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St Mary's Hospital

Patient Safety Incident Response Plan

2022-2025

Safety Differently

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Introduction

Patient safety events are any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare.

This patient safety incident response plan (PSIRP) sets out how Saint Mary's Managed Clinical Service which is part of Manchester University NHS Foundation Trust (MFT) intends to respond and 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. Manchester University NHS Foundation Trust is an NHS Acute Foundation Trust which operates 10 hospitals throughout Greater Manchester. It is the largest NHS trust in the United Kingdom. The Trust was formed on 1st October 2017 following the merger of Central Manchester University Hospitals NHS Foundation Trust (CMFT) and University Hospital of South Manchester NHS Foundation Trust (UHSM), and more recently the acquisition of North Manchester Hospital.

Due to the size and structure of MFT, it has been agreed that there will be a MFT Group level PSIRP which will outline the priorities of the Trust as a whole, and each Hospital/Managed Clinical Service (MCS) will hold its own localised PSIRP, that is aligned to localised patient safety priorities.

Saint Mary's Managed Clinical Service is a centre of excellence for the provision of healthcare for women, children and families. Our four Divisions and one Directorate offer integrated secondary and tertiary services with strong research and innovation programmes.

Components of the Managed Clinical Service include:

- Maternity services
- Newborn services
- Gynaecology
- Genomic Medicine
- Sexual Assault Referral Centre

This plan will enable us to focus our patient safety improvement work in light of our local patient safety incident investigations (PSIIs) by:

- reviewing patient safety events in a holistic way focussing on learning, using data constructively and ensuring patients are at the centre of our safety improvement work
- integrating information from multiple sources and using a systems approach to identify interconnected causal factors and systems issues
- Focusing on addressing these causal factors and the use of improvement science to prevent or continuously and measurably reduce repeat patient safety risks and incidents
- 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
- demonstrating the efficacy of this approach by improving safety across our MCS

The patient safety incident response plan is not a permanent rule that cannot be changed. We will remain flexible and consider the specific circumstances in which patient safety issues and incidents occurred and the needs of those affected.

Scope

A PSIRP is a requirement of each provider or group/network of providers delivering NHS-funded care. This document should be read alongside the introductory Patient Safety Incident Response Framework (PSIRF) 2022, which sets out the requirement for this plan to be developed.

The aim of this approach is to continually improve. As such this document will be reviewed every 12 – 18 months to ensure that the site plan remains appropriate to our changing patient safety profile.

There are many ways to respond to an incident. **This document covers responses conducted solely for the purpose of system learning and improvement.** There is no remit to apportion blame or determine liability, preventability, or cause of death in a response conducted for the purpose of learning and improvement

Responses covered in this plan include:

- Patient Safety Incident Investigations (PSIIs)
- Patient Safety Reviews (PSRs)

Other types of response exist to deal with specific issues or concerns. Examples of such responses include complaints management, claims handling, human resources investigations into employment concerns, professional standards investigations, coroners inquests or criminal investigations. The principle aims of each of these responses differ from the aims of a patient safety response and are outside the scope of this plan.

To be effective in meeting their specific intended purposes, responses that are not conducted for patient safety learning and improvement are separate entities and will be appropriately referred as follows:

- human resource (employee relations) teams for professional
- conduct/competence issues and if appropriate, for referral to professional regulators
- legal teams for clinical negligence claim
- medical examiners and if appropriate local coroners for issues related to the cause of a death
- the police for concerns about criminal activity

SM MCS Strategic Objectives

The MFT Group Quality and Safety Strategy sets the direction for the delivery of quality services within the Trust for the next three years. It supports and builds upon the Trust's proven delivery of high-quality services, whilst supporting its ambition for a continuous improvement of services and sustainable growth.

The Group Quality and Safety Strategy sets out an approach which aims to put quality right at the heart of everything we do. It ensures that quality services are delivered in the Trust in response to the specific requirements of our patients, carers, our staff, the public, our commissioners and regulators. Core to this Strategy is the Trust's values and related behaviours. This Quality Strategy describes a consistent and integrated approach to providing quality services across the Trust.

