

<b>Meeting title:</b>	Trust Board (public)					
<b>Date of the meeting:</b>	10 <sup>th</sup> October 2024					
<b>Title:</b>	Board Assurance Framework and Significant Risk Report					
<b>Report presented by:</b>	Director of Corporate & Legal Affairs					
<b>Report written by:</b>	Head of Risk Assurance					
<b>This paper is for:</b>	Decision/Approval	<input type="checkbox"/>	Assurance	<input checked="" type="checkbox"/>	Update	<input checked="" type="checkbox"/>
<b>Where this report has been discussed previously</b>	Content discussed at Risk Committee and Audit Committee meetings.					

<b>To your knowledge, does the report provide assurance or mitigate any significant risks?</b>
The purpose of this report is to provide assurance around the overarching system of risk management and internal control within UHL.

<b>Impact assessment</b>
None

**1. Purpose of the Report**

The purpose of this report is to provide the Trust Board with assurance regarding the effectiveness and robustness of the Trust’s overarching system of risk management and internal control. This report includes a summary of the following key components:

- The current status of the Board Assurance Framework (BAF); and
- A summary of significant Trust-wide risks identified on the Operational Risk Register.

**2. Recommendation**

The Trust Board is invited to assure itself that the systems and processes established for the management of risk are effective, robust, and operating as intended.

**3. Report detail**

**3.1 The Board Assurance Framework (BAF)**

The Board Assurance Framework (BAF) outlines the Trust's strategic goals and initiatives, along with the associated risks, controls, assurance mechanisms, and key actions aimed at mitigating these risks to support the achievement of the Trust’s objectives.

The content and structure of the BAF have been developed through thorough engagement with the Executive Directors and Non-Executive Directors during Trust Board development sessions and meetings. Additionally, it has been informed by a review of strategic risk themes reflected in the operational risk register. The BAF undergoes regular review by the Trust's Internal Auditors as part of their Head of Internal Audit Opinion.

The BAF remains aligned with the Trust's Strategic Objectives. Following the launch of the Trust's strategy, "Leading in healthcare, trusted in communities," at the Trust Board in October 2023, the risk descriptions within the BAF have been revised where necessary to reflect the new strategic goals.

Monthly meetings have been held between the Head of Risk Assurance, the Transformation Programme Manager, and each designated responsible officer (either the Executive Lead or Deputy) to review and update the strategic risks. These updates are then reported to the respective Board Committees for oversight of the risks assigned to them within the BAF. The Committees are responsible for providing assurance on these risks through their escalation reports to the Trust Board.

There is a well-established process in place to add new risks, remove existing risks, or amend risk ratings within the BAF. Any changes must be reviewed and assured by the relevant Board Committee before escalation to the Trust Board for endorsement as appropriate.

Since the last report to Trust Board in July 2024, a new row has been entered on the People risk relating to the workforce plan (current rating as discussed at Risk Committee is 20). At Committee meetings in September, it was noted that discussions related to this were duplicated across Finance and Investment Committee (FIC) and People and Culture Committee (PCC) and it was proposed that the workforce position only be presented to FIC going forward.

During this reporting period, no risks have been closed on the BAF. However, the Quality Committee has noted revised risk ratings for several threats under the Quality risk category, namely *patients and carers not involved or listened to* – the current risk score has decreased from 20 to 16; *conflicting priorities* – the current risk score has reduced from 20 to 12, which is the tolerable level; *lack of a systematic approach to quality improvement* – the current risk score has lowered from 20 to 12, meeting the tolerable level; *patient involvement in a research study* – the current risk score has been reduced to 6, which aligns with the target rating. Despite these reductions, the overall rating for the Quality Risk remains at 20.

Currently, the following risk themes have an overall rating of 20 on the BAF:

- Quality Risks (including gaps in quality governance arrangements) – monitored by the Quality Committee.
- Activity Risks (relating to Urgent and Emergency Care, Elective services, and Cancer services) – monitored by the Operations & Performance Committee.
- Finance Risks (including financial sustainability and Cost Improvement Programme) – monitored by the Finance Investment Committee.

