

| Policy for Patient Safety Incident Response |                                                                         |
|---------------------------------------------|-------------------------------------------------------------------------|
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## Version Control

| Version | Date         | Author                                                                | Comment                         |
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| 01      | March 2024   | Andrea O'Connell                                                      | First iteration                 |
| 02      | June 2025    | Kirsty Lower, Interim Head of Patient Safety and Quality (Governance) | Review and update of policy     |
| 03      | October 2025 | Kirsty Lower, Medical Governance and QI Manager                       | Amended to add reference to DCB |
| 04      | April 2026   | Kirsty Lower, Medical Governance and QI Manager                       | Review and update to policy     |

### 1. Purpose

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out how New Medical Systems Limited (Trading as Newmedica) and its associated Ophthalmic Joint Ventures (OJV) and Managed Services maintain effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety.

The PSIRF advocates a co-ordinated 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 organizational, systematic patient safety management.

This policy supports and promotes 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 should be read in conjunction with our Patient Safety Incident Response Plan.

### 2. Scope

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

Related Newmedica documents include:

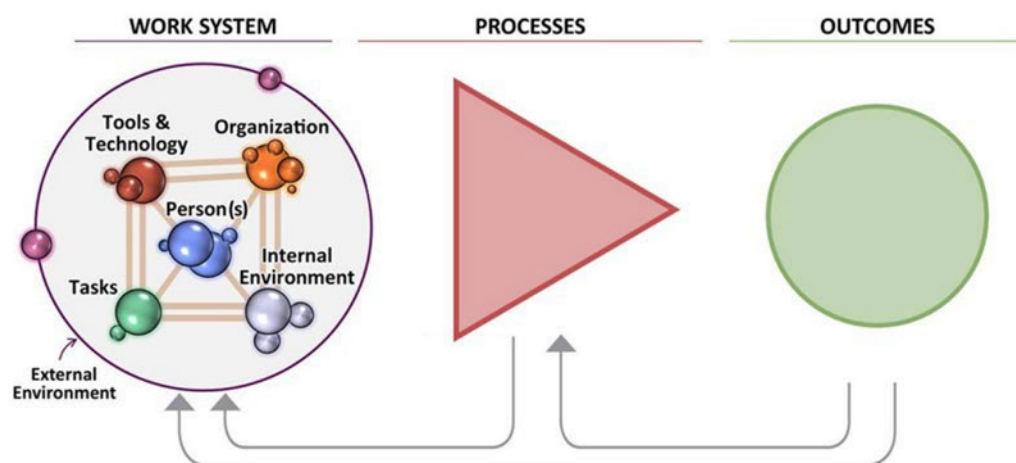
- POL-COR-01 Policy for Governance Structure and Processes
- POL-COR-06 Policy for Clinical Negligence Claims
- POL-CLI-02 Policy for Medical Emergencies
- POL-CLI-04 Policy for Infection Prevention & Control
- POL-CLI-06 Policy for Medicines Management
- POL-GOV-01 Policy for Monitoring Quality
- POL-GOV-07 Policy for Safeguarding Children
- POL-GOV-08 Policy for Safeguarding Adults
- POL-GOV-09 Policy for Being Open and Duty of Candour
- POL-GOV-13 Policy for Incident Management
- POL-GOV-14 Policy for Complaints
- POL-GOV-16 Policy for Clinical and Local Operational Audits
- POL-GOV-17 Policy for Raising Concerns (Freedom to Speak Up)
- POL-H&S-04 Policy for Health and Safety
- POL-P&M-11 Policy for Training, Experience and Qualification of Staff.

PSIRF uses a "systems-based approach" to identify what risks there are for patient safety and how to respond to these, to improve safety.

Newmedica responses to patient safety incidents will not take a ‘person-focused’ approach where the actions or inactions of people, or ‘human error’, are stated as the cause of an incident, but will take a systems approach.

A systems-based approach recognises that healthcare takes place in a complex work system composed of people, tools & technology, tasks, the organisational context and different environments (internal and external) in which care is provided. All these different aspects of the system vary from day to day and interact with each other to produce different outcomes. By exploring how the different aspects of a system work together, a deeper understanding of the risks and issues around patient safety incidents can be gathered, and more effective learning can be identified.

The systems-based approach selected by Newmedica, is the Systems Engineering Initiative for Patient Safety – SEIPS (See Figure 1). The SEIPs model helps organisations understand how the work system operates and interacts within itself (socio-technical system), which in turn can influence processes (work as done), ultimately shaping the outcome.



**Figure 1**

When responding to incidents and safety events under PSIRF, the focus is on learning for improvement and there is no remit to determine liability. Other processes outside of the scope of this policy that look at liability are detailed below:

- Clinical negligence claims
- People & Management policies like: Fitness to Practice, and Policy for Discipline and Conduct

Information from a patient safety response process can be shared with those leading other types of responses, as detailed above, but other processes should not influence the remit of a patient safety incident response.

### **3. Our Patient Safety Culture**

#### **3.1. What is a Just Culture?**

A ‘just culture’ is ‘one that balances fairness, learning and accountability.’ (Nursing and Midwifery Council (NMC), 2021). Accountability means a person taking

responsibility for their own decisions and actions. The success of PSIRF will rely on a just culture where staff, patients and their families can expect to be:

- Treated with kindness when a patient safety incident occurs
- Told the truth about what is known at the time the incident is recognised
- Asked what they would like to find out during the learning response (investigation) to the incident
- Involved in the response process if they choose to be
- Allowed to read, in full, the written response to the incident
- Asked to contribute to any actions which could improve safety where the learning response shows that these are required.

