Physiological Measurements Ltd.

Patient Safety Incident Response Policy

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Contents

1.0 Purpose

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

The PSIRF 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.

2.0 Scope

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

Responses under this policy follow a systems-based approach. This recognises that patient safety is an emergent property of the healthcare system: that is, safety is provided by interactions between components and not from a single component. Responses do not take a 'person-focused' approach where the actions or inactions of people, or 'human error', are stated as the cause of an incident.

There is no remit to apportion blame or determine liability, preventability or cause of death in a response conducted for the purpose of learning and improvement. Other processes exist for that purpose, such as:

- legal claims
- human resources investigations into employment concerns
- professional standards investigations
- coronial inquests
- criminal investigations

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.

3.0 Our Patient Safety Culture

PML is committed to moving away from a retribution response to incidents and establish a just culture within the organisation.

PML will always encourage and support incident reporting where an incident may have or is likely to occur which has caused, contributed to or may lead to harm of a patient, visitor or colleague.

The goals of just culture include:

- empowering staff to understand why an error has occurred
- shifting focus away from outcomes and towards system design and optimisation
- managing behavioural choices
- designing safety into all clinical systems and processes

PSIRF will enhance these by creating stronger links between patient safety events and learning for improvement.

PML is committed to embracing the patient safety incident response framework (PSIRF) approach, fostering collaboration with all stakeholders affected by the patient safety incidents, including patients and their families and our staff. This commitment aims to enhance transparency and openness within our organisation, facilitating the reporting of events and enabling broader engagement both internally and externally. We will work collaboratively with stakeholders across the healthcare system who have been involved in the patient incident pathway to ensure effective communication and coordination in addressing patient safety concerns.

We are clear that patient safety event responses are conducted for the sole purpose of learning and identifying system wide improvements; they are not to apportion blame, liability or define preventability or cause of death.

4.0 Addressing Health Inequalities

PML recognises that health services have a core role to play in reducing inequalities in health by improving access to services and tailoring those services around the needs of the population in an inclusive way.

PML is committed to delivering on its statutory obligations under the Equality Act (2010) and will use data intelligently to assess any disproportionate patient safety risk to patients from across the range of protected characteristics.

In our response toolkit, we will directly address any features of an event which indicate health inequalities, that may have contributed to harm or demonstrate an ongoing risk to any population group, including all protected characteristics.

Engagement of those involved (patients, families/carers, and our staff) following a patient safety event is crucial to our patient safety learning responses. Information resources produced by PML can be made available in alternative formats, such as easy read or large print and may be available in alternatives languages upon request. These requests can be made to our Patient Management Centre (PMC).

PML endorses a zero tolerance of racism, discrimination, and unacceptable behaviours from and towards our staff, patients, carers, and families.

5.0 Engaging and Involving Patients, Families and Staff Following a Patient Safety Incident

PSIRF recognises that learning and improvement following a patient safety event can only be achieved if supportive systems and processes are in place. It supports the development of an effective patient safety response system that prioritises compassionate engagement and involvement of those affected. This involves working with those affected to understand and answer any questions in relation to the event and signpost to relevant support as required.

PML are committed to continuous improvement throughout the services we provide, and to learn from any event where care does not go as planned or expected by our people, patients, their families, carers, and other organisations. Getting involvement right with patients and families in our response is crucial, particularly to support the improvement of the services we provide. This involves being open and honest whenever there is a concern about care/ treatment provided, or when a mistake has been made.

Alongside professional and statutory requirements for Duty of Candour, PML commits to being open and transparent because it's the right thing to do; this is regardless of the level of harm caused by an event.

In line with the PSIRF we will support those involved via our Patient Engagement Lead who will guide our people, patients, and their families through our patient safety learning responses to conclusion. In addition, we have a feedback service for those with a concern or who are unhappy about their experience with PML. This allows the organisation to review the concern and make improvements where necessary and feasible.

PML loves to hear great things about our staff and the services we provide and welcomes compliments from our patients and their families which are used to assist with learning from excellence.

Our teams at PML can support with the following:

- raising a concern, or a complaint
- feedback (positive and/or negative)
- sending a thank you letter
- excellence reporting

All relevant contact details and associated forms can be found on our website here.

PML recognises it can be beneficial for staff to seek support because of a patient safety event they have been involved in and PML advocates the equal importance of both mental and physical health. Our staff are encouraged to contact our specially trained HR Advisor who will signpost to relevant support services as required.

6.0 Patient Safety Incident Response Planning

PSIRF supports organisations to respond to incidents and safety issues in a way that maximises learning and improvement. Beyond nationally set requirements, organisations can explore patient safety incidents relevant to their context and the populations they serve rather than only those that meet a certain defined threshold.

