.2a	Informed at the outset whether there will be a PSII and what to expect from the process.
	M5.2b	Given or signposted to a copy of these national PSII standards and the PSIRF document.
	M5.2c	Informed who will conduct any PSII and of any changes to that arrangement.
	M5.2d	Supported locally throughout the PSII.
	M5.2e	Informed of a realistic timeline for the investigation.
	M5.2f	Informed of any delays in a timely fashion and the reasons for them.
	M5.2g	Interviewed or asked to provide evidence (written and/or verbal) to inform/validate the timeline, analysis and improvement plan.
	M5.2h	Given the opportunity to provide evidence (written and/or verbal) to inform the timeline, analysis and improvement plan, and to validate the timeline.
	M5.2i	Given the opportunity to review the PSII report with a member of the investigation team while it is still in draft.
	M5.2j	Given the opportunity to comment on the PSII report before its completion/publication.
	M5.2k	Given the opportunity to feedback on their experience of the PSII (level of satisfaction with the process, including timeliness, fairness and transparency of the PSII and report).

6.0 EXPERT/CREDIBLE	**M6.0**	**EXPERT/CREDIBLE** – investigators ensure that:
6.1 SYSTEMS-BASED, system-wide and systematic	M6.1a	Current national, standard NHS PSII guidance, methodology and templates are followed to improve quality and rigour.
		INFORMATION GATHERING
6.2 TRUSTWORTHY	M6.2a	Uses the widest range of sources and viewpoints (patient/family/carer testimony – verbal and written; staff testimony – verbal and written; documents; medical records; site visit; other agencies, etc).
	M6.2b	Involves SITE VISITS conducted to gather and preserve information and evidence.
	M6.2c	Results in the MAPPING of a factual timeline of events to chronologically describe what happened, where, when and to whom.
	M6.2d	Involves RESEARCH of POLICY to identify and reference national and local good practice guidance and protocols to determine what was expected to happen (work as imagined).
	M6.2e	Involves review of previous similar investigation findings and resultant improvement activity (locally and nationally).
	M6.2f	Involves OBSERVATION of PRACTICE to determine what normally happens (work as done).
		ANALYSIS includes judicious review of:
6.3 ADEPT – conducted by investigation teams with deep knowledge of safety investigation, human factors, improvement science,[5] health policy and clinical practice to command the confidence	M6.3a	Incident findings, using established approach/techniques consistent with systems-based safety investigation.
	M6.3b	WEAKNESSES in CARE and SERVICE DELIVERY to identify variations from expected practice or outcomes (things that happened or did not happen as planned/expected).
	M6.3c	GUIDANCE (national and local) to identify whether these adequately cover the issues encountered in the incident and investigation.

5 Improvement science is about finding out how to improve and make changes in the most effective way. It is about systematically examining the methods and factors that best work to facilitate quality improvement. Health Foundation (2011) https://www.health.org.uk/publications/improvement-science

of patients/families/carers, the public and staff	M6.3d	The national, standard, comprehensive contributory factors framework to identify underlying, causal and mitigating factors (rather than a shortlist of commonly arising issues).
	M6.3e	The UNDERLYING CONTRIBUTORY FACTORS (including human factors) – identified for each WEAKNESS analysed. Moving the focus of investigation from the acts or omissions of staff to the underlying causes of the incident by asking (or observing) those involved to identify the proximal/superficial reasons behind WHY each problem arose.
	M6.3f	KEY CAUSAL FACTORS – identifying the deep-seated reasons WHY variations to expected practice or outcomes occurred.
	M6.3g	The STRENGTHS in CARE and SERVICE DELIVERY – to identify things that went well.
	M6.3h	The UNDERLYING MITIGATING FACTORS – identified for each STRENGTH analysed, by asking (or observing) those involved about the proximal reasons WHY things went well.
		RECOMMENDATIONS/CONCLUSIONS
	M6.3i	Are based (wherever available) on analysis from more than one example of very similar (narrow focus) incidents wherever available.
	M6.3j	Are drawn and flow logically from the evidence and analysis in the PSII report.
	M6.3k	Are supported by facts, with no unsupported recommendations documented.
	M6.3l	Are sufficient to address the particular circumstances that led to the incident.
		SOLUTIONS/IMPROVEMENTS
	M6.3m	Are based (wherever available) on analysis from more than one example of very similar (narrow focus) incidents wherever available.
	M6.3n	Are targeted towards causal factors (not proximal/superficial factors, problems or themes).
	M6.3o	Are designed to be strong/effective (apply improvement science principles to measurably and sustainably reduce or prevent recurrence of identified risks and/or incidents).