### 3.2. What is psychological safety?

Psychological safety is created in an environment where there is openness and trust that allows team members to feel comfortable taking risks and making mistakes. To be able to work in a psychologically safe environment, it is vital for healthcare professionals and patients to feel comfortable in sharing their concerns, fears or any other issues that might hinder (or reduce) the quality of patient care.’ (Psychological Safety Academy, 2022).

### 3.3. Being Fair Tool: Supporting Staff following a patient safety incident

Within Newmedica, our journey to embed the being fair tool is underway. We already have a strong foundation for embedding the being fair tool, which is completely aligned to our organisational values and behaviours, see Figure 2.



**Figure 2**

Our recent Great Place to Work Survey results identified overall that 84% of our colleagues responded positively to the statement, “taking into account, I would say that this is a great place to work” and 73% of colleagues responded positively to the statement “this is a psychologically and emotionally safe place to work”.

Our safety culture and the ability to speak up can be seen daily through the safety huddles that our services hold. Discussions at these huddles include: the safety and wellbeing of our colleagues, potential patient safety risks, and any recent patient safety incidents.

In addition, at Newmedica, we actively encourage colleagues to speak up and place real value on listening. By raising concerns, sharing ideas, and asking questions, our colleagues play a vital role in continually improving our services for patients and creating a positive, supportive working environment for everyone.

We are committed to ensuring that every colleague has a voice that truly counts and feels safe, confident, and supported to speak up. Equally important is our commitment to listening with care and respect, taking the time to understand the perspectives, concerns, and experiences that sit behind what is being shared.

To fortify our Freedom to Speak Up process, over the next 12 months we will be implementing the Safecall system. This system supports staff to raise concerns confidently and ensuring that actions are taken. This system has been proven to not only provide assurance but has also driven significant changes in practice and policy, ultimately enhancing the working lives of our staff. This is not to replace the current Freedom to Speak Up processes, but to add another avenue for staff to raise concerns. By integrating Safecall, we are providing an additional layer of support and security, ensuring that every voice is heard and every concern is addressed promptly and effectively.

Eye on Safety is our monthly Quality & Patient Safety Brief, that provides services with updates on patient experience, complaints, incidents and national alerts. It also includes highlights from the Medical Advisory and the Clinical Governance Committee's.

All our services have a monthly All Stop Day, whereby learning from local and national patient safety incidents are discussed.

To further support a change in our safety culture we:

- a) Continue to make updates and development to our incident reporting platform, Healthcare Guardian. Healthcare Guardian was rolled out in December 2023 and ensures we can easily capture incident data, identify areas of improvement, and build safety actions. It is a single joined-up assurance, compliance and performance platform that allows us to triangulate data from multiple sources to improve the care we provide.
- b) Introduced a Learning Handbook which pulls together learning summaries from multiple areas including incidents, complaints, good care and thematic

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reviews.

- c) We continue to review our Governance Structure to ensure we have strong oversight of patient safety and quality across all our services.
- d) We undertook a review and revamp of our Learning and Improvement sub-committee to ensure we have in-depth insight into our patient safety incident profile and oversight of quality improvement initiatives across the organization.

In February 2026, we undertook a Patient Safety Survey across our services to understand the current position of our safety culture. Colleagues across our services responded positively as follows:

| Question                                                                                                                 | % of Always & Often Answers |
|--------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| My OJV/Managed Service treats colleagues who are involved in an error, near miss or incident fairly                      | 93%                         |
| My OJV/Managed Service encourages us to report errors, near misses or incidents                                          | 99%                         |
| When errors, near misses or incidents are reported, my organisation takes action to ensure that they do not happen again | 97%                         |
| We are given feedback about changes made in response to reported errors, near misses and incidents                       | 94%                         |
| I would feel secure raising concerns about unsafe practice                                                               | 94%                         |
| I am confident that my OJV/Managed Service would address my concern                                                      | 93%                         |
| The care of patients / service users is my organisation's top priority                                                   | 98%                         |
| My OJV/Managed Service acts on concerns raised by patients/service users                                                 | 99%                         |
| I feel safe to speak about anything that concerns me in this organisation                                                | 90%                         |

These results have been shared across the services to tailor improvement plans to meet the needs of individual services.

### 4. Patient Safety Partners

In 2019, the NHS published the Patient Safety Strategy, which sets out how the NHS will support staff and providers to share safety insight and empower people (patients and staff) with the skills, confidence and mechanisms to improve safety.

Compassionately engaging and involving patients, their families and carers who are affected by patient safety incidents, is key to PSIRF and the Patient Safety Strategy.

PSIRF will enhance our safety and learning culture by creating much stronger links between a patient safety incident and learning and improvement. Our aim is to work in collaboration with those affected by a patient safety incident, our colleagues, our patients, their families and carers, to identify learning that will make a difference.

Transparency and openness with patients, their families and carers will ensure we have greater insight from when things have gone well and where things have not gone as planned.

The introduction of patient safety partners is the start of a journey to significantly change the way providers of NHS care (Newmedica) approaches patient involvement. It requires power sharing, a commitment to openness and transparency between staff and patients, as well as good leadership; it must not be a tokenistic exercise but one that the whole organisation is committed to. Patient Safety Partners are patients, carers or family members who are recruited to work in partnership with staff to influence and improve the governance and leadership of safety within an organisation (Newmedica).

