2024

Medefer

Patient Safety Incident Response Framework (PSIRF) Policy

Title	Patient Safety Incident Response Framework (PSIRF) Policy
Author	Head of Quality Improvement
Responsible Person	CEO
Operational Responsible Person	Head of Quality Improvement
Department	Quality and Safety team
Authorised	Awaiting sign off
Issue Date	February 2024
Review Date	February 2025
Scope	
Who does this Policy apply to? Employees	Particular Departments or all Employees? All individuals in the employ of this establishment ('Employ' means any person who is employed, self-employed, volunteer, working under practising privileges or contract of service with this establishment
Compliance Monitoring	
Audit/ spot checks etc	Audit and regular reporting
Training & Communication	
Training/ Comms	There is a training needs analysis linked to this policy which is saved on Radar
Policy locations and references	
Radar	
Keywords	
Patient Safety, Improvement	

Revision History

Version	Revision Date	Approved by	Summary of Changes
V1	Feb 2024	Board	New Policy

Table of Contents

Executive Summary

This policy supports the requirements set out by NHS England the Patient Safety Incident Response Framework (PSIRF) and sets out our approach to developing and maintaining effective systems and processes for responding to patient safety incidents and issues for the purpose of learning and improving patient safety.

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

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

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

This policy does not supersede the Significant Event Policy. In the event of any Significant Event, (Incident or Learning event), a Significant Event form must be completed in the company's incident management system. The form will trigger an investigation by a Department / Area Lead.

All staff can report incidents and learning events via the incident management system.

1. Aim of this Policy

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

PSIRF uses a "systems-based approach" to learn what risks there are for patient safety and how to respond to these to improve safety. A system-based approach recognises that healthcare takes place in a work system composed of people, tasks, equipment, and the different environments in which care is provided. All these aspects of the system vary and interact with each other to produce different outcomes. By exploring how these different aspects are working together in different situations, a deeper understanding of the risks and issues facing patients and staff can be gathered, and more effective learning can be identified.

When responding to incidents and safety events under PSIRF, the aim is on learning for improvement and there is no remit to determine liability, preventability, or cause of death.

Other processes outside of the scope of this policy are listed below:

- Claims handling
- Human resources investigations into employment concerns
- Professional standards investigations
- Coronial inquests
- Criminal investigations
- Complaints and Safeguarding concerns (except where a significant patient safety concern is highlighted)

Information from a patient safety response process can be shared with those leading other types of responses, but the principle aims of each of these responses differ from those of a patient safety response and are outside the scope of this policy. Other processes should not influence the remit of a patient safety incident response.

Patient safety learning responses are used to investigate and identify learning and improvement opportunities from incidents reported into Medefer's incident and risk management system (Radar)

We conduct patient safety incident responses for the sole purpose of learning and identifying system improvements to reduce risk (not accountability, liability, avoidability and cause of death). This principle is reinforced at the beginning of each safety or governance related meeting and during any type of incident training. It is communicated verbally and in writing to anyone that is interviewed as part of a learning response.

2. Definitions and Abbreviations

- Patient Safety Incident Response Framework (PSIRF)
- Patient Safety Incident Response Plan (PSIRP)
- Local Risk Management System (LRMS)
- Patient Safety Partner (PSP)
- Patient Safety Incident Investigation (PSII)
- After Action Review (AAR)
- Integrated Care Board (ICB)

3. Roles and Responsibilities

All staff

All staff and those working on behalf of Medefer (both as an employee and contractor basis) must be aware of the content of this Policy and are required to support our patient safety culture.

All staff have a responsibility to report any risk issues or safety concerns. Staff should also cooperate in any investigations and can expect to be supported when they are

Medefer Board

The Medefer Board has the responsibility to ensure it receives assurance that the PSIRF plan has been implemented, and that the organisation has a focus on learning and improvement. It will do this through robust reporting arrangements from the relevant sub-committees.

Clinical Governance Committee

Our Clinical Governance Committee will monitor the output of patient safety learning responses on behalf of the Medefer Board. The committee's terms of reference will include the need to ensure regular thematic reviews are undertaken to extract learning and support the development of organisational memory and continuous improvement regarding patient safety. In addition, the committee will have responsibility for receiving appropriate assurance that adequate governance arrangements are in place to monitor the embedding and delivery of PSIRF.