	M6.3p	Are subject to an options appraisal before finalisation.
	M6.3q	Are SMART (specific, measurable, achievable, realistic, time-based).
	M6.3r	Lead to the prompt development of a plan to support the implementation of improvement.
	M6.3s	Result in a named manager with designated responsibility for delivering the improvement plan within a designated timescale.
	M6.3t	Are embedded in work systems, processes and practice.
	M6.3u	Are not shared until they are well embedded, tested and shown to be effective in reducing risks or repeat incidents.
		INVESTIGATION REPORTS
	M6.3v	Are written in a way that professionally and effectively communicates the findings of a PSII.
	M6.3w	The national investigation report template is used, unadapted, to document every PSII (for quality assurance and shared learning purposes).
	M6.3x	Are written succinctly in plain English.
	M6.3y	Each PSII has a single report which can be shared in full (unadapted and unredacted).
	M6.3z	All specialist vocabulary, acronyms and abbreviations are explained in the report or in a glossary or footnotes.
	M63aa	An executive summary sets out the main issues, findings and conclusions/recommendations.
	M6.3ab	A summary incident chronology/timeline is included in the report to illuminate key points; where the full chronology/timeline is included it is attached as an appendix.
	M6.3ac	Provide clear reasons for any missing information or information not made available to the reader.

	M6.3ad	Specific questions from the patient/family/carer set out in the ToR are answered and where this was not possible, the reason is explained in the report.
	M6.3ae	The report is clear about where available information was limited and identifies consequent uncertainties.
	M6.3af	Incidental findings that affect quality of care but lie outside the ToR for the PSII are documented and referred to appropriately.

5. Patient safety investigation standards – in full

Strategic

STANDARDS for BOARDS and COMMISSIONERS on systems-based patient safety investigation (PSII) related to: SYSTEM ARCHITECTURE	Ref no	**PRINCIPLES for systems-based PSII**	Ref no	**STANDARDS for INVESTIGATORS on systems-based PSII related to INVESTIGATION METHODOLOGY**
1.0 STRATEGIC – boards and commissioners ensure that:	**A1.0**	**1.0 STRATEGIC**	**M1.0**	**1.0 STRATEGIC** –investigators ensure that:
An environment of just culture,[6] learning and continuous improvement from patient safety incidents is encouraged by supporting and promoting these principles and standards.	A1.1a	1.1 BOARD OVERSIGHT AND GOVERNANCE		
Time and resources are invested to support PSIIs and subsequent delivery of improvement actions.	A1.1b			
Development of information governance agreements which allow patient safety information sharing between local organisations.	A1.1c			

[6] A culture in which people are not punished for actions, omissions or decisions commensurate with their experience and training, but where gross negligence, wilful violations and destructive acts are not tolerated. Eurocontrol (2019) Just culture.