Whilst Newmedica currently has one Patient Safety Partner, the aim is to recruit additional partners over the course of the next year.

Our Patient Safety Partners will:

- Support our Learning & Improvement Sub-committee.
- Be involved in developing and overseeing improvement projects around patient safety.
- Help review all patient facing documentation.

We have enjoyed the contributions of our patient safety partner and look forward to continuing on this journey to ensure safer, high-quality care tailored to the needs of our patients. Our patient safety partners are the voice of our patients and communities that use our services and ensure that the patient voice is at the forefront of all that we do.

### **5. Addressing Health Inequalities**

Newmedica recognises that those services delivering care on behalf of the National Health Service (NHS) 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 local population in an inclusive way. This includes using data intelligently to assess for any disproportionate patient safety risk to patients across the communities we serve, who may experience health inequalities.

Healthcare Guardian allows incidents to be analysed by protected characteristics and other determinants to give insight into any apparent inequalities. In addition, we are currently making changes to our patient administration system to capture key characteristics which will provide us with further insights.

Under PSIRF, our new incident response processes ensure that any particular part of an incident, which may indicate that health inequalities could have been a contributory factor, are addressed immediately through the use of local learning responses.

As an organisation we will ensure that our safety actions in response to learning from a patient safety incident considers inequalities, and this will be built into our documentation and governance processes.

Compassionate engagement with people who use our services, their families and carers and our colleagues following a patient safety incident is critical, and we will

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ensure that information is accessible to all, which may include developing easy read formats, and having translation and interpretation services available for any information we provide.

### **6. Engaging and Involving Patients, Families and Staff**

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.

All learning responses will be undertaken in psychologically safe environments, and where further emotional support is required, staff, patients, families and carers will be provided with advice for how to obtain this.

#### **6.1. Supporting Patients, Families and Carers**

Newmedica is firmly committed to continuously improving the care and services we provide. We want to learn from any incident where care does not go as planned or expected to prevent recurrence. 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, if we are to improve the care we provide.

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.

All staff should follow Newmedica Policy for Being Open (POL-GOV-09 Policy for Being Open and Duty of Candour). 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 preventing it happening again.

The regulatory aspects of Duty of Candour will be recorded on Healthcare Guardian and monitored at Clinical Governance Committee. Any patient safety incident that has an impact of moderate harm or above is monitored for statutory duty of candour, via Healthcare Guardian. Information provided to patients and families, including fulfilment of duty of candour, will be tailored to the individuals, taking into consideration their questions, concerns and wishes.

Patients and their families will be supported throughout the Patient Safety Incident Investigation process by someone in the local service, who has the skills and expertise to engage and support patients. A number of our services have and continue to invite patients to All-Stop days to share their experience and support teams to understand how care feels for the patient.

In addition, we undertake a carers survey to gather the views of our those that care for our patients and review the data on a monthly basis to understand how we can learn.

Other organisations that can support our patients include:

- Complaints Advocacy - The NHS Complaints Advocacy Service can help our NHS patients navigate our complaint system, they attend meetings and review information given during the complaint.
- Healthwatch - an independent statutory body who can provide information to help make a complaint, including sample letters for our NHS patients.
- The Parliamentary and Health Service Ombudsman makes the final decisions on complaints patients, families and carers deem not to have been resolved fairly by the NHS in England, or providers of NHS care.
- Independent Sector Complaints Adjudication Service (ISCAS) provides independent adjudication on complaints for our private patients.
- The Citizen's Advice Bureau provides UK citizens with information about healthcare rights, including how to make a complaint about care received.

### **6.1.1. The Power of Personal**

The future of healthcare demands more than expertise; it requires experts who care. Person-centered care and clinical excellence are not opposing forces; they are powerful allies. When deep clinical knowledge is combined with a genuine understanding of each individual, care becomes truly personalised: scientifically advanced, compassionate and holistic. This synergy strengthens trust between patients and caregivers, drives better outcomes, and empowers patients to take charge of their health creating the Power of Personal.

### **6.2. Support for Staff**

When things go wrong in healthcare, the staff who are involved can be affected significantly. The emotions and stress involved can impact their health and ability to continue to work. Newmedica offers in service support via the Operational and Clinical Directors, as well as a range of other support services via WeCare. WeCare provides an extensive range of virtual services, delivering holistic support to improve the medical, psychological, legal and financial wellbeing of our employees.

In addition, we have a Freedom to Speak Up Service available to ensure that everyone feels safe and confident to speak up.

## **7. Patient Safety Incident Response Planning**

The PSIRF supports organisations to respond to incidents and safety issues in a way that maximises learning and improvement, rather than basing responses on arbitrary and subjective definitions of harm. Beyond nationally set requirements, organisations can explore patient safety incidents relevant to their context, rather than only those that meet a certain defined threshold.