Patient Safety and Experience Group (PSEG)

The purpose of the Group is to enable the Senior Leadership Team to obtain assurance that high standards of quality and safe patient care are provided by Medefer and, in particular, adequate governance structures, processes and controls are in place. It receives a Quality and Safety report which has an overview of incidents, complaints and claims data. The report contains the monthly submission of learning responses, including Patient Safety Incident Investigations (PSII).

Patient Safety Review and Triage

The Patient Safety Review and Triage is responsible for the operational processes in relation to managing incidents through the PSIRF standards. They will review incidents, ensuring the appropriate level of review is undertaken and confirming which incidents require a PSII.

Roles (individuals and teams)

Chief Executive Officer (CEO)

The Chief Executive Officer is the accountable officer and responsible to the Board for ensuring that resources, policies and procedures are in place to ensure the effective reporting, recording, investigation and treatment of incidents. The Chief Executive Officer is responsible for promoting positive patient safety and reporting culture within the organisation. This is monitored via Medefer's Annual Report and Quality Account.

They are responsible for risk management and ensuring appropriate arrangements are in place for patient safety and the investigation of any incidents. They are also accountable for ensuring the mechanisms are in place for learning.

Chief Medical Officer

Responsible for clinical review of reported incidents and LFPSE discussion and submission. The CMO is also responsible for ensuring Duty of Candour requirements are met.

The Quality and Safety team

The Quality and Safety team work with our internal teams to support local governance processes, including incident and risk management as well as oversee the progression and quality of local learning responses.

Patient Safety Incident Investigators

The Patient Safety Incident Investigators will lead on ensuring that PSIIs are undertaken in line with national standards. They will liaise with patients or their families / carers during any investigation. Link to the list of Patient Safety Incident Investigators is within the External References and Associated Medefer Documents section of this policy.

Health and Safety team

The Health and Safety team reports all incidents that result in harm to patients under Reporting of Diseases and Dangerous Occurrences Regulations (RIDDOR) to the Health and Safety Executive (HSE) when harm to patients arises out of or from activities related to provision of care giving tasks.

Chief Pharmacist/Controlled Drugs Accountable Officer (CDAO)

The Chief Pharmacist/CDAO reports all controlled drugs incidents that result in harm to patients to the NHSE London Region CDAO team, in line with the Controlled Drugs (Supervision of Management and Use) Regulations 2013.

Patient Safety Partners

Patient Safety Partners will work with Medefer to deliver the PSIRF standards by being involved in training, investigations, plans and supporting patients, families and carers involved in incidents.

Learning Response Lead

Learning Response Leads are senior managers who have undergone human factors training. They will work together to summarise and present complex information in a clear and logical manner.

Learning responses are not led by staff who were involved in the patient safety incident itself or by those who directly manage those staff.

4. Our patient safety culture

Medefer promotes a climate that fosters a just and open culture.

Patient safety is our top priority and as such we encourage an open and transparent culture where the learning from an incident or learning event (near miss) can be implemented into practice to ensure that any issues that caused a reported incident are not repeated. This is central to our value of patient-first care.

Creating an open and transparent culture is deeply embedded within Medefer. Patient safety is our top priority and as such we encourage an open and transparent culture where the learning from an incident or learning event (near miss) can be implemented into practice to ensure that any issues that caused a reported incident are not repeated. This is central to our value of patient-first care. The aim of reporting and investigating Significant Events is to support active learning and to ensure that the positive lessons learnt from these events are embedded into our culture and practices.

We conduct patient safety incident responses for the sole purpose of learning and identifying system improvements to reduce risk (not accountability, liability, avoidability and cause of death). This principle is reinforced at the beginning of each safety or governance related meeting and during any type of incident training. It is communicated verbally and in writing to anyone that is interviewed as part of a learning response.

We actively support the promotion of a positive and supportive approach to incident, accident and near miss reporting in a culture of openness and learning; there are a number of meetings held on a regular basis to support this. It is recognised that fear of reprisal, blame, and/or disciplinary action may deter staff from reporting an incident (or potential incident). In order to support an open and fair culture, we implement a number of policies (Significant Event Policy - Incident and SI management, Freedom to Speak Up, Equal Opportunities and Diversity Policy and Being Open, and Duty of Candour policies).

It is our view that disciplinary action should not form part of the response to an incident investigation unless there are exceptional circumstances and / or the outcome of an

appropriate investigation identifies a need for such action. “Exceptional Circumstances” can be defined as the following occasions:

- Deliberate failure to report an incident
- Failure to co-operate with an investigation
- Criminal action, or
- Where it is the view of Medefer and/or professional body that the actions were so far removed from reasonable practice that any competent person would have been able to predict the adverse outcome.