All PSIIs are planned and have specified terms of reference (ToR) which align with national policy.	A1.2a	1.2 PROACTIVE PLANNING of each investigation	M1.2a	All PSIIs are planned and have specified ToR which align with national policy
A patient safety incident response plan (PSIRP) identifies the approach for PSIIs and reviews over a designated period.	A1.3a	1.3 FOCUS ON QUALITY OVER QUANTITY		
The local PSIRP describes how PSIIs will be conducted on a range of incident severity outcomes, selected on the basis of risk and learning potential (following intelligence gathering and triangulation of safety data/metrics and links to the Learning from Deaths programme).	A1.3b			
The local PSIRP identifies the top 3–10 patient safety incident areas of concern – using past reported data and selected based on level of risk and learning potential – and sets out plans to pool findings from 5–10 full, good quality investigations into incidents arising in each category.	A1.3c			
The local PSIRP includes the use of other more appropriate methods of managing incident reports than investigation.	A1.3d			
The local PSIRP requires application of the national standard investigation methodology and templates (both to PSIIs and patient safety incident-related complaint investigations).	A1.3e			
The local PSIRP describes the mechanism of accountability of the board, the investigator and the commissioner/allocator of the investigation in upholding PSII values and standards.	A1.3f			

The local PSIRP includes information about appeal and complaint processes related to PSIIs.	A1.3g			
The local PSIRP describes the timescale for the start of PSIIs and their completion. The aim is that PSIIs start as soon as possible after the incident is identified. PSIIs should be completed within 1–3 months, in consultation with the patient/family. No local PSII should take longer than 6 months.	A1.4a	1.4 TIMELY and RESPONSIVE	A1.4a	PSIIs are started as soon as possible after the incident is identified and should be completed within 1–3 months, in consultation with the patient/family. No local PSII should take longer than 6 months.
PSIIs are not conducted by people involved in the incident or by those directly managing the staff involved. (In some cases, external oversight or external investigation will be required. ToRs should outline the degree of independence required and any competing interests of those undertaking the investigations should also be declared).	A1.5a	1.5 OBJECTIVE	A1.5a	PSIIs are not conducted by people involved in the incident or by those directly managing the staff involved.
The core PSII team consists of more than one person (in addition to any panels) to provide multiple perspectives.	A1.5b		A1.5b	The core PSII team consists of more than one person (in addition to any panels) to provide multiple perspectives.
All PSIIs are led, chaired or overseen by staff with seniority level of Band 8a or above.	A1.6a		A1.6a	All PSIIs are led, chaired or overseen by staff with seniority level of Band 8a or above.
All PSIIs are led or chaired only by those with at least two days' formal training and skills development in a 'systems approach' to PSII.	A1.6b	1.6 RESOURCED	A1.6b	All PSIIs are led or chaired only by those with at least two days' formal training and skills development in a 'systems approach' to PSII.
All PSII oversight is led/conducted only by those with at least two days' formal training and skills development in a 'systems approach' to PSII plus one day's training in PSII oversight.	A1.6c			

PSII training is conducted by those who have attended courses in and related to PSII which amount to more than 30 days; are current in investigation best practice; have delivered high-level investigation courses; and have both conducted and reviewed many investigations – the quality of which has been peer reviewed by other national experts.	A1.6d			
Patient safety investigators attend update training and networking events with other investigators at least annually to build and maintain skills and expertise.	A1.6e		A1.6e	Patient safety investigators attend update training and networking events with other investigators at least annually to build and maintain skills and expertise.
Patient safety investigators have dedicated time – or their role back-filled – to conduct PSIIs.	A1.6f			
PSII leads have a role wider than conducting PSIIs.	A1.6g		A1.6g	PSII leads have a role wider than conducting PSIIs.
PSII teams have access to administration, communications and legal support.	A1.6h			
Clinical subject matter experts have relevant knowledge and skills and are involved throughout PSIIs to provide clinical review, advice and proofreading.	A1.6i		A1.6i	Clinical subject matter experts have relevant knowledge and skills and are involved throughout PSIIs to provide clinical review, advice and proofreading.
All PSII recommendations/solutions/ improvement plans are monitored for IMPLEMENTATION as intended (eg embedding in work systems, processes and practices).	A1.7a	1.7 MONITORED		
All PSII recommendations/solutions/ improvement plans are monitored for EFFICACY and the application of human	A1.7b			

