Patient safety incident investigation (PSII) report

Report status	Complete

Incident ID number:	2024-3028
Date incident occurred:	February – March – April 2024
Report approved date:	18.12.24
Approved by:	Quality and Safety Committee

Distribution list

Name	Position
TM	Chief Nurse
JD	Medical Director
PJ.	Renal Services Clinical Director
EV	Consultant Nephrologist
KH	Director of Estates and Facilities
MA	Deputy CEO and Director of Finance
AM	Deputy Director of Estates
LAKPA representatives	Patient Association
MZ	Director of Nursing and Quality for Unplanned Care
SM	Lead Divisional Director / Divisional Medical Director for Unplanned Care
PT	Divisional Operations Director for Unplanned Care
AG	Heads of Nursing & Quality for Acute Care and Deputy Director of Nursing and Quality for Unplanned Care
Patients / Next of Kin as appropriate	Patients / Next of Kin

About patient safety incident investigations

Patient safety incident investigations (PSIIs) are undertaken to identify new opportunities for learning and improvement. PSIIs focus on improving healthcare systems; they do not look to blame individuals. Other organisations and investigation types consider issues such as criminality, culpability or cause of death. Including blame or trying to determine whether an incident was preventable within an investigation designed for learning can lead to a culture of fear, resulting in missed opportunities for improvement.

The key aim of a PSII is to provide a clear explanation of how an organisation's systems and processes contributed to a patient safety incident. Recognising that mistakes are human, PSIIs examine 'system factors' such as the tools, technologies, environments, tasks and work processes involved and their interdependencies. Findings from a PSII are then used to identify actions that will lead to improvements in the safety of the care patients receive.

PSIIs begin as soon as possible after the incident and are normally completed within three months. This timeframe may be extended with the agreement of those affected, including patients, families, carers and staff.

If a PSII finds significant risks that require immediate action to improve patient safety, this action will be taken as soon as possible. Some safety actions for system improvement may not follow until later, according to a safety improvement plan that is based on the findings from several investigations or other learning responses.

The investigation team follow the Duty of Candour and the Engaging and involving patients, families and staff after a patient safety guidance in their collaboration with those affected, to help them identify what happened and how this resulted in a patient safety incident. Investigators encourage human resources teams to follow the Just Culture guide in the minority of cases when staff may be referred to them.

PSIIs are led by a senior lead investigator who is trained to conduct investigations for learning. The investigators follow the guidance set out in the Patient Safety Incident Response Framework and in the national patient safety incident response standards.

A note of acknowledgement

East and North Herts NHS Trust (ENHT) acknowledges that a patient safety incident occurred which affected 97 patients and impacted on their families and carers. We would like to thank everyone that has discussed the incident with the learning response team and shared their experience with the investigators. We also apologise for the incident and the impact of the experience to all those involved.

The Lister Area Kidney Patients Association (LAKPA) were a pillar of support to those affected by the incident. They worked closely with the Trust and communicated regularly with the patients affected by the incident, supporting the sharing of accurate information about the reasons for closure and actions being taken. The Chair of LAKPA and ENHT Medical Director were jointly interviewed by a local radio station about the situation. LAKPA provided reassurance to the affected patients that their needs were the key priority of the Trust in ensuring that safe dialysis could continue. The Trust is very grateful to LAKPA for its support and presence. The importance of offering support to patients as they returned to dialysis at the Bedford unit was recognised and highlighted at the regular LAKPA committee meeting. Additional support from the Complementary Therapy Service was provided to Bedford patients and this has been popular. LAKPA regularly provides funding for social activities for patients such as trips to the seaside, garden parties and Christmas celebrations. The summer trip to Southend on Sea for Bedford patients took place on 4 August 2024. LAKPA has offered to provide more funding for such activities to Bedford patients this year, if needed. In their input to this learning response LAKPA also noted how grateful they were to the renal and other staff at the Trust, particularly those from the Bedford unity, for their *"incredible efforts"* during this incident.

The Trust further thanks the staff and service providers within the planned and unplanned care groups, the renal technicians, estates and facilities, payroll and the people team members, the finance team and the Bedford Renal Unit staff who engaged with openness and candour during the investigation. Further thanks also for their continued support in identifying improvements and their willingness to support with the implementation of the required improvements. During the time that ENHT patients were no longer able to undergo their dialysis at our sites, other local sites were willing and able to facilitate these patients having their dialysis treatment; specifically, Northampton and Milton Keynes. The Trust is extremely grateful for the support that these hospital sites provided, and their collaborative working to maintain patient safety and minimise the impact on care.

1 Executive summary

1.1 Incident overview

In February 2024, many patients who underwent dialysis at Bedford dialysis unit developed a significant drop in their haemoglobin levels and became anaemic. (Anaemia is a condition in which the number of red blood cells or the haemoglobin concentration within them is lower than normal). Many of these patients required a blood transfusion. This led to a suspension of dialysis at the Bedford unit, with 97 patients being moved to temporarily receive dialysis elsewhere. One patient was felt to have high probability of being harmed as a result and suffered a stroke (A stroke is a serious, life-threatening medical condition that can happen when the blood supply to part of the brain is cut off).

Subsequently, and separate to the Bedford incident, there were concerns about the microbial quality of the dialysis water at the Lister level 6 unit and the decision was to temporarily suspend the dialysis services as a precautionary measure. It is of note that no patients became unwell at the Lister site at this time.

1.2 Summary of Key Findings

- This investigation showed learning categories related to organisational, tasks, tools and equipment and person/human influencing factors. Learning identified that water provided (feed water) to the reverse osmosis membrane was damaged by water softener resin which impacted on the quality of the water being used for dialysis (product water), this is believed to have been a contributing factor to patients developing anaemia.

- Organisational oversight of some critical processes related to risk management and patient safety demonstrated some gaps. Tasks such as monitoring, repair, and maintenance scheduling were not robust and there was no defined documentation or evidence of processes undertaken.

- Knowledge gaps were evident in how to robustly manage processes for some contractual roles and responsibilities within the service, resulting in a fragmented escalation pathway for support to manage the emerging risks identified.

- Repairs (and changes) to the treatment plant environment were not managed as a recognised ‘medical device’, therefore the governance around the repairs lacked input from experts to ensure practice is in line with recommendations and national guidance. Repairs to such devices should have a robust oversight process with clear escalation pathways and risk assessments. There is no clearly documented evidence that this was in place. An immediate safety action was taken to address this gap in the

governance/oversight and new processes in place for which interim standard operating procedures have been developed whilst works are ongoing. Oversight of repairs and maintenance is now held by the corporate Estates and Facilities team, and all works, and scheduled repairs and renewals are carried out by independent specialists.

- Knowledge gaps of expert skills required to repair and maintain the specific reverse osmosis (RO) plant. Independent opinion is that if repairs and maintenance to a medical device is being undertaken, training specific to the make and model should be completed and regularly updated to ensure full competency. Whilst good evidence of relevant training on the maintenance of dialysis machines and other areas of either work did exist, there was a gap in relation to the specific training needed for the repair and maintenance of the RO plant.

- The Bedford renal Unit ran at full capacity. This meant that any engineering work had to be done either over night or on a Sunday. The high utilisation rate meant that the team felt under pressure to always maintain services, as there was no additional capacity within the system.

The investigation team wishes to acknowledge that while risk and gaps existed, there was a positive intent to problem solving by the local renal technical team who were working hard to maintain an effective service, working within the constraints of the equipment, capacity, process and poor response to escalations.

It was also acknowledged that during the response to the incident, all renal staff went above and beyond, including moving to work at different sites, to ensure patient safety and that patients were supported through the incident management. As a result, all patients were able to be dialysed safely at alternative facilities within a very short space of time. There was also a highly responsive and strong support from systems partners across regional renal services and hospitals who took on our patients at short notice.

1.3 Summary of areas for improvement and safety actions

A number of safety actions followed to immediately address risks identified, and immediate, short term and long-term improvements were designed as a result. An incident management group was formed, with executive oversight to facilitate actions, resulting in the safe re-opening of the unit which occurred on 15 April 2024.

The following areas for improvement were identified and are fully detailed in the safety action table.

