Patient Safety Incident Requiring Investigation Policy

Summary

This document outlines the process for managing Patient Safety Incidents Requiring an Investigation (PSIRI) in Marie Curie (MC) Caring Services.

Audience/Scope

The policy applies to all staff and volunteers within Marie Curie Caring Services.
This policy is specific to patient safety incident investigation responses conducted for the purpose of learning and improvement across all care and support services within Caring Services. PSIRF is mandated within English services, however, within Marie Curie, the incident framework will be aligned across all four nations.

Purpose/Aims

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out Marie Curie's approach to developing and maintaining effective and compassionate systems and processes for responding to patient safety incidents and issues for the purpose of learning and continuous improvement in patient safety.

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 that ensures the engagement and involvement of patients and the people who support them in the incident response.

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 which may include patients, and the people who support them and staff/volunteers.
- 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.

Statements

Our Patient Safety Culture

Patient safety incident responses are conducted to address concerns or needs from the impact of the incident on patients and the people who support them and for the purpose of learning and identifying system improvements to reduce risk.

Any patient safety incident response that seeks to find liability, accountability or causality is beyond the scope of this policy.

Incident investigation under this policy follows a systems-based approach, avoiding the person focus approach where the actions or inactions of people, or 'human error', are stated as the cause of an incident.

There is no remit within this approach 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.

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. These types of investigation should be undertaken separately but with relevant teams working together to ensure staff are not unfairly exposed to punitive disciplinary action.

All staff responsible for managing investigations will receive the appropriate training to ensure that the incident response is appropriate, robust, that learning is captured, and individuals involved in safety incidents are offered the appropriate support and concerns answered.

Meaningful and compassionate engagement with patients and those people whose support them substantially improves understanding of what happened, and potentially how to prevent a similar incident in future. Marie Curie promotes the involvement of patients, those people whose support them as partners both in their own care and in the wider oversight of care and service provision. The impact on the patient and those people who support them should not be underestimated and requires their needs to be managed compassionately and effectively and their concerns heard and addressed with planned regular communications.

To ensure that staff involved in patient safety incidents are appropriately supported the Marie Curie Just Culture framework will be used to guide responses, shown in Appendix 1. Patient safety incident response outputs will be undertaken avoiding blaming individuals directly, or indirectly, by inappropriately focusing on individual training and self-reflection.

Patient Safety Partners

Marie Curie recognises the important role that patient safety partners have in helping to improve patient safety across the organisation. Patient safety partners should be appointed to support Marie Curie incident response oversight committees and support policy development in the Quality Trustee Committee and Clinical Reference Group, where appropriate.

Addressing Health Inequalities

It is not possible at present to use data within Marie Curie to identify any disproportionate risk to patients with specific characteristics and use this to inform patient safety incident response, due to the capability of current reporting systems. However, the incident response will consider, explore, and respond to potential issues related to health inequalities identified

through incident investigation and this information will be used to develop, revise and maintain the Marie Curie Patient Safety Incident Response Policy and Plans.

The use of the System Engineering Initiative for Patient Safety (SEIPS) framework will be promoted when responding to patient safety incidents to prompt consideration of inequalities, including when developing safety actions. An individual person-centred approach will be used to engage and involve patients, those who support them, and staff, following a patient safety incident with consideration of their different needs.

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, those who support them 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.

Duty of Candour responsibilities will be upheld in line with the *MC Duty of Candour Policy and the four UK nations regulatory requirements for statutory duty of candour*.

Patient safety Incident Response Planning

In Marie Curie services the application of a range of system-based approaches to learning from patient safety incidents will be taken. Considered and proportionate responses will be taken to patient safety incidents to ensure that there is an appropriate balance of effort between learning through responding to incidents/exploring issues and improvement work.

The SEIPS framework, endorsed by PSIRF, will be promoted, to understand outcomes within complex systems which can then be applied to support the analysis of incidents and safety issues more broadly.