factors understanding as intended (ie achievable/measurable reduction or prevention of risk or repeat incidents).		
All PSII recommendations/solutions/ improvement plans are monitored for SUSTAINED IMPROVEMENT as intended (that is, sustained reduction or prevention of risk or repeat incidents).	A1.7c	
Recommendations/solutions/improvements are not shared until their efficacy in delivering sustained reduction or prevention of risk or repeat incidents has been established.	A1.7d	
PSII standards can be monitored annually (for compliance – via process measures) (and for improvement – via outcome measures) and improvements planned and implemented.	A1.7e	

Preventative

STANDARDS for BOARDS and COMMISSIONERS on systems-based patient safety investigation (PSII) related to: SYSTEM ARCHITECTURE	Ref no	**PRINCIPLES for systems-based PSII**	Ref no	**STANDARDS for INVESTIGATORS on systems-based PSII related to: INVESTIGATION METHODOLOGY**
PREVENTATIVE – boards and commissioners ensure that:	**A2.0**	**2.0 PREVENTATIVE**	**M2.0**	**PREVENTATIVE** – investigators ensure that:
PSIIs are conducted for the sole purpose of learning and identifying improvements which prevent or significantly reduce recurrence.	A2.1a	2.1 SYSTEMIC, DEEP-SEATED, INTERCONNECTED, CAUSAL FACTORS identified and acted on	M2.1a	PSIIs are conducted for the sole purpose of learning and identifying improvements which prevent or significantly reduce recurrence.

		to sustainably prevent or measurably reduce recurrence		
PSIIs are insulated from remits that seek to determine avoidability/preventability/ predictability; legal liability; blame; professional conduct/competence/fitness to practise; criminality; or cause of death.	A2.2a	2.2 PATIENT SAFETY REMIT	M2.2a	PSIIs are conducted entirely separately from investigations that seek to determine avoidability/preventability/predictability; legal liability; blame; professional conduct/competence/ fitness to practise; criminality; or cause of death.
Once systemic, interconnected **causal factors** are robustly identified, improvements are formally resourced and championed by the board via a refocus of activity from investigation to implementation, to embed into everyday care and practice sustainable improvements which significantly reduce the risk of repeat incidents.	A2.2b			

Collaborative

STANDARDS for BOARDS and COMMISSIONERS on systems-based patient safety investigation (PSII) related to: SYSTEM ARCHITECTURE	Ref no	**PRINCIPLES for systems-based PSII**	Ref no	**STANDARDS for INVESTIGATORS on systems-based PSII related to INVESTIGATION METHODOLOGY**
COLLABORATIVE – boards and commissioners ensure that:	**A3.0**	**3.0 COLLABORATIVE**	**M3.0**	**COLLABORATIVE** – investigators ensure that:
Commissioners provide the necessary support to facilitate cross-pathway/setting investigations.	A3.1a	3.1 CROSS-SETTING		
PSIIs involve other providers in all cross-pathway/setting incidents.	A3.1b		M3.1b	PSIIs involve other providers in all cross-pathway/boundary incidents.

Where multiple agencies need to be involved in a single PSII, the investigation is led by the agency with the greatest capacity to investigate the issues of concern.	A3.2a	3.2 SHARED
Where an incident indicates the need for both a clinical complaint investigation and a patient safety incident investigation, these are conducted as a single PSII .	A3.2b	
Learning related to causal factors and improvements should be shared only when effectiveness in significantly reducing the risk of repeat incidents is demonstrable.	A3.2c	
Improvement plans are based on the findings of more than one similar PSII (see A1.3c).	A3.3a	3.3 AGGREGATED

