Royal Papworth Hospital NHS Foundation Trust

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Version Control table

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11/03/2025 27/03/2025	V 2.0	QRMG (Approved) Quality and Risk (Q&R) Committee (ratified)

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1.0	**INTRODUCTION (INCLUDING PURPOSE OF DOCUMENT)**
1.1	This patient safety incident response plan sets out how Royal Papworth Hospital Foundation Trust intends to respond to patient safety incidents commencing from April 2025 until March 2026. The plan is designed to be flexible and responsive to allow consideration for unforeseen circumstances or events that may trigger the need for a specific learning response approach. Our plan will always keep those who are affected by a patient safety event at the heart of our learning and improvement.
1.2	The patient safety incident response plan is supported by Trust policies on incident reporting, responding to patient complaints, risk management and being open and is governed by the clinical governance structure from Ward to Board. Summaries of learning responses in the form of a Learning Bite are available to all staff via our organisation's intranet. The Royal Papworth Patient Safety Incident Response Policy (DN665) should be referred to support the delivery of this plan for pathways for escalation, methods of review, safety action development, safety improvement plans and monitoring improvement.
1.3	This annual plan is a 'live document' with the scope to adapt the use of the learning response tools. It is recognised that there is no 'one size fits all' and each safety incident will be approached according to the circumstances of the occurrence and needs of those involved in order to be proportionate, effective and to maximise learning and improvement opportunities. The patient safety incident response plan is subject to an annual review to ensure our focus remains relevant, appropriately focused and effective. It must factor in ongoing improvement work and recognise our patient safety incident profile is likely to change with the health economy and external drivers. This flexibility will also provide an opportunity to re-engage with stakeholders to discuss and agree changes needed.
2.0	**OUR SERVICES**
2.1	Royal Papworth Hospital (RPH) is a regional centre for the diagnosis and treatment of cardiothoracic disease. It is also a national centre for a range of specialist services, including heart and lung transplantation, pulmonary endarterectomy (PEA) and Extra Corporeal Membrane Oxygenation (ECMO). Royal Papworth Hospital has the largest respiratory support and sleep centre (RSSC) in the UK.
2.2	The Trust moved to its new building on the Cambridge Biomedical Campus in May 2019. The hospital encompasses 246 beds, six operating theatres, six cardiac catheterisation labs and two bronchoscopy rooms. In addition, in April 2022, the Heart & Lung Research Institute (HLRI) opened which houses University of Cambridge (UoC) research laboratories, and a Clinical Research Facility.

3.0	DEFINING OUR PATIENT SAFETY INCIDENT PROFILE
3.1	The Trust first implemented Patient Safety Incident Response Framework (PSIRF) in January 2024, this is our second annual plan. The 2025/2026 plan provides a continuation from the safety incident profile identified in the data capture of the 2024/2025 initial 18-month plan, that first went live in January 2024. **Our first year plan identified 5 key focus areas:** 1. Recognised but unintended outcome of treatment or procedure -with adverse consequences e.g. • Misplacement of central venous catheter, • Hospital acquired infections, • Surgical site Infections (SSI's) • Deteriorating patient. 2. Identified Implementation of care or treatment issues within the patient pathway e.g. • -Referral process • -Appointment delays, cancellations • -Access issues (falling outside of Referral to Treatment (RTT) and Harm review) • -Admission, diagnostic errors, or safety incidents relating to patient transfer or discharge (internal or externally). 3. Medication safety incident e.g. omission of critical medication, prescribing, or administration. 4. Unwitnessed falls resulting in fracture or haemorrhage 5. Hospital Acquired pressure ulcers category 3, 4 or unstageable (including medical device related The Five identified key priorities in 2024/25, although broad were able to provide a framework for the first year on areas that we would focus on as part of our plan. Alongside, this we have reflected on the actions taken, learning that has occurred from implementation of this first year's plan and considered what has changed with the governance and oversight of some of the areas detailed in the year 1 plan for patient safety improvement that have since been embedded changes as business as usual. This has helped provided a steer on our opportunities to improve what we focus on for the next year plan for 2025/26. Detailed in the next section is a further focus on the data and processes reviewed to develop our year 2 plan.

