Royal Devon University Healthcare NHS Foundation Trust

Patient safety incident response plan

2023 – 2025

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Introduction

This patient safety incident response plan sets out how Royal Devon University Healthcare NHS Foundation Trust intends to respond to patient safety incidents over a period of 12 to 18 months. The plan is not permanent and will be refreshed on a regular basis. We will remain flexible and consider the specific circumstances in which patient safety issues and incidents occurred and the needs of those affected.

The key principles of the Patient Safety Incident Response Framework (PSIRF) are closely aligned to our values as a healthcare provider; and our Board of Directors fully endorses the opportunity PSIRF provides for developing our approach to patient safety in a way which aligns to our own strategic objectives and values.

The Trust approved and published its first Patient Safety Incident Response Plan (PSIRP) in November 2023, prior to formally adopting the NHS Patient Safety Incident Response Framework (PSIRF) on 01 December 2024. To ensure that the plan remains fit for purpose it will be subject to an annual refresh, based upon a review of our patient safety data and any

emergent trends which have become apparent. The review for the current plan commenced in June 2024.

The review of data looked at a two-year period of patient safety event data from 01 July 2022 to 31 July 2024. This included a light touch triangulation with other insight sources, including feedback (Complaints and Compliments) and Mortality Data.

The Initial finding from the review were presented to the Royal Devon Patient Safety Committee in September 2024. The Committee accepted the findings of the review and approved their use to refresh the content of the Plan.

The review was not restricted to data, but also included formative review of the Governance and Oversight Arrangements for Patient Safety.

Our services

The Royal Devon University Healthcare NHS Foundation Trust (the Royal Devon) was established in April 2022, bringing together the expertise of the Royal Devon and Exeter NHS Foundation Trust and Northern Devon Healthcare NHS Trust. Stretching across Northern, Eastern and Mid Devon, we have a workforce of almost 16,000 staff, making us the largest employer in Devon. Our core services, which we provide for more than 615,000 people, cover over 2,000 square miles across Devon, while some of our specialist services cover the whole of the peninsula, extending our reach as far as Cornwall and the Isles of Scilly.

We deliver a wide range of emergency, specialist and general medical services through North Devon District Hospital and the Royal Devon and Exeter Hospital (Wonford). Alongside our two acute hospitals, we provide integrated health and social care services across a variety of settings including community inpatient hospitals, outpatient clinics, and within people's own homes. We also offer a range of specialist community services, Sexual Assault Referral Centres (SARC) and a GP practice

In 2023/24 The Royal Devon:

- Cared for 184,902 inpatients, 86,971-day cases, and 1,074,866 outpatients
- Our Emergency Departments had 153,036 attendances; our Minor Injuries Units had 13,822 attendances; and our Walk-In Centre had 26,140 attendances
- We looked after 1,578 people in our community hospitals
- We provided care to 47,105 people in their homes

- Our virtual ward (acute hospital at home) provided care for a total of 2696 patients
- 4,690 babies were delivered

The Royal Devon and Exeter (Wonford) Hospital

The Royal Devon and Exeter (Wonford) Hospital is our district general hospital in Exeter. It provides emergency, urgent and planned care services to people in Exeter, Eastern Devon and the surrounding areas. As a teaching hospital, it delivers undergraduate education for a full range of clinical professions and it is the lead partner for the University of Exeter College of Medicine and Health, as well as a leading centre for high quality research and development in the South West peninsula. The Royal Devon and Exeter (Wonford) Hospital is home to a number of our highly acclaimed specialist units and centres, including the internationally renowned Princess Elizabeth Orthopaedic Centre, our award-winning Centre for Women's Health, and the purpose-built Mardon Neurorehabilitation Centre.

North Devon District Hospital

North Devon District Hospital is our district general hospital in Barnstaple. It provides emergency, urgent and planned care services to people in Northern Devon and the surrounding areas. providing a 24/7 emergency service and is a designated trauma unit operating within a trauma network serving the whole of Devon and Cornwall. The hospital also offers a range of general medical services, including cardio-respiratory, stroke care and gastroenterology, alongside a number of general surgical services including orthopaedics, urology and colorectal specialities.

Integrated Community Health and Social Care Teams

Our teams of integrated health and social care community professionals across Eastern and Northern Devon work to rehabilitate patients, avoid admissions, and promote health, wellbeing and independence. We also support people who may need short term support until they regain their independence or specialist end-of-life care and provide local outpatient and self-referral services, such as sexual health clinics. We manage a range of inpatient and outpatient services from 17 community hospital locations, which provide accessible local hubs for our communities. These span a wide geographical area, and include minor injuries units and a variety of outpatient services. Our community teams work closely with a wide number of health and care professionals, including colleagues working in the acute hospital, social care, primary care, mental health and other partner organisations to support people to self-manage their long-term conditions, improve their mobility and maintain their independence.

Specialist Community Services

The Trust is the main provider of specialist community healthcare services across Northern, Eastern, Mid and South Devon, including podiatry, dentistry and sexual health. We also run Sexual Assault Referral Centres (SARC) across Devon, Cornwall and the Isles of Scilly, as well as adult and paediatric bladder and bowel care services in these areas

Nightingale Hospital

The Nightingale Hospital Exeter is a state-of-the-art facility providing services for patients across Devon, helping to further reduce waiting times for certain procedures in the region. The Nightingale is home to a number of specialist centres, and provides the following services

The Nightingale is now home to the following services:

- Southwest Ambulatory Orthopaedic Centre, which has two operating theatres for day case and short stay elective orthopaedic procedures
- Centre of Excellence for Eyes, which is delivering diagnostic outpatient services and cataract surgery
- Devon Diagnostic Centre (DDC), which is hosting CT, MRI, X-ray, ultrasound and fluoroscopy services
- The Royal Devon University Healthcare NHS Foundation Trust's Rheumatology department
- Buttercup Outpatient Uni, which is an expansion of our diagnostic services, offering a number of speciality one-stop pathways.

Defining our patient safety incident profile

It was essential when defining our patient safety incident profile that it reflected the breadth and diversity of both the services we provide and the communities we serve. There was additional complexity because the Royal Devon was a relatively new organisation when the planning work commenced, and we were bringing together the practice and cultures of our legacy organisations at the same time as developing our new ways of working under PSIRF.

Stakeholder Engagement

The defining of our incident profile was undertaken as part of a broader project to introduce the Patient Safety Incident Response Framework. The Trust formed a Patient Safety Strategy Implementation Project Delivery Group to oversee the work. This group oversaw the functioning of a series of workgroups designed to support the delivery of the Patient Safety Strategy.

The Project Delivery Group was based upon a model of engagement with the following stakeholders;

- Independent patient representatives
- Devon Integrated Care Board representatives (Quality and Safety)
- Divisional and service representatives with a special interest in safety and quality
- Quality Improvement (QI) facilitators
- Staff wellbeing and engagement representatives, leading on the overarching Just Culture programme for the Trust
- Trust patient safety specialists and senior leaders with portfolio responsibility for patient safety.

The project delivery group actively engaged with staff by commissioning a baseline assessment of the Trust's Safety Culture using the Manchester Patient Safety Framework (MaPSaF) - 284 staff actively engaged with this process.

