

Open Strategic Risks by Principal Risk (as at 15.10.2021)

ID	Date of entry	Risk Lead	Source of risk	Assuring Academy	Description	Next review date	Risk Level (Initial)	Consequence (initial)	Likelihood (initial)	Risk Level (Residual)	Consequence (residual)	Likelihood (residual)	Existing control measures	Current Summary of risk treatment plan/mitigation	Target date	Risk level (current)	Consequence (current)	Likelihood (current)
Principal risk: 1. Failure to maintain the quality of patient services																		
3211	07/02/2018	Azeb, Sajid	National Target	Finance and Performance, Quality & Patient Safety Academy	There is a risk of patient harm due to long waits for diagnosis and treatment due to not delivering the national cancer waiting time standards.	31/12/2021	Extreme	(3) Moderate	(5) Will undoubtedly recur, possibly frequently	Moderate	(2) Minor	(2) Do not expect it to happen again but it is possible	Comply with national reporting requirements externally. Reporting in place through Performance Review and Finance & Performance Committee to Board of Directors. Weekly tracking process at patient level. 62 day breach review panel to undertake clinical harm review.	11/10/21 - Total of 31 people over 62 days across all cancer sites. Priority continues in addressing the backlog of people on the PTL, managing and responding to the unmet demand through targeted additional capacity, elective recovery fund activity, with a focus on achieving the 28 day Faster Diagnosis Standard.	31/12/2021	High	(4) Major	(3) May recur occasionally
3313	04/01/2019	Azeb, Sajid	Risk Assessment	Finance and Performance	There is a risk of delay to repatriation of Tuberculosis (TB) testing work from Airedale NHS Trust to BTHFT will be delayed due to a lack of autoclave machinery and the ventilation not meeting regulatory standard.	31/12/2021	Extreme	(3) Moderate	(5) Will undoubtedly recur, possibly frequently	Low	(3) Moderate	(1) Cannot believe that this will ever happen again	Currently samples sent to Airedale are being processed within agreed timescales. TB samples are sent sealed and double bagged separate from other samples. There is a robust booking in process at BTHFT and AGH.	15/09/21: No further update from 18/08 position.	31/10/2021	High	(2) Minor	(4) Will probably recur, but is not a persistent issue
3417	02/08/2019	Azeb, Sajid	Escalated from Governance Committee	Finance and Performance	There is a risk that patient care and safety may be comprised by having duplicate patient records- multiple records which are produced for the same patient and by the creation of confused (mixed up) patient records- when one patient's record is overwritten with data from another patient's record, creating a combined, inaccurate record.	31/12/2021	High	(3) Moderate	(4) Will probably recur, but is not a persistent issue	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible	18/11/20 Mitigation plan continues. This risk is caused by operational user error when staff do not check the national spine and either make an entry on the wrong patient records or open new records and create a duplicate. There has been a significant amount of training provided to key areas and to individuals when errors are found. The records are corrected immediately the error is found by the EPR back office team as soon as identified. Numbers of errors have significantly reduced and the risk has been mitigated to the lowest possible level. It is recommended that the risk can be de-escalated from the SRR and managed at service level. 29/10/20 Full root cause analysis is currently performed and feedback given to the relevant managers/departments. Informatics DQ team and EPR PAS have reviewed patient registration guidelines and a new registration SOP has been created. Regular engagement between Informatics DQ Team and Operational Departments Training Team has conducted additional training to specific areas of concern Bi-weekly meetings between Performance, Resilience, EPR and Informatics where	11/02/2021 - Ongoing Monitoring, number of errors reduced but still not an acceptable sustainable level therefore no change to risk categorisation	31/12/2021	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible

3047	06/02/2017	Rice, Paul	Trust Wide Risk	Quality & Patient Safety Academy	There is a risk that because the legacy Pathology Laboratory Information System (LIM) fails impacting on the delivery of a timely and efficient Pathology service.	01/12/2021	High	(4) Major	(3) May recur occasionally	Moderate	(4) Major	(1) Cannot believe that this will ever happen again	Careful attention to support on call schedule, cross-skilling, and documentation. Business continuity plans.	06 Oct 2021: Risk reviewed no change in score. Data collection and integration activities underway	01/08/2022	High	(4) Major	(2) Do not expect it to happen again but it is possible