- Digital Risks (relating to infrastructure and PAS upgrades) – monitored by the Finance Investment Committee and the Our Future Hospital & Transformation Committee.
- People Risks (including issues relating to transactional services) – monitored by the People & Culture Committee.

A copy of the current BAF is attached as Appendix A.

### **3.2 The Operational risk register**

The operational risk register provides a comprehensive overview of both clinical and non-clinical risks within the Clinical Management Groups (CMGs) and corporate directorates, focusing on risks related to the ongoing day-to-day operations of the Trust.

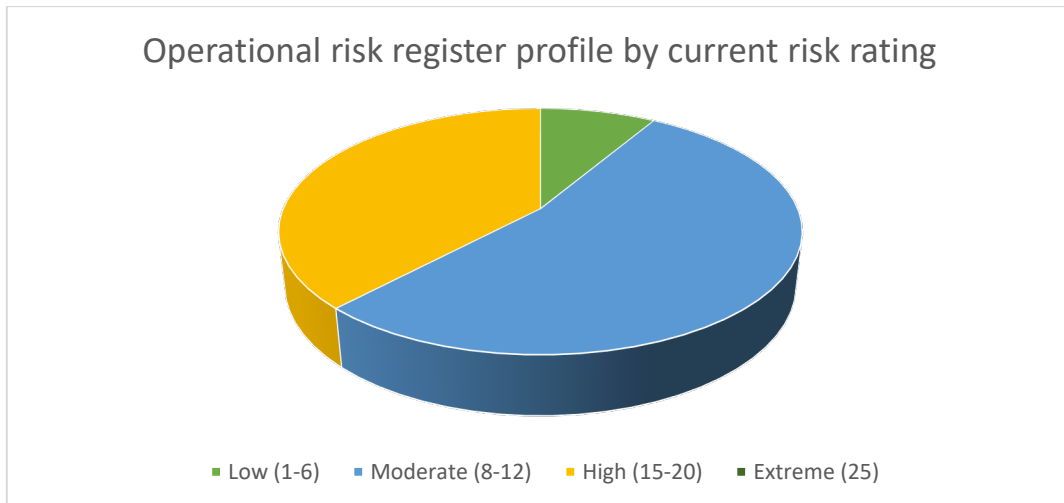
Operational risks encompass a wide range of potential issues, including those to the delivery of Wards / Area specific activities and objectives, Specialty / Department specific activities and objectives, CMG / Directorate specific activities and objectives, and Trust-wide initiatives where multiple services are impacted.

Operational risks have been assessed in terms of their cause and impacts, the likelihood of the risk event occurring, and the typical credible impacts should the risk materialise. The Trust uses a 5 x 5 risk matrix to score and prioritise risks. New risks are formally approved by the relevant CMG leader(s) or corporate director/deputy prior to inclusion in the risk register. This process ensures a thorough review of the current effectiveness of mitigation measures, as well as the development of an action plan to address any gaps between residual and target risk scores.

Risk register findings and performance is reported to the Risk Committee monthly. In September there were 382 open risks on the Datix operational risk register. Of these:

- No risks have an extreme current rating (risk rating of 25).
- 141 are significant risks (rated 15-20).
- 202 are moderate risks (rated 8-12).
- 39 are low risks (rated 1-6).

All operational risks are assigned to a risk owner and a breakdown of the risks by current rating is shown in the graphic below:



Of the 382 open risks, 132 are recognised as Trust-wide risks, which means they affect multiple services and are overseen by a relevant Corporate Director. At present there are 44 significant Trust-wide risks (rated 15 and above) and to provide assurance around progress with mitigations to manage these risks they are now included for discussion at Risk Committee meetings.