1. Monitoring and oversight of water quality processes
2. Service demand and capacity modelling
3. Review of contract tendering and monitoring process
4. Risk Management and mitigation oversight

Contents

2. Background and context

ENHT renal services

Renal services have been provided by ENHT since 1989. The main unit was at Lister hospital site, with a further site opened in St Albans in 1996 and then Luton site in approximately 2000. In 2012 ENHT began a commercial relationship with the contractor when, in partnership, they successfully bid to build and operate dialysis units in Bedford and Harlow. The original plans for the Bedford unit were for a 20-station unit however this was then reduced to 16 stations. the contractor is a healthcare organisation which was founded in Sweden in 1991. It operates internationally, offering a spectrum of renal treatments, ranging from preventative care, centre and home haemodialysis, peritoneal dialysis and holiday dialysis. The arrangement was for the contractor to be funded to design, build and equip the units to a clinical specification, providing the clinical supplies and facilities management functions, with the staff and clinical service provided by ENHT. The renal services of ENHT serve the population of Hertfordshire, Bedfordshire and parts of West Essex, approximately 1.5 million people and are the area with the highest number of dialysis patients across the East of England delivering 90,000 dialysis sessions annually. The number of patients requiring renal services continues to grow each year; and it is noted that ENHT have had an increase in the number of new dialysis patients which is above the UK average. It is recognised that there is variation in the historical dialysis water management operating models in the UK within renal units. Some trusts have outsourced their water management to private companies, others have not. Those that manage their own dialysis water generally do this through a model of having in-house renal technicians who have expertise in this area and draw on advice from their national body *the Association of Renal Technologists.* ENHT dialysis water is managed by the ENHT renal technical team.

Before COVID-19, renal dialysis was funded based on the number of patient sessions through a national tariff system. The pandemic accelerated a planned shift away from this method. Now, NHS providers are paid in two parts: a variable element for elective procedures and a fixed element for everything else, including renal dialysis. Renal dialysis is considered a specialised service, commissioned by NHS England's regional team rather than local Integrated Care Boards. Annually, contracts with commissioners are adjusted for inflation and potential growth, which can be nationally dictated or locally negotiated. The value of income received from the fixed element is split across the services that fall within it based upon expected activity levels.

LAKPA (Lister Area Kidney Patients Association)

LAKPA is a local charity for kidney patients and their carers who are under the care of ENHT renal team. This includes those patients who receive dialysis at the Bedford renal unit. LAKPA are dedicated to improving the lives of local kidney patients and their families. Aligned with this, they have established a strong relationship with renal and other staff at ENHT and were a great point of support for both the patients and staff during the incident.

Dialysis process

There are two types of dialysis; haemodialysis and peritoneal dialysis. This incident centres around haemodialysis which is the process of filtering a patient's blood when their kidneys are not functioning correctly. It involves passing the blood through a tube into an external filter. This filter is called a dialyser and is divided into two parts which make up the dialysis machine (see attached diagram). As the blood passes through one part of the filter, dialysate fluid in the other part of the dialysis machine draws out the waste products from the blood. Dialysate fluid is mostly made up of ultrapure water. The process of haemodialysis requires a substantial amount of ultrapure water (600 litres per session) to assist in the removal of waste products such as creatinine, urea and water which build up when the kidneys are in a state of renal failure.

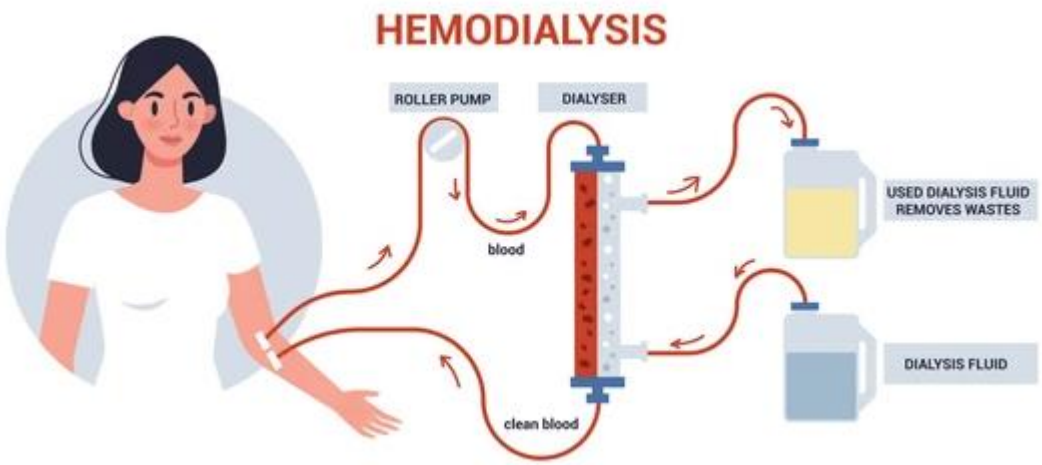

Figure 1 Hemodialysis diagram Shutter.com (accessed October 2024)

The dialysis machine is made up of a series of membranes that act as filters and a special liquid called dialysis fluid. The used dialysate fluid is pumped out of the dialysis machine and the treated blood is passed back into the body. The water quality for dialysis must meet the requirements for ionic and organic chemical purity and must be protected from microbial proliferation**.** Contamination of the water used in dialysis may put patients at risk from both short and long-term complications.

Drinking quality water or feed water coming into the plant is passed through a series of filters and porous membranes to remove contaminants such as endotoxins, metals, chlorides and chlorine dioxides found in drinking water (feed water). This ensures that the water used in dialysis is ultrapure. The feed water enters the filtering system and is passed through a series of filters, carbon filters, softeners and the reverse osmosis membrane with the various decremental filtering stages from 20 microns to 5 microns to remove the contaminants in the water. Service schedules from B-Braun suggests that particle filters should be replaced every 3-6 months dependent on the quality of the feed water (ie the poorer the feed water quality the higher the levels of contaminants and subsequently harder work for the filters), or the number of patients being dialysed.

The water is then fed through granular activated carbon and a water softener system and finally through a reverse osmosis membrane which is the final safety net before the water enters the dialysis machine.

Water is pumped through the filtering system at a consistent pressure to protect the filtering system and various stages within and then enters the dialysis machine at the patient's bedside.

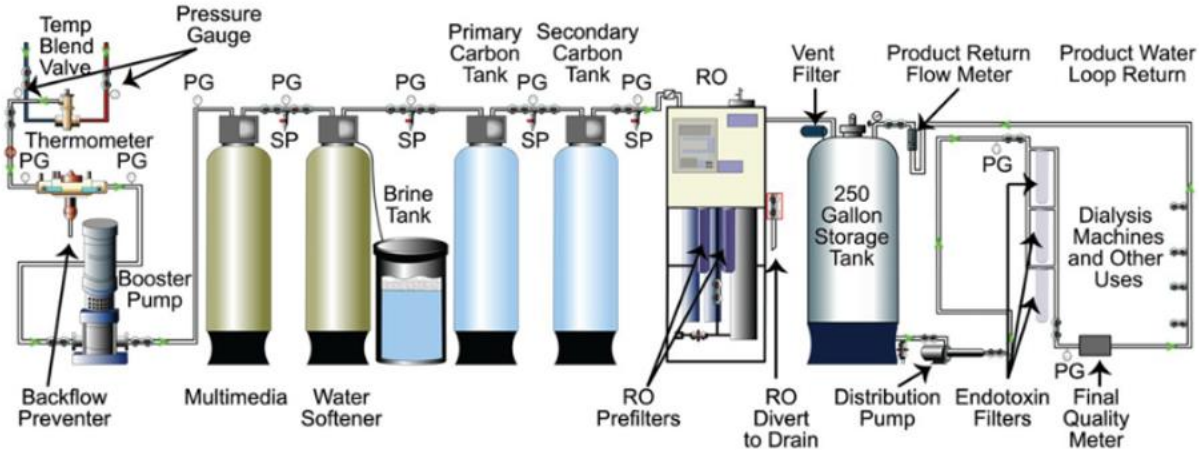

Figure 2 Reverse Osmosis water treatment plant

Authorised engineers (AEs)

The Health Technical Memorandum (HTM) states that hospital trusts should have nominated authorised engineers to support the trust meeting statutory obligations. Authorised engineers are always external contractors. The authorised engineers relevant to renal water safety are the authorised engineer for water and the authorised engineer for decontamination. Authorised engineers are appointed by the Chief Executive, and they link with individual services for the relevant area of work and/or the Estates department where relevant.

Risk Management

Risk is defined as a barrier which, if realised, could impact upon patient safety and/or stop an area from achieving its objectives or impact negatively on its success. It includes hazards, threats and uncertainties as well as opportunities.