3104	31/05/2017	Rice, Paul	Trust Wide Risk	Quality & Patient Safety Academy	There is a risk that there may be total or partial failure of the telephony system as the system is end of life, impacting on the operations of the Trust.	31/12/2021	High	(4) Major	(3) May recur occasionally	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible	Best endeavours support and maintenance contract currently in place, reviewed annually.	7 October 2021: First one of four switch migrations successful, complete by Nov 30 2021	31/12/2021	High	(4) Major	(3) May recur occasionally
3013	07/12/2016	Rice, Paul	Business Continuity	Quality & Patient Safety Academy	There is a risk that cyber security attacks to healthcare organisations could impair the clinical and business operations of the Trust A cyber security attack could result in a data leak of patient and corporate data.	30/11/2021	Extreme	(5) Catastrophic	(4) Will probably recur, but is not a persistent issue	High	(3) Moderate	(3) May recur occasionally	Technical prevention via current firewall. Engagement with NHS Digital CareCert scheme in order to undertake external security assessment and give report and recommendations. Regular security penetration testing undertaken as part of annual Information Governance plan. The Trust has also achieved the ISO27001 accreditation, which ensures the Trust follows best practice in terms of technology, people and process.	7 Oct 2021: Risk reviewed. No change to the current risk or score	31/03/2022	High	(3) Moderate	(3) May recur occasionally
3380	10/04/2019	Dawber, Karen	Incident Reporting	Quality & Patient Safety Academy	There is a risk that patients with a mental health diagnosis may not be treated appropriately due to a lack in staff knowledge/awareness and provision of expert clinical advice (mental health) - Includes restraint and deescalation.	04/10/2021	High	(4) Major	(3) May recur occasionally	High	(4) Major	(2) Do not expect it to happen again but it is possible	Liaison psychiatry service for patients who have self-harmed SLA relating to Mental Health Act provisions, which does include scrutiny of section paperwork and provision of training for staff Named nurse for safeguarding adults is a registered mental health nurse and provides advice to wards about available support services BTHFT Pharmacy Services are provided for BDCFT via an SLA Enhanced care guidance in place Awareness raising sessions (including posters, screensavers) Treat as One Audits to identify gaps Policies and procedures in place OCT 2020 - Close working with BDCFT and Act as one programme. Plans to develop psychiatrist on call telemedicine link to enable closer working.	AUGUST 2021 - Escalating numbers of patients presenting with MH conditions and inability to find appropriate ongoing care in a timely manner. Risk escalated to 20. Discussed at system QC - plan for a system wide quality summit. Plan to replicate at Trust level. Bi Weekly meeting with Exec at BTHFT and BDCFT. Needs system wide solution for long term mitigation.	31/12/2021	Extreme	(4) Major	(5) Will undoubtedly recur, possibly frequently

Principal risk: 1. Failure to maintain the quality of patient services, 2. Failure to recruit and retain an effective engaged workforce, 3. Failure to maintain operational performance, 5. Failure to deliver the required transformation of services, 8. Failure to maintain a safe environment for staff, patients and visitors																		
3671	21/06/2021	Azeb, Sajid	Risk Assessment	Quality & Patient Safety Academy	There is a risk of serious harm or death of patients due to post COVID departmental demand and operational pressures.	31/10/2021	Extreme	(4) Major	(4) Will probably recur, but is not a persistent issue	High	(4) Major	(2) Do not expect it to happen again but it is possible	Patient Volume: •Urgent and Emergency Care programme board in place looking at service improvement and delivery of strategy. •Weekly oversight of performance and operational response as required. •Command Centre Activation Programme in place •Trust Escalation Plans •SOP for specialty review of patients •24/7 senior manager availability for escalation. •24/7 Command Centre provision for operational support. •System escalation as required •Navigation role at front end. •Medical SDEC available (limitations with capacity) •Consultant at front door undertaking review and streaming. Medical Coordinator role in Amber Zone. •Utilization of primary care appointments. •Re issuing of the SAU and MECS SPs to try and encourage direct referral out of the ED. •Senior doctor to redeploy AAA to review all ambulance waits. •Senior doctor to redeploy AAA to review all ambulance waits.	15/10/21 Risk score remains the same. MG staffing pressures remain with some mitigation provided with increased rates for night shifts as well as consultants covering. More consultants have joined the team which has provided more day time cover. Nurse staffing pressures remain acute and demand high in line with previous update. (Edward Cornick)	31/10/2021	Extreme	(4) Major	(4) Will probably recur, but is not a persistent issue