Recognising that some incidents in Marie Curie require a specific type of response as set out in the Marie Curie Incident Policy and/or regulations, the following approach (table 1) to incident response will be used as a framework within Marie Curie. The table is a guide and should there be an unexpected trend or cluster of incidents then a different incident response to that indicated in the table may be required.

Table 1: proportionate response to patient safety incidents

Patient safety incident type	**Required Response**	**Anticipated Improvement Route**
Incidents meeting the Never Event criteria	Patient Safety Incident Investigation (PSII)	Safety Learning Panel
Deaths due to a problem in care (meets learning from deaths criteria)	Patient Safety Incident Investigation (PSII)	Learning from Deaths Safety Learning Panel
Death of a Person with Learning Disabilities where there is reason to believe death was contributed to by one or more patient safety incidents / problems in the healthcare of a service	Patient Safety Incident Investigation (PSII) LeDer Review https://leder.nhs.uk/	Safeguarding Assurance Group Learning from Deaths Safety Learning Panel

commissioned by the NHS		
Safeguarding Incidents	As recommended by Safeguarding Requirements	Safeguarding Assurance Group Safety Learning Panel
Notification of Infectious Disease	Post Infection Review (PIR)	Infection Prevention Control Committee

Patient Safety Incident Type / Issue	**Planned Response**	**Anticipated Improvement Route**
Incidents of Severe Harm Complex incident with potential for significant organisational learning	Duty of Candour Comprehensive Patient Safety Incident Investigation (PSII)	Safety Learning Panel Governance Group appropriate to incident Quality Trustees Committee
Incidents of Moderate Harm where action plan is not currently in place. Less complex incident with potential for significant organisational learning.	Duty of Candour Concise Patient Safety Incident Investigation (PSII)	Safety Learning Panel Group appropriate to subject Integrated Governance and Performance Meeting.
Pressure Damage	Rapid Review Internal benchmarking	Local Action Plan Tissue Viability Group Integrated Governance and Performance Meeting
Falls	Rapid Review Internal benchmarking	Local Action Plan Falls Prevention Group Integrated Governance and Performance Meeting
Medication Errors	Rapid Review Internal benchmarking	Local Action Plan Medication Management Group Integrated Governance and Performance Meeting
Low / No Harm Incidents	Rapid Review for incident categories with a current action plan or potential for learning and new action plan developed / actions added to existing action plan where required. Investigation not required	Local Incident Meeting

NB: If an incident is RIDDOR reportable, as a minimum, a rapid review should be carried

out to meet HSE expectations should they follow up the RIDDOR. If more detailed information or investigation is required, the Health and Safety Team will advise.

Resources and training to support patient safety incident response

The training requirements within Marie Curie acknowledge that specific knowledge and experience are required for those leading patient safety incident responses and those in oversight roles. This includes knowledge of systems thinking and system-based approaches to learning from patient safety incidents including compassionate and effective engagement and support of patients and the people who support them .

Those involved in governance and oversight of patient safety incident response must have the knowledge to constructively challenge the strength and feasibility of safety actions to improve underlying system issues and be able to support the practical application of PSIRF oversight principles and standards.

The training requirements in Marie Curie are detailed in Appendix 2. Anyone undertaking a learning response to a patient safety incident must have had the relevant training. In respect to comprehensive Patient Safety Incident Investigation (PSII) if there is a lack of trained people available to undertake the investigation, the investigation must be supported by a member of the Nursing and Quality team who has completed the two-day systems approach to learning from patient safety incidents.

The patient safety incident response plan

The Marie Curie plan sets out how Marie Curie intends to respond to patient safety incidents over a period of 12 to 18 months. The plan 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 approach to improvement.