### **7.1. Nationally Defined Incidents**

As referenced in our Patient Safety Incident Response Plan, there are patient safety incidents that are nationally defined, which will require a Patient Safety Incident Investigation (PSII). For Newmedica there are three that are applicable, due to the services we provide:

| Patient Safety Incident Type                                                                                                                                       | Anticipated Improvement Route                                                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <b>Nationally Defined Patient Safety Events</b>                                                                                                                    |                                                                                                    |
| Incidents meeting the Never Events criteria.                                                                                                                       | Create local organisational safety actions and feed these into Newmedica quality improvement plan. |
| Death thought more likely than not due to problems in care (incident meeting the learning from deaths criteria for patient safety incident investigations (PSIIs). | Create local organisational safety actions and feed these into Newmedica quality improvement plan. |
| Death of a person with learning disabilities.                                                                                                                      | Respond to recommendations as required and feed safety actions into the quality improvement plan.  |

## 7.2. Locally Defined Incidents

Analysing Newmedica data over the last year (2025/26), has identified two other priorities that Newmedica should focus upon to maximise the impact of learning and reduce harm to patients. Each of our services (if/when applicable) will undertake one PSII and/or undertake a SEIPS review on each of the two priorities detailed below.

|                                                                                                                                                                                                              |                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <b>Locally Defined Patient Safety Events</b>                                                                                                                                                                 |                                                                                                    |
| Incidents associated with <b>patient cancellations</b> (cancellation by patient, cancellation by hospital – patient unfit, inadequate patient assessment).                                                   | Create local organisational safety actions and feed these into Newmedica quality improvement plan. |
| Incidents associated with the <b>integrity of medical records</b> (paper and electronic) including missing medical notes, notes not containing the relevant information, wrong patient information in notes. | Create local organisational safety actions and feed these into Newmedica quality improvement plan. |

It is worth noting that our services may also undertake a PSII after considering:

- The views of those affected, including patients and their families.
- What is known about the factors that lead to the incident(s)
- Whether there is evidence that improvement work is not having the intended effect/benefit
- If an organisation and its ICB are not satisfied risks are being appropriately managed.

This will be a locally led decision, made by the Operations Director and their Clinical Partners.

Irrespective of whether it is a nationally driven PSII response or a locally driven PSII, the learning that comes from these learning responses, will be fed into Newmedica overarching improvement plans. All PSII's will be signed off by the local service and then the Clinical Governance Committee.

### 7.3. Resources & Training to Support Patient Safety Incident Response

Newmedica is committed to ensuring that we fully embed the PSIRF and we have adopted the PSIRF training standards across all our services and within the support office. All learning responses will be adequately resourced (funding, time, equipment and training), whether this is in our local services or from the support office. All colleagues leading a learning response will be trained, in line with NHS England's framework for PSIRF. There are different levels of training for different staff groups across the organisation.

| Heading                 | Course/Topic                                                 | Staff Group                                   | Training Available        | Provided By                                                |
|-------------------------|--------------------------------------------------------------|-----------------------------------------------|---------------------------|------------------------------------------------------------|
| Patient Safety Syllabus | Level 1 a - Essentials for all staff                         | All staff                                     | e-LfH                     | Health Education England                                   |
|                         | Level 1b – For senior leaders and board members              | Senior leaders and board members              |                           |                                                            |
|                         | Level 2 – Introduction to systems thinking and human factors | Staff who undertake learning response         |                           |                                                            |
| PSIRF Mandated          | Systems-based approach to incident investigation             | Learning Response Leads (Investigation Leads) | 2-day in person training  | Internally delivered to include Patient Safety Specialist  |
|                         | PSIRF Oversight                                              | Oversight Lead                                | 1 day in person training  | Internally delivered to include Patient Safety Specialist  |
|                         | PSIRF CPD                                                    | Learning Response Leads (Investigation Leads) | Half day virtual training | Internally delivered, to include Patient Safety Specialist |
| PSIRF                   | Understanding PSIRF & the Clinicians Role                    | Clinical Directors                            | 2 x 1 hour sessions       | Internal to include Patient Safety Specialist              |

Each service will have individuals trained in Oversight and a minimum of two colleagues trained as Learning Response Leads. The Support Office will have Board and sub-board level colleagues trained in Oversight and the Clinical Quality and Governance team trained as Learning Response Leads.

## 7.4. Additional Training

The following additional training will be delivered via Master Classes to further support embedding the PSIRF across all of our services. These Master Classes will have a full slide deck, with learning notes, learning outcomes and training packs. Services, with the support of the Learning & Development Team and the Patient Safety and Quality Team will be able to deliver these master classes in a timeframe/at a pace that suits each individual service over the coming financial year (2026/27). This will help embed PSIRF across all our services and all teams.

In addition, we have implemented a train the trainer program with our Learning and Development team to support our services in rolling out the training in a structured and supported way.

| Master Class                                                                                                                                 | Duration (Hour) |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| What is PSIRF? – An introduction to the Patient Safety incident Review Framework                                                             | 1               |
| Introduction to Human Factors and Complexity in Patient Safety                                                                               | 1               |
| The principles of learning & improving as a result of a patient safety incident or near miss                                                 | 1               |
| The Systems Engineering Initiative for Patient Safety (SEIPS) model and how it is used in patient safety                                     | 1.5             |
| What is a SWARM huddle? – when to use it and how                                                                                             | 1.5             |
| System based learning tools – understanding everyday work (undertaking an observation, walkabout and link analysis)                          | 1.5             |
| Learning response methods – what are Multidisciplinary Team meetings (term) and After-Action Reviews, and top tips for how to undertake them | 1               |
| When and how to undertake a Thematic Review or Horizon Scan                                                                                  | 1               |
| The approach to undertaking a Patient Safety Incident Investigation (PSII) starting with scope and terms of reference                        | 1               |
| Identifying, engaging and managing stakeholders                                                                                              | 1               |