Principal risk: 1. Failure to maintain the quality of patient services, 2. Failure to recruit and retain an effective engaged workforce, 3. Failure to maintain a safe environment for staff, patients and visitors																		
3636	01/04/2021	Dawber, Karen	Risk Assessment	People	There is a risk to staff and patient safety due to the Trust healthcare workers not taking the offer of a COVID vaccine and therefore putting patients and colleagues at additional risk.	31/12/2021	High	(4) Major	(3) May recur occasionally	High	(4) Major	(2) Do not expect it to happen again but it is possible	•Staff compliance with vaccination uptake = 70 – 86% •Infection Control Standard cleaning procedure in place. •Contact tracing process established •Plentiful supply of various items of PPE, including availability of fit testing kits •Instructions and training on use of correct PPE. •Occupational health staff process for coronavirus in place •Fit testing programme focussing on high risk areas and fit testing trainer sessions booked •Powered respirators available in central location •BCR Covid staff testing process in place •Regional and national enquiries have highlighted that other Trusts have mixed compliance and limited drive for compliance •Ability to move staff to area of lower risk	AUGUST 2021 Plans to start roll out of the booster program Improve uptake of vaccination in staff groups through promotion and communication. Ensure staff compliance with right level of PPE. Consideration on one to one basis by staff group of suitability of staff working in AGP and / or Ultra green areas.	31/12/2021	High	(4) Major	(3) May recur occasionally
3489	29/10/2019	Dawber, Karen	Trust Wide Risk	People	There is a risk that staff will have a poor experience (leading to reduced health and wellbeing, reduced retention rates, reduced performance and increased risk of errors) due to reduced staffing levels and the need to move staff.	30/09/2021	High	(3) Moderate	(3) May recur occasionally	Moderate	(2) Minor	(2) Do not expect it to happen again but it is possible	Daily staffing huddles to review actual v planned staffing against acuity levels on each area. Use of professional judgement to supplement the information from SafeCare. Use of temporary staffing (bank / agency) where available to cover gaps in staffing rotas. Newsletter for staff to provide an update on all measures being taken to improved staffing, which included an "etiquette for staff being moved" Recruitment and retention plan in place and the Trust is now a member of the NHSI cohort 5 recruitment and retention collaborative.	AUGUST 2021 Staff are under increasing pressure due to the continuation of COVID and the demands on the service. This is impacting on short and long term sickness absence and the overall moral of the workforce. Risk increased to 20	31/03/2022	Extreme	(4) Major	(5) Will undoubtedly recur, possibly frequently

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3627	10/02/2021	Holloway, Mark	Business Continuity	Quality & Patient Safety Academy	<p>If the Trust does not invest significant capital resources to reduce the identified backlog maintenance and critical infrastructure risk of its estate, significant business continuity impact due to failure of estates infrastructure / engineering systems / building fabric will be experienced.</p> <p>The Trust has identified backlog maintenance and critical risk remedial works calculated at £65m of net cost and circa £90m gross (excluding associated asbestos abatement estimated at a further £30m).</p> <p>Due to the limited financial capital allocations available to the Trust to support the associated risk prioritised remedial work plan, the Trust is unable to significantly reduce the business continuity risk associated with failure of the estate and its engineering system and catch up with the expedient life expiry of the estate.</p>	31/12/2021	Extreme	(5) Catastrophic	(4) Will probably recur, but is not a persistent issue	High	(4) Major	(2) Do not expect it to happen again but it is possible	<ul style="list-style-type: none"> An identified backlog maintenance programme of work has been identified Risk assessments and weighted assessments for backlog risk prioritisation has been undertaken. A current facet survey inspection has been undertaken to identify and allocate funding resources. Planned Preventative Maintenance is undertaken as per HTM/Statutory and good practice guidance to maintain buildings and building services plant and equipment. 	<ul style="list-style-type: none"> The formal submission on 30th April 2021 of SOC to NHSE/I to seek capital funding for new development this is now being reviewed for progression to a formal business case. The Bradford and Craven Estates strategy has been updated to include the SOC as part of the regional estates strategy plans. The SOC has been provided to the West Yorkshire and Harrogate ICS for support and approval. Enhanced investment into Backlog Maintenance Programmes of Work to reduce Critical Infrastructure Risk (CIR). Approval at ETM for £1m to support backlog maintenance program in 21/22. Seek additional NHSE/I capital funding resources. 	31/05/2021	Extreme	(5) Catastrophic	(4) Will probably recur, but is not a persistent issue