Reviewing the patient safety incident response policy and plan

The patient safety incident response plan is a 'living document' that will be appropriately amended and updated as it is used to respond to patient safety incidents. The plan will be reviewed every 12 to 18 months to ensure its focus remains up to date; with ongoing improvement work the 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 the Marie Curie website, replacing the previous version. A rigorous planning exercise will be completed every four years and more frequently if appropriate to ensure efforts continue to be balanced between learning and improvement. This more in-depth review will include reviewing the response capacity, mapping 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

Within MC any of the following patient safety incidents will be reported as an incident:

- Incidents that caused harm or damage

- Incidents that were not intercepted and did not cause harm or damage but could have.
- Near Misses, incidents that were intercepted before harm to the patient occurred.

Immediate risks will be managed appropriately, and preventative action taken to contain any risk and avoid similar repeated incidents. An incident reporting form will be completed on the MC incident database. This will ensure that incidents are cascaded appropriately. For complex incidents or those that appear to have resulted in moderate harm or above a senior manager and Associate Director Nursing & Quality will be notified at the first available opportunity.

The incident will also be recorded in the relevant clinical record in line with the *Marie Curie Clinical Records Policy.*

Any member of staff or volunteer is able to complete an incident form on the MC electronic incident database within two working days of the incident occurring / becoming aware of the incident. Ideally the person who was directly involved in the incident will complete the incident report as soon as possible after the event. Where this is not possible a witness or the person who identified the incident will complete the electronic incident reporting form.

Patient safety incident response decision-making

The Head of Quality and Clinical Practice (or designated deputy) is responsible for determining the proportionate response to the patient safety incident in line with Table 1 above.

Where a rapid review or concise investigation is required the Head of Quality and Clinical Practice will identify an appropriately trained person(s) to lead this response. If a comprehensive investigation is required, this will be discussed with the Nursing and Quality team to agree responsibilities and support.

Responding to cross-system incidents/issues

Where an incident involving multiple providers and/or services across a care pathway is too complex for Marie Curie to manage, the appropriate ICB/Commissioning body will be approached to support the co-ordination of a cross-system response.

The Head of Quality and Clinical practice (or designated deputy) should collaborate with local partners to ensure learning responses are co-ordinated at the most appropriate level of the system.

Marie Curie staff will work together with the relevant external providers to establish and undertake cross system learning responses.

Timeframes for learning responses

A response will start as soon as possible after an incident is identified, and usually completed within one to two months in line with the guide in table 2

Table 2: Guide to timeframes for safety incident response

Response type	Time Frame
Rapid Review	Within 2 working days of becoming aware of the incident
Concise Investigation	Within 30 working days from date of reporting incident in Vantage (incident reporting system)
Comprehensive Investigation	Within 60 working days from date of reporting incident in Vantage

The timeframe for completing the response will be agreed with those affected by the incident, provided they are willing and able to be involved.
In exceptional circumstances a longer timeframe may be needed to respond to an incident. In this case, any extension to timescales should be agreed with those affected (including the patient, family, carer, and staff) where possible.

The Head of Quality and Clinical Practice will monitor response times, and if regularly exceeded will review processes to understand how timeliness can be improved.

Safety action development, improvement plans and monitoring improvement

Improvement plans, in line with the MC Patient Safety Incident Response plan, will be held and overseen centrally by the Nursing and Quality team for cross organisational actions, and locally in each place-based team for local improvements. The plans will be monitored through local governance groups and escalated to the quarterly Integrated Governance and Performance Meeting.

The nominated lead for the incident response will be responsible for identifying areas for improvement which can relate to a specific local context or to the context of the wider organisation. The local team, led by the Head of Quality and Clinical practice will be involved in developing safety actions within their sphere of influence to address. All actions must be added to the improvement plan and implemented in a timely manner.

The Head of Quality and Clinical practice will also be responsible for ensuring that they identify and escalate any actions that the local team need help to meet, or any that require significant resource.

Where there are wider areas for organisational learning and improvement, these should be presented at the Marie Curie Safety Learning Panel and included in a summary report and sent to the Nursing and Quality team who will be responsible for dissemination. The reports should be considered, and discussion recorded in local governance meetings and with local teams, and actions added to improvement plans where appropriate.

