Patient Safety Incident Response Plan

Version 1

Policy Profile	
Version:	1
Policy Owner:	Head of Clinical Governance & Risk
Responsible Executive Director:	Medical Director (Board level)
Author/s	Louise Harrison, Kim Kaur
Target audience:	All Optegra
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Document Management

(latest version at the top of the list)

Version	Date	Changes made by:	Summary of changes:
1.1	24.05.2024	KK (Kim Kaur) Governance and Quality Lead	TOR updated with AAR Implementation updated with QILT responsibility and safety action plan development guide

Contents:

1.0 Introduction

The patient safety incident response framework (PSIRF) represents a significant shift in the way clinical organisations respond to patient safety incidents. It is a key part of the NHS patient safety strategy.

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

- 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
- Supportive oversight focused on strengthening response system functioning and improvement.

When things go wrong, patients are at risk of harm and others may be affected. The emotional and physical consequences for patients and their families can be devastating. For the staff involved, incidents can be distressing and members of the clinical teams to which they belong can become demoralised and disaffected. Safety incidents may incur costs through lost time, additional treatment and support, complaints, and litigation. most commonly these incidents result from system design issues, not mistakes by individuals.

2.0 Purpose

This patient safety incident response plan (PSIRP) sets out how Optegra will seek to learn from patient safety incidents reported by staff and patients, their families and carers as part of our work to continually improve the quality and safety of the care we provide.

This plan will help us measurably improve the efficacy of our patient safety incident investigations (PSII) by:

a. Refocusing Patient safety incident investigation towards a systems approach and the rigorous identification of interconnected causal factors and system issues.

b. Focusing on addressing these causal factors and the use of improvement science to prevent and reduce repeat patient safety risks and incidents.

c. Transferring the emphasis from the quantity to the quality of PSIIs such that it increases our stakeholders' (notably patients, families, carers and staff) confidence in the improvement of patient safety through learning from incidents.

d. Demonstrating the added value from the above approach.

3.0 Scope

This Policy applies to all members of staff throughout the organisation including locum, bank, agency staff and contractors whether they deal with patients and visitors face-to-face or on the telephone.

4.0 Definitions

PSIRF	Patient safety Incident response framework
PSIRP	Patient safety incident response plan
PSII	Patient safety incident investigation
QILT	Quality Improvement learning & safety team
IS	Investigation Supervisor
LI	Lead Investigator
FTSU	Freedom to Speak Up
AAR	After Action Review

5.0 Roles and Responsibilities

Managing Director

Responsible to the Board of Directors

The Managing Director has overall responsibility for the effective management of all patient safety incidents, including contribution to cross-system/multi-agency reviewed and/or investigations where required.

With the executive and non-executive team, model behaviours that support the development of patient safety reporting, learning and improvement system.

Ensure that systems and processes are adequately resourced including: funding, management time, equipment and training.

Medical Director

Executive lead responsible for supporting and overseeing implementation of the Patient Safety Incident Response Framework (PSIRF)

Head of Clinical Governance & Risk

Is the Patient Safety Specialist. Ensuring processes are in place to support an appropriate response to patient safety incidents (including contribution to cross-system/multi-agency reviews and/or investigation where required).

Oversee development and review of Optegra's PSIRP.

Agrees sufficient resources to support the delivery of the PSIRP, including support for those affected, e.g. named contacts for staff, patients, families, and carers where required.

Ensures Optegra complies with the national patient safety investigation standards.

Establishes procedures for agreeing patient safety investigation reports in line with the national patient safety investigation standards.

Develops professional development plans to ensure that staff have the training, skills and experience relevant to their roles in patient safety incident management.

The Quality Improvement and Learning Safety Team

Ensures that patient safety investigations are undertaken for all incidents that require this level of response.

Ensures that Optegra reports incidents to the LFPSE (Learn from Patient Safety Events) system.