3.2	The data reviewed for the 2025-2026 plan included information that was gathered from the Trust Datix incident reporting system for the period between April 2020 – December 2024 (3 years 9 months). This data range includes the period of service delivery changes during and after the COVID 19 pandemic. Within the preparation for the plan, we have considered the themes from the learning responses during year one of PSIRF implementation period, mapping of incidents with current Trust improvement priority works streams, key priorities from the Trust's preceding annual reports and quality accounts. This has provided a broad range of context. The top local patient safety risks from the Trust risk register have been considered, alongside all incidents that are reported to identify opportunities for learning and improvement using the following criteria for the review: **The potential for harm** • People: physical, psychological, loss of trust (patients, family, caregivers) • Service delivery: impact on quality and delivery of healthcare services; impact on capacity • Public confidence: including political attention and media coverage. **The likelihood of occurrence** • Persistence of the risk • Frequency • The potential for escalation/deterioration.
3.3	**Key identified areas from the data period April 2020- December 2024 review:** Trust's patient safety incident profile is represented below. The data set reviewed included all patient safety incident and organisational incidents that had or could have led to patient harm, within this data period there were a total of 14647 incidents reported that were related to patient safety using the criteria of potential for harm and likelihood of occurrence as described in 3.2 above. From this review the most significant six types of incidents were identified and subject to a further deep dive.

3.4 The Trust incident profile analysis of the six significant safety incident types is summarised below in Table 1.

Table 1-top incident types identified related to patient safety from Datix from April 2020- December 2024.

Incident categories	No Harm (inc near misses)	Low	Moderate	Severe	Fatal	Total
Medication (Overall Total)	**1855**	**281**	**6**	**1**	**1**	**2144**
Prescribing	433	85	2	0	0	520
Preparation of Medicine/Dispensing	167	14	0	0	0	181
Monitoring	76	31	2	0	0	109
Administration	991	112	2	1	0	1107
Advice	30	7	0	0	0	37
Adverse reaction	10	20	0	0	1	31
Other Medication incidents e.g. includes documentation, storage, patients own drugs	188	12	0	0	0	200
Pressure ulcers (Overall Total)	**23**	**1354**	**6**	**1**	**0**	**1385**
MASD-	4	469	1	0	0	474
Device related injury	1	335	1	0	0	337
Category 1	4	194	0	0	0	198
Category 2	2	56	0	0	0	58
Category 3	0	1	4	0	0	5
Category 4	0	0	0	1	0	1
Other skin injury e.g skin tears,	12	299	2	0	0	312
Accidents (Overall Total)	**582**	**360**	**21**	**0**	**0**	**963**
Patient Falls	516	263	19	0	0	802
Medical Devices (Overall Total)	**785**	**264**	**5**	**0**	**1**	**1055**
Device unavailable	261	42	0	0	0	303
Device malfunction	273	92	3	0	1	368
Assembly/user error	140	32	1	0	0	173
Other e.g. includes product damaged, decontamination/ storage, additional instrument in pack/missing instrument	111	98	1	0	0	210
Implementation of care or treatment within the patient pathway	**1290**	**445**	**6**	**8**	**0**	**1749**
Admission	186	50	0	0	0	236
Appointment/follow up/ waiting list	144	80	1	3	0	228
Discharge	196	54	1	1	0	252
Transfer	189	91	1	1	0	282
Referral	117	23	0	0	0	140
Laboratory diagnosis	153	26	0	0	0	179
Investigation incorrect/not performed	68	21	1	1	0	91
Delayed/missed diagnosis	39	13	2	1	0	53
	198	87	0	0	0	285