The project Delivery Group reported into the Trust's Safety and Risk Committee, which appraised the Governance Committee. This ensured executive oversight of the project.

The working groups were developed across the following themes:

Safety & Quality Systems

This led on development of the Trust's Risk Management System in preparation for transfer to the Learning from Patient Safety Events (LFPSE) platform.

This was achieved through engagement with other Devon Safety Systems teams (Plymouth, Torbay and South Devon, NHS Devon ICB). Partnership working with our Risk Management System provider (RL Datix) and NHS England LFPSE team.

Insight and planning

This led on generation and analysis of the data to inform the development of this patient safety incident response plan. Engagement for this workstream included:

- Governance Leads
- Legal and claims
- Mortality leads
- Patient experience representatives
- Patient safety specialists
- Quality improvement facilitators
- Risk managers
- Safety systems
- Service and clinical representatives
- Staff representatives and Freedom to Speak Up Guardians

Oversight and Governance

This workstream led on developing the new oversight framework for PSIRF, and engaged for this workstream included:

- Independent patient representatives
- Patient Safety Specialists
- Governance leads
- Quality improvement facilitators
- Divisional and clinical representatives

Improvement

This workstream engaged directly with teams and the transformation service to map current improvement work related to patient safety being carried out within the Trust.

Education and Training

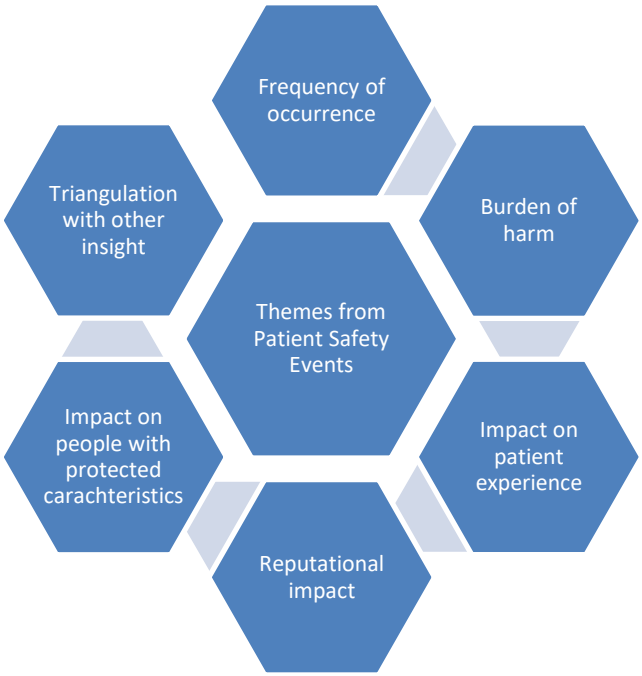
This workstream undertook the Training Needs Analysis work to map staff against the requirements of the National Patient Safety Syllabus.

Data Sources

A broad range of both quantitative and qualitive data sources were utilised to shape our Patient Safety Profile. The decision was made to increase the review period for developing

this plan from three years to five years. This was due to concern that our incident profile would be distorted by the impact of the Covid-19 Pandemic if it focussed on the years 2020 – 2023. By collating data from two years prior to Covid the Trust sought to normalise the profile of patient safety events.

This identified just under 117,000 events which were thematically reviewed against the following themes:



By frequency of occurrence the Trust's largest number of incidents were Pressure Ulcers and Falls. Both of these incidents are well understood and have established safety improvement programmes associated with them.

The burden of harm from patient safety events is low, with over 99% of all incidents being reported as no harm or low harm. This is significant for two reasons.

1. Where Trusts are reporting high numbers of low / no harm incidents this indicates a positive reporting culture. Trusts with a poor reporting culture would tend to focus upon reporting incidents which have resulted in actual patient harm, and this would lead to an increased proportion of incidents being reported with significant harm.

2. Our investigatory focus under the 2015 Serious Incident framework was based upon less than 0.18% of all patient safety events. Such a small range of incidents are, by their nature, unusual events.

The analysis also included a review of over 4,000 complaints, 744 of which were associated with patient safety events. This allowed consideration of the impact on patient experience of our safety event profile.

Consideration of reputational impact was based upon an analysis of our patient safety events alongside our claims data (including a review of the NHS Resolution balanced scorecard). We also reviewed issues which had been raised by partner organisations, other providers and our commissioning bodies. This included issues raised through the Yellow Card and subsequent pitch process.

We attempted to review the impact of patient safety events against protected characteristics, to provide additional insight regarding the impact of health inequalities. This proved to be incredibly challenging, particularly when drawing information from two separate organisations legacy systems. This is an incredibly important aspect of insight which requires further development in order to understand how protected characteristics may affect outcomes for patients.

To ensure triangulation of our incidents we involved our lead Freedom to Speak Up Guardian, so that our analysis could be balanced against concerns raised by our staff.

During the period we were undertaking our analysis the Trust revised its approach to Risk Management, introducing an Enterprise Risk Management approach. This methodology provides greater clarity on our organisational risk burden, and specifically where we are holding risks with the potential to impact on patient safety.

Our final aspect of analysis was to work alongside our clinical lead for mortality, to ensure that any significant work associated with our learning from deaths agenda was reflected as part of our safety profile.

Maternity Services Patient Safety Events

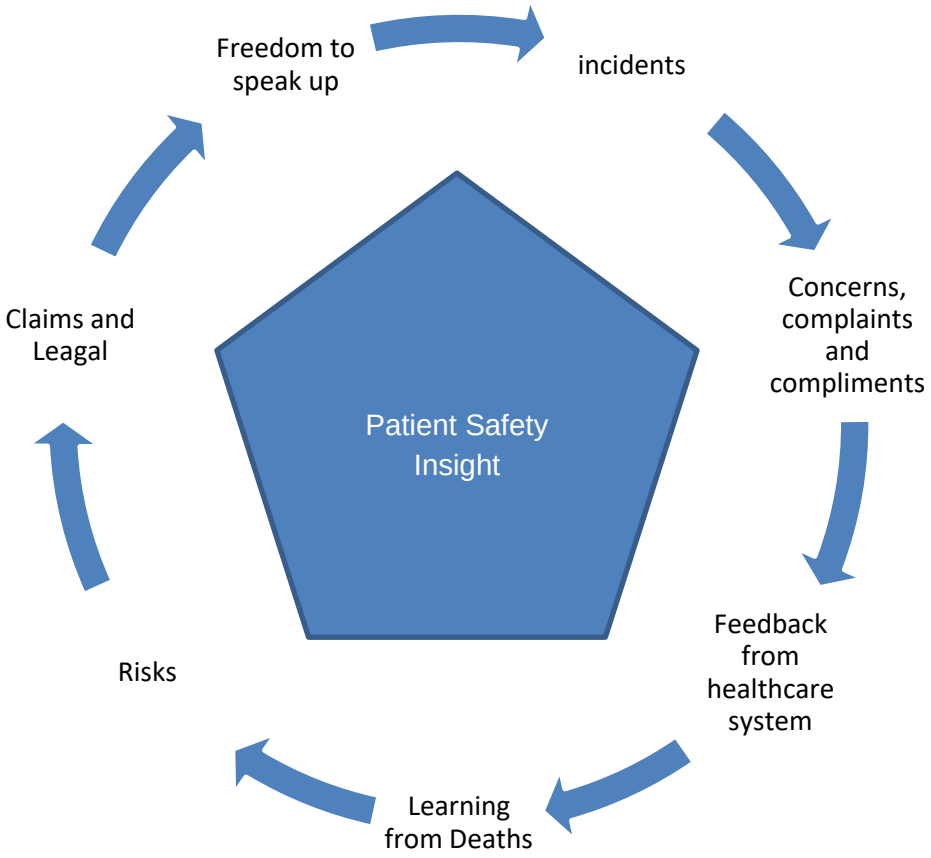
We undertook a similar process for our maternity patient safety events, and examined five years of incident data. This was to establish a baseline of events to enable tracking of key safety themes. We met with our maternity service leads to review the findings of the data analysis, and agree local processes for incidents which do not meet national reporting requirements. Incidents which require a statutory response are those meeting criteria for either:

- The Maternity and Newborn Safety Investigations (MNSI) programme
- Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK)

There will be regular monitoring of incident data and broader insight to the Patient Safety Event Review Group; this will include statistical process control analysis to highlight any variance in our maternity safety events profile.

Infection Prevention, control and Decontamination Patient Safety Events

Data analysis of patient safety events relating to healthcare associated infections were significantly complicated by the Covid-19 pandemic. There were a high proportion of patient experience feedback and reported incident related to healthcare acquired Covid-19 infection. Working with infection control colleagues we have agreed to keep a broad overview of all IPC incidents until our data begins to normalise post Covid. Details are contained in our local response plan.



The following themes were identified as potential areas for Patient Safety Incident Investigation. Further revision of these themes was undertaken with subject matter experts with the aim to:

- Scope what is already understood about the safety theme
- Scope what actions are in place to mitigate the current patient safety risks
- Scope any gaps in our knowledge where PSII / systems analysis could generate learning as basis of future improvements

Discharge from Hospital

- There were a significant number of incidents and complaints related to discharge. These were also associated with poor patient experience and dissatisfaction. We had system feedback supported prioritising these incidents.
- As the burden of harm was not signifficant these incidents had not been subject to in-depth patient safety analysis. This suggests that the potential for systemic learning and improvement is high.

Ommission of medication

- There have been few serious incidents identified in the past five years relating to medication errors, however there is high impact on patient experience from these incidents, and although actual harm is low, the potential for harm is high.
- There is potential for broad systemic learning, and improvement work could significantly impact upon the number of events, and so reduce the risk of harm being actualised.

Care of Deteriorating Patient

- This is a national and regional patient safety priority. Incidents involving the care of critically ill patients are very rare, but when they do occur theyften result in significant harm. The impact of these events can be devastating for patients, their families and the staff involved in providing care.
- There is a high potential for systems learning through detailed analysis of care provided following identification of deterioration which could lead to improved outcomes.

Outcomes for patients admitted as emergencies at weekends

- Summary Hospital-level Mortality Indicator (SHMI) report suggested potential learning from analysis of care of patients admitted as emergencies over weekends

Following this review themes 1 – 3 were adopted as Patient Safety Events which would be subject to a Patient Safety Incident Investigation.

In discussion with subject matter experts the Mortality Review Group has identified improvement work relating to theme 4, outcomes for emergency admissions, and this theme would not benefit from PSII at this time.

Refreshing our Patient Safety Incident Profile

Refresh of data October 2024

The refresh of data looked at a two-year period of patient safety event data from 01 July 2022 to 31 July 2024. This included a light touch triangulation with other insight sources, including feedback (Complaints and Compliments) and Mortality Data.

The initial most numerous incidents were mapped against our existing plan, as demonstrated by the table below;

#	**Safety Event Category**	**Current profile**
1	Pressure Ulcers	There is a planned response to pressure ulcers within our current PSIRP. In addition to this the Trust has a Tissue Viability Steering Group which reports into the Patient Safety Improvement Forum (PSIF). PSIF has oversight of the Tissue Viability Work Plan and Improvement Work.
2	Slips, Trips and Falls	There is a planned response to patient falls within our PSIRP. In addition to this the Trust has a Falls and Frailty Steering Group which reports into the PSIF. PSIF has oversight of the Steering Group Work Plan and Improvement Work.
3	Discharge/waiting times & transfer issues	There is a plan to commission a Patient Safety Incident Investigation for Discharge errors within the local priorities of our PSRP. This is currently being redefined through work with the Discharge Quality Steering Group. The main sub-set within discharge and transfer issues relates to 12-hour breaches within the two Emergency Departments. This has seen significant improvement..
4	Communication	The main sub-set within communication relates to communication with external teams. Further analysis highlighted that this has significant areas of overlap with transfer and discharge issues above.
5	Security Issues	These issues are not currently covered by the PSIRP. The Trust has recently commissioned a Patient Safety Incident Investigation, relating to a patient leaving the hospital to self -harm. This

		was commissioned due to the potential for significant learning. The main contributory factor for the significant increase in security issues correlates to the care and treatment of people who require mental health services.

The review of Security Incidents revealed that the most common sub-categories are restraint to Assist Procedure and Patient Absconded / Missing. The Trust has a restrictive practice steering group which is leading on improvements relating to the use of restraint and other restrictive practices, and this group has led on the introduction of a restrictive practice navigator on the Electronic Patient Record, together with a range of other improvement focussed activity.

Overall, the increase in reporting of security incidents is linked to events relating to patients with mental health problems, learning disabilities, dementia, delirium or other cognitive impairments.

General Security incidents usually relate to patient safety events reported by the security team when they attend to respond to a patient who is being assaultive towards others, or is actively attempting to abscond from a ward or department

The issues relating to patients absconding or leaving are significant for the Trust, the frequency of these patient safety events has effectively doubled over the past two years.

There has also been an increase in the reporting of patient safety events involving people with complex mental health problems. It is important to note that in the majority of cases this is not relating to patients with no criteria to reside. These incidents are relating to patients requiring hospital care for a medical or surgical health issue, whose care and treatment is impacted by significant co-morbidities, both psychiatric and physiological.

Despite the significant increase in absconding, violence and aggression and other safety events affecting this population these events remain within a normal variation, and are well understood by the services supporting these patients.