This definition is as per Trust policy prior to November 2023. It defines that risks should be discussed locally prior to entry to the Trust's risk register system. A risk lead will be selected and would have overall responsibility for maintaining the record on the risk register and for managing or delegating actions, including on-going monitoring of the risk, ensuring controls and further actions were in place to mitigate the risk, and reporting on its overall status.

The policy outlined that risks scoring between 8 and 12 were accountable to the Divisional Director, Clinical Director & Senior Team with oversight at the relevant Divisional Governance Committee or meeting prior to Divisional Board. Previous structures included the operational model of services reporting into two large divisional structures, Planned and Unplanned.

Figure 3 Previous operational management structure (Pre-Feb 2024)

At the time, the Divisional Board was the highest divisional level forum to discuss controls and action plans for divisional risks. It was also the forum where risks were approved for escalation to the Divisional Executive Committee for consideration for inclusion on the Corporate Risk Register (CRR), or for agreement that the risk would be continued to be managed at divisional level on the Divisional Risk Register.

All risks scoring 15 and above were to be escalated by the risk owner to the divisional board for consideration of their management. The divisional board confirms if the risk needed be escalated to the Executive Committee for additional support, because the division was not able to provide adequate mitigation for the risk to be tolerated.

If the risk was escalated, and approved by the Divisional Executive Committee, then it was entered on the Corporate Risk Register (CRR).

Since November 2023 the Trust Risk Management Group (RMG) was introduced where risks are escalated and agreed for entry to the CRR by all divisions and regular deep dives of all risks, regardless of scores are completed for group discussion.

3. Description of the patient safety incident

In February 2024 water softener and dialysis water conductivity abnormalities were detected at the Bedford satellite renal unit and were being managed locally. During the period from the recognition of the abnormalities to March 2024, 69 of the 97 patients who attended for dialysis developed a drop in their haemoglobin levels from their previous baseline levels with features of haemolysis (the rupture or destruction of red blood cells).

To avoid any further risk to patients, the unit was closed on 28 February 2024, and a decision made to dialyse patients at the Lister site.

On 7 March 2024 dialysis at Lister hospital on level 6 was also suspended, due to concerns over water safety due to elevated endotoxin levels (endotoxin: a toxin present inside a bacterial cell that is released when it disintegrates). Patients were therefore relocated to the East and North Hertfordshire Dialysis satellite infrastructure (Lister Renal unit including starting a nocturnal dialysis program, Chiltern Kidney Centre self-care unit, home therapies unit) as well as seeking regional support at Northampton and Milton Keynes dialysis units.

The elevated endotoxin levels were found on routine water quality testing on ward 6B (Lister site) and full disinfection of the system was required. Due to the incident at the Bedford Unit, the renal technicians did not have the capacity to run the required disinfection and therefore the precautionary decision was made to close Ward 6B and for works to be completed to ensure that

the water quality met the required standards. It is of note that despite the presence of endotoxins being identified, patients were protected by dialysis machine filters before the water entered the machine and no patient harm was identified.

Once remedial works were completed the Bedford Renal Unit re-opened on 15 April 2024.

3.1 Patient harm

Over the period from February to March 2024:

1) 25 Bedford haemodialysis patients were admitted to the Lister or Bedford Hospitals of which 11 were related to the incident, 10 were unrelated and 4 were potentially related.
2) 30 patients required a total of 71 units of blood to be transfused with a further 4 patients declining to receive transfusions to be managed with non-transfusion measures.
3) 2 patients passed away following admissions to Bedford General Hospital
4) 2 patients had strokes

Harm reviews were carried out by the Renal team. In relation to the 2 patients who passed away, both have been reviewed through ENHT incident review process, in conjunction with post mortem detail and clinical information from Bedford hospital, and concluded that the deaths were not directly related to the incident. It is also noted that the Bedford Coroner requested a Renal Consultant consensus meeting for one of the patients.

Whilst the deaths were considered unrelated to the incident, the Trust acknowledges and apologises for the distress caused to the families. In relation to the two patients who sadly suffered strokes, one was concluded to be unrelated however for one patient it was concluded that there was a high probability that this was directly related to the water incident. This patient (A) is discussed further below.

3.2 Patient A

Patient A is an 80-year-old man who had been on haemodialysis at the Bedford unit site since 1 April 2023. He had some cognitive impairment and was reported to be becoming more forgetful. He had carers who attended twice a day. Whilst he was able to make himself hot drinks, he needed carers to make his meals.

On 16 February 2024, he presented to Kettering General Hospital (his local hospital) having had an unwitnessed fall and with reduced conscious level. He presented with significant anaemia. He was subsequently transfused 2 units of blood which caused respiratory failure. He was taken to the Intensive Therapy Unit at Kettering for haemofiltration (a renal replacement therapy similar to hemodialysis which is used almost exclusively in the intensive care setting) and respiratory support. He was later noted to have bilateral upper limb weakness and MRI scan of his head showed bilateral watershed infarcts indicating that he had had a stroke.

He was transferred to Northampton General Hospital for stroke rehabilitation and inpatient haemodialysis. He was discharged home with ongoing dialysis at Northampton on 15 May 2024. He remains under the care of the community stroke team.

Subsequent review considered that his anaemia, was highly likely because of the problems with the dialysis, and this had high clinical probability of contributing to the stroke.

3.3 Immediate events leading up to incident

Nursing staff at the renal unit were completing 4-time weekly checks on water quality to measure conductivity and levels of chloramines and chlorine in the water[1]. These tests were carried out in the water treatment room where the level of water purity is measured as the water exits the softening and filtration process. Dip stick tests for chlorine and chloramine were recorded in the week of 8 February 2024 and were within range. However, there were concerns relating to the conductivity levels of the water, which could indicate an issue with the quality of the water. Conductivity levels are displayed on the plant, RO machine and recorded on paper, recorded at the beginning and end of each session.

Based on the manual testing results, staff identified that there was an indication of high conductivity, which the renal technicians deemed to be indicative of a calcified membrane. High conductivity readings are present when there are impurities in the water that have passed through the filtering systems. It is of note that if the softener is not functioning properly, the reverse osmosis membrane can become calcified (as in a kettle) which can lead to contaminants being able to pass through the membrane as the pores become stretched. The reverse osmosis panel on the plant itself would then indicate the raised levels (red light) with no audible alarm in the unit. The red indicator on the plant was acknowledged by the staff when they entered the treatment room to complete the water checks, and this was escalated to the renal technicians.

When it was identified by the nursing staff that the conductivity levels were outside of recognised parameters the renal technicians were called in to review the plant and check the water quality. The renal technicians regenerated the water softener that reduced the conductivity levels to within normal parameters and dialysis continued.

De-scaling took place over the weekend of 10/11 February however there were further concerns throughout the following week related to higher than usual conductivity levels. Further descaling was undertaken, the system was disinfected, and the softener vessels and resin replaced. This appeared to settle the conductivity levels and dialysis continued.

[1] Chlorine is a disinfectant that kills germs in water. Chloramines are a group of chemical compounds that contain chlorine and ammonia.

Staff noted a drop in patients' haemoglobin levels which triggered a full review of the water readings and test results over the previous few days, and this indicated that there were some issues with the water quality. This recognised that there had been an impact on patient safety and the decision was therefore made to cease using the Bedford Renal Unit for dialysing patients. Arrangements were made for all the patients to undergo their dialysis at other sites whilst the review was ongoing.

Immediate incident management was put into place with a Renal Safety Incident Oversight group and various sub-groups underneath, leading the required work streams in line with business continuity, as detailed in figure 3.