	Other pathway/diagnostic e.g. includes, investigation delayed, monitoring not completed correctly/delayed/ECMO pathway						
	Unintended outcome treatment or condition (Overall Total)	**1038**	**601**	**44**	**11**	**1**	**1654**
	Category -Treatment/ procedure **Subcategories**						
	- Infusion injury	12	104	0	0	0	116
	- Treatment/procedure delayed	257	26	1	0	0	284
	- Other treatment procedure- includes complication, sudden cardiac arrest, arterial puncture, amputation, haemorrhage,	286	233	11	8	0	537
	- Treatment process Incomplete/incorrectly (including patient monitoring) performed	79	33	10	1	0	123
	- Incorrect/insufficient Planning/preparation	41	16	0	0	0	57
	- Treatment/Procedure not performed	39	9	0	0	0	48
	- Wrong treatment/procedure	23	8	1	0	0	32
	- Retention of a foreign object						
	- Missing object (needle/swab/Instrument etc)	6	1	1	0	1	9
	-Lower number categories (including unintended injury during treatment, escalation of care, extended stay, unplanned return to theatre, arterial sheath removal, hypoxic brain injury)	22 273	2 169	0 20	0 2	0 0	24 444
							Total 8950

Table 1: Datix Incidents by date of reported April 2020- December 2024

3.5 **Summary and analysis of the six significant safety incident types:**

Medication Safety

Medicines are the most common interventions in the NHS, it is logical that incidents relating to medication are consistently within the highest reported categories for the Trust. Reporting no and low harm incidents is actively encouraged through the medication safety group and promotes identification of opportunities for learning and improvement.

In 2024 a focused review and scoping exercise using the Systems Engineering Initiative for Patient Safety framework was undertaken, exploring work as done within medication processes and the influences of and wider task and system factors. In 2025 we will continue to build on the findings from this and apply the same methodology to gather insight and understanding of factors in prescribing and preparing/dispensing incidents to better understand how our medication processes fit with technology and the hospital environment.

Pressure Ulcers
The Trust has an established process for review and scrutiny of pressure ulcers and pressure ulcer prevention improvement work is part of the tissue viability team core workplan, overseen by the Harm Free Care Panel. The data has shown low incidences of Trust acquired pressure ulcers. For 2025-2026 the Trust will continue to monitor patient harm and potential risk via Harm Free Care, the Trust Quality and Risk Report. Pressure Ulcer prevention will not be part of the focus of the 2025-2026 Patient Safety Incident Response Plan.

Patient Falls
The incidence of patient falls has seen a reduction in the last year. Learning from falls, themes and systems reviews are shared at the Trust falls prevention group. This groups have initiated improvement work, and task and finish groups to continue to the reduction in patient falls. Unwitnessed falls remains a focus for the group. For 2025-2026 the Trust will continue to monitor patient harm and potential risk via Harm Free Care, the Trust Integrated Performance Report and Trust Quality and risk Report. Patient falls unless a new risk is identified will not be part of the focus of the 2025-2026 Patient Safety Incident Response Plan.

Medical Device related incidents
Medical device incidents pose a significant risk to patient safety. Although these have been largely reported as no or low harm, over the data capture period there was one fatality and 5 incidents where moderate harm occurred. For that reason these were highlighted and subject to further analysis. During 2024-2025 risk management of medical devices has strengthened and the medical device committee provide scrutiny further against the risks with the Medical Device Safety Officer and deputy support the committee and with oversight of the potential harm and a direct link to safety and governance. Medical device related incidents, unless a new risk is identified will not be part of the focus of the 2025-2026 Patient Safety Incident Response Plan.

Identified Implementation of care or treatment issues within the patient pathway.
This incident type encompasses critical steps along the patient journey, from referral to discharge. Each step has the potential for harm, and incidents are often complex, multi-speciality and involving several providers. The volume reported is large and analysis was undertaken to identify the areas of most risk. These are within our referral pathways, capacity and waiting lists. Individual speciality led workstreams are in place in many areas and through the Patient Safety Incident Response Plan further system analysis will support change and improvement. During 2024 we undertook thematic PSII focussing on our TAVI service. The learning from this is being taken forward as an improvement workstream. The value of applying safety system analysis methodology to other services has been recognised and will be continued as a focus in specific the 2025-2026 plan.