There is significant oversight and improvement activity guided by a number of forums, including:

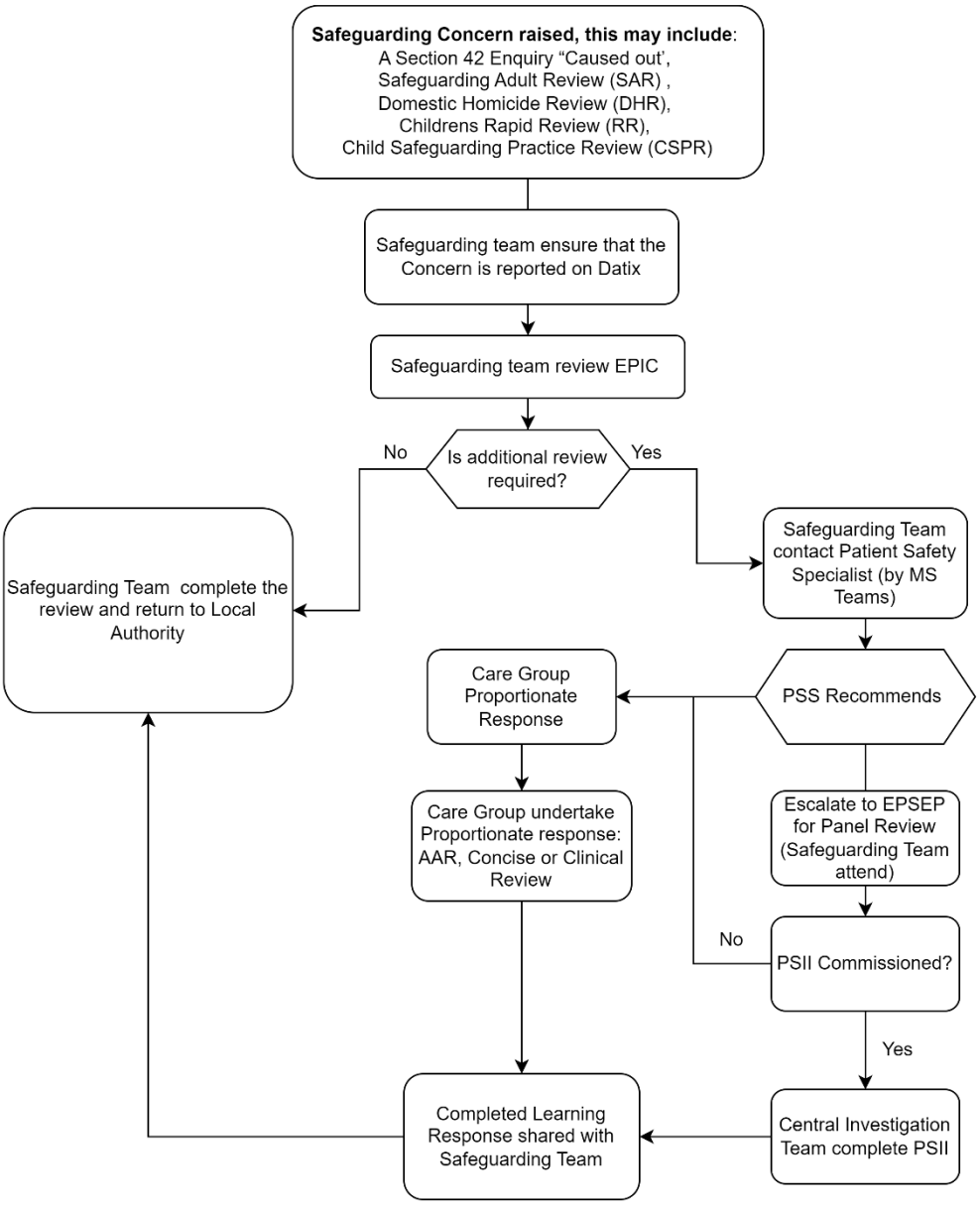
- Mental Health Steering Group
- Restrictive Practice Steering Group
- Violence and Aggression Steering Group

The refresh of our insight data has identified that our patient safety incident response plan should not be updated to include a local priority in this area. The current improvement work will continue to address these issues, working closely with partner organisations to deliver learning.

Additional work will be undertaken with the Community Services Care Group. Our community colleagues report 14% of these patient safety events and are providing care in significantly less predictable or controllable environments. There may be benefit to a local learning response specifically for this community services.

Safeguarding

Royal Devon Process for managing safeguarding enquiries through PSIRF



Learning from the first year of PSIRF has identified a need for additional clarity on the interface between Safeguarding and Patient Safety Incident Investigations. The flowchart above has been developed in partnership with Safeguarding colleagues to provide this clarity and ensure we are able to provide a proportionate response to all safeguarding issues.

Maternity Services

Patient Safety Events for maternity services have been reviewed for the from 01 July 2022 to 31 July 2024. This was to ensure that the profile of events remains consistent with the original benchmarking completed for the original Response Plan. Review of this data has confirmed that our event profile has not significantly changed, and our current responses for Maternity patient safety events remain relevant.

Defining our patient safety improvement profile

The Royal Devon has established patient safety workstreams in place for areas of improvement. These are represented in our **Patient Safety on a Page** Plan.

This plan provides a high-level overview of the patient safety priorities for the Royal Devon. This does not present the totality of Patient Safety Work undertaken by the organisation.

Patient Safety on a Page		
Slips Trips and Falls • Improvement activity regarding Slips, trips and falls is coordinated by the **Falls and Frailty Steering Group** • The Falls and Frailty Steering Group has an annual work plan which provides details of the Trust's improvement activity together with monitoring of data and reviewing learning from safety events. • The workplan is presented to the Patient Safety Committee • The group provides the Committee with regular updates on the progress of the work plan and any risks to non-completion	**Pressure Ulcers** • Improvement activity regarding Pressure Ulcers is coordinated by the **Tissue Viability Steering Group** • The Tissue Viability Steering Group has an annual work plan which provides details of the Trust's improvement activity together with monitoring of data and reviewing learning from safety events. • The workplan is presented to the Patient Safety Committee • The group provides the Committee with regular updates on the progress of the work plan and any risks to non-completion	**Deteriorating Patients** • Improvement activity regarding Deteriorating Patients is coordinated by the **Resuscitation Steering Group** • The Resuscitation Steering Group has an annual work plan which provides details of the Trust's improvement activity together with monitoring of data and reviewing learning from safety events. • The workplan is presented to the Patient Safety Committee • The group provides the Committee with regular updates on the progress of the work plan and any risks to non-completion
Discharge • Improvement activity regarding Slips, trips and falls is coordinated by the **Discharge Improvement Group** • The Discharge Improvement Group is developing its first work plan which will detail improvement priorities together with the approach for monitoring the quality of discharge information. • The group provides the Patient Safety Committee with regular updates on the progress of it's work and any risks to non-completion	**Assessment and Prevention of VTE** • The Trust is currently reviewing and consolidating its activity supporting improvements in the assessment and prevention of VTE • The procedural framework is being updated • The approach to monitoring quality improvement metrics is currently being designed. • The Governance and oversight approach for this workstream is currently being developed. • This workstream will begin reporting in Q2 2025 - 2026	**Identification of Patients** • A safety collaborative approach between the Patient Safety Team, The Transformation Team and the Clinical Care Groups is under development to review the Trusts approach to Patient Identification and establish safety recommendations.

Our patient safety incident response plan: national requirements.

The overall aim of our patient safety response is to ensure that learning activity is held by the services and Divisions. The central team and Oversight forums will operate in a supportive framework which will help adoption and spread of learning and improvement activity.