Develops and maintains local risk management systems and relevant incident reporting systems to support the recording and sharing of patient safety incidents and monitoring of incident response processes. (RADAR)

Ensures Optegra has procedures that support the management of patient safety incidents in line with Optegra's PSIRP (including convening review and investigation teams as required and appointing trained named contacts to support those affected).

Established procedures to monitor/ review investigation progress and the delivery of improvements.

Works with executive lead to address identified weaknesses/areas for improvement in Optegra's response to patient safety incidents including gaps in resource including skills and training.

Supports and advises staff involved in the patient safety incident response.

Investigation Supervisors

Ensure that investigations are undertaken in line with the patient safety investigation standards.

Ensure they are appropriately trained and skilled to undertake the investigation assigned to them and if not request it is reassigned.

Undertake patient safety investigations and patient safety investigations related duties in line with current national guidance and training.

Lead Investigators

With the direction of the investigation supervisor undertake investigations in line with the patient safety investigation standards.

Ensure they are appropriately trained and skilled to undertake the investigation assigned to them and if not request it is reassigned.

Undertake patient safety investigations and patient safety investigations related duties in line with latest national guidance and training.

Lead investigators will complete a systems approach to learning from patient safety Incidents level 2 as a minimum.

6.0 Strategic Aims and Objectives

Improve the safety of the care we provide to our patients and improve our patients' and their families' experience of it.

Further develop systems of care to continually improve their quality and efficiency.

Improve the experience for patients and their families and carers wherever a patient safety incident or the need for a PSII is identified.

Improve the use of valuable healthcare resources.

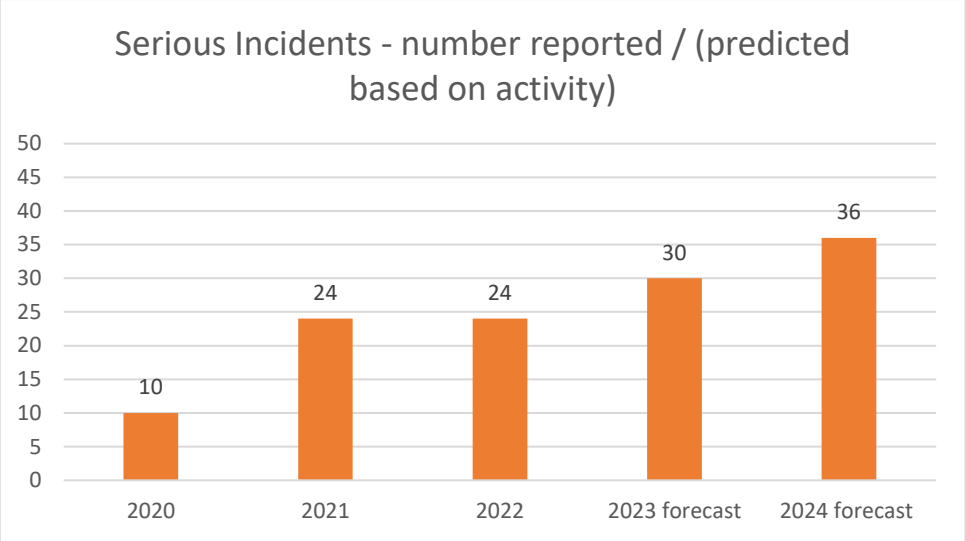
Improve the working environment for staff in relation to their experiences of patient safety incidents and investigations.

Act on feedback from patients, families, carers, and staff about the current problems with patient safety incident response and PSIIs.

Develop a climate that supports a just culture and an effective learning response to patient safety incidents and good practice.

7.0 Local review of activity and resources

Optegra serious Incident investigations activity. Information gathered from RADAR Incident reporting system. Predicted numbers based on organisation growth predications.



Based on available data the number of incidents reaching the threshold for serious incident categorisation will grow in line with organisational growth.