Recognised and unintended outcome of treatment or procedure.
This is a broad type of safety incident which includes known complications of critical clinical conditions, high risk treatment and procedures. Some of which were found to be unavoidable and could be considered under LFPSE an ‘outcome event’. Analysis of these incidents has however, identified areas where we could do better. Reporting of

	these types of incidents is encouraged in conjunction with the morbity and mortality review process clinical audit and outcome measures to identify areas for improvement and learning. A recurrent theme idenfied from learning responses completed in 2024 has been how we monitor and respond to signs of clinical deterioration in patients. Improvement work is continuing through a focused task and finish group. This category will remain in the plan for 2025-2026.
4.0	**OUR PATIENT SAFETY INCIDENT RESPONSE PLAN: LOCAL FOCUS**
4.1	Our plan will build on the themes identified in 2024/2025 and continue to embed the principles of PSIRF within the Trust. We will continue to review how we use the learning response methodology for our identified safety incident profile and measure the effectiveness of these within the delivery of the Trust safety improvement plans. Table 2 lays out the 3 focus areas for 2025/2026 and the approach the Trust proposes to take. 1). Medication safety incidents-with a focus on Medication administration. 2). Unintended outcome of treatment or procedure, where there has been a delay in recognition of or escalation of a change in patient condition. 3). Patient pathway issues- Where harm or potential for harm may occur due to the unavailability of appointments and waiting lists.
4.2	Table 2 below lays out the three priorities for 2025/26 PSIRF plan: **Priority 1: Medication**

Patient safety incident type and examples	Planned response	Anticipated improvement route and resourcing
Medication safety incidents. **Examples are:** **Prescribing, preparation/dispensing and administration.**	Administration errors form the largest proportion of reported medication incidents. In 2025 we will continue to build on 2024 learning and carry through to practice via Trust wide improvement project. Applying the same scoping exercise to prescribing and preparation of medicines. Cases where significant risk or avoidable harm is suspected the following responses will be considered: **Tools available** Hot Debrief or After-Action Review (AAR) Gap Analysis completed to determine if events are within the scope of the improvement work. This may include observations of work as done using SEIPS model and whole systems analysis. Consideration of PSII if a previously unknown factor has been identified or current actions do not provide mitigation.	Through Specific Medication Administration Task and finish groups. Overseen by Trust Medication Safety Committee and the Trust Quality and Risk Management Group (QRMG). Outcome from learning response to feed into the Divisional Safety Improvement Plan. Trust Medicines Safety Improvement plan and overall monitored and supported by QRMG.

Priority 2: Unintended outcome of treatment or procedure, where there has been a delay in recognition of or escalation of a change in patient condition.

Patient safety incident type and examples	Planned response	Anticipated improvement route and resourcing
Unintended outcome of treatment or procedure, where there has been a delay in recognition of or escalation of a change in patient condition. Examples are: Inadvertent arterial puncture Unplanned sternotomy Pseudoaneurysm requiring surgical repair Surgical Site infections Unexpected deterioration of patient clinical condition.	The Trust has robust process of reviewing treatment and procedure events through Morbidity and Mortality meetings. Cases where significant risk or avoidable harm is suspected the following responses will be considered: Hot Debrief or After Action Review as soon as incident occurs. Initial review via gap analysis to determine if events fall outside of what was a possible outcome for an individual patient condition. Observations of work as done using SEIPS model and whole system analysis within a clinical review tool. Round Table (MDT) Review with key stakeholders Patient Safety Incident Investigation (PSII) if a new risk to patients or current actions do not provide mitigation.	Reviewed through Speciality Morbidity and Mortality meetings. Oversight by Deteriorating Patient Group and ALERT steering Group Outcome from above learning response to feed into the Divisional Safety Improvement Plan, and Trust improvement plan. Overseen by QRMG.

Priority 3: Patient pathway issues- Where harm or potential for harm may occur due to the unavailability of appointments and waiting lists.