Patient safety incident type	Required response	Anticipated improvement route
Deaths thought more likely than not due to problems in care *(A death that has been clinically assessed using a recognised methodology of case record/note review (Medical Examiner Review or Structured Judgement Review) and determined more likely than not to have resulted from problems in healthcare and therefore to have been potentially avoidable)*	Patient Safety Incident Investigation (PSII) led by the organisation where the care was provided.	The patient safety investigation will be reviewed by the Patient Safety Event Review Group to ensure learning is identified and shared with the Patient Safety Improvement Forum. The Forum will scope potential quality improvement activity. Learning and improvement activity will be shared with the Mortality Review Group, who will offer expertise relating to improvement activity relating to the mortality agenda
Child deaths	Refer for Child Death Overview Panel. *Providers should liaise with the panel to identify if the potential for significant learning may require a locally led PSII alongside the investigation panel.*	Learning and will be shared with the Lead Nurse for Children, who will offer expertise relating to improvement activity relating to children's services. They will be a standing member of the Patient Safety Improvement Forum.
Deaths of people with learning disabilities or autism	Refer for Learning Disability Mortality Review (LeDeR)	Learning will be shared with the Mortality Review Group, who will offer expertise relating

Patient safety incident type	Required response	Anticipated improvement route
	Providers should liaise with LeDeR to identify if the potential for significant learning may require a locally led PSII alongside the LeDeR review.	to improvement activity relating to the mortality agenda. The Learning Disability Operational Group will support the development of quality improvement work in partnership with the Patient Safety Improvement Forum.
Incidents meeting the 2018 Never Events Criteria *(Please see Appendix Four for listing)*	Patient Safety Incident Investigation (PSII) led by the organisation where the event occurred.	The patient safety investigation will be reviewed by the Patient Safety Event Review Group to ensure learning is identified and shared with the Patient Safety Improvement Forum. The Forum will scope potential quality improvement activity**.**
Maternity and neonatal incidents meeting Maternity and New-born Safety Investigations (MNSI) criteria.	Refer to MNSI for independent PSII	The investigation and safety recommendations will be reviewed by the Patient Safety Event Review Group to ensure learning is identified and shared with the Patient Safety Improvement Forum. Maternity services will lead on improvement activity with support from the Patient Safety Improvement Team.
Maternity and Neonatal Safety Events • All late fetal losses 22+0 to 23+6;	These cases will be reported to MBRRACE-UK and reviewed using the Perinatal Mortality Review Tool.	Incidents are reviewed each month within the Maternity Governance Forum's through our maternity dashboard. If there is a category (i.e. PPH)

Patient safety incident type	Required response	Anticipated improvement route
• All antepartum and intrapartum stillbirths; • All neonatal deaths from birth at 22+0 to 28 days after birth; All post-neonatal deaths where the baby is born alive from 22+0 but dies after 28 following care in a neonatal unit; the baby may be receiving planned palliative care elsewhere (including at home) when they die.	Monthly incident trend reports for our governance meetings which highlight the number of incidents within each category to prompt discussion and enable regular monitoring of 'low level' incidents	which appears to be 'red' within the RAG rating element of the dashboard for subsequent months, an Audit is prompted to see if there is any learning or concerns that can be identified. **Maternity dashboard** reviewed monthly through mat gov – trends and themes are noted and if concerns thematic review/audit commissioned. **MBRRACE figures published annually** to trust.
All deaths of pregnant women and women up to one year following the end of the pregnancy (regardless of the place and circumstances of the death).	These cases will be reported to MBRRACE-UK Monthly incident trend reports for our governance meetings which highlight the number of incidents within each category to prompt discussion and enable regular monitoring of 'low level' incidents.	**Maternity dashboard** reviewed monthly through mat gov – trends and themes are noted and if concerns thematic review/audit commissioned. **MBRRACE figures published annually** to trust.
Safeguarding Incidents in which: • babies, children, or young people are on a child	Refer to local authority safeguarding lead.	The Integrated Safeguarding Committee will lead on the identification of learning and potential improvement activity

Patient safety incident type	Required response	Anticipated improvement route
protection plan; looked after plan or a victim of wilful neglect or domestic abuse/violence • adults (over 18 years old) are in receipt of care and support needs from their local authority • the incident relates to FGM, Prevent (radicalisation to terrorism), modern slavery and human trafficking or domestic abuse/violence	*Healthcare organisations must contribute towards domestic independent inquiries, joint targeted area inspections, child safeguarding practice reviews, domestic homicide reviews and any other safeguarding reviews (and inquiries) as required to do so by the local safeguarding partnership (for children) and local safeguarding adults boards*	from safeguarding reviews within the Trust, and from system learning from the Devon Safeguarding system.
Incidents in NHS Screening Programme	Refer to local Screening Quality Assurance Service (SQAS) for advice. *They will consider the scale, risk of harm and potential for recurrence and advise the provider whether to complete the screening incident assessment form (SIAF).* *Discussion may be required to agree if a locally led PSII is required alongside any*	Incidents

Patient safety incident type	Required response	Anticipated improvement route
	review commissioned by SQAS	

Our patient safety incident response plan: local focus

Patient safety incident type or issue	Planned response	Anticipated improvement route
Harm occurring during transfer of patients between a care home and acute or community hospital, where quality of discharge has been identified as a contributory or causative factor to either a complaint or readmission. Initial focus will be upon events assessed as resulting in minor or moderate physical or psychological harm. For this issue, complaints include issues raised by the patient, and carer or professional from their care service or GP.	Incidents will be identified by the Community Services Division, and flagged to the Emerging Patient Safety Event Panel for Local Patient Safety Incident Investigation The Trust will initially undertake 3 investigations (2 from eastern services and one from northern services.) Following this, the Trust will review initial learning and agree on the additional number of investigations required to ensure improvement or if additional insight is required.	The patient safety investigation will be reviewed by the Patient Safety Event Review Group to ensure learning is identified and shared with the Patient Safety Improvement Forum. The Forum will scope potential quality improvement activity. The learning and improvement plan will be overseen to completion by the patient safety committee
Patient harm occurring as a result of the omission or incorrect dose of anticoagulant medication. Anticoagulants are medications that help prevent blood clots forming. They are given to people at a high risk of developing clots to reduce	Incidents will be identified by the Surgical and Medical Services Divisions via the dashboard. They will be reviewed through current Divisional processes. The Dashboard will be visible to the Trust's Medication Safety Officer and VTE lead, who will support Divisions to identify the	The Trust will initially undertake 5 investigations. Investigations will cover a range of outcomes from no harm to severe harm; this will support developing an understanding of the protective factors which prevented harm occurring following the omission or incorrect dosing of anticoagulants.

Patient safety incident type or issue	Planned response	Anticipated improvement route
their risk of developing a stroke or heart attack. An algorithm will be developed to flag medication incidents involving the most common anticoagulants on the . This will identify both prescription and administration errors which will populate a dashboard, which the Relevant Divisions can review.	most appropriate cases for PSII review. These will be escalated to the Emerging Patient Safety Event Panel for Local Patient Safety Incident Investigation.	The patient safety investigations will be reviewed by the Patient Safety Event Review Group to ensure learning is identified and shared with the Patient Safety Improvement Forum. The Forum will scope potential quality improvement activity. The learning and improvement plan will be overseen to completion by the patient safety committee
Patients becoming critically unwell and requiring multiple (>2) emergency medical responses (MET / Outreach call) who are subsequently admitted to ITU or experience a fatal outcome. Repeated escalations can be identified through reporting from the electronic patient record. These reports will be reviewed by the Trust Resuscitation Lead and Clinical Matron for Patient Safety who will escalate for Divisional Review where potential learning is identified. They will also review any cases identified through	Incidents will be identified by the Medical Services Division, and flagged to the Emerging Patient Safety Event Panel for Local Patient Safety Incident Investigation	The patient safety investigation will be reviewed by the Patient Safety Event Review Group to ensure learning is identified and shared with the Patient Safety Improvement Forum. The Forum will scope potential quality improvement activity. The learning and improvement plan will be overseen to completion by the patient safety committee