Priority investigations will focus on:

- Never Events
- Unexpected incidents which signify an extreme level of risk to patients
- Actual and potential impact of the incident's outcome (harm to people, service quality, public confidence, products, funds, etc.)
- Likelihood of recurrence (including scale, scope and spread)
- Potential for new learning in terms of:
    - enhanced knowledge and understanding of the underlying factors.
    - improved efficiency and effectiveness (control potential)
    - opportunity to influence wider system improvement.

- Optegra priorities based on local risk assessments these include but are not limited to.
    - Endophthalmitis cases
- Unplanned outcomes for patients where sight outcomes following treatment have not reached the pre- surgery agreed expectation.

The table below represents 12 months data of serious incidents 2022 (24) which would fall into the patient safety investigation process.

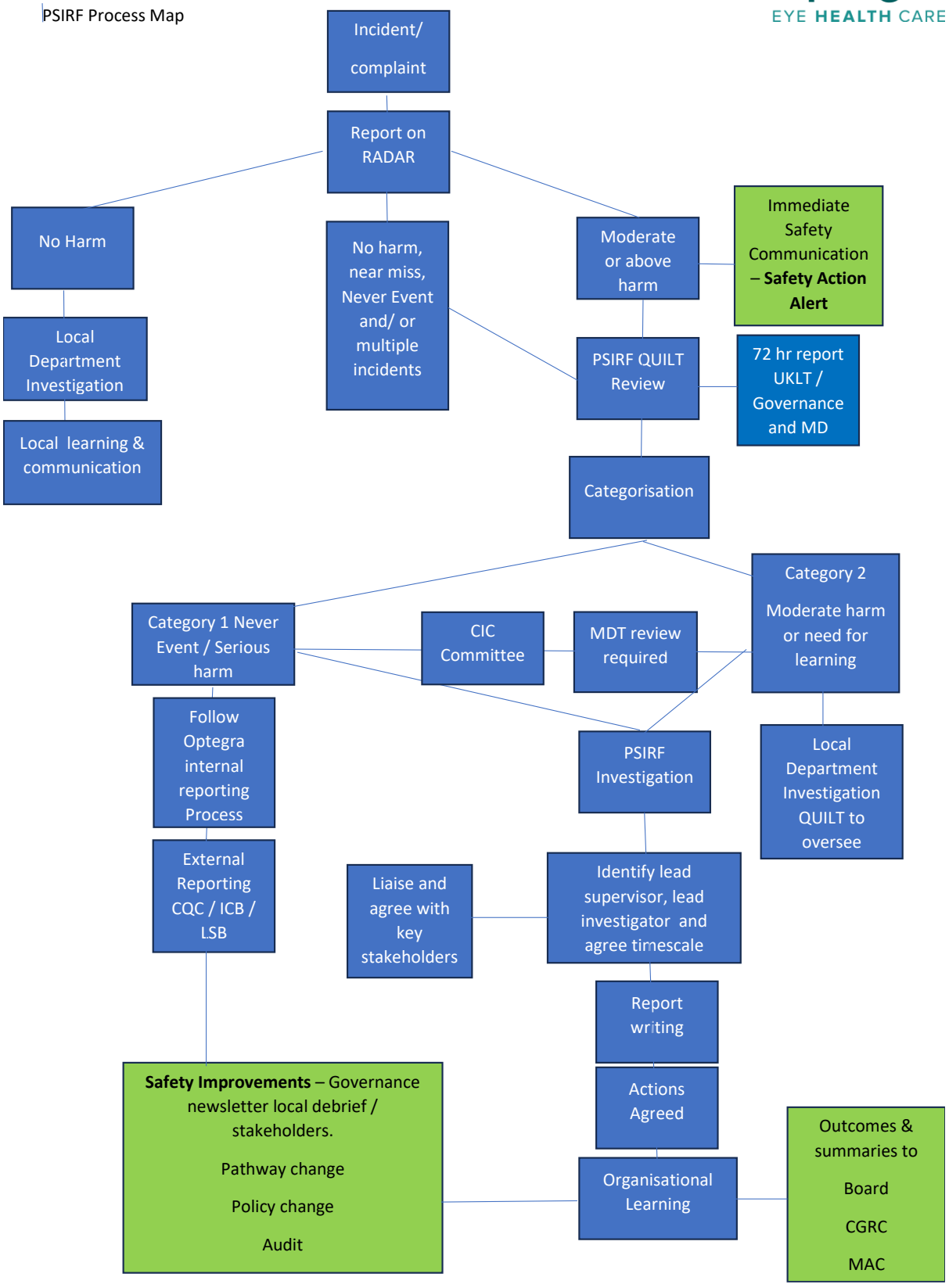
Category	Number
Endophthalmitis – unconfirmed or confirmed	6
Wrong Lens – may or may not be categorised as a Never Event	5
Wrong Site surgery (Never Event)	1
Complication of surgery resulting in poor outcome for the patient	12