Patient safety incident type and examples	Planned response	Anticipated improvement route and resourcing
Patient pathway issues- Where harm or potential for harm may occur due to the unavailability of appointments and waiting lists. **Examples are:** Referral process Appointment delays, cancellations Access issues (falling outside of Referral to Treatment (RTT) and Harm review) Admission, diagnostic errors, or safety incidents relating to patient transfer or discharge (internal or externally)	The Trust recognises the impact the expanding patient population and referral base has on patient safety. In conjunction with the existing Trust wide demand and capacity initiatives the following responses will be considered: Initial review via gap analysis to determine if events fall short of what was expected for that individual patient. Observations of work as done using SEIPS model and whole system analysis within a clinical review tool. Themed reviews, Patient Safety Incident Investigation (PSII) Escalation if Patient Safety Investigator (PSI) or lead has identified a new risk to patients or current actions do not provide mitigation.	Initiation of a Trust oversight group for pathway improvement work. Consideration of improvement work on patient flow, referral pathways and theatre prioritisation. Outcome from above learning response to feed into the Divisional Safety Improvement Plan or Trust improvement plan, overseen by QRMG. Consideration of cross- organisation or system wide incident response.

5.0	**LOCAL FOCUS CONTINUOUS IMPROVEMENT**
5.1	The patient safety incident response plan does not diminish existing work plans for current groups. The tools outlined in the PSIRF Policy (DN665) can be used to further strengthen the improvement profile, such as embedding the use of thematic reviews of past learning responses to inform the development of their safety improvement plan, or alternatively, a 'horizon scan' may be useful where pathway issues are identified or predicted regardless of whether or not an incident has occurred.
5.2	The Trust will focus is on the continued development of safety improvement plans across our most significant incident types. We will remain responsive and consider improvement planning as required where a risk or patient safety issue emerge from our own ongoing internal or external insights.
5.3	Clinical quality and risk assurance is monitored through an established governance structure. When a new clinical oversight or improvement group is formed, this will be under the umbrella of this governance structure with clear terms of reference and reporting format. These groups are responsive and driven by the recognition of emerging risks and are flexible to ensure we are continuously monitoring and learning. All patient safety workstreams report into the Trust Quality and Risk Management Group (QRMG), through the internal structure to Trust Board.
6.0	**OUR PATIENT SAFTY RESPONSE PLAN: NATIONAL REQUIRMENTS**
6.1	Some events in healthcare require a specific type of response as set out in national policies or regulations. These responses may include review by or referral to another body or team, depending on the nature of the event. Incidents meeting the Never Events criteria (2018) and deaths thought more likely than not due to problems in care (i.e., incidents meeting the Learning from Deaths criteria for PSII) require a locally led PSII. These are laid out in the Trust's Patient Safety Incident Response Policy (DN665) section 16.
7.0	**ENGAGING AND INVOLVING PATIENTS, FAMILIES AND STAFF FOLLOWING A PATIENT SAFETY INCIDENT**
7.1	The NHS PSIRF recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. Our patient safety incident response plan encourages the development of an effective Trust wide patient safety incident response system that prioritises compassionate involvement of patients and /or their families.
	We endeavour to involve those affected in a meaningful way and ensure the standards laid out in both DN665 Patient Safety Incident Response Framework (PSIRF) Policy and DN153 Duty of Candour and Being Open Policy are followed.

7.2	Psychological safety and wellbeing of staff involved with a safety event is integral to our learning and to upholding our Trust Values. When a safety event is identified the Trust will ensure staff are treated fairly and compassionately, with signposting to support during the process.
8.0	**IMPLEMENTING OUR PLAN AND RESPONDING TO CROSS-SYSTEM SAFETY INCIDENTS**
8.1	We recognise that patient safety incidents can often be complex and involve a number of organisations. When this occurs the clinical governance team will ensure appropriate cross system or partnership engagement and that the relevant organisations are identified and information is shared, with partnership colleagues engaged in investigations and learning as required.
8.2	The agreed learning response and duty of candour will be led by the organisation best placed to investigate the concerns and may depend on capability, capacity, or remit. For further details of how we will achieve cross-system engagement and learning see section 15 in DN665 Patient safety incident response Framework (PSIRF).
8.3	System learning across the Cambridgeshire and Peterborough Integrated Care System (ICS) is overseen by the Integrated Board and this will be facilitated through the locally run Community of Practice forum, which is attended by each Trust named Patient Safety Specialist or senior leads. Royal Papworth Hospital also covers other Integrated Care System as part of the work they are commissioned to provide, where incidents link to other ICS this will be also locally agreed with the relevant ICS lead and cross learning shared and agreed.
9.0	**OVERSEEING CONTINUOUS IMPROVEMENT THROUGH OUR DEVELPOMENT OF OUR ANNUAL PLAN**
9.1	The collection of information and insights from learning responses is only part of the safety improvement journey. We must move from identifying the learning to the implementation of the lessons learned and recommendations for change. The Divisional teams will hold recommendations from learning responses and have responsibility to turn these into opportunities for improvement. This may be via specific actions and/or service/system developments or via workstream that has oversight of improvements. Where there are Trust wide themes and commonalities in learning and recommendation, a Trust improvement plan will be initiated. These are key steps in our approach to continuous quality improvement of our care and safety for patients.
9.2	Delivery of these improvement plans will continue to be monitored by the Trust Quality Risk Management Group (QRMG) via their respective specialist subgroup with executive oversight by Quality and Risk Committee to Board.