Reports from Incident Investigations will be reviewed by the PSEG, which will disseminate the report and action plans to appropriate groups including Senior Leadership Team (SLT), Information Governance Committee (IGC). Clinical Governance Committee (CGC) and the Board of Directors. and appropriate risk management action plans discussed. They will also monitor the implementation of any action plans that arise from these reviews.

Patient Safety Partners (PSP)

The PSP will have an important role in supporting our PSIRF providing a patient perspective to developments and innovations to drive continuous improvement.

A Patient Safety Partner (PSP) is a new and evolving role. They will be involved in the designing of safer healthcare at all levels in the organisation. They will offer support alongside our staff, patients, families/carers to influence and improve patient safety and communicate rational and objective feedback focused on ensuring that the patient voice is heard and included in our safety and governance processes. Their input will support maximising the things that go right and minimising the things that go wrong for patients when they are receiving treatment, care and services from us.

PSPs will use their lived experience as a patient, carer, family member or a member of the local community to support and advise on activities, policies and procedures that will improve patient safety and help us to deliver high quality care.

Full role descriptions will be provided for PSPs along with any support requirements they may need to maximise their opportunities for involvement and ensure they are fully supported and enabled.

Addressing health inequalities

As a provider of elective care services, we have a key role to play in tackling health inequalities in partnership with our local partner agencies and services.

We recognise that key to understanding, improving and monitoring health inequalities are good data on the key determinants of inequality. As part of our implementation of PSIRF, we are committed to utilising data and learning from investigations to support a better understanding of issues related to actual and potential health inequalities and make recommendations to our Board and partner agencies on targeted action aimed at improving care and outcomes for these populations, including how to measure the impact of such action. We recognise that the more holistic, integrated approach to patient safety under PSIRF will require us to engage collaboratively with the patient experience and inclusivity agenda and ensure investigations and learning do not overlook these important aspects of the wider health and societal agenda.

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 must always 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 staff following a patient safety incident

The PSIRF recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. It supports the development of an effective patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents (including patients, families and staff). This involves working with those affected by patient safety incidents to understand and answer any questions they have in relation to the incident and signpost them to support as required. As such, we are committed to all learning responses being undertaken in a safe environment, and where further emotional support is required, staff, patients, families and carers will be provided advice for how to obtain this, as described below.

Involving Patients & Families

Our Being Open and Duty of Candour policy encourages an open and transparent culture. The policy sets out the process that must be followed when things go wrong with the care and treatment of a Medefer patient; this includes, providing information regarding the incident, providing reasonable support, and an apology when things go wrong.

We recognise and acknowledge the significant impact patient safety incidents can have on patients, their families, and carers. Getting involvement right with patients and families in how we respond to incidents is crucial, particularly to support improving the services we provide. This includes the opportunity to provide their perspective on what happened and to raise questions about what happened.

Those affected will be provided with a named main contact within the organisation with whom to liaise about any learning response and support.

They will be allowed to involve an advocate, family member or friend in any meeting that is part of the learning response process they are involved in and to review the learning response while still in draft. Timeframes for any learning response will be discussed and agreed with those involved, and any delays or changes will be communicated.

All staff are encouraged to be transparent and open whenever there is a concern about care not being as planned or expected, or when a mistake has been made regardless of the level of harm involved. This is emphasised in patient safety training and at the beginning of corporate governance meetings.

All staff follow the organisation's Being Open and Duty of candour policy.

Saying sorry is always the right thing to do. It is not an admission of liability. It acknowledges that something could have gone better and is the first step to learning from what happened and prevent it happening again.

Written information provided to patients and families, including in fulfilment of duty of candour, will be tailored to the individuals taking into consideration their questions, concerns and wishes. Patient and families will be signposted to where they can obtain specialist

advice and/or advocacy and/or support from independent organisations regarding learning response processes.

Involving Staff and Partners

Involvement of staff and colleagues (including partner agencies) is of paramount importance when responding to a patient safety incident to ensure a holistic and inclusive approach from the outset. Our Significant Event Policy positions that we support the promotion of a positive and supportive approach to incident, accident and near miss reporting in a culture of openness and learning. It is recognised that fear of reprisal, blame, and/or disciplinary action may deter staff from reporting an incident (or potential incident).