Patient safety incident type or issue	Planned response	Anticipated improvement route
Medical Examiner Scrutiny and reported as potential incidents		
Incidents of healthcare acquired grade two or greater pressure ulcers, where the damage has occurred whilst Royal Devon was responsible for care	Incidents will be identified by the Tissue Viability Team. The ward team will undertake an **after-action review.** If the tissue viability issue has resulted in major harm they will refer the case for a speciality **M&M Review**. A member of the Tissue Viability Team will usually attend the M&M review. In extremis, a pressure ulcer may meet the criteria of National reporting requirements. These events should be discussed with a patient safety specialist ad considered for escalation to the Emergent Patient Safety Event Panel.	The central investigation team will support the Tissue Viability Steering Group with the trending and theming of learning from after action reviews. The Tissue Viability Steering Group will present learning from the trending and theming to the Patient Safety Improvement Forum, who will identify opportunities for formal improvement work as part of the Trust's patient safety improvement plan.
Falls resulting in moderate or greater harm, including fractures.	Incidents will be identified by the Division where the fall occurred. A falls **Swarm** will be undertaken as soon as possible after the event on the ward where the fall occurred.	The central investigation team will support the Falls Steering Group with the trending and theming of learning from Swarms The Falls Steering Group will present learning from the

Patient safety incident type or issue	Planned response	Anticipated improvement route
	In extremis, harm from a fall may meet the criteria of National reporting requirements. These events should be discussed with a patient safety specialist and considered for escalation to the Emergent Patient Safety Event Panel.	trending and theming to the Patient Safety Improvement Forum, who will identify opportunities for formal improvement work as part of the Trust's patient safety improvement plan.
Infection Prevention and Control	Please refer to the Infection Prevention & Control Patient Safety Incident Response Framework Learning Matrix (Below) for the detailed responses to Infection Prevention and Control Patient Safety Events.	
Other Maternity and Neonatal Events	Matron for Quality and Safety and Head of Midwifery undertake weekly review of all incidents. These are subject to a senior team review (MDT) to identify immediate learning, safety actions or if appropriate escalation to Emergent Patient Safety Event panel. For lower-level incidents, these are graded and allocated to one of the Band 7 midwives to review (managers investigation) Monthly incident trend reports for our governance	Any learning identified will be disseminated either to the individual or via our weekly 'effective handover' which goes out to all maternity staff. Midwifery services will regularly report learning from patient safety events to the patient safety improvement forum; where opportunities for Trust wide learning will be developed.

Patient safety incident type or issue	Planned response	Anticipated improvement route
	meetings which highlight the number of incidents within each category to prompt discussion and enable regular monitoring of ‘low level’ incidents.	

Infection Prevention & Control Patient Safety Incident Response Framework Learning Matrix

Incident	Apportioning	Mandatory reporting	Datix	IPC Incident response document required	Formal Duty of Candour (DoC)	Patient Safety Event Escalation Report (PSEER) requirement	Internal governance/ communication (in addition to IPC team daily communication and via DATIX system)	External governance/ communication
MRSA bacteraemia	HOHA	Yes UKHSA HCAI Data Capture System	Yes	MRSA Bacteraemia Infection Control (IC) Review	To be determined for appropriateness by the responsible clinical team following review and documented when required. Governance team input ensures DoC follow up upon receipt of DATIX	Yes	• Each case fed back to relevant clinical team & governance following the MRSA bacteraemia proportionate response guide • Monthly Audit and Surveillance Infection Prevention & Control (IPC) Multidisciplinary Team (MDT) meeting • Monthly Integrated performance report (IPR) • Care Group notification of HCAI cases • Quarterly Infection Prevention and Decontamination Assurance Group (IPDAG) meeting	• UKHSA regional and national mandatory enhanced surveillance (MES) teams • Integrated Care Boards (ICB) • Regional and National trends raised at NHS England Regional Network meeting • Regional and National trends raised at professional body Infection Prevention

							including source data	Society regional and national meetings • Targeted regional NHS England South West HCAI sharing & resource group
	COHA COCA	Yes UKHSA HCAI Data Capture System	Not routinely	MRSA Bacteraemia IC Review	To be determined for appropriateness by the responsible clinical team following review and documented when required	Only if IC review identifies Trust learning requiring escalation	• Cases fed back to relevant clinical team & governance following MRSA bacteraemia proportionate response guide • Monthly Audit and Surveillance IPC MDT meeting • Monthly IPR • Care Group notification of HCAI cases • Quarterly IPDAG including source data	
MSSA Bacteraemia	HOHA COHA	Yes UKHSA HCAI Data Capture system	Not routinely	MSSA Bacteraemia IC Review with full enhanced surveillance detail completed	No	Not routinely	• Any learning fed back to clinical teams • Monthly Audit and Surveillance IPC MDT meeting • Monthly IPR • Care Group notification of HCAI cases • Quarterly IPDAG including source data	• UKHSA regional and national mandatory enhanced surveillance (MES) teams • Integrated Care Boards (ICB) • Regional and National trends raised at NHS England
	COCA	Yes	Not routinely	MSSA Bacteraemia	No	Not routinely	• Monthly Audit and Surveillance	

		UKHSA HCAI Data Capture System		IC Review with targeted enhanced surveillance data			IPC MDT meeting • Monthly IPR • Quarterly IPDAG including source data	Regional Network meeting • Regional and National trends raised at professional body Infection Prevention Society regional and national meetings • Targeted regional NHS England South West HCAI sharing & resource group
Gram-negative bacteraemia identified via the UK HSA mandatory surveillance programme	HOHA COHA COCA	Yes UKHSA HCAI Data Capture System	Not routinely	Localised IC Data Collection Form. Note that targeted surveillance data collection, gathered on adapted, localised data collection forms, is undertaken in addition to UKHSA MES	Where appropriate	Not routinely	• Monthly Audit and Surveillance IPC MDT meeting • Quarterly IPDAG including source data • Monthly IPR • Care Group notification of HCAI cases • Cases pertaining to care homes are monitored for further input	• UKHSA regional and national mandatory enhanced surveillance (MES) teams • Integrated Care Boards (ICB) • Regional and National trends

				data requirements. The mandate for this will change in response to active MES organism reduction and infection prevention improvement initiatives			by the IPC CIMS team.	raised at NHS England Regional Network meeting • Regional and National trends raised at professional body Infection Prevention Society regional and national meetings • Targeted regional NHS England South West HCAI sharing & resource group
C difficile toxin positive	HOHA COHA	Yes UKHSA HCAI Data Capture System	Yes, for all cases	PIR/PSIRF huddle led by CNM, required to complete template for presentation to CD MDT to determine severity of infection/harm and lessons to be learnt. If C diff on part 1 of the death	To be determined for appropriateness following CD MDT. If required, to be undertaken by responsible clinical team and documented. Governance team input ensures DoC	Only if PIR/PSIRF review identifies Trust learning requiring escalation	• Datix by IPCT • Datix will then be completed by CNM and Governance will review and feed back to clinical team any shared learning • Monthly Audit and Surveillance IPC MDT meeting	• UKHSA regional and national mandatory enhanced surveillance (MES) teams • Integrated Care Boards (ICB) • Regional and