3637	14/04/2021	Dawber, Karen	Risk Assessment	Quality & Patient Safety Academy	<p>There is a risk that unplanned admissions, that require aerosol generating procedures (AGP)'s may not always be accommodated in side rooms side rooms leading to a risk from the transmission of undiagnosed COVID-19 infection.</p>	31/12/2021	Extreme	(5) Catastrophic	(3) May recur occasionally	High	(5) Catastrophic	(2) Do not expect it to happen again but it is possible	<ul style="list-style-type: none"> Unplanned patients requiring AGP's should be admitted to available single side rooms in the Green zone of ward 31. If single side room capacity is breached, patients not suspected of having COVID-19 infection are then nursed in the open Respiratory High Dependency Unit (HDU) bay in the green zone, on ward 31, with ongoing clinical surveillance: Respiratory Consultant Team clinically assess each patient for COVID-19 risk, daily; All patients who screen negative on admission should be rescreened for COVID-19 on day 3, day 5 and in some instances day 7 and every 7th day until discharge; Beds in the dedicated green respiratory HDU (AGP bay) should be spaced at least 2 metres apart. 	AUGUST - This risk will continue whilst managing covid and green resp demand	31/03/2022	Extreme	(3) Moderate	(5) Will undoubtedly recur, possibly frequently

Principal risk: 1. Failure to maintain the quality of patient services, 8. Failure to maintain a safe environment for staff, patients and visitors, 9. Failure to meet regulatory expectations and comply with laws, regulations and standards

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3561	16/06/2020	Campbell, Pat	National Guidance	People	There is a risk that the organisation does not provide a safe working environment for staff during the COVID pandemic	26/11/2021	High	(3) Moderate	(4) Will probably recur, but is not a persistent issue	Moderate	(2) Minor	(2) Do not expect it to happen again but it is possible	Social distancing and hygiene education in place across all staff groups Individual staff risk assessments undertaken for high risk staff (as defined by the NHS) and mitigation in place in relation to individual risk factors Range of risk assessments and associated actions to ensure correct PPE is worn in clinical areas Detailed cohorting plan to ensure safe management of COVID patients Increased cleaning Increased informatics infrastructure to enable remote working Face to face meetings are the exception-by default are web based Outbreak analysis tool to enable rapid assessment of areas where cross infection of staff in suspected. Psychological support in place for all staff if required	11/10/21 - social distancing working arrangements maintained.Risk to be reviewed again at next Safe Working group meeting.	30/06/2021	Moderate	(2) Minor	(3) May recur occasionally
Principal risk: 3. Failure to maintain operational performance																		
3615	17/12/2020	Rice, Paul	Business Continuity	Finance and Performance	There is a risk of failure of core elements of the trusts IT infrastructure as they become end of life and unsupportable over time. There is currently no confirmed funding to facilitate the required refresh programme: • The on-site hosted data centres are end of life and require replacement or outsourcing • Elements of the physical wired data network are gradually becoming end of life and will require replacement • The wireless network becomes end of life in 2021/22 and will require replacement • Elements of IT devices implemented as part of the deployment of EPR are becoming end of life and will require replacement over time	31/12/2021	High	(4) Major	(3) May recur occasionally	Moderate	(4) Major	(1) Cannot believe that this will ever happen again	• Supplier maintenance contracts in place • Internal and external tests undertaken • Regular reviews of individual risk elements • Testing of business continuity plans • Internal audits and external reviews	7 Oct 2021 : Migration to the new data centre ongoing.	31/03/2022	High	(4) Major	(3) May recur occasionally