Risk register performance is reported monthly to Risk Committee for scrutiny and challenge around operational risks. Risk Committee continues to review all newly identified significant risks (rated 15 and above), alongside closed risks and longstanding Trust-wide risks. In addition, CMGs and Corporate Directorates provide regular assurance reports, summarising progress in managing significant risks within their areas of responsibility.

The operational risk register is a standing agenda item at CMG Boards, reviewed on a monthly basis to guide discussions and decision-making related to risk management. Additionally, performance is reported monthly to CMG Performance Review Meetings (PRMs), where they specifically address risks that have exceeded their scheduled review dates or have actions with elapsed due dates. CMGs are required to provide assurance to the Leadership Team at PRMs, detailing the corrective actions they have taken to address any variances in their risk data.

For the reporting period, the October Risk Committee noted that 8% of operational risks had elapsed review dates, which is in line with the target of less than 10%.

An analysis of risk themes confirms alignment between the operational risk register and the strategic risks identified on the BAF. Key themes within the operational risk register include:

- **Workforce Gaps:** Issues related to recruitment, retention, and the skill mix of both clinical and non-clinical staff across various services. Workforce threats are also reflected as a strategic risk on the BAF.
- **Patient Activity and Flow:** Challenges in managing demand and capacity within urgent and emergency care services, addressing elective care backlogs, and

providing timely care for cancer patients. These themes are mirrored in the strategic risks reported on the BAF.

- Estates and the Environment: Risks associated with ageing infrastructure, particularly in operating theatres and ICU environments, as well as the broader estate. Estate related threats are also reported as strategic risks on the BAF.
- Equipment and Supplies: Concerns about ageing clinical equipment and the need for improvements in IM&T infrastructure and digital systems. Digital threats, including those related to the PAS (Patient Administration System) and EPR (Electronic Patient Record), are similarly reported as strategic risks on the BAF.
- Finances: Risks concerning capital funding needed for addressing backlog maintenance, managing increased costs, and ensuring long-term financial sustainability. Capital funding and financial sustainability are also recognised as strategic threats on the BAF.

A summary of the Operational Trust-wide significant risk register is attached as Appendix B.

Appendix A - UHL Board Assurance Framework

Strategic Goals: Leading in Healthcare, Trusted in Communities: High-quality care for all A great place to work Partnerships for impact Research and education excellence