Responsibilities

NB Overarching responsibilities for policies are detailed in the MC Policy for the development and management of clinical policy, standards, procedures, and guidelines, and within the body of this policy

Chief Nursing Officer
Monitor the progress with the implementation of this policy across the organisation.
Chair the Safety Learning Panel. Highlight serious incidents with potential for media and/or litigation action or referral to professional registration bodies to Executive Leadership Team (ELT).

Associate Directors of Nursing and Quality
Monitor and support the implementation of this policy across specified place-based services and provide assurance of the adequacy and completion of appropriate patient incident responses to the Quality Trustee Committee. Escalate to Chief Nursing Officer incidents with potential for media and/or litigation or referral to professional registration bodies and share ELT Briefing Report where required.

Deputy Chair for Safety Learning Panel

Nursing and Quality Team
The Nursing and Quality Team has the responsibility for the management of patient safety incident response investigations through the Safety Learning Panel and for reporting to the Quality Trustee Committee and Executive Leadership team, as required.
Monitor and report high level incident statistics, trends and progress and outcomes of improvement action plans to relevant MC Committees.
Co-ordinate the incident reporting database (Vantage).

Head of Experience of Care and Support
Provide support to the process of compassionate engagement with the patient and those people who support them using the expertise of the Experience of Care and Support team.

Associate Director of Strategic Partnerships
Responsible for ensuring that this Policy is implemented across services within their Place and that incidents are reported in line with the escalation requirements

Heads of Quality and Clinical Practice
Ensure appropriate preventative or remedial action has been taken following an incident.
Provide support, direction and debriefing for staff involved if required.
Ensure the patient involved in the incident and those who support them are spoken with promptly to ascertain their understanding of events and any key questions or concerns they would like addressed, as well as provide reassurance of immediate safety actions taken. They should be given a key point of contact and a timeframe for any planned further communication.
Ensure all sections of the incident reporting form are filled in and grade the incident using the risk matrix.
Ensure that the appropriate incident response is undertaken, and that staff assigned to lead the investigation have the appropriate level of training and experience.
Report relevant incidents to external agencies such as Medical and Healthcare Products Regulatory Agency (MHRA) and regulators
Ensure statutory Duty of Candour is completed and all records of discussion / correspondence are maintained.
Ensure all incidents are reviewed at the local management /governance meetings and provide a quarterly escalation report for the Integrated Governance and Performance meeting
Monitor and analyse local incidents and trends and ensure organisational learning results.
If a member of their staff is involved in an incident, ensure that timely support is offered including, where appropriate, referral to Occupational Health Services.

Incident Response Leads
Ensure that they have the correct level of training and experience before accepting responsibility to lead the incident response.
Develop and progress action plans and keep the incident reporting database (Vantage) updated

Ensure staff, service users and those who support them receive appropriate information at planned intervals throughout the incident and investigation process.

All employees and volunteers
Ensuring they are aware of how to report and complete incident report forms on the MC incident database.
Completing Incident reporting and where appropriate reporting verbally (in person or by phone) to their immediate line manager before the end of shift/ working day, all incidents and near misses discovered.
Supporting and co-operating with any incident response.
Participating in supportive conversations or writing a factual statement of events when requested.
Participating in developing and implementing improvement actions and progressing action plans to continually improve safety and quality of service.

Implementation & Controls

Monitoring
Adherence to this policy will be monitored through monthly safety learning panels, annual quality visits, quarterly escalation reports and benchmarking. If evidence suggests that the policy statements are not being adhered to support will be provided by the Nursing and Quality team to ensure that appropriate improvement actions are taken.

Communication/Dissemination
This policy will be stored in the clinical policy section of the MC intranet. It is expected that line managers will ensure that all new employees or volunteers are made aware of this policy during their induction.

Training
See training section above.