Fair and just

STANDARDS for BOARDS and COMMISSIONERS on systems-based patient safety investigation (PSII) related to: SYSTEM ARCHITECTURE	Ref no	**PRINCIPLES for systems-based PSII**	Ref no	**STANDARDS for INVESTIGATORS on systems-based PSII related to: INVESTIGATION METHODOLOGY** **on Systems-Based Patient Safety Investigation (PSII) related to:** **INVESTIGATION METHODOLOGY**
FAIR AND JUST – boards and commissioners ensure that:	**A4.0**	**4.0 FAIR AND JUST**	**M4.0**	**FAIR AND JUST** – investigators ensure that:
Promotion of a climate that fosters a just culture.	A4.1a	4.1 FAIR and JUST	M4.1a	Where investigators believe that an individual professional may be subject to criticism

				following a patient safety incident, the professional is referred to HR for individual management/performance review with reference to the A just culture guide. Unfair blame is avoided.
Unfair blame is avoided. Disciplinary action is only appropriate and considered for acts of wilful harm or wilful neglect. Bias and discrimination are avoided for staff with different protected characteristics (eg BAME groups) who have traditionally faced disproportionate disciplinary actions.	A4.1b		M4.1b	Unfair blame is avoided. Referral for individual management/ performance review or disciplinary action is only appropriate for acts of wilful harm or wilful neglect. Bias and discrimination are avoided for staff with different protected characteristics (eg BAME groups) who have traditionally faced disproportionate disciplinary actions.
Support and promotion of open, honest and transparent information to patients/ families/carers and staff on incidents of moderate or more severe harm in which they are involved.	A4.2a	4.2 OPEN, HONEST and TRANSPARENT	M4.2a	Patients/families/carers and staff are informed of any incident of moderate or more severe harm in which they were involved. (For patients, families and carers this involves applying Duty of Candour where: the incident is described; a formal, meaningful, authentic apology and regret is expressed; the greatest possible degree of openness and transparency is provided, ie not inhibited or constrained by anticipation of a PSII).
Promotion of additional or professional support of patients/families/carers and staff where required to further aid recovery.	A4.2b		M4.2b	Patients/families/carers and staff are offered/signposted to professional support and advocacy services where required to further aid recovery.

People focused

STANDARDS for BOARDS and COMMISSIONERS on systems-based patient safety investigation (PSII) related to: SYSTEM ARCHITECTURE	Ref no	PRINCIPLES for systems-based PSII	Ref no	STANDARDS for INVESTIGATORS on systems-based PSII related to: INVESTIGATION METHODOLOGY
PEOPLE FOCUSED – boards and commissioners provide:	**A5.0**	**5.0 PEOPLE FOCUSED**	**M5.0**	**If a PSII is to be conducted, then PATIENTS/FAMILIES/CARERS are:**
Support for informing patients/families/ carers of any PSII at the outset and what to expect from the process.	A5.1a	5.1 PATIENTS/ FAMILIES/CARERS are ACTIVE and SUPPORTED PARTICIPANTS	M5.1a	Given the opportunity to receive information at the outset on whether there will be a PSII and what to expect from the process.
			M5.1b	Given or signposted to a copy of these PSII standards and the Patient Safety Incident Response Framework (PSIRF) document.
			M5.1c	Informed who will conduct any PSII and of any changes to that arrangement.
Promotion of local support for patients/ families/carers during any PSII to aid recovery.	A5.1d		M5.1d	Given the opportunity to receive local support throughout a PSII to aid recovery (including that enabling meaningful understanding of what happened; agreement on ToR; and discussion of final findings, clinical issues and contributory/causal factors identified).
			M5.1e	Engaged and given the opportunity to input into: ToR including the addition of any special questions; and further meeting arrangements.
			M5.1f	Given the opportunity to agree a realistic timeframe for any PSII.
			M5.1g	Informed in a timely fashion of any delays with the PSII and the reasons for them.