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|                                                               |     |
|---------------------------------------------------------------|-----|
| Engaging patients and colleagues                              | 1   |
| Undertaking a timeline as a core component of the PSII        | 1.5 |
| How to have effective 'Exploratory Discussions'               | 1.5 |
| What is a Work System Scan? – how to do it and when to use it | 1   |

| Master Class                                        | Duration (Hour) |
|-----------------------------------------------------|-----------------|
| Effective safety action development for improvement | 1               |
| Writing a good PSII report                          | 1               |

### 7.5. Our Patient Safety Incident Response Plan

Our plan sets out how Newmedica and its associated OJVs intend to respond to patient safety incidents over a period of 18 to 24 months. Our plan is not a permanent rule that cannot be changed. As an organisation, we will remain flexible and continually review patient safety incidents and patient feedback to identify any new, emerging themes or trends in patient safety that may influence this plan and future iterations. The plan is underpinned by our organisational policies and electronic incident reporting system, Healthcare Guardian.

To identify our patient safety risks and incident profile, Newmedica undertook a thematic review of the following information from the 1 April 2025 to the 31 March 2026:

- a) Patient safety incidents
- b) Complaints
- c) Claims
- d) Subject access requests
- e) Patient Feedback

### 7.6. Reviewing our Patient Safety Incident Response Policy & 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 18 to 24 months 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 to 18 months.

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

## **8. Responding to Patient Safety incidents**

### **8.1. Patient Safety Incident Reporting Arrangements**

Reporting patient safety events, whether they result in harm or not, provides vital insight into what can go wrong in healthcare, and the reasons why. As such, Newmedica reports into the Learn from Patient Safety Events (LFPSE) service. This is a national system for the recording and analysis of patient safety events that occur in healthcare. At national level, it allows for new, or under recognised safety issues to be quickly identified and acted upon on a wide scale, ensuring providers across the country take action to reduce risk.

#### **8.1.1. Internally Reported**

All staff within Newmedica and across our services are responsible for reporting any potential or actual patient safety incident on Healthcare Guardian, our internal incident management system. The reported incident will be reviewed initially at service level and a decision made on what response, if any, is required. There should be regular service reviews of incidents by the governance lead/operational director or manager to ensure incidents are appropriately classified and then responded to in a proportionate and timely manner. The local service may seek support from the Clinical Quality and Safety Team.

For those incidents that meet the national or local criteria for a PSII, or where a CQC notification is required, the service will contact the Clinical Quality and Safety team for advice and a decision will be made on who leads the investigation. The Clinical Quality and Safety team will support services when liaising with external bodies and partners.

The type of response the service chooses to utilise will be based on the following three areas:

- a) Learning – If contributory factors are not well understood and local improvement work is minimal, a learning response may be required to fully understand the context and underlying factors that influenced the patient safety incident and outcome. Types of PSIRF tools used in this scenario include: PSII, Multi-disciplinary learning event, swarm huddle, after action review. May supplement findings with everyday work using observation, walkthrough or link analysis.
- b) Improvement – Where a safety issue or incident type is well understood (e.g. because previous incidents of this type have been thoroughly investigated and national or local improvement plans targeted at contributory factors are being implemented and monitored for effectiveness) resources are better directed at improvement rather than repeat investigation. Types of PSIRF tools used in this scenario include: Thematic review, horizon scanning.
- c) Assessment – For issues or incidents where it is not clear whether a learning response is required. Types of PSIRF tools used in this scenario include: Structured judgement review, case note reviews.

### 8.1.2. Externally Reported

Patients, families, carers and external agencies may report a Newmedica patient safety incident via the NHSE website NHS England – [Patient and Public Reporting Website – Reporting Form Step 1 \(nrls.nhs.uk\)](https://nrls.nhs.uk)

### 8.2. Patient Safety Incident Response Decision Making

Besides the locally and nationally mandated patient safety incidents, that require a PSII, the PSIRF has not set any further rules or thresholds to determine what method of response should be used following a patient safety incident. This will be a local service decision. Services must follow the process below:

| STAGE ONE (Incident)                                      |                                                                                                                     |                                                                                                                                |                       |
|-----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Is everyone OK?                                           | 1. Incident or near miss identified.                                                                                |                                                                                                                                | Immediate             |
|                                                           | 2. Ensure staff, patients, environment safe.                                                                        |                                                                                                                                |                       |
|                                                           | 3. Compassionate engagement of those impacted by incident (Patient, family, carers or staff).                       |                                                                                                                                |                       |
| Immediate learning - What do we know, validate the facts? | 4. Where applicable, identify and record immediate learning (SEIPS Template).                                       |                                                                                                                                | Immediate             |
| STAGE TWO (Incident Triage)                               |                                                                                                                     |                                                                                                                                |                       |
| Record Incident                                           | 5. Record on Healthcare Guardian                                                                                    |                                                                                                                                | Within 2 working days |
| Assess Incident                                           | 6. Assign Harm Level                                                                                                |                                                                                                                                |                       |
|                                                           | 6.1 – No or Low Harm                                                                                                | 6.2 – Moderate or Above Harm                                                                                                   |                       |
|                                                           | For no or low harm incidents, or no safety concerns – ensure openness and transparency with patient, family, carers | For moderate or above incidents – ensure Statutory Duty of Candour process followed. Contact Clinical Quality and Safety team. |                       |
|                                                           | 7. Is the incident a national or local priority                                                                     |                                                                                                                                |                       |