The Group policy has identified seven quality and safety aims to support the delivery of this strategy.

These aims are:

- **Our care is safe:** we continuously, systematically and consistently prioritise patient safety in everything we do
- **Our care is effective:** we provide the best possible clinical care whilst demonstrating a culture of continuous improvement and learning
- **We are caring:** Respect, dignity, kindness and compassion are at the core of our service provision
- **Our care is responsive:** our services are quick and convenient to use and responsive to individual needs
- **We are well led:** this strategy is underpinned by high quality leadership
- We make our data count and measure for improvement
- We are confident that our care is of high quality and we understand, contextualise and manage risk consistently

Our patient safety incident response plan (PSIRP) sets out how Saint Mary's Managed Clinical Service (MCS) will seek to learn from patient safety events 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.

Our PSIRP will assist us to make more effective use of current resources by transferring the emphasis from the quantity of investigations to a higher quality, more proportionate response to patient safety incidents. The aim is to:

- make PSIIs more rigorous and, with this, identify causal factors and system-based improvements
- engage patients, families, carers, and staff in PSII and other responses to incidents, for better understanding of the issues and causal factors
- develop and implement improvements more effectively

We will also continue to foster a climate that supports a 'just culture' and an effective learning response to patient safety incidents.

Addressing Health Inequalities

When people already negatively affected by unfavourable social determinants of health seek care, healthcare itself may exacerbate health inequalities rather than mitigate them. One way in which this occurs is when patients experience disproportionate levels of harm from the healthcare they receive.

For example, a 2022 review in the UK found that ethnic minority women's experiences of poor communication and discrimination during interactions with healthcare staff may explain some of the stark inequalities observed in maternal health outcomes. Healthcare may therefore be less safe for some patients than others.

Evidence is growing that patient safety incidents are experienced unequally. Inpatient safety data from the US indicate that adjusted rates of perioperative pulmonary embolism and sepsis among black patients are 28% and 24% higher, respectively, compared with white patients admitted to the same hospital. These data add to evidence from a range of high-income settings that patients from ethnic minority communities are at increased risk of hospital acquired infections, adverse drug events, and pressure ulcers.

Socioeconomic disadvantage has been associated with higher rates of death from avoidable causes such as delayed healthcare interventions, as well as delays in promptness of resuscitation after in-hospital cardiac arrest. In addition, patients with learning disabilities have been shown to experience harmful delays in the timely diagnosis of sepsis. Such failures in patient safety lead to higher levels of harm for these patients.

People from marginalised ethnic backgrounds are more likely to be harmed by healthcare because of interpersonal and structural factors that shape their care experiences. These factors include ineffective communication during clinical care, implicit biases among healthcare providers, and medical educational and clinical treatment approaches designed around white patient populations as the norm.

Ineffective communication between clinicians and patients can cause harm to any patient. However, those with poor proficiency in the dominant language of the healthcare system, including migrants, are at heightened risk of harm because of medication errors and misunderstanding verbal advice.

Risk of harm from healthcare is experienced unequally and compounds existing vulnerabilities to poor health outcomes, ultimately exacerbating health inequalities. SM MCS has a key role to play in tackling health inequalities in partnership with our local partner agencies and services. SM MCS has developed a draft health equality action plan to address some of the most urgent issues. However, most of the fundamental factors driving inequalities in health are beyond the responsibility of the health care system, for example education; economic and community development in our most deprived neighbourhoods; employment levels; pay and conditions; and availability of quality of housing.

Through our implementation of PSIRP, we will seek to utilise data and learning from investigations to identify actual and potential health inequalities and make recommendations to support tackling these. We are already actively considering language barriers and social deprivation in our incident reviews.

Our engagement with patients, families and carers following a patient safety investigation must also recognise diverse needs and ensure inclusivity for all. Any potential inclusivity or diversity issues must always be identified through the investigation process and engagement with patients and families, for example, during the duty of candour / being open process.