3154	23/10/2017	Azeb, Sajid	External Bodies	Finance and Performance	There is a financial and reputational risk to the Trust following the deferral of Joint Advisory Group on Gastrointestinal Endoscopy (JAG) accreditation.	12/11/2021	Extreme	(4) Major	(5) Will undoubtedly recur, possibly frequently	Low	(1) Negligible	(1) Cannot believe that this will ever happen again	•The Service has implemented a working group to respond to the key actions- on line to deliver •Got agreed action plan led by COO, to validate and provide working patient tracking list. •An action plan is in place to address the failure to meet JAG targets. The AP is to be implemented in 3 – 6 months. (A separate risk assessment is being undertaken to assess the risk to patients from extended waiting times).	17.8.21- CBU presented at Moving to Outstanding meeting 22/6/21. In summary The actions and mitigations will allow us to meet the standards. CBU to request an accreditation assessment in April 2022 (3months of compliant waiting times data) On going modelling data will allow us to plan ongoing capacity needs. Financial investment in new reporting tool will be needed in next 6months	31/10/2021	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible

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3638	15/04/2021	Horner, Matthew	Corporate Objective	Finance and Performance	There is a risk that the Trust has insufficient cash & liquidity resources to sustainably support the underlying Income & Expenditure run rate	31/10/2021	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible	"MAY 21: 1. Reporting arrangements to Finance & Performance Academy on the cash and liquidity, with trajectories and projections signposting risks and corrective action (monthly in the finance report and quarterly treasury management reporting updates) 2. The cash & liquidity position is managed and monitored by the cash committee with updates provided to the Finance & Performance Academy. 2. Curtailment of the Capital programme in 2019/20 to limit the cash outlay (if required) 3. Continued sourcing of cash releasing efficiencies 4. Additional measures taken to improve financial control in the immediate and longer term	JULY 21 - The cash position remains ahead of plan at the end of Q1 with not immediate risks identified. The financial regime for the first half of 21/22 remains in place with Trust delivering a run rate in line with plan. Uncertainty remains for the second half of the year with CBU's requested to explore run rate improvement opportunities in anticipation of a change to the income quantum (yet to be confirmed).	31/03/2022	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible
3639	15/04/2021	Horner, Matthew	Corporate Objective	Finance and Performance	There is a risk that the Trust Fails to maintain financial stability and sustainability in the current economic climate with the Trust facing a continued financial challenge associated with cost inflation, increased demand for services and System/Place affordability.	31/10/2021	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible	1. Continued evolution of the Clinical Business Unit financial management arrangements and framework, with associated accountability and performance management framework (inclusive of updated budgetary management & service development guidance/principles) 2. Establishment of a improvement group (name to be determined but not operational during COVID period) 3. Standing Financial Instructions, Scheme of Delegation, internal financial control environment 4.Reinstatement of financial governance and control arrangements	The financial regime introduced in 20/21 to manage the Covid pandemic has been rolled forward in to the first half of 21/22. The financial framework for the period 1 Apr 21 to 30 Sep 20 allocates a breakeven financial target at an organisational level, which is consolidated up to a place and ICS quantum. The financial planning guidance allocates a 0.28% efficiency target for the first half of 21/22, which it is anticipated will be managed through underlying run rate or non recurrent measures. The detail of the challenge is not currently known, with the work to establish the financial and activity plans underway. The systems (both at place and ICS level) have established a number of principles to support organisations/places to deliver a balanced position at the ICS level. The risk share arrangements will need to address both the cash and income and expenditure challenge should they arise. The relatively strong cash position can cover a level of deficit. JULY 21 - The financial regime for the first half of 21/22 remains in place with Trust delivering a run rate in line with plan, with a projected breakeven position by 30 September 2021. Uncertainty remains for	31/03/2022	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible
3556	04/06/2020	Horner, Matthew	Corporate Objective	Finance and Performance	There is a risk that Trust is unable to maintain equilibrium between financial sustainability and delivering safe quality services resulting from the economic challenge faced and the increasing internal and external demands to improve the quality and safety of the services provided.	31/10/2021	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible	The governance arrangements associated with the implementation of Cost Improvement Plans include a robust Quality Impact Assessment/evaluation process.	JULY 21 - The financial regime for the first half of 21/22 remains with no risks identified. There remains uncertainty regarding the income quantum for the second half of the year with CBU's requested to review run rate improvement opportunities in anticipation of an efficiency requirement	31/03/2021	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible

Principal risk: 7. Failure to deliver the benefits of strategic partnerships

3516	06/01/2020	Holden, John	Corporate Strategy and Objectives	Board of Directors	There is a risk that as a system we fail to deliver seamless, integrated care for the people of Bradford District and Craven if the Trust does not effectively influence implementation of the Strategic Partnering Agreement and other elements of local system integration (e.g. Community Partnerships and Primary Care Networks).	31/03/2022	High	(3) Moderate	(3) May recur occasionally	Moderate	(3) Moderate	(2) Do not expect it to happen again but it is possible	Signed up to the Strategic Partnering Agreement Active participation in Health and Care Partnership Board and associated governance groups. Extensive collaboration between BTHFT clinicians and system partners.	6 October 2021 Continued engagement across BTHFT with partners as the plans for implementation of the proposed legislation and guidance from NHS England continue. Interim structure for the new partnership has been released, and review of BTHFT involvement in the different Committees/Boards etc is being undertaken to ensure there is appropriate representation across the trust.	31/03/2022	High	(3) Moderate	(3) May recur occasionally
3613	14/12/2020	Holden, John	Trust Wide Risk	Board of Directors	There is a risk that as a system we fail to deliver seamless, integrated care for the people of West Yorkshire and Harrogate if the Trust does not effectively identify and develop opportunities for collaboration and alignment. This may be through relationships with partners in the West Yorkshire Association of Acute Trusts (WYAAT) or West Yorkshire and Harrogate Health and Care Partnership (WYHCP), or through the agreed work programmes.	31/03/2022	High	(3) Moderate	(3) May recur occasionally	High	(3) Moderate	(3) May recur occasionally	<ul style="list-style-type: none"> Chairman's involvement in and leadership of WYAAT Committee in Common CEO involvement in and leadership of ICS and WYAAT programmes Active participation in ICS and WYAAT governance groups at all levels Extensive collaboration between BTHFT clinicians and system partners Proactive involvement in the development of the system response to the Government's White Paper on the Future of Integrated Care and subsequent legislation, including the structural changes which will be required.	6 October 2021 The Bill is going through Parliament and BTHFT is involved in discussion on the implementation of the proposals as they affect WYAAT and is working with partners as the ICS develops into the ICP and ICB.	31/03/2022	High	(3) Moderate	(3) May recur occasionally
Principal risk: 8. Failure to maintain a safe environment for staff, patients and visitors																		
3142	07/02/2017	Holloway, Mark	Risk Assessment	Quality & Patient Safety Academy	There is a risk to staff safety in E Block SLH, in that the upper floors are understrength for the current usage of the building. This is due to excessive loads of medical records and poor physical integrity of the building.	30/10/2021	Extreme	(5) Catastrophic	(3) May recur occasionally	Low	(2) Minor	(1) Cannot believe that this will ever happen again	Whilst not in imminent danger of collapse, no further loads are to be placed on the floors in their current condition A structural survey and report was commissioned by E&F to determine the structural integrity of the floors of E Block. The report has found that the floors are significantly understrength for the current usage of the building and recommends a significant reduction in the loads placed on the upper floors or immediate structural repairs / works to support the floors. Condition of building to be monitored until a solution is found / funded	25/08/2021 The programme of works for the safe removal and transition to off site records storage is progressing well. It is anticipated records from both medical records library and E block will have been removed by November 2021.	31/12/2021	High	(5) Catastrophic	(2) Do not expect it to happen again but it is possible