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|                                       |                                                                                                                                                                                                                               |                                                                                                               |                          |
|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|--------------------------|
|                                       | Yes: Report to Clinical Quality & Governance team, agree if PSII is required and who will lead.                                                                                                                               | No: The Service decides on local learning response, may seek support from Clinical Quality & Governance team. |                          |
|                                       | Both types of responses may use any of the suite of PSIRF Tools detailed below.                                                                                                                                               |                                                                                                               |                          |
| STAGE THREE (Learning Response)       |                                                                                                                                                                                                                               |                                                                                                               |                          |
| Gather Information, Identify Learning | 8. Learning response begins, the decision on next steps is based on:<br>a. Initial learning (Nº. 4)<br>b. Whether there are any safety concerns<br>c. Does the response need to focus on learning, improvement or assessment? |                                                                                                               | Within 7-14 working days |
|                                       | 9. Gather information using the PSIRF tools and involve those affected                                                                                                                                                        |                                                                                                               | Within 60 working days   |
|                                       | 10. Finalise learning                                                                                                                                                                                                         |                                                                                                               |                          |
| Improvement                           | 11. Develop safety actions                                                                                                                                                                                                    |                                                                                                               |                          |
|                                       | 12. Upload learning and safety actions onto Healthcare Guardian                                                                                                                                                               |                                                                                                               |                          |

All our services have access to a suite of PSIRF tools to help guide them in their response, process as detailed below:

| <b>SUITE OF PSIRF TOOLS FOR NEWMEDICA SERVICES</b> |                                        |                                          |                                          |
|----------------------------------------------------|----------------------------------------|------------------------------------------|------------------------------------------|
| <b>Overarching Approach</b>                        | SEIPS Framework                        |                                          |                                          |
| <b>National/ Local Priority Tools</b>              | <b>General Learning Response Tools</b> | <b>Understanding Everyday Work Tools</b> | <b>Broad Patient Safety Issues Tools</b> |

| SUITE OF PSIRF TOOLS FOR NEWMEDICA SERVICES                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                     |                                                                                                                                              |                                                                                                       |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>Stakeholder Map</li> <li>Terms of reference template</li> <li>PSII Report template &amp; Evaluation</li> <li>Interview templates</li> <li>Safety action development tools</li> <li>Debrief tools</li> <li>Timeline mapping</li> <li>Work system scan</li> </ul> | <ul style="list-style-type: none"> <li>Multi-disciplinary Learning Event</li> <li>Swarm Huddle</li> <li>After Action Review</li> <li>Timeline mapping</li> <li>Interview tools</li> <li>Work system scan</li> </ul> | <ul style="list-style-type: none"> <li>Link analysis</li> <li>Observations</li> <li>Interview tools</li> <li>Walkthrough analysis</li> </ul> | <ul style="list-style-type: none"> <li>Horizon scanning</li> <li>Thematic review templates</li> </ul> |

Emergent issues and trends will be identified locally in services governance meetings, and via the Learning and Improvement Sub-committee for all organisational wide issues and trends.

### 8.3. Responding To Cross-System Incidents/issues

The Clinical Quality and Safety team will liaise directly with any external organisation to support wider system learning. We will work closely with all our ICB's to facilitate any incident that crosses more than one organisation. This encourages a more cohesive and effective method of learning.

### 8.4. Timeframes for Learning Responses

We recognise the impact prolonged investigations can have on patients, their families and carers and our staff. We are committed to limiting time frames to ensure the opportunity to implement change has not passed and that our patients, their families and carers and staff, get a satisfactory, timely response. Whilst the timeframe for each incident will be agreed locally, in conjunction with those involved, we are limiting the overall timeframe for a PSII to 60 working days. In exceptional circumstances, a longer timeframe may be required for completion of the PSII, if so, this will be agreed following discussions with those involved.

The majority of learning responses will be completed between 5 and 30 working days.

Throughout our learning responses we will maintain close contact with those involved to keep them updated.

### 8.5. Safety Action Development, Monitoring Improvement, Improvement Plans

Safety actions will be developed by the local services, with the support if needed, of

## POLICY FOR PSIRF

the Clinical Quality and Safety team. Staff in the area that the incident occurred, will be directly involved in developing the safety actions. The safety actions will be based on the recommendations of the learning response leads/investigator.

The safety actions should be signed off by the Operational and/or Clinical Directors and then monitored at the monthly governance meetings. All actions should be Specific, Measurable, Achievable, Relevant and Time-bound (SMART).

Safety actions developed as part of any Newmedica wide improvement plan will be monitored at the Learning and Improvement Sub-committee and Clinical Governance Committee. There will be local and Newmedica service improvement plans. Local service improvement plans will focus on local incidents. Newmedica wide improvement plans will be developed when there are re-occurring incidents across all services, such as the three local priority areas identified.

### 9. Sharing Learning

Learning will be shared via several mechanisms:

- Shared Learning Handbook
- Clinical Governance Committee
- Medical Advisory Committee
- Local All Stop Days

### 10. Oversight Roles and Responsibilities

#### 10.1. 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.

- Newmedica will follow the PSIRF 'mindset' principles to underpin the processes we have put in place to allow us to implement PSIRF:
  - Improvement is the focus: We will enable and monitor improvements in the safety of care, not simply monitoring investigation quality.
  - Blame restricts insight: Our learning will focus on identifying system factors that contributed to the PSII/s, not finding individuals to blame.
  - Learning from PSI is a proactive step towards improvement: In responding to a PSII for learning, we will be taking an active step towards continuous improvement.
  - Collaboration is key: We will embed collaborative oversight across all of our services, as meaningful approaches to oversight cannot be developed and maintained by individuals or organisations working in isolation.
  - 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.
  - Curiosity is powerful: Our leaders have a unique opportunity with

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PSIRF to do more than measure and monitor. They can and should use their position to influence improvement through curiosity – asking questions to understand, rather than judge.