Our Services

SM MCS has four clinical divisions **and one directorate** providing a wide range of services.

Division of Genomic Medicine

Childhood metabolic paediatric disorders
Lysosomal Storage Disorders
General Adult Genetic Clinics
General Paediatric Clinics
General Cancer Genetic Clinics
Genetic Counsellor Clinics
Outreach Clinics
NW Genomic Laboratory Hub
The Division offers the following specialist clinics:
Adult endocrine
Heart conditions
Cleft lip and palate
Deafness
Genetic dermatology
Inherited neurological problems
Rare forms of interited cancer (inc. NF1, NF2)
Rare childhood developmental disorders Kidney
Eye conditions

Division of Gynaecology

Benign Gynaecology including: Menstrual disorders, hysteroscopy, colposcopyand vulval disorders
Paediatric and Adolescent Gynaecology
Reproductive Medicine including IVF, endometriosis and menopause
Urogynaecology
MESH complication service

Division of Maternity Services

Antenatal Assessment Units
Diabetic pregnancy service
Fetal cardiology Fetal Medicine
Joint obstetric cardiology clinic
Joint obstetric haematology
Joint obstetric neurology
Joint obstetric / HIV clinic
Lupus in Pregnancy (LIPS) clinic
Manchester Antenatal Vascular Service (MAViS)
Specialist midwifery service for asylum seekers and refugees
Obstetric ultrasound service
Young parents' specialist service
Manchester placenta clinic
Obstetric anaesthetic clinic
Perinatal mental health clinic
Obstetric cardiac clinic
Renal hypertension antenatal
Preterm labour clinic
Physiotherapy
Rainbow clinic
Raised BMI clinic

Division of Newborn Services

Neonatal intensive care
High dependency and special care
Complex respiratory diseases
Complex renal conditions
Complex cardiac conditions
Complex neurological conditions
Babies who require surgical care
Complex genetic and metabolic disorders

Sexual Assault Referral Centre

24 hour forensic medical examinations for all ages and genders
STI/pregnancy advice for adults
HIV/Hepatitis B Prophylaxis
Specialist Child Clinics
Specific STI Clinics for Children
Child medical examinations-FGM
Crisis work support (including 24 hour helpline ISVA)
Counselling including pre-trial therapy, group intervention and psycho-education courses
SAFEPlace Merseyside

Defining our patient safety incident profile

Over the past 2 years, SM MCS as part of MFT has focused on improving our response to and learning from patient safety incidents. We have already initiated a number of important safety processes to facilitate this such as the establishment of the SM MCS Serious Incident panel and our SM MCS Patient Safety Response Group which was established to focus on sharing learning from patient safety events. Essential to this has been fostering a patient safety culture in which people feel safe to report incidents, share experiences and be actively involved in the development of safety actions.

Our patients are key partners in our safety responses and our staff involve patients to ensure that where possible their experience is heard, and they have the opportunity to contribute their questions about a safety event and contribute to safety action planning.

It is important to recognise that there are good reasons to carry out an investigation. Sharing findings, speaking with those involved, validating the decisions made in caring for patients and facilitating psychological closure for those involved are all core objectives of an investigation. The challenge for us is to develop an approach to investigations that facilitates thematic insights to inform ongoing improvement. Our approach must acknowledge the importance of organisational culture and what it feels like to be involved in a patient safety incident.

Patient safety incidents and Hospital level risks for SM MCS have been profiled using organisational data including:

- Incident Reports: Two years of data has been reviewed and review of any special cause variation considered and triangulated with other data sources.
- Complaints and compliments themes were reviewed
- Risk Register: a review of the risk register was undertaken
- National & Clinical Audit outcomes and recommendations were reviewed, and the themes triangulated with other data
- CQC reports and those of recent maternity service inspections were reviewed

Incident Profile

Patient safety events are reported via the Trust Ulysses system and each event is reviewed by a manager within our MCS. Events that have potentially caused serious harm or had the potential to do so if corrective action had not been taken are reviewed in detail and discussed by a multi-disciplinary team at our SM MCS serious incident panel. Whilst each incident is reviewed individually every month the totality of our incident data is reviewed to ascertain if there are any trends and identify areas that may benefit from further safety improvement work. Analysis of these profiles has been a major contributor to our priorities within this plan.