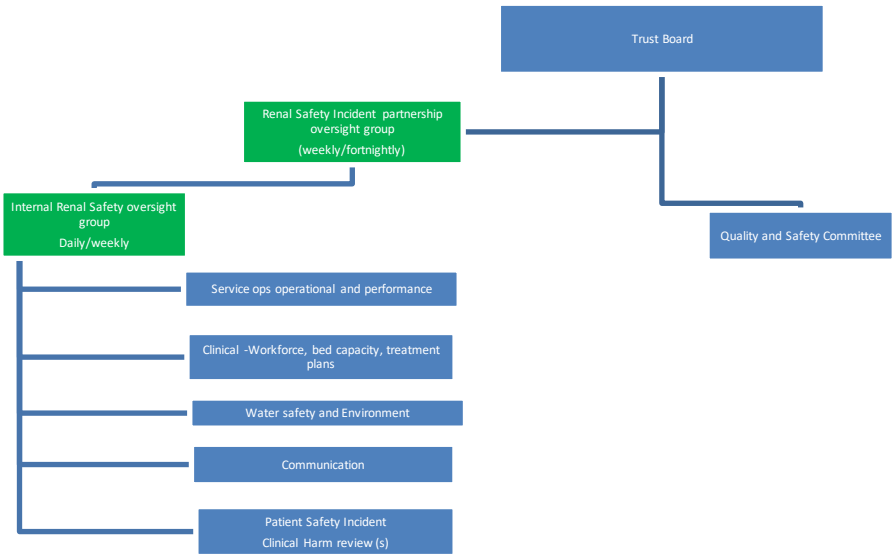

Figure 4 Incident response structure

4. Investigation approach

4.1 Investigation team

Role	Initials	Job title	Dept/directorate and organisation
Investigation commissioner/convenor	J Daniels	Medical Director	Corporate /Executive
Investigation lead:	J Bramall	Patient Safety Specialist	Corporate Governance
	C Carr	Patient Safety Manager	Corporate Governance
	S Hoskins	General Manager	Planned Care
	K Walker	Business & Commercial Service Manager	Cancer Services

The draft report was reviewed by an external legal team. They were asked to:
-Review the drafting of the PSII Report to ensure that it clearly and succinctly tells the story of what has happened.
-Suggest stylistic changes to the text to improve accessibility to the reader.
-Provide comments on any areas that may benefit from more significant revision because it is unclear, irrelevant or misleading.
-Consider whether the report contains any information (such as personal data) that should not be included in a published report.

4.2 Summary of investigation process

Once it was recognised that there was a patient safety impact from the water quality at the Bedford Renal Unit, the unit was closed, and a patient safety incident response triggered.

The incident was reported on the Trust reporting system and the senior executive team were notified and an incident management team was commissioned led by the Medical Director. Patients were advised that they would temporarily not be able to dialyse at the Bedford Unit and alternative arrangements were swiftly made. LAKPA were promptly notified of the incident and worked closely with the Trust and communicated regularly with Bedford patients during the period of closure. Their representative(s) were invited to attend the weekly meetings led by the renal team and the incident oversight meetings chaired by the Medical Director.

Staff working at the Bedford dialysis unit were provided with de-brief supportive space lead by the renal team. This provided them with a confidential safe space to share their experience, discuss what happened and ensure they had any required ongoing support if required.

The Serious Incident Review Panel which consists of clinical and non-clinical staff, together with the relevant Executive team declared the incident as requiring investigation under the Patient Safety Incident Response Framework. A Patient Safety Incident Investigation (PSII) was commissioned, and a Learning Response Lead identified.

The learning response team identified the relevant work streams and round table discussions were undertaken including subject matter technical experts to inform the investigation.

Immediate improvements were identified, and the unit remained closed while repairs to the water treatment plant were undertaken. Routine incident oversight management meetings continued to monitor actions and relevant repairs with regular water quality testing and external reviews. Once repairs and renewals were completed external water quality testing took place and the water met the required safety levels. Dialysis recommenced for patients on 16 April 2024.

External engineering reports were obtained as part of the initial incident response. The findings of which were collated by the Deputy Director of Estates and Facilities and informed this learning review.

Once complete, the PSII report will be approved through Unplanned Care divisional safety oversight meeting, Unplanned Care Divisional Board, Patient Safety Event Response Panel, the Trust's Quality and Safety Committee and Trust Board.

4.3 Scope and Terms of reference

Scope

The investigation reviewed what led to the failure of the water treatment plant and any events that may have impacted on the outcome which led to the water quality not meeting safety standards.

The learning response team reviewed the patient impact and engaged specifically with some of the patients involved including visiting the unit and encouraging patients to engage. Further information was given to LAKPA for any patients who wanted to further engage with the investigators. LAKPA provided a summary of the impact of the incident on patients which is detailed earlier in this report, this included patient harms, a response to which is captured in this learning response. Most concerns raised were related to the impact while the closure of the renal unit was being managed: The inconvenience of the dialysis times (nocturnal), additional travel and stress caused by the closure of the unit. Patients were asked to attend units that they were unfamiliar with which added to their stress.

Terms of reference

- Review and stratify any patient harm and quantify to ensure the relevant duty of candour has been completed.
- Understand the oversight of the safe provision of dialysis water and identify areas for learning and improvement related to key governance aspects:
  - Governance of safe dialysis water and how they are implemented and monitored.
  - Governance of the maintenance and upkeep of the Renal estate.
  - Governance of the monitoring and escalation of dialysis water quality.
  - Governance and oversight of renal technician workforce requirements.
- Review Divisional and Corporate processes and behaviours/culture associated with risk management and escalations, and the impact on the provision of safe dialysis water.
- Understand the governance of contracts within the Trust, and the potential impact on this incident.
- Review demand and capacity modelling within dialysis service to establish the additional risk of the unit capacity being 100% and not in line with national average usage
- Consolidate learning from incident management.
- Engage and involved affected patients/families where appropriate, understand their concerns and experience and seek learning from their perspective.

4.4 Information gathering

The methodology for information gathering included the completion of round table discussions within each of the identified work streams. Each meeting included both clinical and non-clinical staff and executive level input from subject matter experts.

Throughout the investigation the SEIPS (Safety Engineering Initiative for Patient Safety) model was used as a lens to understand the events and draw conclusions. The SEIPS model describes how a work system can influence process, which in turn shapes outcomes. The key headings are tools and technology, tasks, environment, people and organisation.

A review of the working environment with a visit to the Bedford renal unit was undertaken and staff and patients were given the opportunity to participate with the discussions and to share their insight and share any concerns that they had.

A collective assessment of all relevant and documented evidence in relation to the contracts history, risk management and escalations was made by the team, with outcomes reviewed and noted. The investigation team considered how factors such as the environment, equipment, tasks and policies influenced the decisions and actions of staff. Additional questions and discussions also took place in smaller fora to identify clarity of information gathered and pathways not documented or evidenced in the round table discussions.
Engagement with staff and patients during the investigation was undertaken through site visits, observation of the environment and processes, interviews and discussion with staff and service users and feedback collated through feedback surveys.

LAKPA also worked closely with those patients affected and the Trust to ensure regular, open communication with those affected. As part of the PSII, LAKPA provided examples of the impact that the closures had on the patients. These included:

- Transport on initial transfer of patients particularly to Northampton Renal Unit -the East of England drivers were provided with the old Postcode. Thus, it took 3 hours for patients to reach the unit. This prolonged the day away from their family for up to 11 hours rather than the time taken for the normal dialysis session of no more than 6 hours.
- Itchy legs were reported to clinical staff but there was no feedback on this.

- In some cases, the anaemia or haemoglobin was very low, sometimes reaching a dangerous level requiring a blood transfusion.
- Some patients experienced cramps, both during dialysis sessions and on the journey back to home. This could be dangerous if a patient was driving.
- There were psychological and mental health issues with some patients experiencing periods of anxiety and stress
- Feedback suggested a patient missed the opportunity to proceed with planned kidney transplant surgery, possibly due to blood transfusion or other medical issues.
    - The investigation found that whilst the patient felt unwell during the incident and was contacted about a possible transplant on two occasions the transplants did not proceed because the organs were not suitable rather than because of the water incident. The possibility remains that patient's future transplant prospects may be affected because they had a blood transfusion

In addition, other potential individual patient harms identified by LAKPA were brought to the attention of the review, and these are covered in this report.

5. Key Findings

5.1 Organisational factor: Water Quality

Guidance prepared by the Renal Association and the Association of Renal Technologists in January 2016, suggested that routine testing for renal units should form part of the renal unit policy. Each water treatment system should have a standard operating procedure in place for sampling, monitoring, and recording of feed, product and dialysis water quality. The rationale for the development of these standards is to protect patients from adverse effect arising from known chemical and microbiological contaminants found in water and improperly prepared dialysis fluids. According to this guidance, water conductivity levels should be measured daily before dialysis commences however it appears that practice was for 4 times weekly on a six-day dialysis programme. The renal water testing protocol in place was noted to be very old and had not been updated.

5.2 Task factor – water testing

Tests were conducted in the water treatment room where the level of water purity is measured as the water exits the softening and filtration process. Dip stick tests are completed and recorded manually as there is no digital system for recording or monitoring. Dip stick tests for chlorine and chloramine were recorded in the week of 8 February 2024 and were within range however there were concerns relating to the conductivity levels of the water, indicating the presence of contaminants in the water. The conductivity was high, but within range and technical team were working in response to this. The level of conductivity must be within range for safe use for continuing to dialyse.