Support for the engagement of patients/families/carers in PSIIs.	A5.1h		M5.1h	Given the opportunity to provide evidence (written and/or verbal) to inform/validate the timeline, analysis and improvement plan.
			M5.1i	Given the opportunity to be updated at specific milestones in the PSII (not a running commentary but to be informed about progress).
			M5.1j	Given the opportunity to review the PSII report with a member of the investigation team while it is still in draft.
			M5.1k	Given the opportunity to comment on the PSII report before its completion/publication.
			M5.1l	Given the opportunity to feedback on their experience of the PSII (level of satisfaction with the process, eg timeliness, fairness and transparency of the PSII and report).
PEOPLE FOCUSED – boards and commissioners provide:				**If a PSII is to be conducted, then STAFF involved or with an interest/expertise in the field are:**
Support for informing staff of any PSII at the outset and what to expect from the process.	A5.2a	5.2 STAFF are ACTIVE and SUPPORTED PARTICIPANTS	M5.2a	Informed at the outset whether there will be a PSII and what to expect from the process.
			M5.2b	Given or signposted to a copy of these national PSII standards and the PSIRF document
			M5.2c	Informed who will conduct any PSII and of any changes to that arrangement.
Promotion of local support for staff during PSIIs.	A5.2d		M5.2d	Supported locally throughout the PSII.

Support for the full participation of staff in PSIIs.	A5.2g		M5.2e	Informed of a realistic timeline for the investigation.
			M5.2f	Informed of any delays in a timely fashion and the reasons for them.
			M5.2g	Interviewed or asked to provide evidence (written and/or verbal) to inform/validate the timeline, analysis and improvement plan.
			M5.2h	Given the opportunity to provide evidence (written and/or verbal) to inform the timeline, analysis and improvement plan, and to validate the timeline.
			M5.2i	Given the opportunity to review the PSII report with a member of the investigation team while it is still in draft.
			M5.2j	Given the opportunity to comment on the PSII report before its completion/publication.
			M5.2k	Given the opportunity to feedback on their experience of the PSII (level of satisfaction with the process, including timeliness, fairness and transparency of the PSII and report).

Expert and credible

STANDARDS for BOARDS and COMMISSIONERS on systems-based patient safety investigation (PSII) related to: SYSTEM ARCHITECTURE	Ref no	**PRINCIPLES for systems-based PSII**	Ref no	**STANDARDS for INVESTIGATORS on systems-based PSII related to: INVESTIGATION METHODOLOGY**
Expert/credible – boards and commissioners ensure that:	**A6.0**	**6.0 EXPERT/CREDIBLE**	**M6.0**	**Expert/credible** – investigators ensure that:
The accuracy and credibility of their PSIIs.	A6.1a	6.1 SYSTEMS-BASED, system-wide and systematic	M6.1a	Current national, standard NHS PSII guidance, methodology and templates are followed to improve quality and rigour.
				INFORMATION GATHERING
Support and promote the professionalisation of patient safety investigators.	A6.2a	6.2 TRUSTWORTHY	M6.2a	Uses the widest range of sources and viewpoints (patient/family/carer testimony – verbal and written; staff testimony – verbal and written; documents; medical records; site visit; other agencies, etc).
			M6.2b	Involves SITE VISITS conducted to gather and preserve information and evidence.
			M6.2c	Results in the MAPPING of a factual timeline of events to chronologically describe what happened, where, when and to whom.
			M6.2d	Involves RESEARCH of POLICY to identify and reference national and local good practice guidance and protocols to determine what was expected to happen (work as imagined).

			M6.2e	Involves review of previous similar investigation findings and resultant improvement activity (locally and nationally).
			M6.2f	Involves OBSERVATION of PRACTICE to determine what normally happens (work as done).
				INFORMATION ANALYSIS includes judicious review of:
Incident findings, using established, systems-based approach/techniques for safety investigation.	A6.3a	6.3 ADEPT – conducted by investigation teams with deep knowledge of safety investigation, human factors, improvement science,[7] health policy and clinical practice to command the confidence of patients, families, the public and staff	M6.3a	Incident findings, using established approach/techniques consistent with systems-based safety investigation.
Support and promote the importance and value of expertise in PSII.	A6.3b		M6.3b	WEAKNESSES in CARE AND SERVICE DELIVERY to identify variations from expected practice or outcomes (things that happened or did not happen as planned/expected).
			M6.3c	GUIDANCE (national and local) to identify whether these adequately cover the issues encountered in the incident and investigation.
			M6.3d	The national, standard, comprehensive contributory factors framework to identify underlying, causal and mitigating factors (rather than a shortlist of commonly arising issues).