3540	30/03/2020	Dawber, Karen	Infection Control	Quality & Patient Safety Academy	There is a risk that the Trust is not compliant with HSE/Manufacturer's guidance in relation to fit testing FFP3 masks leading to inadequate protection for staff resulting in harm, litigation and/or prosecution	30/11/2021	Extreme	(4) Major	(4) Will probably recur, but is not a persistent issue	High	(4) Major	(2) Do not expect it to happen again but it is possible	JANUARY 2021 - WE CONTINUE TO IMPLEMENT FIT TESTING CLINICS - REDUCTION IN AVAILABILITY OF 3M MASKS MEANS WE NEED TO RE TEST HIGH NUMBERS OF STAFF. THIS IS BEING WORKED THROUGH. ALTERNATE FFP3 MASKS ARE IN PLACE FOR SOME STAFF INCLUDING FULL FACE RESP AND CONE MASKS. THE DUPPLY ISSUES RELATET TO THE DUCK BILL 3 M. THIS WILL REMAIN AN ONGOIGN ISSUE FOR THE DURATION OF THE PANDEMIC OR UNTIL SUPPLY CHAINS ARE STABILISED TO SUPPLIERS NATIONALLY. Frontline staff have been fit tested as per original protocols Posters in clinical areas on fit check process, as an alternative, if not fit test available in extremis All staff trained to do a fit check when donning PPE	August - continued pressure with doctor change over and new starters, fit testing demand continues	31/03/2022	Extreme	(4) Major	(4) Will probably recur, but is not a persistent issue
Principal risk: 8. Failure to maintain a safe environment for staff, patients and visitors, 9. Failure to meet regulatory expectations and comply with laws, regulations and standards																		
3551	19/05/2020	Dawber, Karen	National Guidance	Quality & Patient Safety Academy	There is a risk that we will not be able to monitor and control infection during the COVID19 pandemic, leading to avoidable harm to patients and staff. Also see risk ID 2542 (Hand sanitizer)- closed 7/9/2020 and Risk ID 3540 (fit testing)	30/11/2021	Extreme	(5) Catastrophic	(4) Will probably recur, but is not a persistent issue	High	(5) Catastrophic	(2) Do not expect it to happen again but it is possible	The NHSE Board Assurance (infection control) has been reviewed and we have measured ourselves against the standards. The evidence and gaps in assurance have been documented and will be used to populate and control this risk	AUGUST 21 Continue with robust processes in place	31/03/2022	High	(5) Catastrophic	(2) Do not expect it to happen again but it is possible
Principal risk: 9. Failure to meet regulatory expectations and comply with laws, regulations and standards																		
3696	18/08/2021	Azeb, Sajid	Business Conthuity	Finance and Performance, Quality & Patient Safety Academy	There are a number of significant risks to the organisation arising from the age and condition of the pharmacy aseptic unit. The risks are specifically:- 1. patient safety risk arising from the potential inability to provide critical medicines such as chemotherapy and total parenteral nutrition 2. reputational risk to the organisation arising from the potential failure of, and or regulatory intervention into the, pharmacy aseptic unit. 3. risk to organisational performance against RTT targets arising from this risk due to the potential inability to deliver treatment within specified timescales. The risk arises from the due to:- 1. The unit being almost 25 years and no longer up to current design standards. 2. The inability of the air-handling unit and associated pipework being able to deliver the required number of room air changes per hour. 3. The poor design of said pipework meaning it is impossible to satisfactorily test the integrity of the terminal HEPA filters due to leak paths of unknown origin. 4. Some of the filter housings being modified by a third party from top entry to side entry	12/11/2021	Extreme	(5) Catastrophic	(4) Will probably recur, but is not a persistent issue	High	(3) Moderate	(4) Will probably recur, but is not a persistent issue	Environmental Monitoring and SOPs Colleagues working in the unit follow standard operating procedures (SOPs) for all functions undertaken. These SOPs cover all aspects of the operation of the unit but specific to this risk cover the cleaning and environmental monitoring regimens. The SOPs are part of the wider Quality Management System which operates in the unit. The QMS ensures that all products produced are produced according to the SOPs and to the required regulatory standards. Where deviations from the SOPs occur e.g. due to a product failing a final check an official deviation investigation is commenced which includes Corrective and Preventative Actions (CAPA) to minimise the chance of the deviation occurring again. In the event of a change in practice is needed a change control form is raised which ensures that any change is safe and effective, approved by both the production and quality managers and that it is cascaded to all. In relation to this deterioration of the DOP testing results, a change control form was implemented to increase the intensity and	Additional steps have been taken to increase cleaning regimens and environmental monitoring. Workload has been reduced to ensure these regimens can be maintained. Contingency plans are being worked up with neighbouring trusts should the unit fail. Clinical teams are being asked to improve / review their workflows in order to support the unit to meet their patients needs. A Review has been commenced to quantify the nature and consequences, in terms of patient care, of a unit failure / shut down. Plans are being developed to identify potential future options for the unit.	31/12/2021	Extreme	(4) Major	(4) Will probably recur, but is not a persistent issue