5.3 Tools and equipment factors – panel maintenance

If the contaminant or conductivity levels are outside of the safety parameters there should be a system that alerts staff to this deviation. There is such an alarm panel on the ward which should indicate when these parameters are not met. However, staff have reported that despite escalation of this and visits by the installers, this alarm panel has not worked since installation. The human element and established work around practice to this issue has been for staff to rely on the treatment room checks. Whilst staff shared that this issue had been escalated, the investigation did not find any evidence of escalation recorded since 2019. Whilst this not considered to have impacted on this incident, the investigation recognises that equipment in ward areas should be fit for purpose.

5.4 People factors – communication

Based on the manual testing results, staff identified that there was an indication of high conductivity, which was believed to be indicative of a calcified membrane. High conductivity readings are present when there are impurities in the water that have passed through the filtering systems. The red indicator on the plant was acknowledged by the staff when they entered the treatment room to complete the water checks, and this was communicated and escalated to the renal technicians and discussed with the Renal Consultant. Further communication and escalation were not evident.

5.5 Organisational factors - governance

The oversight of the quality of dialysis water was not clear. The Trust's authorised engineer for water quality and the water committee dealt with quality of feed water but dialysis water was not included. There was a suggestion that this should have been the remit of the "decontamination" engineer, however this was not formalised. The investigation team found that the water quality engineer did provide some advice around dialysis water, but this was not a formal oversight role.

The identified gap in the process for the escalation of abnormalities of the treatment room and plant was recognised and the investigation team notes that this has since been addressed with a new escalation process when readings are reported as showing abnormal levels.

The investigation team recognises that it is important to recognise the difference between 'de-scaling' and 'disinfecting' as the process for these procedures is different and prompted by differing risk factors. The feed water into the renal unit in Bedford is deemed to be particularly hard and therefore can lead to scaling up of the filtering system if the water softener performance is poor. This is duly treated with a citric acid formula which is flushed through the system to reduce the scale (such as in a domestic kettle). The manufacturer's recommended fluid contains citric acid and water, however the type of fluid described as being used in the Bedford Unit plant (Citristeril) had a lower concentration of citric acid with an addition of malic acid and lactic acid. The Renal technical team stated that this fluid was used as it was the one that was in the unit. Independent opinion obtained was that these additives could cause damage to the membrane as it is not in accordance with manufacturer's specification. The suggestion was that this may further impact on the integrity of filters and seals and allow for harmful resins being pushed through the system impacting the porous membranes and increasing the size of the pores sufficiently to allow larger particles to pass through.

5.6 Organisational factor – governance and reporting

The established arrangements at ENHT were that the renal technical team were line managed by the operational team as per historic mutual agreement between services. The renal technicians have always been part of the renal clinical service with their reporting line being to an operational manager within the clinical service. Consequently, the operational managers within the service had the responsibility of approving the requests for equipment and servicing. The renal service manager role does not have technical experience in the management of the engineering systems and therefore relied upon the renal technicians to describe the requirements and risks around maintenance and replacement. There was no oversight of this process. It is acknowledged that the role of a renal technician is complex requiring close links with the clinical service and the technical oversight of the relevant Authorised Engineers (AE). The AE's relevant to renal water safety are AE for water and AE for decontamination. Prior to this incident, the authorised engineer for decontamination did not have any engagement with the renal technical team. The AE for water had limited engagement with renal water safety processes, this was focussed only on the domestic water supply, not treated water.

The investigation found that there was a gap in the escalation process for when there were concerns raised by staff at the unit, with little oversight of decision making, rationale and risk stratification relating to the implications of running the plant outside of local safety parameters.

5.7 Task factor – plant maintenance

It was noted that the manufacturer was undertaking elements of planned preventative maintenance (PPM) on the plant. The hindsight review of the documentation following these PPM reviews is unclear, as there are instances where there are gaps in sections of the completed reviews and whose responsibility they were to take forward. For example, the manufacturer recommends changing the filters every 6 weeks and the B-Braun service documentation notes that the renal technicians were changing the filters. However, the renal service was changing them every 6 months. There was no documented record of the softener resin change that took place approximately 5 years ago. The independent engineering team who completed a subsequent inspection of the plant noted a concern over the completion of some of the maintenance being carried out by the renal technicians and not by qualified water engineers. It is of note however that the decision making around who should be carrying out the repairs was discussed within the service and was driven by the need to keep the unit open due to the reliance of 97 patients on completing their dialysis. At no time was there any indication that the repairs were impacting on the safety of the dialysis that was taking place.

5.8 Tools and equipment factors – plant management

It is of note that approximately 6 weeks prior to the incident, the pump for the treatment plant was changed due to a failure. The replacement pump was one that was held in stock and was used to ensure that the service was able to continue. The installed pump was noted as being pressure controlled with a variable frequency drive. However, no pressure reducing valve was installed. According to the independent reviewer's report, there was evidence to suggest that there may have been some impact to parts of the filtration system caused by the installation of this replacement pump. The pump recommended by the manufacturer of the treatment plant has a lower pumping pressure which is moderated to ensure a consistent pressure throughout the system: however, the pump installed does not function in the same way and may have pumped the water through at a higher pressure with possible spikes in the flow rate. The pump used was one that the renal team already had available as they are used for home dialysis units. The investigation team notes the potential for these spikes on water flow rates cannot be ruled out as a contributing factor and may have caused the softener resin being pumped through the system and damaging the RO membrane.

5.9 Organisational factor- governance

Discussions with the staff involved in the running of the unit and the renal technicians have identified that a culture had developed of making short term fixes to ensure the continuation of the service at Bedford and that resource was not always available. It is however important to note that due to the lack of formal process, escalation attempts were ineffective. Some of the risk was being held outside of the correct structure of risk mitigation. This therefore meant some senior team members, or experts, were not aware of some of the works being undertaken nor was there an understanding of the implication of the risks.

From the water quality round table meeting it was identified that there was no robust oversight of works being carried out. There was little evidence of a robust scheduling arrangement for the replacement and monitoring of parts of the plant that needed regular replacement.

5.10 Person factors – skills, knowledge and training

Works completed by the renal technicians do not appear to have had any review or oversight regarding the safety of the repairs or maintenance checks undertaken. Whilst it is acknowledged that the technicians in the team have considerable experience, the investigation team found there to be a gap in the technical oversight and assurance that changes to the system were in accordance with recommendations and safety standards. It is noted that all renal technician competencies and qualifications are up to date in other aspects however there are protocols related to specialist knowledge and safety assurances that were not met regarding work on the reverse osmosis plant. Four technicians had certified supplier technical training in 2010 however

have had no certified updated training since. On-site non-certified training for the Bedford equipment was given by the supplier in 2013. The remit and responsibilities of the renal technicians are wide ranging; they are required to maintain, repair, service and install dialysis machines alongside their responsibilities related to the home dialysis patients. The increasing demands on such a small team (5.5 WTE) with the substantial increase in the number of patients requiring dialysis and the associated impact on the need for servicing repairs, installation, maintenance for the ever-increasing numbers of home dialysis patients is a risk to the service and patients using the service.

Independent opinion is that if repairs and maintenance to a medical device is being undertaken, training specific to the make and model should be completed and regularly updated to ensure full competency. Whilst the renal technical team have had no specific training on the repair of the RO plant, there was good evidence of up-to-date training on the maintenance of dialysis machines and other areas of their work.

On occasion, running repairs undertaken on the plant to ensure the service could continue to operate were conducted, which have, in hindsight, been identified as possibly impacting on the events which led to the temporary closure of the unit. There was no oversight process to support the works completed with no external expertise or guidance to the service to ensure that safety standards were being adhered to. Of note, expert opinion is, that full training for the plant and conducting repairs should be in place and up to date.

5.11 Organisational – governance

The draft facilities management contract/agreement documents reviewed following this incident were not clear as to the understanding of responsibilities about maintenance and repairs at the Bedford site, with a section on rolling replacement which appears not to have been active. Repairs were being carried out by the ENHT team of renal technicians to support the unit to keep running the service, although it remains unclear where the oversight for this was being monitored as advice was only being sought when the renal technicians were unable to address the issue with the plant.

The investigation team found that there has been a breakdown in the understanding of the responsibilities around the maintenance and servicing of the plant. This is partly related to the lack of contract, partly related to the ambiguity of the wording of the original agreement and the timeframe over which workarounds and normalisation of deviance occurred.