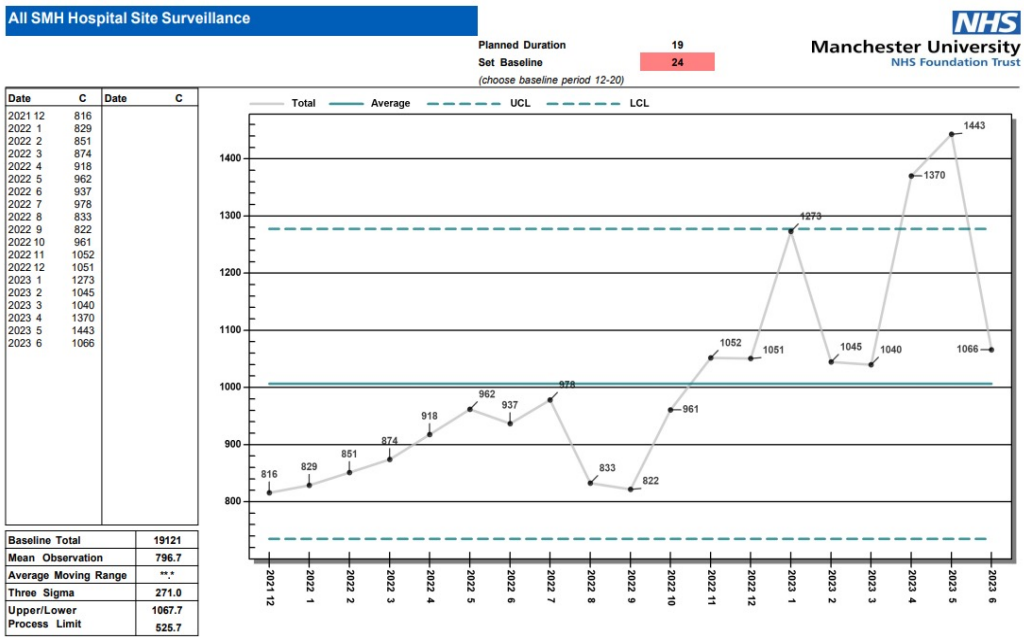

Figure 1: Graph illustrating the total number of potential patient safety events reported across SM MCS in the period December 2021 – June 2023