When things go wrong in healthcare, the staff who are involved can be impacted significantly. The emotions and stress involved can impact their health, wellbeing and ability to continue to work. We aim to ensure the health, safety and wellbeing of all individuals working with Medefer and we have appropriate risk assessments in place to eliminate stress or control the risks from stress and mental health. Risk assessments identify controls and adjustments to support individuals, and we are also able to refer individuals to an outsourced Occupational Health Provider if appropriate. We offer all employees access to an Employee Assistance Programme (EAP) that offers counselling services and support, We also offer a Private Healthcare Scheme for employees to participate in upon the successful completion of the probationary period. We encourage employees to talk openly with their managers and the HR team are also available to meet with individuals as well as managers to talk through, and provide support on any issues or concerns raised.

We are currently developing a Stress Policy and will be looking to offer Mental Health First Aider training internally within the business to further support the wellbeing of individuals working with us.

Oversight roles and responsibilities

Relevant staff have undergone Oversight training to ensure they understand the Oversight mindset.

Oversight mindset

The following ‘mindset’ principles should underpin the oversight of patient safety incident response:

1. Improvement is the focus

PSIRF oversight will focus on enabling and monitoring improvement in the safety of Care, not simply monitoring investigation quality.

2. Blame restricts insight

Oversight will ensure learning focuses on identifying the system factors that contribute to patient safety incidents, not finding individuals to blame.

3. Learning from patient safety incidents is a proactive step towards improvement

Responding to a patient safety incident for learning is an active strategy towards continuous improvement, not a reflection of an organisation having done something wrong.

4. Collaboration is key

A meaningful approach to oversight cannot be developed and maintained by individuals or organisations working in isolation – it must be done collaboratively.

5. Psychological safety allows learning to occur

Oversight requires a climate of openness to encourage consideration of different perspectives, discussion around weaknesses and a willingness to suggest solutions.

6. Curiosity is powerful

Leaders have a unique opportunity to do more than measure and monitor. They can and will use their position of power to influence improvement through curiosity. A

valuable characteristic for oversight is asking questions to understand rather than to judge.

It is important to triangulate a mixture of qualitative and quantitative measures to get a clear understanding of the effectiveness of the patient safety incident response systems and processes in place. Data can be outcome or process based and it is important to use both.

Oversight of Patient Safety Responses will take a range of formats. The policy standards will be under the oversight of our Board, this will be delivered through a quarterly report.

Patient safety incident response planning

Resources and training to support patient safety incident response

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.

All staff are required to complete mandatory patient safety training which covers the basic requirements of reporting, investigating, and learning from incidents.

Our patient safety incident response plan

Our plan sets out how we intend 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.

The PSIRP is based on a thorough analysis of themes and trends from all incidents from 2021-2023 (including low harm, no harm and near misses), complaints, concerns, risks, legal claims, mortality reviews and other forms of direct feedback from staff and patients, and reflects the following standards:

1. A thorough analysis of relevant organisational data.
2. Collaborative stakeholder engagement.
3. A clear rationale for the response to each identified patient safety incident type.

The priorities identified in the PSIRP will be regularly reviewed against quality governance reports and surveillance to ensure they are responsive to unforeseen or emerging risks. Our

PSIRP will be published alongside this overarching policy framework. **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, or earlier if appropriate, to ensure our focus remains up to date; with ongoing improvement work our patient safety incident profile is likely to change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 12 months.

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

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

Resources and training to support patient safety incident response

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.

All staff are required to complete mandatory patient safety training which covers the basic requirements of reporting, investigating, and learning from incidents. See our PSIRF Training Needs Analysis for further information, link in Section 7 of this policy.

Investigations are led by staff who have completed the Systems Approach training.

Responding to patient safety incidents

Patient safety incident reporting arrangements

Patient safety incident reporting is in line with our Significant Events Policy, with all incidents and learning events being reported on the company's incident management system.

Incidents are discussed at a departmental level as well as by senior members of staff. We have robust reporting to both the Senior Leadership Team as well as the Board.

Certain incidents require external reporting to national bodies such as HSE, RIDDOR and MHRA, ICO, the process for reporting these incidents externally can be found within our Significant Events Policy.

Patient safety incident response decision-making

In addition to the incident reporting procedures described above, we also have governance and assurance systems to ensure oversight of incidents, at both a Departmental and Organisational level. Clinical and operational managers work together to ensure the following arrangements are in place:

- Identification and escalation of any incidents that have, or may have caused significant harm (moderate, severe or death).