5.12 Equipment and technical tasks - Engineering review

As part of the incident management, the system was reviewed by external engineers. The suggestion was that the softener had in fact failed and softener resin had been pumped through the system. According to the engineering review, the cause of the resin release was attributed to one or both of the following factors:

1. Inadequate installation of softener components resulting in the release of softener resin, damaging filters and membranes. *'The top basket on tank A was not in position which has resulted in a further resin loss due to inadequate installation'* Siren report.
2. Installation of inappropriate pump with no pressure reducing set. *'The system original design included supply feed pumps previously Calpeda at 4.5m3/hr output, these have failed and have been taken out of service. As a replacement a retrofitted Esybox pump/pressure set has been installed, this installation is rated at 120L/pm (7.2m3/hr) with a max operating pressure of 8 bar. This replacement pump set has no pressure reducing valve installed and the max operating pressure of the Clack WS1 TT head is <8 bar. There is significant evidence of the resin passage from the Clack water ion exchange plant and it would be interesting to know if this Esybox was installed prior to the resin escape causing the initial breakdown...' This increase in pressure and flow with no pressure reducing protection may well be the reason why the resin has escaped from the softener unit, contaminating and damaging the plant further downstream in the process'* Waterman Environmental report.

In relation to point 1 noted above, the Siren report goes on to note their "...*opinion that this is a result of non-water treatment personnel completing tasks on the plant as well as the riser pipe being situated slightly off centre. Therefore, when the control valve has been secured to the neck it will have likely dislodged the top basket from the valve. Tank A's riser pipe is also shorter than it should be (lower than the top of the tank neck) although once the valve is secured in place this may just have sealed within the central o-ring of the control valve but is less than ideal and should be replaced."* The Renal team provided detail that a very similar case was reported by a London hospital in 2020 with 30 patients having haemolysis (Leonard et al, "*Hard water syndrome: a case series of 30 patients from a London haemodialysis uni*t) and this also reports softener resin being dislodged downstream.

Further suggestion from the independent report (external engineers) suggests that the assumption that the conductivity results could be addressed by de-calcifying the system was incorrect. According to the analysis of the water treatment plant and a review of the filters and RO membrane, the leaking resin was noted to have damaged the carbon filter media and the 5 micron pleated filters. The cause of this may have been due to additional pressure produced by the replacement pump as detailed in point 2) above. However, based on the presumption that the increased conductivity levels were due to the failure of the RO unit, a de-scaling process was

carried out. It is of note that the fluid used was not the manufacturers recommended one as discussed above in the 'water quality' section. Further compromise to the system may also have been caused by the bypassing of the first stage of the RO unit which was indicating that there was an error, however once the de-scaling had been completed the assumption was that the system was safe to re-start. The error indicator was therefore by-passed, and the system re-started. Following this the test results indicated that the error had been successfully addressed and that it was safe to continue dialysing.

This de-scaling took place over the weekend of 10/11 February however there were further concerns throughout the following week related to higher than usual conductivity levels. Further descaling was undertaken, the system was disinfected, and the softener vessels replaced. This appeared to settle the conductivity levels and dialysis continued.

5.13 Organisational factor- Risk Management

During the investigation the evidence reviewed suggested that risks for the renal service have been added to the risk register over the years. These risks related to capacity modelling and the age of the plant at the Luton and Dunstable site. It is of note that there is a further risk recorded relating to the potential plant failure due to the age of the equipment at the St Albans site plant. This was acknowledged by the service and business cases were completed indicating the need for additional resources to be made available. The chief technician requested capital for replacement plant at Lister and St Albans in December 2023. Due to lack of funding and other barriers, the plant failure risk remains on the divisional risk register, and this has been under review since August 2023. The risk related to capacity is on the corporate risk register and has been since December 2019. Reviews and plans for mitigation have been discussed but no solution has yet been identified.

It is also of note that some risks which had been on the risk register and reviewed by the renal service team, had temporary mitigations which had subsequently resulted in the risks being removed from the register or the score being reduced in line with usual risk management processes. Consequently, the risks did not require escalation to the corporate risk register. In addition, some of the risks were closed due to appropriate mitigations being in place. In some cases, the mitigation had been the completion of plant service or repairs to the plant; however, the overall feeling has been that due to the ambiguity of the contract, a full overhaul of the system should have been completed and fully reviewed by the relevant external engineers before the risk was removed.

The investigation identified the following relevant risks details set out in the table below:

Risk ID	Description	Opened date	Closed date	Risk score (if still open as of July 24)
1926	Risk to service associated with the relocation of renal dialysis services from the L&D hospital site to standalone facility	February 2016	January 2022	
1531	Risk of failure of aging water plant at Luton dialysis unit	December 2017	January 2020	
1702	Risk of reduced dialysis capacity at L&D due to drain problems at L&D unit	August 2019	July 2021	
3013	Water safety at Bedford renal unit (relating specifically legionella and pseudomonas)	April 2023	December 2023	
3154	St Albans Dialysis water plant replacement overdue	August 2023	Remains open	15
1897	Risk to service provision for patients due to lack of contract to manage HF and SFM to Harlow and Bedford Renal units	January 2023	Remains open	10
3336	Risk of significant patient harm due to poor dialysis water quality for the inpatient dialysis areas including CCU (non-compliant with national recommended standards)	March 2024	Remains open	15

A common theme noted from review of the risks is that they remain open on the risk register for several years. The ownership of risks seems to be the individual highlighting the risk but not always with the ability/authorisation to action or resolve the problems leading to the risk.

The investigation also noted that the reporting process allowed risks to be assigned to individuals without individuals being aware that they had been assigned as the owner.

5.14 Organisational factor – governance

The investigation team found that there was no signed copy of the contract with the contractor able to be located. The the contractor contract was negotiated during 2012. The negotiation was approved at Board level (not the contract) and once written, the contract should then have been presented at Board and signed off by the division and relevant team. The agreement being negotiated was for a three-year term with an extension clause of 3 x 8 months which gave an additional term of two years. This would have been a five-year period covered by the contract. The agreement was to incorporate a sum payable to cover the capital investment and lease of the building and plant and a sum payable relating to consumables, which was based on the demands of the unit and sessions completed. This calculation was based on figures for 2012 and there is no evidence that this was amended or increased over the whole period. It is also not possible to identify the capital repayment schedule to identify if the annual payments to cover this should have been reviewed after 5 years. The value of the contract with the contractor was £1.8m per year.

Reviewing the maintenance and upkeep of the renal estate at Bedford is part of the agreement that had been entered into at the beginning of the contract and despite no formal signed version being found, the contractor have agreed that this was the case. the contractor and the Trust's understanding was that the maintenance of the estate, the upkeep of the grounds, the domestic water, the air conditioning, and feed water supply were the responsibility of the contractor and the implied responsibility continued throughout the period. There was also an understanding that plant and machines would be replaced within the terms of the agreement. the contractor had made multiple requests to renegotiate the contract, which would have included equipment replacement. The plant itself was to be maintained and repaired by the Trust with oversight of the manufacturer and the team at the contractor to ensure quality repairs.

In 2017-2018 there were issues raised regarding the arrangement with the contractor and those concerns were discussed at divisional level, and work commenced on establishing an extension for the assumed 'contract' agreement for a further two years. There is no evidence at this point that there was any recognition of the lack of signed original contract.

There is no evidence of any regular meetings between the Trust and the contractor to review contract performance and delivery. There is evidence of attempts to establish an agreement with various escalations to the contracts team from the renal service for support to write the specification for the contract. Escalation to the Estates team to assist with relevant requirements relating to service schedules and contract content were also made however based on information shared by the operational team, there were still issues outstanding. There is also some evidence of the external procurement team being involved in trying to resolve this in more

recent times. The process of obtaining a formal agreement/contract was never completed despite several escalations through various meeting forums and Trust Management meetings. When the incident leading to the closure of the unit occurred, there is no evidence that any contract arrangement was ever resolved. Whilst it is acknowledged that this may have only been a small contributory factor yto the eventual incident, the lack of a clear contract and schedule of responsibility is evident. The difficulties this led to was that there was no clear documentation of who was wholly responsible for the management, servicing, or replacement of equipment. It was therefore not clear whether any of the work being completed at the unit was based on the implied understanding of the contract. There is no escalation or oversight plan evident from the perceived agreement and therefore most of the repairs and maintenance were being undertaken by the renal technicians to ensure the continuation of the service.