Strategic initiatives	Strategic BAF Risk	Executive Leads	Board Committee	Highest Current Rating	Tolerable Rating	Target Rating	Current Rating Movement
1 Care Quality and Experiences Safety Clinical and Commercial Research Healthcare and Education Training Continuous Improvement	Strategic BAF risk 01 - Quality Governance Condition: Lack of a Quality Governance and Assurance framework Risk: Failure to maintain and improve patient safety, clinical effectiveness and patient experience	CN, MD	Quality Committee	20	12	6	↔
2 Access Place-based Services and Primary/Secondary Care Integration	Strategic BAF risk 02 - Activity (UEC, Elective, Cancer) Condition: Demand overwhelms capacity and delays access to services Risk: Failure to meet national standards for timely urgent , elective and cancer care	COO	Operations & Performance Committee	20	12	9	↔
Strategic risk 3 - Material misstatements in the Trust's restated 2019/20 balance sheet, with implications for audit opinion on 2020/21 and future accounts	Closed: Strategic risk 3 - Finance (Balance Sheet)		Finance and Investment Committee	Closed in May 2023 - Extraordinary FIC, 02.05.2023 agreed to close the treated risk. This was escalated in the FIC report and closure approved by Trust Board in May 2023.			
Strategic risk 4 - Culture of weak financial management, governance with longer term planning not yet embedded	Closed: Strategic risk 4 - Finance (Governance)		Finance and Investment Committee	Closed in February 2023 - FIC, 27.01.2023 agreed to reduce the rating and to incorporate the residual risk regarding culture (training & development) into operational risk 3922. This was escalated in the FIC report and closure approved by TB in Feb 2023.			
Strategic risk 5 - Lack of financial grip and control, governance and financial processes	Closed: Strategic risk 5 Finance (Grip & Control)		Finance and Investment Committee	Closed in August 2023 - FIC, 28.07.2023 agreed to close the risk and to incorporate the residual risk into the operational risk register. This was escalated in the FIC report and closure approved by Trust Board in August 2023.			
6 Financial Capital Management	Strategic BAF risk 06 - Finance (Capital) Condition: Insufficient capital funding Risk: Unable to address statutory requirements such as health and safety standards and legislation, and address backlog maintenance requirements (concerning medical equipment, estate and IM&T)	Interim CFO	Finance and Investment Committee	16	12	9	↔
Strategic risk 7 - Failure to deliver the 2022/23 financial plan reforecast	Closed: Strategic risk 7A - Finance (Annual Plan)		Finance and Investment Committee	Closed in May 2023 - Extraordinary FIC, 02.05.2023 agreed the risk has met its target rating and to incorporate the residual risk into the operational risk register. This was escalated in the FIC report and approved by Trust Board in May 2023.			
7 Financial Sustainability	Strategic BAF risk 07 Finance (Sustainability) Condition: Significant financial challenge across the LLR system over the next 3 years, to meet both operational and inflationary pressures Risk: May result in failure to deliver in line with the financial plan	Interim CFO	Finance and Investment Committee	20	12	8	↔
8 Digital, Data, and Technology Horizontal Integration with other acute trusts	Strategic BAF risk 08 - Digital Condition: IT Infrastructure unfit for the future Risk: Unable to provide safe, high quality, modern healthcare services	CIO	Finance and Investment Committee Our Future Hospitals and Transformation Committee	20	12	9	↔
9 New Hospitals programme Community Anchor - Green Plan Financial sustainability Horizontal Integration with other acute trusts	Strategic BAF risk 09 - Estates & Facilities Condition: Estate Infrastructure unfit for the future Risk: Unable to provide safe, high quality, modern healthcare services	Interim DEF	Finance and Investment Committee Our Future Hospitals and Transformation Committee	16	12	9	↔
10 Wellbeing Equalities and Engagement Workforce Development Horizontal Integration with other acute trusts	Strategic BAF risk 10 - People Condition: Failure to recruit, retain, redesign and transform the workforce Risk: Insufficient workforce capacity, capability and lacking diversity	CPO	People and Culture Committee	20	12	9	↔











**BAF scoring matrix KEY:**

**Likelihood** is a reflection of how likely it is the risk event will occur 'x' **impact** is the effect of the risk event if it was to occur

		Impact				
		Rare	Minor	Moderate	Major	Extreme
Likelihood	Extremely unlikely	1	2	3	4	5
	Unlikely	2	4	6	8	10
	Possible	3	6	9	12	15
	Likely	4	8	12	16	20
	Almost certain	5	10	15	20	25

Score	Rating
1-6	Low
8-12	Moderate
15-20	High
25	Extreme

**BAF assurance rating KEY:**

**Not Assured:**

- Controls are NOT working, AND/OR
- Lack of assurance, AND/OR
- The risk impact has deteriorated AND/OR
- Negative or high risk 3<sup>rd</sup> party / independent assurance e.g. Internal or external audit, regulator assessment

**Partially assured:**

- Timescales for actions are slipping AND/OR
- Limited / inconclusive assurance
- Qualified or medium risk 3<sup>rd</sup> party / independent assurance e.g. Internal or external audit, regulator assessment

**Positively assured:**

- No gaps in controls or assurance OR
- Gaps in controls and assurance are being addressed to agreed timescales
- Positive or low risk 3<sup>rd</sup> party / independent assurance e.g. Internal or external audit, regulator assessment