Support
Further guidance and support in relation to this policy should be sought from your line manager, head of Quality and Clinical Practice or by contacting the Nursing and Quality team.

References

NHS England (2022) Patient safety learning response toolkit, Available from: https://www.england.nhs.uk/publication/patient-safety-learning-response-toolkit/ Accessed 02.06.23

NHS England (2022) Patient Safety Incident Response Framework. Available from: https://www.england.nhs.uk/patient-safety/incident-response-framework/ Accessed 02.06.22

NHS Scotland (2019) Learning from adverse events through reporting and review

A national framework for Scotland. Available from: https://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/national_framework.aspx Accessed 02.06.23

NHS Wales (2023) Patient Safety Incidents. Available at: https://du.nhs.wales/patient-safety-wales/patient-safety-incidents/ Accessed 02.06.23

RQIA (2023) Statutory notification of incidents and deaths guidance for registered providers and managers of regulated services. Available from: https://www.rqia.org.uk/RQIA/files/71/71c280d0-b1d0-4002-ad91-663445d1fb05.pdf. Accessed 02.06.23

Related links

- Incident Management Policy
- Complaints Management Policy
- Duty of Candour Policy
- Scrutiny of Hospice Deaths by Medical Examiner Service Policy

Governance

Version	*1*
Type	*Policy*
Policy owner	*Chief Nursing Officer*
Support contact(s)	*Nursing and Quality team*
Contact department	*Nursing and Quality team*
Author	*Jane Eades, Acting Director of Nursing and Quality*
Relevant for	*Caring Services*
Related topic	Incident Management
Policies this policy replaces	*Caring Services Incident Management Policy, Serious Incident Policy, Medication Incidents policy*
Ongoing approval/review process	
Review cycle	3 yearly
Ratified/approved by	Document Approval Group
Date of audit	October 2023
Valid to	October 2026
Required for intranet migration	
Key words	*To enhance search function – 3 single words max.* 1. _Patient 2. _Response *3.* _Incident
Description	*This policy describes Marie Curie's approach to responding to patient safety incidents and issues for the purpose of learning and improving patient safety.*

Equality Impact Assessment

This policy has been assessed using an equality impact assessment initial screening template and is deemed to meet current equality requirements. Date undertaken: 02.06.23

		Y/N	Comment
1	Does the policy/guidance affect one group less or more favourably than another on the basis of:	N	
	• Race	N	
	• Ethnic origins (including gypsies and travellers)	N	
	• Nationality	N	
	• Gender	N	
	• Culture	N	
	• Religion or belief	N	
	• Sexual orientation including lesbian, gay • and bisexual people	N	
	• Age	N	
	• Disability - learning, physical, sensory impairment and mental health problems	N	
2	Is there any evidence that some groups are affected differently?	N	
3	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	N/A	
4	Is the impact of the policy/guidance likely to be negative?	N	
5	If so, can the impact be avoided?	N/A	
6	What alternatives are there to achieving the policy/ guidance without the impact?	N/A	
7	Can we reduce the impact by taking different action?	N/A	
If you have identified a potential discriminatory impact of this procedural document, please refer it to the Head of Clinical Policies and Standards together with any suggestions as to the action required to avoid/reduce this impact.			