PML will take a proportionate approach to its response to patient safety events, ensuring the focus is on maximising improvement. Our Patient Safety Incident Response Plan (PSIRP) will detail how this will be achieved alongside how we intend to meet both national and local requirements for patient safety incident responses.

7.0 Resources and Training to Support Patient Safety Incident Response

PML has committed to ensuring that we fully embed PSIRF and meet its requirements. We have therefore used the NHS England patient safety response standards (2022) to frame the resources and training required. As part of our staff mandatory training requirements, we have included patient safety level 1 and 2 modules.

PML will have governance arrangements in place to ensure that learning responses are not led by staff who were involved in the patient safety incident itself.

Responsibility for designating leadership of any learning response sits within the Governance Team in liaising with senior leaders across PML. A learning response lead will be nominated, and the individual should have an appropriate level of experience and training to respond to an incident. This may also depend on the nature and complexity of the incident and response required. Although national guidance states that learning response leads should be Band 8a (or equivalent) and above, PML is a small organisation with limited resources, and so it is accepted practice that lower bands will be trained to complete local incident responses but will have full support of the senior management team (SMT) and have direct oversight at director level.

PML will have governance arrangements in place to ensure that where possible learning responses for more complex cases are not undertaken by staff working in isolation. The Governance Team will support learning responses wherever possible and can provide advice on cross-system and cross-divisional working where this is required.

Those staff affected by patient safety incidents will be afforded the necessary managerial support and be given opportunity to participate in learning responses.

Training

PML has implemented a patient safety training package to ensure that all staff are aware of their responsibilities in reporting and responding to patient safety incidents as follows:

- Level 1 Essentials for Patient Safety: This is an e-learning module that all staff are required to complete every 3 years.
- Level 2 Access to Practice: This is an e-learning module for staff members with potential to support or lead patient safety incident management. They are required to complete training every 3 years.
- HSSIB - A systems approach to investigating and learning from patient safety incidents: This is a CPD accredited course for staff members leading incident investigations and other learning responses, and staff in PSIRF oversight roles.

8.0 Our Patient Safety Incident Response Plan (PSIRP)

Our plan sets out how PML intends to respond to patient safety incidents over a period of 12 months or as required. 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.

A copy of our current plan can be found on the PML website - https://www.physiologicalmeasurements.com/clinicalgovernance

9.0 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 as required 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 any previous versions.

A rigorous planning exercise will be undertaken every four years or more frequently if appropriate (as agreed with our integrated care board (ICB)) to ensure efforts continue to be balanced between

learning and improvement. This more in-depth review will include reviewing our response capacity, mapping our services, a wide review of organisational data (for example, patient safety incident investigation (PSII) reports, improvement plans, complaints, claims, staff survey results, inequalities data, and reporting data) and wider stakeholder engagement.

10.0 Responding to Patient Safety Incidents

Patient Safety Incident Reporting Arrangements

All staff are responsible for reporting any potential or actual patient safety incident to PML's Governance Team and all incidents are recorded on our incident reporting system (Radar). Senior members of staff are also expected to record any identified risks on the company risk register and manage these risks according to company policy.

Local managers and senior staff members ensure that patient safety incidents are responded to proportionately and in a timely fashion. This includes consideration where Duty of Candour may apply (following PML's Duty of Candour Policy).

Most incidents will only require local review within the service, however for some, where it is felt that the opportunity for learning and improvement is significant, these should be escalated appropriately (see Patient safety incident response decision-making below). The Governance Team will escalate any incident which appears to meet the requirement for reporting externally. This is to allow PML to work in a transparent and collaborative way with our ICB(s) and the CQC if an incident meets the national criteria for PSII or if supportive co-ordination of a cross-system learning response is required. The Governance Team will act as liaison with external bodies to ensure effective communication via a single point of contact for PML.

Patient Safety Incident Response Decision-Making

PML will have arrangements in place to allow it to meet the requirements for review of patient safety incidents under PSIRF. Some incidents will require mandatory PSII, others will require review by, or referral to another body or team depending on the event. These are set out in our PSIRP.

PSIRF itself sets no further national rules or thresholds to determine what method of response should be used to support learning and improvement.

Reporting of incidents will continue in line with existing policy and guidance. PML has governance and assurance systems in place to ensure oversight of all incidents. The Governance Team work with clinical and operational managers 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

- identification of any incidents requiring external reporting or scrutiny
- identification of any other incidents of concern, such as serious near-misses or significant failures in established safety procedures

The Governance Team will provide regular reports to the Senior Management Team to identify and track emerging themes and trends outside of normal variation. This information will be reviewed regularly against our identified priorities in the PSIRP to determine whether any shift in focus is required.