When the contract was being negotiated there was a lack of clarity from the service as to appropriate point of support and engagement outside of the division and no clear pathway to ensure compliance and traction on finalising the contract negotiations. Due to the subject matter expertise required to negotiate and formally sign off a contract there should be a clear pathway for high level oversight and governance which is not evident in this case. There also is a trust wide gap in the oversight and monitoring of contracts that are in place to ensure the relevant tendering applications are made in a timely way. The Trust's procurement team is hosted by West Hertfordshire NHS Trust. It was not clear who within this team was responsible for helping to re-negotiate the contract.

5.15 Organisational factor- Capacity Modelling

The initial figures supplied for occupancy at the Bedford renal unit demonstrated that it runs at 85% capacity, which would imply that there is spare capacity to accommodate more patients or to allow time for maintenance work etc to take place. This was not the experience of the clinical team who said that there was no spare capacity or possibility of down time for the unit. This difference in opinion between the published data and the experience of the team was further explored and subsequently explained by the fact that not all the patients dialyse 3 times per week. There are 16 dialysis chairs, and the unit runs 3 sessions per day, 6 days per week; thus meaning there are 288 'slots'. If the unit was running at 100% capacity that would be 96 patients dialysing 3 times per week. However, there are approximately 15 patients who only dialyse twice per week therefore the occupancy of the slots is approximately 85%. It is not possible for these slots to be used by another patient (nobody only needs dialysis once a week). Therefore although the published occupancy is 85% there is no extra capacity. When this was discussed with the finance and renal teams together, it was identified that this was recognised as an issue nationally and there was a suggestion that the nationally accepted metric should be the number

of patients dialysing rather than the number of slots. This would also give a more holistic patient centred measure of capacity.

At the time of the incident the Bedford unit served 97 patients, one more than the theoretical maximum. The service also highlighted that they are funded for operating with 90 patients however the funding formula is based on dialysis sessions which is currently on a block payment meaning there is a shortfall in the funding. This places additional pressure on the unit and the treatment plant which may indicate the need for a more intense monitoring programme or at least consideration of a more intense monitoring programme. There has been approximately a 20% increase in the number of patients being dialysed over the last few years, without a similar increase in resources. The Bedford unit performs dialysis from Monday – Saturday with Sunday being the only day that dialysis is not undertaken. Consequently, other than overnight work, this is the only day when routine servicing or repair can be scheduled. This includes the process of de-scaling and disinfection. Automatic heat sanitisation is performed weekly on a Sunday.

A key focus for the Renal Service has been to increase home dialysis for patients thus reducing the occupancy figures within the satellite and Lister based units. Whilst additional home dialysis patients would reduce the occupancy at the satellite units, it is noted that this increases the workload for the technicians. Currently the plan to reduce the occupancy within the units by increasing the number of home dialysis patients has not had the required outcome. A reduction in patients within the satellite units may also allow for more flexible maintenance checks/repairs as needed.

The investigation team has been informed that there has been an ongoing excess in demand for the dialysis service in general and particularly at the Bedford Renal Unit. The number of agreed sessions has increased to the level that the unit is running at 100% capacity. Therefore, when this incident occurred, all 97 patients had to be relocated to receive their dialysis at other sites or hospitals and this had to be completed in a very timely way to ensure that no sessions were missed. Unfortunately, later in the timeline of the incident some patients who were impacted by inconvenient transport times and length of travel together with the inconvenience of nocturnal dialysis, did chose not to attend some sessions.

It is of note that other renal dialysis units do not run to full capacity, and this was evident when these units were able to accommodate our dialysis patients at very short notice and with minimal disruption to their own services. Therefore, a review of their service model should be completed to assess whether any lessons can be learned for our service capacity model.

5.16 Organisational – Staffing model

The renal technical team felt that their workload was not safely sustainable. The renal technicians cover all satellite units which include Bedford, St Albans, Luton, and Chiltern together with the dialysis unit at Lister Hospital and home dialysis patients. The capacity for home dialysis has increased substantially and is now up to 60 patients. Each new patient requires the equipment to be installed in their home, every home dialysis unit has to be serviced twice a year, and any faults are attended to by the renal technicians. This has been in addition to their ongoing responsibility to the renal unit repairs and maintenance requirements.

A key focus for the Renal Service has been to increase home dialysis for patients thus reducing the occupancy figures within the satellite and Lister based units. Additional home dialysis patients will increase the workload for the technicians however would aim to reduce the occupancy at the satellite units down in line with other Units (approximately 75-80%). Currently the plan to reduce the occupancy within the units by increasing the number of home dialysis patients has not had the required outcome, as the satellite dialysis units are running over capacity. This reduction in patients within the satellite units would also allow for more flexible maintenance checks/repairs as needed.

Peripheral learning to this incident also found the nursing workforce to be consistently overspent as multiple shifts and vacancies must be covered utilising bank or agency workers. This is due to an insufficient number of trained substantive renal staff to meet the current demand and capacity of the service. There is currently discussion with the finance team to assist in aligning the staffing workforce with the service demands. The team can appropriately reduce the staffing for certain sessions, where there are fewer patients due to the 15 patients who only dialyse twice a week.

5.17 Physical environment

Some environmental standards were found to be below the acceptable standards. While the local oversight of the plant room was observed and safety checklists completed, some of the environment conditions were functioning with temporary fixes.

Figure 5 Photo of the feed water pumps in Bedford renal unit

Figure 6 Photo of the alarm panels in Bedford Renal Unit

6. Summary of findings, areas for improvement and safety actions

The investigation team identified several contributory factors that led to the incident and subsequent temporary closure of the Bedford Renal Unit. The causal factors for the closure of the Lister 6B dialysis unit were precautionary rather than incident related. No patients were medically affected prior to the closure of 6B, and remedial works are ongoing to ensure patient safety and that the water quality meets the required standards.

6.1 Organisational factor - Repairs and Maintenance

The investigation team acknowledges that there were gaps in the completion of routine maintenance and the replacement of filters within the recommended timeframes. There did not appear to be any scheduling other than for annual servicing by the manufacturer of the plant.

Furthermore, there was limited oversight of the processes in place and a gap in the understanding of the risk implications relating to delays in routine maintenance due to lack of resources or technician availability.

Work undertaken to ensure that the dialysis of the 97 patients registered for dialysis at the Bedford Renal Unit could continue to meet the demand, was not overseen by expert independent engineers specifically trained on the maintenance and repair of the specific treatment plant. Repairs and replacements were not checked or verified by the manufacturers or any independent source to ensure suitability.

An independent report commissioned following the incident suggests that there were some sub-optimal repairs and replacements completed on the plant. The report suggests that oversight and an independent review should have been carried out following any repair or maintenance with clear documentation detailing works undertaken.

Due to the ambiguity of the contract/agreement and the lapse in that agreement, roles and responsibilities were ambiguous and therefore works were being carried out in house.

6.2 Organisational factor – Contract management

It has been identified that there was ambiguity around the responsibilities related to repairs, renewal and replacement as the facilities management contract was out of date. Work was underway to renew the contract, which had lapsed in 2015 and had continued as a rolling agreement, however the contract renewal had not been completed. The Trust process was that local teams retained the responsibility for the day-to-day management of their contract relationship and performance. There was no central team managing contracts within the Trust or central oversight of contract management. There was insufficient evidence of a routine and robust mechanism to effectively discharge this responsibility either within the local team or within the wider Trust.

There is a central registry of contracts held by procurement on behalf of the Trust. Thus the Trust and the service were aware the contract needed to be renewed however the process to achieve that renewal repeatedly broke down. The staff in the service were unable to identify the relevant team within the organisation to support with this as the local team were unclear as to what the formal process was and the appropriate expertise to assist.

The Bedford contract was for 3 years with an option to extend for 2 years. Bedford was short terms because it fitted with the schedule of agreements for dialysis employed by the Commissioners at that time. There wasn't any rolling programme of machine or water plant replacement in such a short contract. In longer dialysis outsourcing contracts (eg, 10 or12 years), agreements around Haemodialysis machine replacement at 7 years are usually included and the water plant after 10 years in some.

6.3 Organisational factor– Risk management

Whilst there were recognised risks within the renal service, specifically related to the Bedford Renal Unit, these were being addressed, and actions taken to temporarily fix or mend the equipment. The permanent solution to the risk often required capital input which was not available and therefore work arounds were in place to mitigate the risk to continue providing the service. This may have led to false assurance that the risks had been mitigated and no longer existed.

It is also of note that risks on the register were often allocated for management to a member of staff (by name) and not by role. This is impacted if that staff member subsequently leaves or changes role. There is evidence that whilst some risks have been entered onto the risk register, they were allocated without the staff member being notified that they were the risk lead.