- Identification of themes, trends or clusters of incidents within a specific service
- Identification of themes, trends or clusters of incidents relating to specific types of incidents.
- Identification of any incidents relating to local risks and issues (e.g. CQC concerns).
- Identification of any incidents requiring external reporting or scrutiny (e.g. Never Events, RIDDOR).
- Identification of any other incidents of concern, such as serious near-misses or significant failures in established safety procedures.

As outlined in the Significant Event Policy, the process for completion of a Patient Safety Incident Investigation to determine any further investigation or escalation required will remain. This, however, will now include a wider range of options for further investigation outlined in the PSIRF. The principles of proportionality and a focus on incidents that provide the greatest opportunity for learning will be central to this decision making under our PSIRP.

All reported Significant Events are investigated, reviewed and discussed at a series of meetings held on a weekly basis.

At a minimum this will include ensuring that any patients affected are safe, that we understand the cause of the incident and ensure that it has been resolved.

This may often mean no further investigation is required, where the incident falls within one of the improvement themes identified in the PSIRP.

Responding to cross-system incidents/issues

Service managers and the Quality and Safety team will ensure any incidents that require cross system or partnership engagement are identified and shared through existing channels and networks.

Medefer works in partnership and alongside many different Trusts and providers. All Medefer's subcontractors are CQC-registered, and independent healthcare providers in their own right. They are all expected to comply with the regulatory requirements, including Patient Safety Incident Response Framework. As part of their subcontract with Medefer, they are required to provide regular incident reports to Medefer.

When an incident occurs that includes an external organisation, Medefer will capture the incident in our incident management system, and the source of incident is clearly captured. This will allow Medefer to monitor the incidents and any developing themes across our partner ecosystem.

Timeframes for learning responses

A response must start as soon as possible after an incident is identified, and usually completed within one to three months. Timescales will be set where possible for all response methods.

The timeframe for completing a Patient Safety Incident investigation[1] (PSII) will be agreed with those affected by the incident, as part of setting the terms of reference for the PSII. PSIIs (and other local response) should take no longer than six months.

Agreed timeframes will be reported as KPIs and processes will be reviewed if the agreed KPIs are not being met on a regular basis in order to understand how timelines can be improved. It is recognised that in exceptional circumstances (e.g. when a partner organisation requests an investigation is paused), a longer timeframe may be needed to respond to an incident. In this case, any extension to timescales should be agreed with those affected (including the patient, family, carer, and staff).

The time needed to conduct a response must be balanced against the impact of long timescales on those affected by the incident, and the risk that for as long as findings are not described, action may not be taken to improve safety or further checks will be required to ensure the recommended actions remain relevant. Where external bodies (or those affected by patient safety incidents) cannot provide information, to enable completion within six months or the agreed timeframe, our local response leads will work with all the information they have to complete the response to the best of their ability; it may be revisited later, should new information indicate the need for further investigative activity.

The PSIRP provides more detail on the types of learning response most appropriate to the circumstances of the incident. Highly prescriptive timeframes for learning responses may not be helpful so the following are included as a guideline only:

- Initial incident investigation – as soon as possible, within 5 working days of reporting
- Further learning response (eg: PSII, AAR, SEIPS) – within 20-40 working days of reporting depending on complexity
- Comprehensive Investigation – 60 - 120 working days depending on complexity

Safety action development and monitoring improvement

Safety actions will be developed with the teams involved in the area that the incident occurred and be based on the recommendations of the Triage team. The actions will be monitored by the PSEG. All actions should be SMART (Specific, Measurable, Achievable, Relevant and Time-bound). Progress of actions will also be included in papers submitted to the CGC. Any actions that are difficult to resolve should be escalated to the PSEG.

Monitoring the effectiveness of actions will be overseen be the SLT via quarterly reports.

Safety improvement plans

Safety improvement plans will be a mixture of approaches depending on the incident.

Approaches will include:

- create an organisation-wide safety improvement plan summarising improvement work
- create individual safety improvement plans that focus on a specific service, pathway or location.
- collectively review output from learning responses to single incidents when it is felt that there is sufficient understanding of the underlying, interlinked system issues.
- create a safety improvement plan to tackle broad areas for improvement (I.e. overarching system issues).

[1] https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-PSII-overview-v1-FINAL.pdf

Whichever approach is taken the rationale for that approach will be included in the learning response process and agreed upon with the relevant stakeholders.