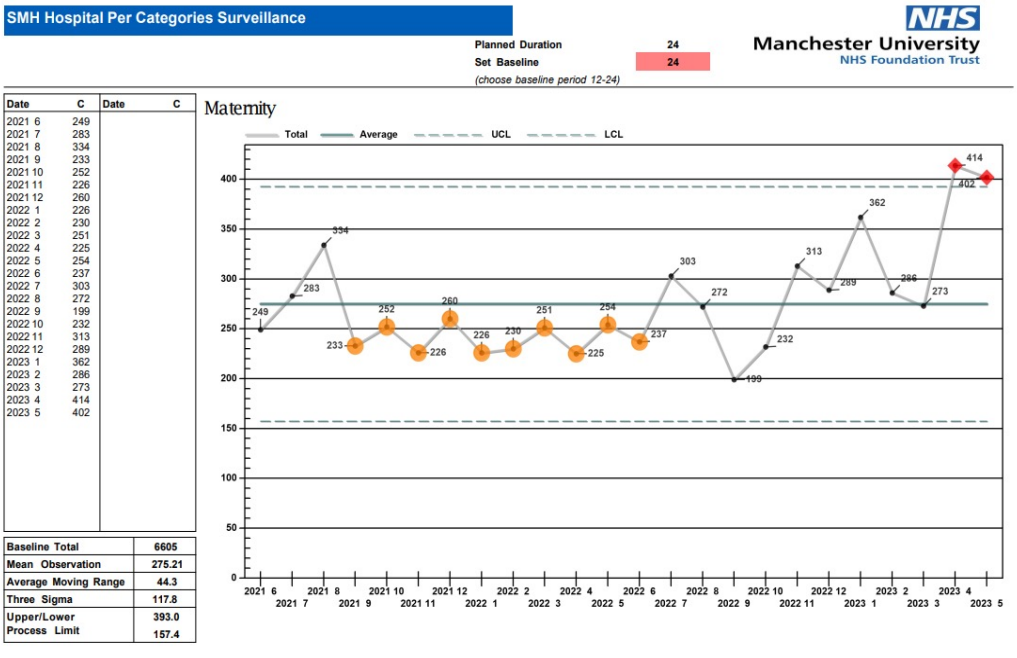

Figure 2: Graph illustrating the total number of potential patient safety events reported within maternity services in the period June 2021 – June 2023

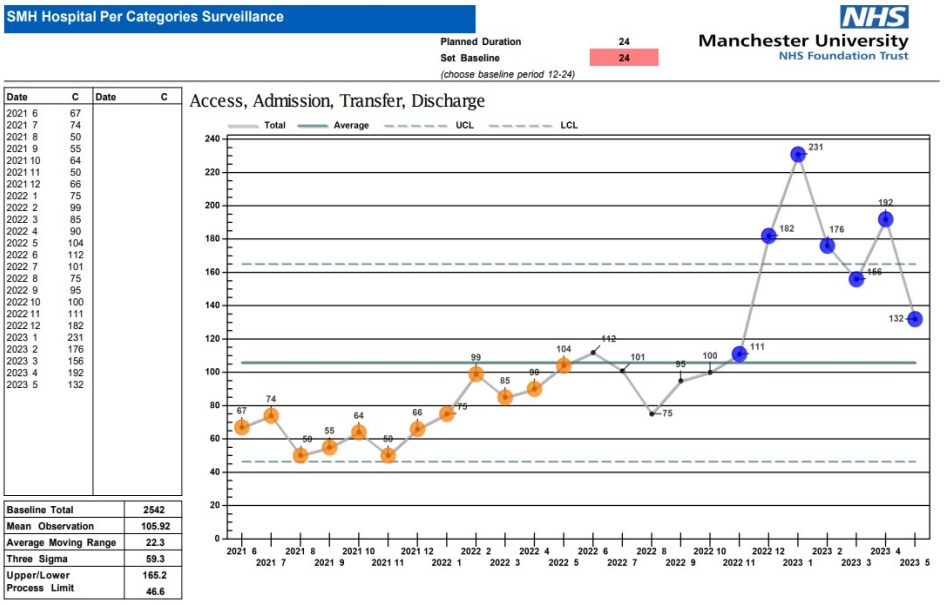

Figure 3: Graph illustrating the number of potential patient safety events related to access, admission, transfer ad discharge reported across SM MCS in the period June 2021 – June 2023