The principles of proportionality and a focus on incidents that provide the greatest opportunity for learning will be central to this decision making under PML's PSIRP. This may often mean no further investigation is required, especially where the incident falls within one of the improvement themes identified in the PSIRP, and this will be considered on a case-by-case basis with justification where necessary.

Timeframes for Learning Responses

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

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

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

Timescales for other forms of learning response
A learning response must be started as soon as possible after the patient safety incident is identified and should ordinarily be completed within one to three months of their start date. Quality improvement projects may have longer term timescales applied, depending on their complexity and resources available.

If the decision is made to report the incident on the Learning from Patient Safety Events (LFPSE) system, this should be completed by a member of the Governance Team as soon as is reasonably practicable using the Radar Quality Management System. All decisions to report to LFPSE must be made by a member of the Governance Team or Senior Management Team.

11.0 Safety Action Development and Monitoring Improvement

PSIRF moves away from the identification of 'recommendations' which may lead to determining a resolution at an early stage of the safety action development process.

PML acknowledges that any form of patient safety learning response (PSII or review) will allow the circumstances of an incident or set of incidents to be understood, but that this is only the beginning. To reduce risk, safety actions are needed.

PML will have systems and processes in place to design, implement and monitor safety actions using an integrated approach to reduce risk and limit the potential for future harm. This process follows on from the initial findings of any form of learning response that might result in the identification of further areas for improvement. PML will generate safety actions in relation to each of these defined areas for improvement. Following this, PML will have measures to monitor any safety action and set out review steps.

Safety action development will be completed in a collaborative way with a flexible approach and with the support of the Governance Team's quality improvement expertise.

Safety Action Development

PML will use the process for development of safety actions as outlined by NHS England in the Safety Action Development Guide (2022) as follows:

- agree areas for improvement – specify where improvement is needed, without defining solutions
- define the context – this will allow agreement on the approach to be taken to safety action development
- define safety actions to address areas of improvement – focussed on the system and in collaboration with teams involved
- prioritise safety actions to decide on testing for implementation
- define safety measures to demonstrate whether the safety action is influencing what is intended as well as setting out responsibility for any resultant metrics
- safety actions will be clearly written and follow SMART principles and have a designated owner

Safety Action Monitoring

Safety actions will consciously be monitored by the Governance Team to ensure any actions put in place remain impactful and sustainable.

12.0 Safety Improvement Plans

Safety improvement plans bring together findings from various responses to patient safety incidents and issues. PML's Governance Team has a centralised actions tracker in place and centrally manage PML wide quality improvement projects.

The PML PSIRP outlines the local priorities for focus of investigation under PSIRF. Where overarching systems issues are identified by learning responses outside of the local priorities, a safety improvement plan will be developed. These will be identified through the PML PSIRF governance structure and progress will be reported to the Senior Management Team via the Governance Team.

Safety action development will be completed in a collaborative way with a flexible and multidisciplinary approach and with the support of the Governance Team's quality improvement expertise.

13.0 Oversight Roles and Responsibilities

Principles of Oversight

Working under PSIRF, organisations are advised to design oversight systems to allow an organisation to demonstrate improvement rather than compliance with centrally mandated measures. PML has a PSIRF governance structure in place that enables effective incident management oversight as well as oversight of learning and safety actions completion and monitoring of their effectiveness.

Responsibilities

Alongside our NHS regional and local ICB structures and our regulators, the Care Quality Commission (CQC), we have specific organisational responsibilities with the Framework.

In order to meet these responsibilities, PML has designated the Deputy Director of Governance to support PSIRF as the executive lead.

The Deputy Director of Governance will provide direct leadership, advice, support in complex/ high profile cases, and liaise with external bodies, as required. The Deputy Director of Governance has the overarching responsibility for the quality of patient safety learning responses and PSIIs.

PML is committed to working with the ICB(s) and other national commissioning bodies as required. Oversight and assurance arrangements will be developed through joint planning and arrangements must incorporate the key principles detailed in the guidance, namely:

1. Compassionate engagement and involvement of those affected by patient safety incidents
2. Policy, planning and governance
3. Competence and capacity
4. Proportionate responses
5. Safety actions and improvement

14.0 Complaints and Appeals Process

Concerns and complaints are a valuable resource for monitoring and improving patient safety. PML recognises that there will be occasions when patients, residents, family members or advocates are

dissatisfied with aspects of the care and services provided. All types of feedback at PML are managed via the Complaints Policy & Procedure.

Complaints will usually be acknowledged within 3 working days, with a full response within 20 working days, and can be made in the following ways:

- By phone - 01691 676 496. Any option can be selected.
- By email – stwccg.feedback.pml@nhs.net
- Via the feedback form on our website - here
- In writing –
    - F.A.O Patient Experience
      Physiological Measurements Ltd
      The Old Malthouse
      Willow Street
      Oswestry