The tables below outline the framework. the stages of the investigation process and the estimated resource for each patient safety incident investigation.

Investigation Stage	**Responsibility**	**Estimated Resource (HRs)**
1. Plan the investigation QIL Team		
a. Appoint investigators who are trained, competent, have secure protected time and sufficient support. b. Inform and engage with the patient/family and staff involved in agreeing scope.	QIL Team Investigation Supervisor and/or Lead	2 hours weekly
2. **Gather and map the information** (**WHAT** Happened**)**		
c. Identify the WHO, WHERE and WHEN of the incident. d. Identify WHAT happened. e. Map the incident timeline from the HCR, incident report and/or complaint letter.	Lead Investigator/ Investigation Supervisor 10 working days	

f. Add further detail and achieve mutual understanding via meetings/interviews with the patient/family and staff involved.	
3. Identify Problems (HOW it happened and variations from what was expected to happen)	
g. Identify and reference good practice requirements (work as imagined) h. Identify the key problems arising.	Lead Investigator/ Investigation Supervisor /Subject Matter Expert 5 working days
4. **Analyse contributory and causal factors** (**WHY** these key problems arose)	
i. Observe and discuss how work is routinely done (work as done) j. Search for contributory and causal factors for each key problem (deep-seated reasons WHY)	Lead Investigator/ Investigation Supervisor 5 working days
5. **Write Investigation Report-** with clarity, openness and in full consultation with patient/family and staff	
k. Write investigation report.	Lead Investigator/ Investigation Supervisor 5 working days
6. Develop Recommendations and Action Plan	
l. Identify and develop strong systemic improvements (using HF principles) m. Develop action plan. n. Review effectiveness of actions/improvements in reducing or preventing repeat incidents. o. Arrange an after action review meeting	Lead Investigator/ Investigation Supervisor QIL Team/Safety Investigation Assurance and Learning Group 1 working day

PSIRF Process Map



8.0 Implementation

All incidents with the severity of moderate harm and above and those which are considered a near miss or with the potential to cause harm will be discussed weekly by the Quality Improvement and Learning team who will review the incidents against the framework and agree a planned approach for each incident. Complaints where harm is identified will also be reviewed by the QIL Team.

Priorities for 'being open' conversations and Duty of Candour include:

- all patient safety incidents leading to moderate harm or above.
- all incidents for which an investigation is undertaken.

Guidance on Duty of Candour is available in Optegra's Duty of Candour Policy.

The Quality Improvement and Learning Safety team will meet weekly to discuss and agree the planned approach for incidents. The Quality and learning safety team will work with and seek advice and guidance from the already established National Medical Advisory and the Complaints, Incidents and Claims Committees.