**Appendix B - Operational Trust-wide Significant Risk Register**

Risk ID	CMG	Opened	Risk Description	Current Risk Score	Target Risk Score
3695	Estates and Facilities	03/11/2020	If areas requiring specialist ventilation for infection prevention are not updated to the current healthcare standards, caused due to age and condition of the plant and lack of access, then it may result in a reduction in infection control, leading to potential patient harm, adverse reputation, service disruption and financial loss	20	5
4045	Estates and Facilities	02/12/2022	If the Trust does not have the required competent mechanical engineers (Pressure and Steam) to safely manage and maintain existing Pressure Systems (including Steam Boilers at LRI and LGH) then this may result in interruption / disruption to critical business functions for a period outside of current BCP timescales leading to severe harm and service disruption	20	10
4097	Finance and Procurement	07/06/2024	If our financial position deteriorates, there will be a reduction in cash and we are unable to pay liabilities as they fall, then it may result in disruption to critical business function, leading to adverse impact on operational performance and reputational damage	20	9
4232	Finance and Procurement	07/06/2024	If the Trust fails to meet it's 2024/25 CIP target, there is a risk the Trust may fail to achieve the annual financial plan, leading to a deficit in excess of the plan	20	10
4298	IM&T	25/09/2024	There is a risk of a cyber incident occurring	20	12
4244	Corporate Operations	07/06/2024	Due to activity increases and higher acuity the existing (Lot 2) contract for all ED patient transfers and discharges does not meet the demand to support the service, this may result in limited or non-provision of ambulance transport for emergency patients, leading to adverse patient experience, delay for treatment and harm.	20	10
4255	Corporate Operations	14/06/2024	Due to levels of demand across the hospital and wider LLR system outstripping the capacity funded and provided (covering all primary, acute, mental health and social care for patients flowing into, through and out of the hospital), then it may result in a risk to maintaining sufficient capacity to meet the needs of patients attending and being admitted for planned/elective care and unplanned (acute) care, leading to extreme service disruption across the Trust	20	9
4087	Reconfiguration	14/04/2023	If the Trust is not awarded the full capital funding required for UHL's 'preferred way forward' by NHSE (the New Hospital Programme - NHP), then it may result in the Reconfiguration programme not being delivered in its entirety to mitigate the clinical risk of working across 3 acute sites, as per public consultation.	20	10
3143	Estates and Facilities	11/01/2018	If sufficient capital funding is not committed to reduce backlog maintenance across the estate and infrastructure, then it may result in a prolonged disturbance to the continuity of core services across the Trust leading to potential service disruption and patient harm	20	4
4096	Finance and Procurement	07/06/2024	If insufficient capital funding is available, then it may result in the Trust being unable to address statutory requirements such as health and safety standards / legislation or address backlog maintenance requirements, leading to an increase in clinical service incidents and adverse effect on service continuity, productivity and patient and staff experience	20	12
3996	Corporate Operations	27/07/2022	If there is insufficient capacity to meet the Urgent and Emergency Care demand in UHL, then it may result in significant service disruption to patients attending the Emergency Department, Clinical Decisions Unit and Surgical Admission Unit(s), leading to harm and adverse reputation	20	12
4009	Corporate Operations	31/08/2022	There is a risk of breaching the requirement to see and treat elective patients within national access standards, due to not significantly increasing capacity beyond pre-pandemic levels to support patients awaiting elective care (both admitted and non-admitted), leading to potential patient harm.	20	12
4177	Corporate Operations	21/12/2023	If there is not a significant increase in capacity and resources to meet the increased demand in Cancer services within UHL, then it may result in a significant delay in progressing patients through cancer pathways, leading to an adverse impact on patient experience, inability to meet the national cancer waiting times targets and adverse patient outcomes	20	12
4023	Corporate Operations	21/10/2022	If the Trust is unable to fully comply with the NICE quality standards relating to Safe and Timely Discharge/ Transfer of Care, then it may result in an event that threatens the safety of patients, leading to potential harm from delays in their reablement / recovery, and poor patient experience	20	12