[7] Improvement science is about finding out how to improve and make changes in the most effective way. It is about systematically examining the methods and factors that best work to facilitate quality improvement. Health Foundation (2011) https://www.health.org.uk/publications/improvement-science.

	M6.3e	The UNDERLYING CONTRIBUTORY FACTORS (including human factors) – identified for each WEAKNESS analysed. Moving the focus of investigation from the acts or omissions of staff to the underlying causes of the incident by asking (or observing) those involved to identify the proximal/superficial reasons behind WHY each problem arose.
	M6.3f	KEY CAUSAL FACTORS - identifying the deep-seated reasons WHY variations to expected practice or outcomes occurred.
	M6.3g	The STRENGTHS in CARE and SERVICE DELIVERY – to identify things that went well.
	M6.3h	The UNDERLYING MITIGATING FACTORS – identified for each STRENGTH analysed, by asking (or observing) those involved about the proximal reasons WHY things went well.
		RECOMMENDATIONS/CONCLUSIONS
	M6.3i	Are based (wherever possible) on analysis from more than one example of very similar (narrow focus) incidents wherever available.
	M6.3j	Are drawn and flow logically from the evidence and analysis in the PSII report.
	M6.3k	Are supported by facts, with no unsupported recommendations documented.
	M6.3l	Are sufficient to address the particular circumstances that led to the incident.

		SOLUTIONS/IMPROVEMENTS
	M6.3m	Are based (wherever possible) on analysis from more than one example of very similar (narrow focus) incidents wherever available.
	M6.3n	Are targeted towards causal factors (not proximal/superficial factors, problems or themes).
	M6.3o	Are designed to be strong/effective (apply improvement science principles to measurably and sustainably reduce or prevent recurrence of identified risks and/or incidents).
	M6.3p	Are subject to an options appraisal before finalisation.
	M6.3q	Are SMART (specific, measurable, achievable, realistic, time-based).
	M6.3r	Lead to the prompt development of a plan to support the implementation of improvement.
	M6.3s	Result in a named manager with designated responsibility for delivering the improvement plan within a designated timescale.
	M6.3t	Are embedded in work systems, processes and practice.
	M6.3u	Are not shared until they are well embedded, tested and shown to be effective in reducing risks or repeat incidents.

		INVESTIGATION REPORTS
	M6.3v	Are written in a way that professionally and effectively communicates the findings of a PSII.
	M6.3w	The national investigation report template is used, unadapted, to document every PSII (for quality assurance and shared learning purposes).
	M6.3x	Are written succinctly in plain English.
	M6.3y	Each PSII has a single report which can be shared in full (unadapted and unredacted).
	M6.3z	All specialist vocabulary, acronyms and abbreviations are explained in the report or in a glossary or footnotes.
	M63aa	An executive summary sets out the main issues, findings and conclusions/ recommendations.
	M6.3ab	A summary incident chronology/timeline is included in the report to illuminate key points; where the full chronology/timeline is included it is attached as an appendix.
	M6.3ac	Provide clear reasons for any missing information or information not made available to the reader.
	M6.3ad	Specific questions from the patient/family/carer set out in the ToR are answered and where this was not possible, the reason is explained in the report.

	M6.3ae	The report is clear about where available information was limited and identifies consequent uncertainties.
	M6.3af	Incidental findings that affect quality of care but lie outside the ToR for the PSII are documented and referred to appropriately.

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Publication approval reference: 000682