The Quality Improvement and Learning Safety team will ensure agreed PSII's will be reported to NHS Integrated care boards for logging on the Strategic Executive Information System (StEIS) and Learning from Patient Safety Events platform (LFPSE) .
The completion timeframe for a PSII will be mutually agreed between QILT and those affected provided they are willing and able to participate in this decision-making process. It's crucial to strike a balance between conducting a comprehensive PSII, considering the potential impact of extended timelines on those involved, and mitigating the risk of delayed findings negatively impacting safety .

Safety Action Development Guide:

1. Agree areas for improvement
2. Define context
3. Define safety actions to address for improvement
4. Prioritise safety actions
5. Define safety measures
6. Write safety action
7. Monitor and review

All safety actions will be added to the applicable PSI case on Radar (Optegra incident management system, Safeguard, so that implementation can be monitored.

72-hour reports will be completed for every PSII declared for investigation. The report will contain the known facts relating to the incident and be sent to the UKLT and where appropriate the NHS Integrated Care Board within the 72 hours following the identification of the PSII.

The purpose of the 72-hour report is to recognise and mitigate immediate risks at an early stage of the investigation.

Some incidents may trigger an immediate safety flash notice from the central governance team – this will be communicated as a notice on RADAR.

Some incidents may trigger a specific type of multi-agency review and/or PSII to ensure system wide learning. This will be communicated via the Clinical Governance team as a notice on RADAR.

Where required, Optegra will engage early with commissioning teams and/or relevant teams within the wider sustainability and transformation partnership (STP), ICS to support the co-ordination of a cross-system PSII within a local system.

RADAR is the electronic system utilised by Optegra to report and record incidents. Optegra's incident reporting policy states 20 working days to review, investigate and close all clinical and non-clinical incidents. Exceptions to this will be those declared as PSII's. Each declared PSII will be recorded on RADAR and assigned an identification number. Additional time is then allowed for a PSII – this will be agreed at the outset of the investigation and communicated to all stakeholders. The RADAR record will hold all relevant documents, progress notes, internal communications, and the final report. It will be the responsibility of the supervisors to ensure the records are accurate and up to date.

Executive Team Members will review and approve all final PSII reports. Any feedback required from the Executive Panel will be communicated to the relevant SI supervisor for review and amendment. The two nominated Executive Leads are:

- Medical Director (Governance)
- Managing Director

Once the report has been approved by the at least one of Executive Team Members the ongoing management of PSIIs including action completion, Optegra learning and monitoring of ongoing compliance with completed actions/changes will be undertaken via the local head of clinical services and the central clinical governance team.

9.0 Categorisation of incidents and response

Incidents will be categorised by the QILT team into three categories which determines the required response.

		Response
Category 1	The most serious incidents with risk of harm or harm have occurred meeting the criteria for a PSII investigation. Will include Never Events Appendix XX CQC reporting process	PSII required identify investigation supervisor and investigation lead. Consult Medical Director for clinical cases. Complete reporting requirements internally and externally
Category 2	Near miss incidents where errors were made with opportunity for learning. For example, complication of surgery with good outcome for patient but opportunity for learning identified. Low harm incidents	Managed locally by hospital teams and overseen by QILT for organisational learning. (could be a PSIRF investigation) Managed within RADAR- timelines determined on RADAR
Category 3	Other incidents could be non-critical, non-clinical, no harm to patients or staff	Managed locally by hospital on RADAR – timelines determined on RADAR
Category 4 (other)	**Safeguarding Incidents** reported to Local Safeguarding Board. **Death of a patient** reported to the coroner	Will not fall into the PSIRF process. Optegra will support investigations undertaken by the Local Safeguarding Board. Optegra will complete an internal investigation and will support inquest investigations.

10.0 Thematic Reviews and Evaluation

Robust findings from PSIIs and reviews provide key insights and learning opportunities, but they are not the end of the story.

Findings must be translated into effective improvement design and implementation. This work can often require a different set of skills from those required to gain effective insight or learning from patient safety reviews and PSIIs. This will be undertaken by the Complaints., Incidents & Claims and Medical Advisory Committees who will provide insight and guidance to the Corporate Governance & Risk Committee where risks will be identified, and mitigating actions are approved.