Oversight roles and responsibilities

Relevant staff will undergo Oversight training to ensure they understand the Oversight mindset.

Oversight mindset

The following 'mindset' principles should underpin the oversight of patient safety incident response:

1. Improvement is the focus
PSIRF oversight will focus on enabling and monitoring improvement in the safety of Care, not simply monitoring investigation quality.

2. Blame restricts insight
Oversight will ensure learning focuses on identifying the system factors that contribute to patient safety incidents, not finding individuals to blame.

3. Learning from patient safety incidents is a proactive step towards improvement
Responding to a patient safety incident for learning is an active strategy towards continuous improvement, not a reflection of an organisation having done something wrong.

4. Collaboration is key
A meaningful approach to oversight cannot be developed and maintained by individuals or organisations working in isolation – it must be done collaboratively.

5. Psychological safety allows learning to occur
Oversight requires a climate of openness to encourage consideration of different perspectives, discussion around weaknesses and a willingness to suggest solutions.

6. Curiosity is powerful
Leaders have a unique opportunity to do more than measure and monitor. They can and will use their position of power to influence improvement through curiosity. A
valuable characteristic for oversight is asking questions to understand rather than to judge.

Whether organisations are improving based on learning from patient safety incident response cannot be determined from a single measure. It is important to triangulate a mixture of qualitative and quantitative measures to get a clear understanding of the effectiveness of the patient safety incident response systems and processes in place. Data can be outcome or process based and it is important to use both.

Oversight of Patient Safety Responses will take a range of formats. The policy standards will be under the oversight of our Board, this will be delivered through a quarterly report.

Complaints and appeals

We recognise that there will be occasions when a patient or patient representative are dissatisfied with aspects of the care and services provided by Medefer or the outcome of a patient safety incident investigation.

Complaints and appeals relating to our response to patient safety incidents will be dealt with in line with our Complaint Policy and Process

5. Confidentiality

Staff should be aware of the importance of maintaining confidentiality. Additionally, disclosure of information may breach Medefer's obligations under the Data Protection Act. The overall focus is to ensure that communication lines are clear, concise, and kept to a minimum. Advice on this matter may be sought from the Information Governance Lead or the Caldicott Guardian (Chief Medical Officer). A strategy for the release of information where appropriate to the patient, the relatives and the media will be developed on a case-by-case basis and discussed with the Medical Director.

6. External bodies

- NHS England
- CQC – Care Quality Commission
- ICB

7. External References and Associated Medefer Documents

- Patient Safety Incident Response Plan (available to view on Radar)
- Significant Event and Incident Management Policy (available to view on Radar)
- Being Open Policy and Duty of Candour Policy (available to view on Radar)
- Complaint Policy and Process (available to view on Radar)
- Patient Safety Incident Response Framework (PSIRF) training needs analysis
- List of Patient Safety Incident Investigators: https://medefer.atlassian.net/wiki/x/ToD7q (internal access only)
- Patient Safety Incident Response Framework (PSIRF) training needs analysis: https://medeferhealth.sharepoint.com/:w:/r/sites/ClinicalGovernance/PSIRF/Training%20needs/Patient%20Safety%20PSIRF%20training%20needs%20analysis%20v1.docx?d=w5a377b651bce4c8abd0b543dffea4424&csf=1&web=1&e=kja4c6

Note that the policy is based on NHS England's Patient Safety Incident Response Framework (PSIRF)_(https://www.england.nhs.uk/patient-safety/patient-safety-insight/incident-response-framework/)

Patient safety incident response plan

Table of Contents

Introduction

This patient safety incident response plan sets out how Medefer intends to respond to patient safety incidents over a period of 12 months. The plan is not a permanent rule that cannot be changed. We will remain flexible and consider the specific circumstances in which patient safety issues and incidents occurred and the needs of those affected.

Our services

Medefer is a provider of consultant-led elective care services, providing a GP referral to treatment pathway in collaboration with NHS and Independent Sector sub-contractors and partners. Medefer is regulated by the CQC for the delivery of the virtual outpatient component of the pathway.

Medefer outpatient services are delivered on a remote-first basis. Medefer has ensured there are mitigations in place to reduce risks associated with this clinical model. Medefer Consultants work online to review GP referrals and manage those referrals through the entire pathway. Medefer works closely with partners, which can include the independent sector and / or the NHS Trusts to deliver the diagnostic and treatment parts of the pathway for the patient. The patient remains under the care of Medefer, even when referred for a physical appointment at one of the partners, unless the care of the patient is formally transferred to another organisation under Inter-Provider Transfer (ITP) arrangements.