## 10.2. Responsibilities

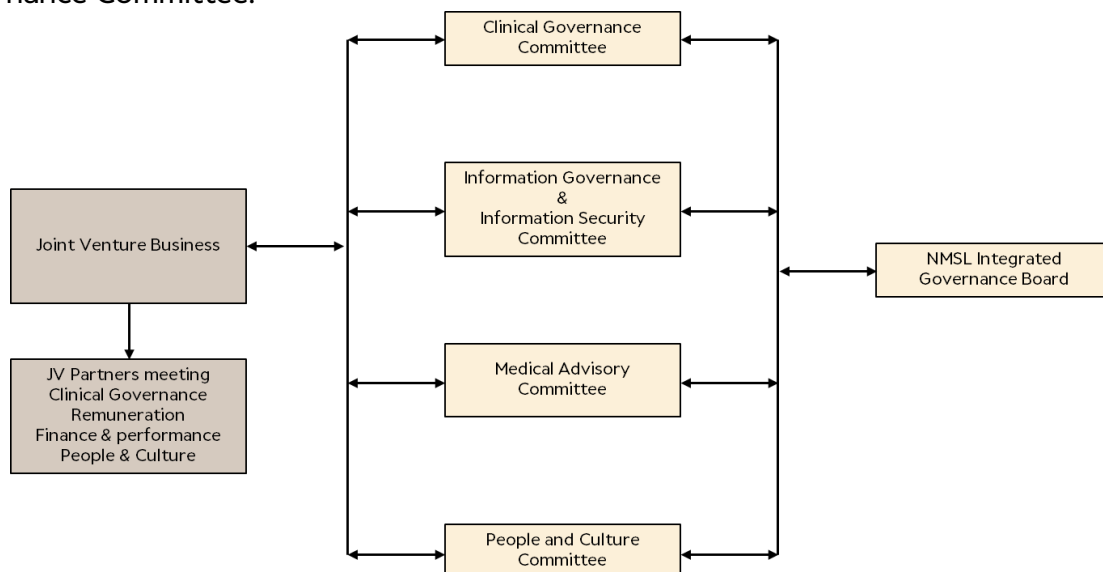
Alongside our NHS regional and local ICB structures and our regulator, the Care Quality Commission, we also have specific organisational responsibilities with the Framework.

To meet these responsibilities, Newmedica has designated the Clinical Quality and Governance Director to support PSIRF as the executive lead. Their role will be to ensure that the organisation meets the national patient safety standards. They will also oversee the development, review and approval of the Newmedica's policy and plan ensuring that they meet the expectations set out in the patient safety incident response standards. The policy and plan will promote the restorative just working culture that the Newmedica aspires to.

To achieve the development of the plan and policy, Newmedica will be supported by internal resources within the Clinical Quality and Safety team.

### 10.3. Governance Arrangements

New Medical Systems Board will receive assurance regarding the implementation of PSIRF and associated standards via existing reporting mechanisms such as the Clinical Governance Committee.



Services will provide assurance to the Learning & Improvement Sub-committee and the Clinical Governance Committee that PSIRF and related workstreams have been implemented to the highest standards. Our services will be expected to ensure Healthcare Guardian is continually updated and there is ongoing monitoring and review of all their patient safety incidents and delivery of safety actions and improvement.

Each service will have arrangements in place to manage the local response to patient safety incidents and ensure that key incidents that require escalation to the Clinical Quality and Safety team are escalated appropriately.

#### 10.4. Quality Assuring Learning Response Outputs

The Clinical Quality and Safety team will ensure that PSIs are conducted to the highest standards, to support the executive sign off process at service level and via Clinical Governance. A PSI evaluation document has been created to support evaluation both at service and support office level.

The Clinical Quality and Safety team will ensure that learning is shared across the organisation and safety improvement work is adequately directed.

#### 11. Complaints and Appeals

Newmedica is firmly committed to continuously improving the quality of care and services it provides. One of its aims is to ensure the satisfaction of its patients and their families. It therefore encourages the views, comments and suggestions of its patients, their relatives, and all other users of the services provided by Newmedica.

Any patient or member of their family who is dissatisfied is entitled to voice their comments, concerns or complaints, and to have them taken seriously; properly investigated, explained and resolved. This will be achieved through open conversations, explanations being provided, errors being acknowledged, an apology being made where appropriate and lessons being learnt. The aim will always be to resolve the complaint locally to the satisfaction of all involved. Patients, their families or carers may raise an informal concern or complaint as detailed below:

**Informal Concern:** An informal concern or enquiry may be received in writing or verbally to the local service, requiring staff to act on a local level focusing on early resolution as appropriate. This may take the form of clarifying the situation and/or acting to remedy the problem. An informal concern is resolved promptly, ideally within 24 to 48 hours and does not require a formal written response, although discretion falls with the service as to whether they wish to provide one if deemed appropriate.