Optegra will also seek to learn from a variety of sources of information not just complaints and incidents. Other sources of information will form part of regular themed reviews and will inform quality improvement priorities, these include patient feedback (formal and informal), good practice, near miss reporting, Care Quality Commission investigation reports and Internal clinical review programme outcomes.

Improvement work should only be shared once it has been monitored and demonstrated that it can be successfully and sustainably adopted, and that the changes have measurably reduced risk of repeat incidents and will improve patient safety.

Reports to the board and the UK leadership team will be monthly and will include aggregated data on:

- patient safety incident reporting
- audit and review findings.
- findings from PSIIs
- progress against the PSIRP
- results from monitoring of improvement plans from an implementation and an efficacy point of view.
- results of surveys and/or feedback from patients/families/carers on their experiences of Optegra's response to patient safety incidents
- results of surveys and/or feedback from staff on their experiences of the Optegra's response to patient safety incidents.

11.0 Supporting patients and families

Optegra is open with patients and relatives when errors are made and ensures that the principles of Being Open and Duty of Candour (DoC) are applied and adhered to.

This is integral to the response to incidents, complaints, legal and safeguarding processes. Being open is part of a 'just" culture required of all healthcare providers and is fundamental to being a learning organisation.

Local arrangements for supporting patients, families and carers are detailed within the Optegra's Being Open (Duty of Candour) Policy and associated documents.

12.0 Patient Safety Partners

Optegra will seek to address how patient safety partners will be integrated into the Optegra PSIRF plan and process. This will be an ongoing process with support from external partners such as Integrated Care Boards and the Care Quality Commission.

13.0 Supporting Staff

It is essential that with any PSI the staff involved are genuinely supported throughout the entirety of the process. It is well documented that staff that are involved in such incident are potentially a 'second victim' and clear procedures to ensure and escalate the appropriate support is pivotal to the developed PSIIRF.

In keeping with the ethos of 'just culture' staff should be informed as soon as possible that an incident they have been involved in is to be investigated as a PSI. Significantly a clear explanation of the 'how's and whys' the incident is to be investigated needs to be explained in a transparent way to ensure the staff are confident that the investigation is fair and appropriate.

The initial acknowledgement to staff is important and can 'set the tone' of the perceived investigation to follow in the eyes of the staff. Rather than being too prescriptive the initial contact should be based on 'best for staff' utilising local management knowledge of said individuals. A verbal and 'face to face' discussion with the staff should always be followed up with an 'individualised' written response to follow.

Key components that should be explained to staff at the onset and indeed reinforced in written follow up:

- Just culture
- Emphasis is on identifying organisational learning.
- Staff to be provided with a copy of the national PSII standards to which the investigation will be completed.
- Emphasis that their input / questions and contribution is pivotal to any investigation.
- Shared understanding of the potential stress associated (staff should absolutely be provided with written evidence of support options available)

- Clear time frames explained (avoid the possible concern that periods of 'no news is bad news')
- Emphasis that there is no hidden agenda, transparency is key. (Access to FTSU given)
- Regular 'touch base' periods built into any investigation.
- Draft reports to be shared with staff to encourage feedback and promote the ethos of transparency.
- Final report to be shared and debrief arranged as required.

14.0 Complaints and appeals

Patient experience and feedback offer learning opportunities that allows us to understand whether our services are meeting the standards we set and addressing patients' expectations and concerns. With these objectives very much in mind, we take all patient and stakeholder feedback very seriously, clearly identifying any lessons and using these to improve our service.

We report trends and emerging themes through Optegra's governance processes. With the implementation of PSIRP we will continue to manage complaints in the usual way in accordance with Optegra's complaints policy, with close liaison with the Quality Improvement and Learning Team in relation to any complaints about incidents that are also the subject of a thematic review.