				certificate, an after-action review will be undertaken	follow up upon receipt of DATIX		• Care Group notification of HCAI cases • Monthly IPR • Quarterly IPDAG	National trends raised at NHS England Regional Network meeting & NHS England South West HCAI sharing & resource group • Regional and National trends raised at professional body Infection Prevention Society regional and national meetings
	COIA COCA	Yes UKHSA HCAI Data Capture System	Not routinely	Localised IC data collection form. COCA and COIA infection episodes managed as part of CIMS workstreams – targeted surveillance activity and response to	Where appropriate	Not routinely	• Information retrieved, reviewed by antimicrobial pharmacist, IPC and Microbiologist • Monthly Audit and Surveillance IPC MDT meeting	• UKHSA regional and national mandatory enhanced surveillance (MES) teams • Integrated Care Boards (ICB) • Regional and National trends raised at NHS England Regional

				be updated through ICB Annual Programme			• Quarterly IPDAG • Learning fed back to relevant clinical teams, governance and external prescribers or external care providers as appropriate	Network meeting and targeted regional NHS England South West HCAI sharing & resource group • Regional and National trends raised at professional body Infection Prevention Society regional and national meetings • External prescribers & care providers as appropriate
Surgical Site Infections identified via UKHSA protocol led surgical site infection surveillance	Superficial, Deep, Organ/Joint space per UKHSA surveillance definitions	Yes UKHSA Surgical Site Infection Surveillance Service, HCAI, Fungal, AMR, AMU & Sepsis Division	Not routinely unless cluster outbreak	Surgical Site Infection (SSI) IC Review	Where appropriate	Not routinely unless cluster outbreak or event requiring escalation	• Each case fed back to relevant clinical team & speciality governance groups • Monthly Audit and Surveillance IPC MDT meeting • Relevant Infection MDTs • Quarterly SSIS report (official and localised summary) • Reports and specific learning presented at	• UKHSA Surgical Site Infection Surveillance Service, HCAI, Fungal, AMR, AMU & Sepsis Division • Integrated Care Boards (ICB) • Regional trends raised at NHS England

							specialist governance / safety meetings • Quarterly IPDAG	South West Regional Network meeting and targeted regional NHS England South West SSI group • Regional and National trends raised at professional body Infection Prevention Society regional and national meetings
Central Intravascular & Peripheral Vascular Device Related Bacteraemia	All Eastern laboratory blood cultures processed per Nosocomial Infection National Surveillance Service (NINSS) definitions with learning shared Trust wide	No	Yes for Royal Devon University Healthcare NHS Foundation Trust cases	Central Intravascular & Peripheral Vascular Device Related Bacteraemia IC Review	To be determined for appropriateness by the responsible clinical team following review and documented when required. Governance team input ensures DoC follow up upon receipt of DATIX	Not routinely	• Monthly Audit and Surveillance IPC MDT meeting • Quarterly line bacteraemia report distribution Trust wide • Each case fed back to relevant specialist clinical & governance teams	Nil

							• Quarterly IPDAG	
Outbreaks & other IC incidents	As guided by NHSE / UKHSA requirement	No (except voluntary reporting of Norovirus outbreaks)	Yes, for all outbreaks or cases resulting in bay or ward closure	Ward huddle/swarm documentation if required as identified by the IPCT	To be determined for appropriateness by the responsible clinical team following review and documented when required. Governance team input ensures DoC follow up upon receipt of DATIX	Only if IPC Review identifies Trust learning requiring escalation	• Monthly Audit and Surveillance IPC MDT meeting • Each case fed back to relevant specialist clinical teams • IPDAG by relevant care group	• Guided by NHS England / UKHSA requirements • Regional and National trends raised at professional body Infection Prevention Society regional and national meetings • Regional trends raised at NHS England South West Regional Network meeting and targeted regional NHS England South West HCAI sharing & resource group
New isolates of multi drug resistant organisms (MDRO) including MRSA (screening or clinical isolates)	New inpatient or regular attender cases in the absence of same prior organism	No	Only if learning identified. HOHA/COHA cases	IPC team review with shared learning fed back to clinical area	To be determined for appropriateness, flowing review by the IPCT. If required, to be undertaken by the responsible clinical team. Governance team input ensures DoC follow up upon receipt of DATIX	Not routinely unless cluster outbreak or event requiring escalation	• Monthly Audit and Surveillance IPC MDT meeting • If investigation completed, cases fed back to relevant specialist clinical teams & governance • Quarterly IPDAG	Nil

IPC PSIRF Investigation MATRIX information box

Formal Duty of Candour: Responsibility to complete DoC, where appropriate, remains with the ward/governance/specialist or clinical team not the Infection Prevention & Control team. Of note: Status for DoC is routinely required within the Patient Safety Event Escalation Reporting (PSEER) template prior to escalation at the Emerging Patient Safety Event Review Panel (EPSERP). DoC may be required, when known, where healthcare associated infection is listed in Part 1a or b of the Death Certificate.

Infection Prevention & Control incident response documents relate to documents utilised by the Infection Prevention & Control team designed to incorporate mandated reporting and surveillance requirements in conjunction with PSIRF pathways. 'IC review' documents, where named above, amalgamate the after-action review and/or concise learning review process and are an adjunct to, not a replacement for, existing clinical review process and documentation held within the electronic patient record when an infection incident occurs.

Healthcare associated infection definitions for the purpose of this matrix are defined as the follows:

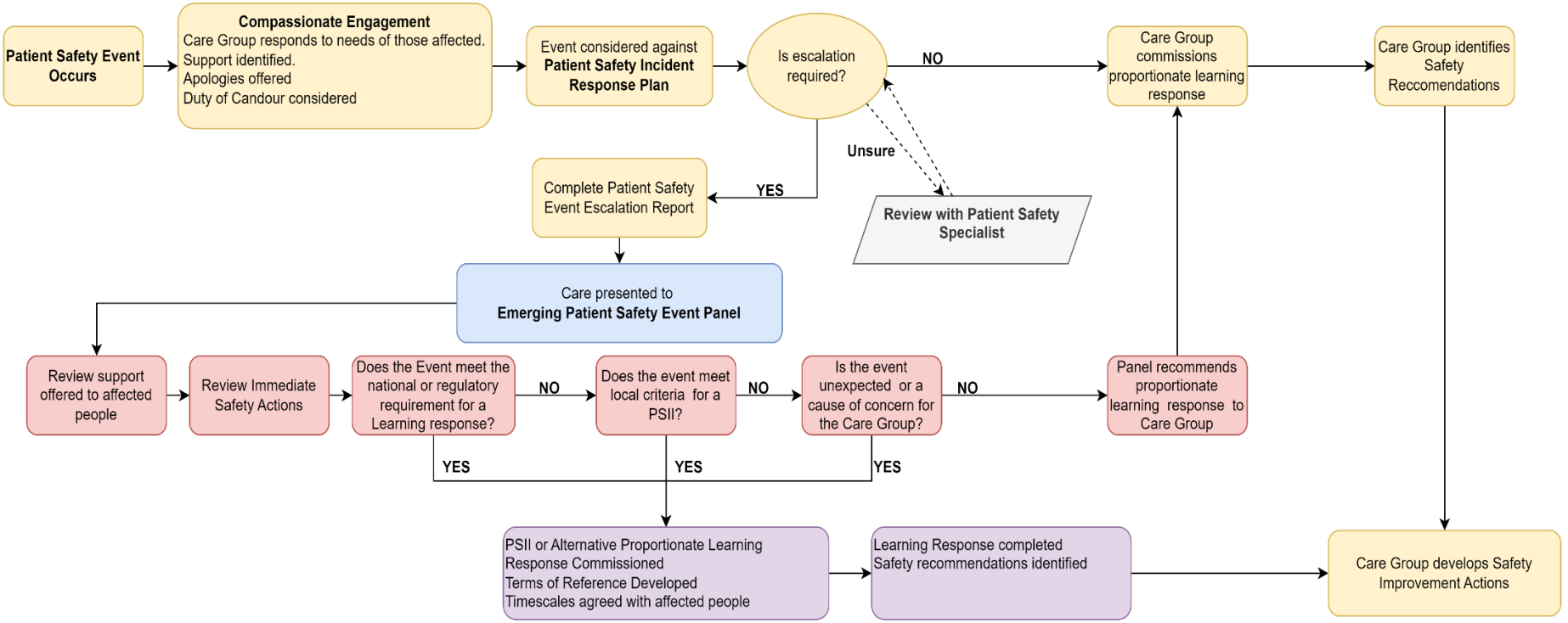
For MRSA, MSSA & Gram-negative bacteraemia; new MRSA positive clinical isolates & screening isolates from augmented care; new isolates of MDRO:
Hospital Onset Healthcare Associated (HOHA) – Any NHS patient specimens taken on the third day of inpatient admission onwards (i.e. ≥ day 3 when day of admission is day 1).

Community Onset Healthcare Associated (COHA) - Any case reported by an NHS acute trust not determined to be HOHA but where the patient was discharged from the reporting organisation within 28 days prior to the current specimen date (where date of discharge is day 1).

Community Onset, Community Associated (COCA) - Any case reported by an NHS acute trust not determined to be HOHA but where the patient has not been discharged from the reporting organisation within the past 28 days, to the current specimen date (where date of discharge is day 1).

For C difficile infection there is further stratification for onset within the community as follows:
Community Onset Indeterminate Associated (COIA) – Any case reported by an NHS acute trust not determined to be HOHA or COHA but where the patient was discharged from the reporting organisation within 84 days prior to the current specimen date (where date of discharge is day 1).

Appendix One: Patient safety incident response decision making tree



Appendix Two: Patient Safety Event Escalation Report

Patient Safety Event Escalation Report

Please complete this report as soon as is reasonably practicable following a patient safety event which you would like to escalate.

Please submit the completed form to rduh.safetyandriskadmin@nhs.net

PART ONE

Incident ID	
Incident Date	
Incident Category / Subcategory	
Outcome for Patient	
Will there be an External Review (e.g. Safeguarding; Coroners).	
Report completed by	
Reason for Escalation	

PART TWO

Brief Description of Event
Immediate Safety Actions Taken
Support provided to patient /family

Support provided to affected staff
Duty of Candour or apology provided to patient / appropriate other person
Have similar incidents occurred in the past? **What actions were taken? Have these been completed?**

Has any learning activity been undertaken in relation to this incident? (please check box ☒)

		Brief Details from learning activity
Clinical Review	☐	
MDT Review	☐	
Huddle / Swarm	☐	
After Action Review	☐	
Managers Investigation (Datix).	☐	
Other	☐	

Any other comments on the event

PART THREE – For Emerging Patient Safety Event Review Panel

Outcome from EPSERP Review

Appendix Three: Summary of Never Events

1. **Wrong Site Surgery**

   An invasive procedure performed on the wrong patient or at the wrong site (eg wrong knee, eye, limb). The incident is detected at any time after the start of the procedure.

2. **Wrong implant/prosthesis**

   Placement of an implant/prosthesis different from that specified in the procedural plan, either before or during the procedure. The incident is detected any time after the implant/prosthesis is placed in the patient

3. **Retained foreign object post procedure**

   Retention of a foreign object in a patient after a surgical/invasive procedure

4. **Mis-selection of a strong potassium solution**

   when a patient is intravenously given a strong3 potassium solution rather than the intended medication.

5. **Administration of medication by the wrong route**

   - intravenous chemotherapy by the intrathecal route
   - oral/enteral medication or feed/flush by any parenteral route
   - intravenous administration of an epidural medication that was not intended to be administered by the intravenous route
   -

6. **Overdose of insulin due to abbreviations or incorrect device**

   - a patient is given a 10-fold or greater overdose of insulin because the words ‘unit’ or ‘international units’ are abbreviated; such an overdose was given in a care setting with an electronic prescribing system
   - a healthcare professional fails to use a specific insulin administration device – that is, an insulin syringe or pen is not used to measure the insulin
   - a healthcare professional withdraws insulin from an insulin pen or pen refill and then administers this using a syringe and needle

7. **Overdose of methotrexate for non-cancer treatment**

a patient is given a dose of methotrexate, by any route, for non-cancer treatment that is more than the intended weekly dose; such an overdose was given in a care setting with an electronic prescribing system

8. Mis-selection of high strength midazolam during conscious sedation

a patient is given an overdose of midazolam due to the selection of a high strength preparation (5 mg/mL or 2 mg/mL) instead of the 1 mg/mL preparation, in a clinical area performing conscious sedation

9. Failure to install functional collapsible shower or curtain rails

- failure of collapsible curtain or shower rails to collapse when an inpatient attempts or completes a suicide
- failure to install collapsible rails and an inpatient attempt or completes a suicide using non-collapsible rails.

10. Falls from poorly restricted windows

A patient falling from a poorly restricted window. This applies to:

- windows 'within reach' of patients; this means windows (including the window sills) that are within reach of someone standing at floor level and that can be exited/fallen from without needing to move furniture or use tools to climb out of the window
- windows located in facilities/areas where healthcare is provided and that patients can and do access
- where patients deliberately or accidentally fall from a window where a fitted restrictor is damaged or disabled, but not where a patient deliberately disables a restrictor or breaks the window immediately before they fall
- where patients can deliberately overcome a window restrictor using their hands or commonly available flat-bladed instruments as well as the 'key' provided.

11. Chest or neck entrapment in bed rails

Entrapment of a patient's chest or neck between bedrails or in the bedframe or mattress, where the bedrail dimensions or the combined bedrail, bedframe and mattress dimensions do not comply with Medicines and Healthcare products Regulatory Agency (MHRA) guidance.

12. **Transfusion or transplantation of ABO-incompatible blood components or organs**

    Unintentional transfusion of ABO-incompatible blood components

13. **Misplaced naso- or oro-gastric tubes**

    Misplacement of a naso- or oro-gastric tube in the pleura or respiratory tract that is not detected before starting a feed, flush or medication administration.

14. **Scalding of patients**

    Patient scalded by water used for washing/bathing.

15. **Unintentional connection of a patient requiring oxygen to an air flowmeter**