4149	Corporate Medical	26/09/2023	Due to a lack of investment to procure replacement, and maintain existing, medical equipment, then it may result in equipment failure and a prolonged downtime to the continuity of core clinical services across the Trust, leading to patient harm	16	8
4256	Estates and Facilities	04/06/2024	If the existing lift and lifting gear installations across the Trust are not replaced and/or subject to significant investment and refurbishment as part of a prioritised programme, then it may result in systems failures, leading to unavailability of equipment for extended periods of time, failed LOLER Inspections and enforcement action	16	4
4225	Estates and Facilities	13/05/2024	If the condition of previously identified Asbestos Containing Materials (ACMs) across the estate deteriorate due to Environmental impact (such as water ingress) or damage by other means (accidental or deliberate) and not remediated in a timely manner, then it may result in asbestos contamination and/ or uncontrolled fibre release of friable, airborne, and respirable asbestos in the workplace, leading to impact on the Health, safety and welfare of patient / staff and visitor harm	16	8
4226	Estates and Facilities	13/05/2024	If unknown Asbestos or Asbestos Containing Materials (ACMs) are uncovered as part of maintenance and or refurbishment activities adjacent to planned work area(s) without suitable funding available to make safe, then it may result in increased financial burden to manage in situ via monitoring and reinspection, leading to impacts on harm	16	8
4227	Estates and Facilities	13/05/2024	If there is insufficient funding available to address the quantity of significant findings identified across UHL via the Fire Risk Assessment process in a timely manner (relating to fire detection / early warning systems / compartmentation), then it may result in a fire event occurring, leading to impact on the Health, safety and welfare of patient / staff and visitor harm through exposure to fire and smoke; and breach of legislation	16	8
4228	Estates and Facilities	13/05/2024	If all identified Fire Doors across the UHL Estate are not inspected and maintained in line with Legislative and Industry best practice standards by a competent person, then it may result in a fire event with spread of smoke and fire throughout the hospital, leading to impact on the health, safety and welfare of patient / staff and visitor harm	16	8
4257	Estates and Facilities	04/06/2024	If all identified environmental defects and damaged equipment within ward kitchens are not actioned / replaced in a timely manner, then it may result in failure to adhere to established food safety standards, leading to harm and enforcement action	16	4
4282	Estates and Facilities	07/08/2024	Due to insufficient funding and restricted access to clinical spaces needed to address systematic issues with mechanical systems (balancing) and the replacement of aging and deteriorating water infrastructure, which requires isolation, there is a risk of significant systemic microbiological contamination of the water systems, leading to potential harm.	16	12
3981	Estates and Facilities	07/07/2022	If the systems and processes for managing waste in UHL are inadequate, then it may result in multiple breaches of UK Waste Management Regulations, leading to potential for adverse reputation, service disruption, harm and financial impact.	16	9
3428	Estates and Facilities	18/03/2019	Due to there being various ligature anchor points in an acute care setting that cannot be entirely eliminated, there is a risk patients might use these points to attach ligatures, potentially leading to self-harm	16	8
4258	Estates and Facilities	04/06/2024	If the Health and Safety service is below establishment due to current financial position, then it may result in a Health and Safety incident, leading to potential for harm and prosecution.	16	8
4245	Finance and Procurement	07/06/2024	If UHL fail to deliver the 2024/25 financial plan, then it may result in increased scrutiny from the regulator and impair the ability of the Trust to exit the Recovery Support Programme, leading to adverse reputation	16	12
4231	Human Resources	21/05/2024	If band 2 and 3 HCA's are not banded correctly following the job profile review in August 2021, then it may result in significant unplanned expenditure, leading to non-delivery of the financial plan.	16	12
4071	IM&T	15/02/2023	If the Xcellera application is incompatible with the security updates provided by Microsoft, then it may result in cyber security breach, leading to service disruption	16	2
4241	IM&T	31/05/2024	If the Trust does not upgrade all devices to use the Windows 11 operating system and continues the use of outdated core software that is widely used, then it may result in a cyber-attack as Windows 10 will no longer receive security patches from October 2025 leading to the potential for major service disruption	16	6