Appendix 1: Just Culture Framework

Following initial compassionate conversation, or at any point during an investigation consider the following assessment and actions:				
Staff member's thinking was impaired by drugs or alcohol, cognitive impairment, or significant mental health issues	The staff member wilfully intended to cause harm, disruption, or damage	The staff member knowingly breached a policy or well understood process and made an unsafe choice. No consideration of risk or the impact of their actions appears to have been present.	The staff member made an unsafe decision. This may be due to poor decision making or to benefit the staff member as an outcome.	The staff member makes or participates in an error or incident. The staff member was working in an appropriate manner with no intent to cause harm or damage.
Impaired Judgement	**Malicious Action**	**Reckless Action**	**Risky Action**	**Unintentional Error**
• Actively support and advise the staff member. • Maintain regular contact, including supportive letters/emails where appropriate. • The staff member should be involved in the systems investigation where they are able.				
Discuss immediately with a HR Advisor Consider occupational health referral. Consider a suspension risk assessment if performance is impaired.	Discuss immediately with HR Advisor Progress to a suspension risk assessment	Discuss immediately with HR Advisor Consider a suspension risk assessment if staff member is unable to articulate how this can safely be prevented from re-occurring	Consider discussion with HR Advisor (see questions below)	
Undertake a HR Investigation **and** a systems investigation.	Undertake a HR Investigation **and** a systems investigation.	Undertake a systems investigation. A HR investigation may be needed depending on severity and re-occurrence (see questions below).	Undertake a systems investigation.	Undertake a systems investigation.
		Would other staff in the same position have done the same? If yes –		
		Accountability for the incident should be shared and systems learning implemented alongside any agreed HR actions.	The system is likely to have failed and efforts should be focussed on system wide learning.	The system supports errors to be made and requires attention and widely shared learning.
		If No –		
		Consider a HR investigation / use of Performance Improvement procedure. This action will be specific to the incident and require HR support in decision making.	Consider an individual performance improvement plan utilising the Performance Improvement procedure.	Consider an individual performance improvement plan utilising the Performance Improvement procedure.
		Has the staff member made repeated similar errors and a performance improvement plan previously been agreed?		
		If yes – review with HR Advisor as to best course of action based on previous investigations / actions. Follow the performance improvement procedure.		

Appendix 2: Marie Curie PSIRF Training Requirements

Topic	Duration	Provider	Content	Rapid review lead	Concise investigation lead	Comprehensive investigation lead	Engagement Leads	PSIRF oversight roles
Patient safety syllabus level 1: Essentials for patient safety	30 mins	HEE eLearning	Listening to patients and raising concerns The systems approach to safety: improving the way we work, rather than the performance of individual members of staff Avoiding inappropriate blame when things don't go well Creating a just culture that prioritises safety and is open to learning about risk and safety	√	√	√	√	√
Patient safety syllabus level 2: Access to practice	30 mins	HEE eLearning	Introduction to systems thinking and risk expertise Human factors Safety culture	√	√	√	√	√
Investigation training	4 hours	Virtual in house	Introduction to SEIPS, systems thinking and human factors, Just Culture		√	√		
Systems approach to learning from patient safety Incidents	2 days	HSIB eLearning	Introduction to complex systems, systems thinking and human factors Learning response methods: including interviewing and asking questions, capturing work as done,			√		

			data synthesis, report writing, debriefs and after-action reviews Safety action development, measurement, and monitoring					
Oversight of learning from patient safety incidents	6 Hours	Blended in house or external	NHS PSIRF and associated documents Effective oversight and supporting processes Maintaining an open, transparent and improvement focused culture PSII planning					√
Engaging those affected by patient safety incidents s	6 Hours	Blended inhouse or external	Creating psychological safety Relationship building and being available to those affected Person centred, sensitive communication including active listening skills Meaningful involvement and engagement Compounded harm Restorative culture/practice Being open and apologetic Duty of Candour Just Culture Guide Supporting with their review of draft report with findings Signposting and support Sharing their experience via Experience of Care Team			√	√	√
Engaging those affected	2 hour	Inhouse	Creating psychological safety	√	√			

by patient safety incidents			Relationship building and being available to those affected Person centred, sensitive communication including active listening skills Meaningful involvement and engagement Compounded harm Restorative culture/practice Being open and apologetic Duty of Candour Just Culture Guide Supporting with their review of draft report with findings Signposting and support Sharing their experience via Experience of Care Team					
Continuing professional development (CPD)	At least annually	Self-directed	To stay up to date with best practice (e.g., through conferences, webinars, etc) Contribute to a minimum of two learning responses	√	√	√	√	√