Monitoring Table

What key element(s) need(s) monitoring as per local approved policy/ procedure or guidance?	Who will lead on this aspect of monitoring? Name the lead and what is the role of the multidisciplinary team or others.	What tool will be used to monitor/check/ observe/assess/ inspect/ authenticate that everything is working according to this key element from the approved policy/ procedure?	How often is the need to monitor each element? How often is the need complete a report? How often is the need to share the report?	Who or what committee will the completed report goes to. How will each report be interrogated to identify the required actions and how thoroughly should this be documented in e.g. meeting minutes.	Which committee, department or lead will undertake subsequent recommendations and action planning for any or all deficiencies and recommendations within reasonable timeframes?	How will system or practice changes be implemented the lessons learned and how will these be shared?
Element to be monitored	**Lead**	**Tool**	**Frequency**	**Reporting arrangements**	**Acting on recommendations and Lead(s)**	**Change in practice and lessons to be shared**
Annual Evaluation of PSIRF plan	***Clinical Governance Team***	***Audit of Learning Responses***	*Annual*	*QRMG*	*QRMG who will report to Q&R Committee*	**Required changes to practice will be identified & actioned within a specific time frame. A lead member of the team will be identified to take each change forward. Lessons will be shared with all the relevant stakeholders.*

Rapid Equality Impact Assessment Tool

When looking at the impact on the equality groups, you must consider the following points in accordance with General Duty of the Equality Act 2010:
In summary, those subject to the Equality Duty must have due regard to the need to:

- eliminate unlawful discrimination, harassment and victimisation;
- advance equality of opportunity between different groups; and
- foster good relations between different groups

EQUALITY IMPACT ASSESSMENT – WHAT IS THE IMPACT TO DIFFERENT GROUPS IN SOCIETY?		
If you believe there has been No impact or a Positive impact, please choose Yes for Negative impact please choose No. Please provide supporting comments, both on positive and negative impacts. You may be asked to complete a FULL EQUALITY IMPACT ASSESSMENT to understand the impact further.		**COMMENTS**
Age: Consider and detail across age ranges on old and younger people. This can include safeguarding, consent and child welfare.	Yes	
Disability: Consider and detail on attitudinal, physical and social barriers.	Yes.	
Race: Consider and detail on difference ethnic groups, nationalities, Roma gypsies, Irish travellers, language barriers.	Yes	
Sex: Consider and detail on men and women	Yes	
Gender reassignment: (including transgender) Consider and detail on transgender and transsexual people. This can include issues such as privacy of data and harassment	Yes	
Sexual orientation: Consider and detail on heterosexual people as well as lesbian, gay and bi-sexual people.	Yes	
Religion or belief: Consider and detail on people with different religions, beliefs or no belief.	Yes	
Pregnancy and maternity: Consider and detail on working arrangements, part-time working, and infant caring responsibilities.	Yes	
Marriage and civil partnership status	Yes	
Environment: Consider impact on transport, energy and waste	Yes	
Other identified groups: Consider and detail and include the source of any evidence on different socio-economic groups, area inequality, income, resident status (migrants) and other groups experiencing disadvantage and barriers to access.	Yes	
Were any NEGATIVE impacts identified?	No	
If YES, you will need to complete a full Equality Impact Assessment. Please contact the Equality, Diversity and Inclusion team papworth.edi@nhs.net for the full assessment template.		