Local arrangements for complaints and appeals relating to the Optegra's response to patient safety incidents are detailed within the Complaints Policy.

15.0 Training & Awareness

Members of the central clinical governance team and regional heads of clinical services have completed Patient Safety Incident Response framework training Level 2 and will continue to increase their knowledge of systems approach to investigations. Central governance team members will act as investigation supervisors and / or lead investigators.

Regional Heads of clinical services and key staff members will undertake investigation training – Patient Safety Incident Response framework training Level 2 they will undertake the role of lead investigators.

Optegra's medical director for governance will assume responsibility for training and informing board members of Optegra's PSIRF plan.

16.0 Monitoring

This plan is subject to change and will eventually be incorporated into Optegra's Incident policy.

17.0 References

1. NHS England » Patient Safety Incident Response Framework
2. Our courses (hsib.org.uk)
3. Get PSIRF ready with Radar Healthcare | Radar Healthcare

18.0 Associated Documents & Appendices

PSIRF quick reference guide

PSIRF – Guidance for Involving family and staff.

PSIRF – just culture guide

PSIRF – safety action development guide

PSIRF – reflective account template

PSIRF – report template

PSIRF – consent to use personal information in report.

PSIRF – 72 hr report

Optegra Incident Policy

Optegra Clinical Governance Policy

Optegra Duty of Candour Policy

Optegra Complaints policy

Optegra Safeguarding policy.

Appendices

Risk Profile

Quality Improvement plan

19.0 Sign off by Lead Integrated Care Board - Statement

The development of the Patient Safety Incident Response Plan by Optegra is a significant step forward in enhancing patient safety and care quality. This plan is designed to align with the Patient Safety Incident Response Framework (PSIRF), which is a new approach to managing patient safety incidents effectively.

The PSIRF emphasizes the importance of learning from incidents to improve patient safety. It sets out clear guidelines for healthcare providers on how to respond to patient safety incidents, ensuring that they are managed promptly and efficiently, with a focus on learning and improvement rather than assigning blame.

Optegra's adoption of this framework demonstrates their commitment to patient safety and continuous improvement.

The ongoing collaboration with Optegra as they roll out this plan is crucial. It allows for sharing best practices, addressing challenges, and ensuring that the plan is implemented effectively. The ultimate goal is to create a safer healthcare environment where patient safety incidents are minimized, and when they do occur, they are managed in a way that fosters learning and improvement.

Kate Provan,

Associate Director for Patient Safety, Patient Safety Specialist Greater Manchester Integrated Care Board

20.0 Equality Impact Assessment

Name of document to be assessed:	Optegra Patient Safety Incident Response Plan	
New or existing document:		New
Document aim:		
Document Objectives:		
Document – intended outcomes:		
How we measure the outcome:		
Who is intended to benefit from the policy:	All staff and users of services	

Is consultation required with the workforce, equality groups, local interest groups:	Yes	
If yes have these groups been consulted?	Yes	
Please list any groups that have been consulted with.	Lead Integrated Care Board	

Are there concerns that the policy could have differential impact on:

Equality Strands:	Yes	No	Rationale for assessment / existing evidence
Age		**x**	
Sex		**x**	
Race/ Ethnic communities / groups		**x**	
Disability		**x**	
Religions / other beliefs Marriage and Civil partnership		**x**	
Pregnancy and maternity		**x**	
Sexual orientation, bisexual, Gay, heterosexual, lesbian		**x**	

You will need to continue to a full equality impact assessment if the following have been highlighted:

- You have ticked 'Yes' in any column above **and**
- No consultation or evidence of there being consultation – this <u>excludes</u> any *policies* which have been identified as not requiring consultation **or**
- Major service redesign or development

Is a full equality analysis recommended		No
If a full impact assessment is not recommended, why?		
Name of individual completing assessment:	Louise Harrison	
Date:	26/3/24	