In some circumstances, Medefer may deliver services to other organisations, such as NHS Trusts, where the other organisation retains responsibility for the governance of the patient. Even in such situations, as a CQC-registered organisation, the patient is clinically under the care of the Medefer consultants, even though Medefer will have significantly reduced control over the diagnostic and treatment pathways for the patient.

Defining our patient safety incident profile

Medefer continually develops and improves internal governance processes to ensure we gain insight from patient safety incidents and this feeds into our quality improvement approach.

We will continue to draw on guidance and feedback from our partners, national and regional level NHS bodies, regulators and other key stakeholders to identify and define the quality improvement work we need to undertake.

The Patient Safety and Experience Group (PSEG) will provide assurance that quality improvement measures, including any safety improvement plans (an improvement that has come out of a review of safety incidents), continue to be of the highest standard. The PSEG will be responsible for the oversight of this quality improvement work including the robust use of quality improvement methodology. PSEG reports to the Clinical Governance Committee.

The PSEG will also provide assurance during the development of new safety improvement plans following reviews undertaken within PSIRF to ensure they have followed robust processes during development are sufficient to allow us to improve patient safety in future.

We plan to focus our efforts on development of safety improvement plans across our most significant incident types either those within national priorities, or those we have identified locally. We will remain flexible and consider improvement planning as required where a risk or patient safety issue emerges from our own ongoing internal or external insights.

Defining our patient safety improvement profile

Our patient safety risks were identified through the review of the following data sources over the period of 2021-2023

- Significant Events (Incidents and Learning Events)
- Complaints
- Mortality reviews

Significant Events (Incidents and Learning Events) Category

Pathway Management: Management of the patient pathway between Medefer and other organisations	43%
System Management: Incidents regarding the management of the patient pathway on the Medefer electronic patient record (EPR) system and other software platforms	34%
Other	23%

Significant Events (Incidents and Learning Events) Subcategory

Onward referral: Delay to onward referral leading to adverse or potentially adverse outcome	34%
Investigation management: Delay to investigation leading to adverse or potentially adverse outcome	28%
Administrative errors: Wrong document uploaded or sent	22%
Non EPR system management (Freshdesk etc): Adverse or potentially adverse outcome due to the non-EPR platforms not working as expected.	12%
Diagnosis: Delayed, missed or incorrect cancer diagnosis	4%

Complaints and Concerns

Pathway Problems	38%
Service Delay	28%
Communication	18%
Other	8%
Administration	4%
Data Protection	2%
Staff (Attitude, Conduct etc)	2%

A closer look at the most common themes highlighted within Complaints and Concerns analysis

Letters	Miscommunication or disagreement with information in record
Medication	Disagreement or concern about medication recommendations
Investigation and Results	Longer than expected wait time to investigation appointment or longer than expected wait time to result being received
Consultation	Appointment time not kept

Mortality Reviews

Number reviewed	136
Closed after 1st stage review	81%
Second stage review required	19%
Escalated to Clinical Governance Committee	1%
Number of unexpected deaths	0
Areas of concerns highlighted were around Suitability of referral for Medefer pathway and Patient DNA/ cancelled appointment	

Coroner Inquests

Number of Coroner Inquests	0

We also considered:

- Freedom to Speak Up reports
- Staff survey results
- Claims
- Staff suspension data

Freedom to Speak Up reports

No Freedom to Speak up reports have been received since the implementation of the Freedom to Speak Up Policy and Guardians were introduced. Regular reminders are sent to staff via email and in meetings to ensure they understand the Freedom to Speak Up Policy and Process and feel confident in raising concerns.

Staff Survey results

Our most recent Staff Survey was held in September 2023. Our overall engagement score was 78%.

Under the topic of trust, Medefer scored well for the questions:

- It is okay to be human and doubt my abilities and standards of work.
- We discuss and learn from mistakes without judgement. We focus on the solution, not the problem.

Responses and feedback have been shared with the business as well as individual departments. Questions raised have been responded to and reassurances given around some areas that scored lower. A further survey is to be launched and sessions will be arranged with departments to talk through results, improvements since the last survey and any areas of improvement that can be considered.

Claims

Medefer has received one claim, which has been closed with no fault.