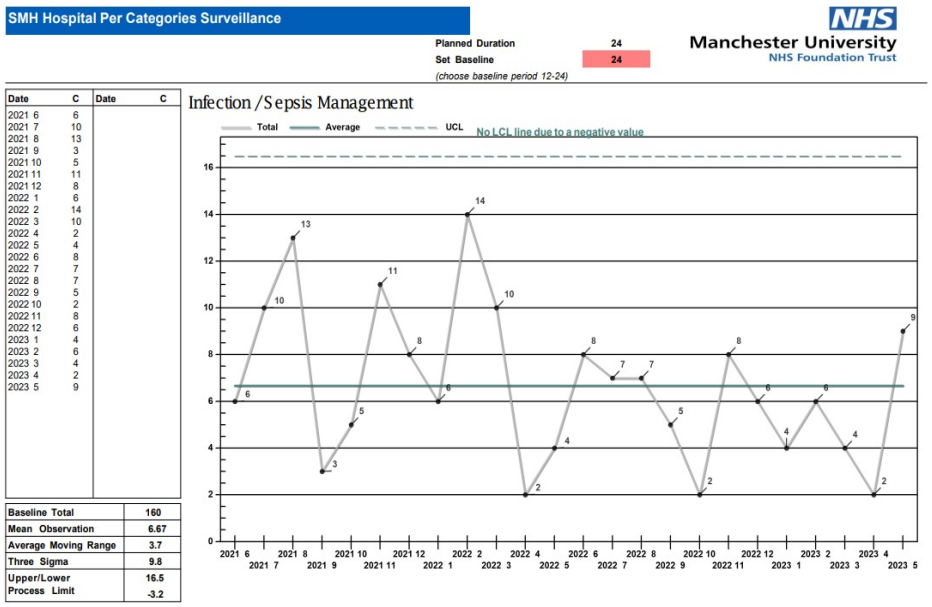

Figure 4: Graph illustrating the number of potential patient safety events related to infection and sepsis management reported across SM MCS in the period June 2021 – June 2023

Our patient safety priorities are

- Safe and timely management of patients accessing SM MCS for assessment and treatment
- Working towards closing the gap in health inequalities by working with patients and staff to develop services that effectively provide care to patients across all sites and from all backgrounds and ethnicities
- Safe and effective care of women attending maternity triage across the MCS
- Safe, effective and responsive management of infection
- Safe and effective escalation of the deteriorating patient

These key priorities are discussed, and assurance given of progress through the following groups and committees:

- SM MCS Quality & Patient Safety Committee
- Divisional Quality and Safety Committee meetings
- SM MCS Patient Safety Summit
- SM MCS Patient Safety Response Group

Developing our patient safety improvement program

SM MCS has developed a comprehensive quality and safety strategy and each division/directorate has its own action plan. Although the strategy covers a 3 year period the action plans are dynamic to enable them to be responsive to changing priorities within the service. Our clinical governance framework enables a robust assurance process, providing assurance that improvements are being made, embedded and sustained

SM MCS works collaboratively with patient representatives such as our maternity voices partners, charities such as the neonatal charity Spoons, our colleagues from across MFT and the Local Care Organisation (LCO), as well as external stakeholders to improve safety.

Our patient safety incident response plan: **national requirements**

Patient Safety incidents that 'must' be investigated under PSIRF are detailed below in table 1.

Patient safety incident type	Required response	Anticipated improvement route
Never Events	PSII	Create local organisational actions and feed these into the SM MCS and MFT quality improvement strategies. Review previous safety improvement work that was undertaken following previous Never Events and ensure safety actions are embedded and sustained.
Learning from Deaths: death thought more likely than not due to problems in care (incident meeting the learning from deaths criteria for patient safety incident investigations (PSIIs))	PSII	Improve the processes for interlinking learning from national review processes such as PMRT and MBRRACE to maximise safety improvement both within SM MCS and working with MFT colleagues.
Deaths of Persons with learning disabilities	PSII	Ensure that the learning disability champions within SM MCS are involved should there be a death of a person with a learning disability within our service.
Safeguarding Incidents	PSII	Create local organisational actions and feed these into the SM MCS and MFT quality improvement strategies
Incidents in NHS Screening Programmes	PSII	Ensure learning from all NHS screening programme related patient safety events is shared at the SM MCS PSRG meeting for shared learning as well as with regional screening teams.

Our patient safety incident response plan: **local focus**

The SM MCS safety profile has identified five incident categories which require an increased focus in relation to patient safety. Table 2, details the locally identified areas of focus and improvement.

Several system-based learning response methods are available to respond to a patient safety incident or cluster of incidents. These will be applied where contributory factors are not well understood, and further local improvement work is required to enable the greatest potential for new learning and improvement.