**Formal Complaint:** A formal complaint is usually (but not necessarily) written. A formal complaint is one that cannot be resolved immediately and will usually require investigation. All formal complaints require a written response from the relevant Registered Manager or Clinical Director/ Clinical lead, or from the Managing Director, dependent on the stage of the complaint, and this management process distinguishes the formal complaint from the informal concern. There are three stages to the formal complaints process:

- Stage 1 – Local Resolution Stage 1 is dealt with by the Registered Manager or Clinical Director for the Service.
- Stage 2 – Complaint Review Stage 2 is dealt with by the Managing Director who will assign to the Complaint and Patient Experience Lead, as an independent investigation manager for the complaint.
- Stage 3 – Signposting to an Ombudsman Service Stage 3 is conducted (once Stages 1 and 2 have been completed) by the Parliamentary and Health Service Ombudsmen if the patient is funded by the NHS or by Independent Healthcare Sector Complaints Adjudication Service (ISCAS).

## 12. DCB-0160 Compliance Statement

Newmedica's governance framework incorporates the NHS Digital Clinical Safety Standard DCB-0160 to ensure the safe deployment and use of health IT systems across the organisation. Compliance is overseen by our Clinical Safety Team through our Clinical Risk Management System, which aligns with Newmedica Risk Management Policy and our governance structure and includes the following key components:

- **Clinical Risk Management Plan:** This document outlines the governance responsibilities, processes, and escalation pathways for managing clinical risks associated with digital systems.
- **Hazard Log:** Maintained for each system, this log records identified hazards, risk assessments, mitigations, and status updates. It is reviewed by the Clinical Safety Team and relevant governance committees.
- **Clinical Safety Case Report:** Developed for each health IT system, this report consolidates safety assurance evidence and confirms that clinical risks have been appropriately addressed.

These documents are governed centrally and reviewed in line with our policy lifecycle and governance oversight processes. All relevant committees, including the Clinical Governance Group and Medical Advisory Committee, are accountable for ensuring DCB-0160 compliance is upheld and documented.

**13. Equality Impact Assessment**

|    |                                                                                                                                                                                                       | Yes/No | Comments |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------|
| 1. | Does the policy/guidance affect one group less or more favourably than another on the basis of:                                                                                                       |        |          |
| a  | • Gender.                                                                                                                                                                                             | No     |          |
| b  | • Marital Status (including Civil Partnership),                                                                                                                                                       | No     |          |
| c  | • Gender Reassignment,                                                                                                                                                                                | No     |          |
| d  | • Disability including <ul style="list-style-type: none"> <li>– Learning Disabilities,</li> <li>– Physical Disabilities,</li> <li>– Sensory Impairment,</li> <li>– Mental Health Problems,</li> </ul> | No     |          |
| e  | • Race, Nationality or Culture,                                                                                                                                                                       | No     |          |
| f  | • Age,                                                                                                                                                                                                | No     |          |
| g  | • Sexual Orientation (including Lesbian Gay or Bisexual People),                                                                                                                                      | No     |          |
| h  | • Religion or Belief,                                                                                                                                                                                 | No     |          |
| i  | • Trade Union Membership,                                                                                                                                                                             | No     |          |
| j  | • Pregnancy or Maternity,                                                                                                                                                                             | No     |          |
| 2. | Is there any evidence that some groups are affected differently?                                                                                                                                      | No     |          |
| 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?                                                                                                                                           | No     |          |
| 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    |          |

**Appendix 1: PSII Evaluation Document****Patient Safety Incident Investigation: Quality Evaluation Checklist**

This document sets out a structured approach to evaluating the quality of PSII's. Its purpose is to support a consistent and learning focused review of investigations, ensuring they align with the principles of PSIRF. By focusing on systems-based learning, compassionate engagement, and meaningful improvement actions, this document helps ensure investigations contribute to safer care rather than simply describing events.

|                    |  |
|--------------------|--|
| Incident Reference |  |
| Reviewer           |  |
| Date Reviewed      |  |

**A. PSIRF alignment and proportionality**

- ☐ The scope of investigation is proportionate
- ☐ The investigation focuses on learning, without blame
- ☐ The terms of reference and key questions are answered within the report

**B. Systems-based analysis**

- ☐ The report explains how and why the incident occurred
- ☐ Contributory factors beyond individual actions are explored
- ☐ System factors considered

**C. Engagement and involvement**

- ☐ Compassionate engagement with those affected is evident
- ☐ Patient / family perspectives are reflected where appropriate
- ☐ Staff involved have been supported and engaged

**D. Quality of learning and improvement**

- ☐ Clear learning is identified
- ☐ Learning is system-focused
- ☐ Safety actions link directly to identified learning
- ☐ Safety actions address system issues
- ☐ Safety actions are specific, owned and measurable
- ☐ Monitoring arrangements are clear

**E. Overall quality and clarity**

- ☐ The report is clear and well structured
- ☐ The report has been checked for spelling and grammatical errors
- ☐ Explains how and why the incident occurred, not just what happened.
- ☐ Someone unfamiliar with the incident can follow the report
- ☐ Report language aligns with a fair and just culture
- ☐ Organisational and PSIRF expectations are met

### What good looks like

- Clear rationale for the investigation approach
- Strong systems-based analysis
- Investigation findings linked back to TOR's / Key Questions
- Meaningful engagement with patients, families and staff evident
- Insightful and specific learning
- Actionable, system-focused improvement actions
- Respectful language aligned with just culture

### Common Pitfalls

- Over-descriptive reports with limited analysis
- Focus on individual error rather than system factors
- Token engagement
- Actions not linked to learning
- Hindsight bias
- Unclear ownership of actions