Staff suspension data

Staff suspension data showed no link to patient safety incident

Our patient safety incident response plan: national requirements

Some events in healthcare require a specific type of response as set out in national policies or regulations. These responses may include review by or referral to an external organisation, depending on the nature of the event. Incidents meeting the Never Events criteria (2018) and deaths thought more likely than not due to problems in care (i.e., incidents meeting the Learning from Deaths criteria for PSII) require a locally led PSII.

Included below are incidents that meet the national event requirements relevant to Medefer, a provider of elective care services

Patient safety incident type	**Required response**	**Anticipated improvement route**
Incidents meeting the Never Events criteria	Patient Safety Incident investigation PSII	Create local organisational actions and feed these into the quality improvement strategy
Death thought more likely than not due to problems in care (incident meeting the learning from deaths criteria for patient safety incident investigations (PSIIs))	Patient Safety Incident investigation PSII	Create local organisational actions and feed these into the quality improvement strategy
Safeguarding Incidents	Internal Safeguarding review	Respond to recommendations as required and feed actions into the quality improvement strategy
Deaths of patients detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies, where there is reason to think that the death may be linked to problems in care (incidents meeting the learning from deaths criteria)	Patient Safety Incident investigation PSII	Respond to recommendations as required and feed actions into the quality improvement strategy
Deaths of persons with learning isabilities or an autistic person (LeDeR)	Refer for Learning Disability Mortality Review (LeDeR). Locally led PSII (or other response) may be required alongside the LeDeR – organisations should liaise with this	Respond to recommendations as required and feed actions into the quality improvement strategy

Our patient safety incident response plan: local focus

Patient safety incident type or issue	Description	Detailed description	Planned response	Anticipated improvement route
Pathway Management	Management of the patient pathway between Medefer and organisations	**Diagnosis:** Delayed, missed or incorrect cancer diagnosis **Investigation management:** delay to investigation leading to adverse outcome **Onward referral:** delay to onward referral leading to adverse outcome	Patient Safety Incident investigation PSII, Systems Engineering Initiative for Patient Safety SEIPS or After Action Review AAR depending on the opportunity for organisational learning.	Create local organisational actions and feed these into the quality improvement strategy Update improvement plan with any new actions Share progress, actions and monitor impact via the Patient Safety and Experience Group
System Management	Incidents regarding the management of the patient pathway on the Medefer platform and other software platforms	**External system management** (e.g.: interoperability with another platform, eRS, Emis): Delay to patient care due to interoperability failure leading to adverse outcome **Internal system management** (eg: regression, release does not work as expected etc) Adverse outcome due to the Medefer platform not working as expected. **Non EPR system management** (Freshdesk etc) Adverse outcome due to the Non EPR platform not working as expected.	Patient Safety Incident investigation PSII, Systems Engineering Initiative for Patient Safety SEIPS or After Action Review AAR depending on the opportunity for organisational learning.	Create local organisational actions and feed these into the quality improvement strategy Update improvement plan with any new actions Share progress, actions and monitor impact via the Patient Safety and Experience Group

Communication Strategy/ Reporting

Monthly updates to the Senior Leadership Team, and regular updates to the board via the Clinical Governance Committee. Team updates will be made via All Hands, the intranet and departmental updates.

External stakeholders will be updated as and when required.

Proportionate Response

The Patient Safety Incident Response Framework (PSIRF) empowers healthcare organisations to tailor their response to each incident based on the severity and frequency of the incident, and the desired learning outcomes all influence the chosen response method.

The Patient Safety Incident Response Framework (PSIRF) allows healthcare organisations to adjust how they respond to patient safety incidents based on the severity of the incident, its frequency, and the desired learning.

However, regardless of the specific approach adopted, all PSIRF responses share the same overarching goals:

1. Addressing concerns: PSIRF ensures concerns raised by patients, families, or staff regarding a safety incident are promptly addressed and acknowledged.

2. Understanding the cause: Through investigation and analysis, PSIRF aims to uncover the contributing factors that led to the incident, fostering a deeper understanding of its root cause.

3. Identifying improvement areas: PSIRF leverages the incident as a learning opportunity, identifying areas where healthcare processes and systems can be improved to enhance patient safety.

4. Enhancing future safety: By implementing necessary changes and learning from past incidents, PSIRF strives to create a safer environment for future patients.

5. Minimising Recurrence: PSIRF actively seeks to reduce the risk of similar incidents occurring again by implementing effective preventative measures.

In essence, PSIRF emphasises flexibility while maintaining a consistent focus on learning and improving patient safety across all response methods.