Table 2

	Patient safety incident type	Speciality	Planned/Suggested Response(s)	Anticipated improvement route
1	Medication Safety	All	HILA MDT SWARM PSII Observation Walkthrough	SM MCS Harm Free Care committee Trust Medicines Safety Committee
2	Access, Admission, Transfer, Discharge	Maternity Services	HILA MDT SWARM PSII Observation Walkthrough	Maternity Triage Safety improvement workstream in progress SM MCS Quality and Safety Committee
3	Patient Care, Monitoring, Review: • Delay/Failure in assessing patient • Delay/Failure to monitor Ensuring safe and effective follow up of care	All	HILA MDT PSII SWARM	Locally identified workstreams or QIP appropriate to theme and improvement identified SM MCS Quality and Safety Committee
4	Infection / Sepsis Management	All	Outbreak review Thematic Review	SM MCS Harm Free Care committee Outbreak meetings
5	Positive Patient Identification	All	HILA MDT Walkthrough	Locally identified workstreams or QIP SM MCS Quality and Safety Committe

Where a PSII is required (as defined in this Plan for both local and national priorities), the investigation / review will start as soon as possible after the patient safety incident is identified. PSII will usually be completed within one to three months of their start date, but not exceeding six months. Any PSII anticipated to require an extended timeframe should be agreed with the patient/family/carer.

Thresholds

There is no legal duty to investigate a patient safety incident. Once an incident that meets the Statutory Duty of Candour threshold has been identified, the legal duty, as described in Regulation 20 says we must:

- Tell the person/people involved (including family where appropriate) that the safety incident has taken place.
- Apologise. For example, "we are very sorry that this happened"
- Provide a true account of what happened, explaining whatever you know at that point.
- Explain what else you are going to do to understand the events. For example, review the facts and develop a brief timeline of events.
- Follow up by providing this information, and the apology, in writing, and providing an update. For example, talking them through the timeline.
- Keep a secure written record of all meetings and communications.

A review of compliance with Regulation 20: The Statutory 'Duty of Candour' under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 presented to Group Quality and Safety Committee in June 2021 highlighted that there are gaps in assurance regarding the approach to, and the quality of, Duty of Candour disclosures across the Trust. A Review of Saint Mary's MCS compliance with Regulation 20: The Statutory 'Duty of Candour' under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 in January 2023 has confirmed that there remain gaps in assurance.

A process is now in place to review our local compliance data with Duty of Candour statutory requirements. Monthly reminders have been instituted. Training is being organised at group level for staff who undertake Duty of Candour.

Resource Analysis

The current incident management structure relies on clinicians, undertaking reviews in their allotted governance role time allocations. The SM MCS Governance Team do not have any line management responsibilities with regards investigators and are supported by the medical director, director of nursing and midwifery and the clinical heads of division to assist investigators to prioritise their time for investigations. Investigation reports have SM MCS senior leadership team level approval prior to submission to the group governance team or external agencies.

In order to effectively deliver the requirements of the patient safety incident investigation standards and the PSIRF, consideration of the required resources and training is required.

Learning response leads, those leading engagement and involvement and those in PSIRF oversight roles require specific knowledge and experience. Learning responses are not led by staff who were involved in the patient safety incident itself or by those who directly manage those staff and it is recommended that learning responses are led by staff at Band 8a and above.

Therefore, job planning and time is required to enable identified staff to complete the required PSIIs.

Table 3 below outlines the proactive response planning and overview of estimated resource allocation for patient safety incidents that fall outside national priorities.

Table 3

Response Type	Category	Total number of responses	Hours
PSII (formally referred to as Serious Investigation Reports)	Locally defined PSIIs	Approx 20 per year	***Minimum 30 hours per investigation for:*** • 1 lead investigator • 1 support investigator ***Up to 15 hours per investigation for:*** • subject matter expertise • family liaison ***Plus Up to 15 hours per investigation for:*** • investigation oversight and support administration support • interview and statement time of staff involved in the incident • SLT approval and sign off
	Unanticipated Incidents identified as requiring PSII	5	As above
PSRs (often referred to as Practice Reviews)	All types including learning from work went well (safety II)	500	Approximately 10 hours per response review (MDT Approach)