4242	Corporate Nursing	05/06/2024	If the current interpretation and translation service is not to the required level of service, then it may result in poor provision of information between the patient and healthcare professional, leading to poor patient and carer experience	16	9
4178	Corporate Nursing	21/12/2023	If the organisational processes and IT systems are not in place to comply with the requirements of the Accessible Information Standard, then it may result in issuing information or communication to patients, carers or parents in an incorrect format, leading to poor patient experience and potential harm	16	4
4208	Corporate Nursing	08/03/2024	Due to the increasing number of referrals and demands on the safeguarding service exceeding the team's capacity to fulfill its key functions, there is a risk that children or adults requiring additional support and care may be overlooked, leading to potential harm.	16	8
3125	Corporate Operations	13/12/2017	If the Trust was to experience the loss of IM&T and Telecommunications infrastructure caused by a planned / unplanned outage, then it may result in a prolonged disturbance to the continuity of core services across the Trust leading to service disruptions and potential patient harm	16	9
3872	Research and Innovation	02/02/2022	If capacity in the clinical trials pharmacy aseptic laboratory is not enhanced (including to specific patient groups including cancer and renal), then it may result in delays to safe and timely preparation of the most modern advanced therapies, leading to potential harm, loss of reputation as a centre of excellence and research active Trust and loss of commercial income	16	12
4034	Human Resources	06/11/2022	If the Trust does not improve the systems and processes to deliver transactional services aligned to the current and future needs of the organisation, then it may result in systematic failure to deliver high quality service to the workforce, leading to dissatisfaction from our staff in relation to their pay and an inability to attract candidates in a competitive market due to a reputational impact	15	9
4302	IM&T	30/09/2024	There is a risk of loss of network connectivity across the LRI campus, due to the LRI distribution switch infrastructure entering an unplanned hung state, leading to an impact on patient care with inability to access critical clinical applications	15	4
4304	IM&T	30/09/2024	There is a risk of IM&T being unable to fulfil the demand for new IT equipment and peripherals, due to insufficient allocation of capital and revenue funding, leading to delays in fulfilling IT equipment requests, which could hinder daily operations, reduce workflow efficiency, and negatively impact patient care and service delivery	15	4
4072	IM&T	21/02/2023	If the IM&T service is not sufficiently resourced with specialist technical consultancy and business engagement capacity, then it may result in delays to delivery of the Trust's digital transformation objectives, leading to significant fragmentation of patient records due to siloed approach and multiple systems proliferated	15	6
3955	IM&T	21/06/2022	If the clinical workstation system providing a full electronic patient record in adult and paediatric diabetes & endocrinology at the LRI is not replaced, then it may result in untimely provision of patient information, leading to interruption to critical business functions, potential impact on quality with delays in decision making and financial impact	15	3
3960	IM&T	22/06/2022	If out of support IM&T software running critical services fails, then it may result in interruption to critical business function, leading to service disruption, potential impact on quality with delays in decision making and financial impact	15	2
3958	IM&T	21/06/2022	If obsolete clinical IT systems (e.g. Proton, Clinical Workstation) are not upgraded or replaced to be supported to the required level, then it may result in interruption to critical business function, leading to service disruption, potential impact on quality with delays in decision making and financial impact	15	2
4190	Corporate Nursing	23/01/2024	Due to a known issue where the air cells in the Medstrom Aria Flex mattress used at LRI and LGH are misaligned, then it may result in patients suffering skin damage, leading to patient harm	15	6
1693	Corporate Operations	02/08/2011	If clinical coding is not accurate, then it may result in a loss of income resulting in financial impact and loss of Trust reputation	15	4
4132	Strategy	20/07/2023	If there is a failure of investment from the ICS in some planned schemes requested by UHL, due to challenged financial position with demand for expenditure exceeding the LLR allocation, then it may result in failure of some support services to deliver constitutional standards, leading to patient harm	15	9