Changes to the Trust management of risk were made through policy publication in 2023. Risk management processes reflected in the Risk Management Strategy and Policy, support the Trust's new organisational management structure, (launched in Jan 2024), that provides the overarching framework, mandate and commitment by which risk is managed and is fully endorsed by the Trust Board. It focuses on risk management arrangements from an organisational rather than an individual basis. Risk management knowledge, maturity and processes continue to mature.

6.4 Patient and staff experience

Patients and staff were given the opportunity to feedback regarding the impact of the closure of the renal unit, with members of the learning response team attending the Bedford unit on several occasions. Feedback received was both negative and positive with a general feeling from patients/their relatives that communication could have been better. There was an understanding of the efforts made to ensure that no dialysis sessions were missed and recognition that other units were relied upon for their sessions. However, the impact to patients awaiting transplant, who had to receive blood transfusion was considerable due to the impact this could have on their transplant standing. Additional time for blood testing and compatibility must be undertaken following transfusion with a minimum of an additional three-month delay.

Several actions to address identified areas for improvement have already been designed because of the incident management group findings, to facilitate the efforts to make safe and re-open the unit which occurred on 15 April 2024.

Ongoing areas for improvement have been identified as:

1. Monitoring and oversight of water quality processes
2. Capacity modelling
3. Alignment and review of contract tendering and monitoring process
4. Risk management

Safety action summary table

Area for Improvement 1: Monitoring and oversight of water quality, including engineering processes.								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool / measure**	**Measurement frequency**	**Responsibility for monitoring / oversight**	**Planned review date**
1.a Organisational factor	Review all renal water safety policies and SOPs, including Reporting / escalation processes related to monitoring water quality	Head of Operations care group 3	Interim water safety SOP now in place. Final SOP will be completed once water plant works completed (December 2024)	Completed Water Safety Policy (2027) in place	Published SOP	As per SOP guidance	Unplanned Care divisional board	Monthly governance meetings oversight
1.b Organisational	Update Trust 'Water Safety Plan' to reference updated	Deputy director of	Final Safety plan will be completed	Water safety plan EST 029	Published water safety	As per plan guidance	Chair of Trust Water Safety	Annually through Safety water group

Area for Improvement 1: Monitoring and oversight of water quality, including engineering processes.								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool / measure**	**Measurement frequency**	**Responsibility for monitoring / oversight**	**Planned review date**
factor	renal water policies and SOPs	Estates	following final SOP (December 2024)	(April 2027)	plan		group	work plan
1.c Organisational factor	Trust water safety group work plan / ToR to receive reports from renal water safety group to include assurance on RO water	Chair of the Renal water Safety group	June 2024	July 2024	Reports published in Trust Safety Water group	Monthly	Chair of Trust Water Safety group	Annually through Safety water group work plan
1.d Organisational factor	Review operational reporting structure	Head of Operations, care group 3 and EBME Service lead	March 2025	In progress	Published reporting structure to Divisional Board	N/A	Divisional Director of Operations Unplanned Care and Deputy Director of	As required

Area for Improvement 1: Monitoring and oversight of water quality, including engineering processes.								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool / measure**	**Measurement frequency**	**Responsibility for monitoring / oversight**	**Planned review date**
							Estates	
1.e Organisational and Human factor	Complete training needs analysis both renal technical team and other ancillary staff, across technical skills and SOPs, policies and escalation ladders.	Renal Service operational lead and EBME Service lead.	Jan 2025		Published TNA presented to divisional board	Annually as per trust TNA plans	Unplanned Care Divisional board	
1.f Organisational factor	Benchmark the current staffing establishment and workload of renal technicians in line with national recommendations/	Renal Service operational lead and EBME Service lead	Feb 2025		Published establishment review shared in Divisional Board	Annually	Head of Operations Care Group 3	

Area for Improvement 1: Monitoring and oversight of water quality, including engineering processes.								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool / measure**	**Measurement frequency**	**Responsibility for monitoring / oversight**	**Planned review date**
	national peers and long term capacity modelling							
1.g Organisational factor	Review of the process for oversight repairs, remedial work and PPM maintenance of the Bedford plant	Deputy Director of Estates	Completed, April 2024	April 2024	Waterman service input into relevant details onto database. There is ongoing monitoring at Trust WSG	Monthly	Chair of Trust Water Safety Group	Continuous
1.h External Environment	All renal water safety stakeholders to have access to the live database owned by	Deputy Director of Estates	Feb 2025		Confirmed access archived and minutes noted	N/A	Chair of the Renal Water Safety Group	

Area for Improvement 1: Monitoring and oversight of water quality, including engineering processes.								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool / measure**	**Measurement frequency**	**Responsibility for monitoring / oversight**	**Planned review date**
	Waterman and any relevant training				in renal service water group			
1.i Organisational factor	Implement a decontamination audit process with direct involvement form Authorised Engineer	Deputy Director of Estates	Feb 2025		Audit presented to decontaminati on group, and evidenced in minutes	Annual audit	Decontamination group chair	As per decontamination group work plan
1.j Organisational factor	Overarching plan for remedial engineering works				Capital project summary plan complete, Dec 2024	Weekly	Chair of Critical Infrastructure Group	As per Infrastructure Group Work plan
	Bedford site	Deputy	Dec 2024	In progress				

Area for Improvement 1: Monitoring and oversight of water quality, including engineering processes.								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool / measure**	**Measurement frequency**	**Responsibility for monitoring / oversight**	**Planned review date**
	Lister level 6	Director of Estates	Dec 2024	In progress				
	St Albans site		Dec 2024	In progress				
	Home Therapies level 3		TBC	In capital planning stage				
	Lister main renal unit level 3		March 2025	In capital planning stage				
1.k Organisational factor	Improve reliability of capital equipment replacement, and procurement in relation to renal commissioned services. Including central log of all	Operational lead for renal services	June 2024	August 2024		Monthly	Chair of Renal Dialysis Procurement Group	As per renal procurement group workplan

Area for Improvement 1: Monitoring and oversight of water quality, including engineering processes.								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool / measure**	**Measurement frequency**	**Responsibility for monitoring / oversight**	**Planned review date**
	requirements.							

Area for improvement 2: Alignment of contract tendering and monitoring processes.								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool / measure**	**Measurement frequency**	**Responsibility for monitoring/ oversight**	**Planned review date**
2.a External factor	Scope from similar tertiary centres a comparison and understanding of other renal water safety operational model structures	Chief Operating Officer	July 2024	July 2024	Feedback to TMG	N/A	N/A	N/A
2.b Organisational factor	Develop standard work for operational processes across ENHT contract management processes that are value adding and reduce waste and establish clarity of responsibility by	Deputy Chief Finance Officer	March 2025		Published SOP/Guidance	As per SOP guidance	Chair of Finance and Performance review Committee	Annually

Area for improvement 2: Alignment of contract tendering and monitoring processes.								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool / measure**	**Measurement frequency**	**Responsibility for monitoring/ oversight**	**Planned review date**
	staffing group.							
2.c Organisational factor	Consider a central repository of contracts	Deputy Chief Finance Officer	March 2025		Published SOP/ Guidance	As per SOP guidance	Chair of Finance Performance and People Comittee	Annually
2.d Organisational factor	Training needs analysis for operational leads on contract management skills and knowledge	Deputy Chief Operational Officer	Jan, 2025		Published TNA	Annual TNA		Annually as per Trust TNA

Area for Improvement 3: Demand and Capacity modelling within dialysis services								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool/ measure**	**Measurement frequency**	**Responsibility for monitoring/ oversight**	**Planned review date**
3.a Organisational factor	Review of ENHT dialysis occupancy measures	Head of Clinical Services Chronic Care Group	January 2025		Review of risk register entries and scores. Incidents reported and business continuity incidents related to dialysis capacity.	Monthly	Renal Business meeting with care group 3.	Monthly
3.b Organisational factor	Establish ENHT dialysis occupancy target metrics	Head of Clinical Services Chronic Care Group Information	Power BI system implementation due 1 April 2025			Annually		Monthly

Area for Improvement 3: Demand and Capacity modelling within dialysis services								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool/ measure**	**Measurement frequency**	**Responsibility for monitoring/ oversight**	**Planned review date**
		and Business Intelligence team						
3.c Organisational factor	D&C planning long term for dialysis capacity in ENHT managed units	Deputy Director of Finance and Associate Director of Planning team	April 2025	In progress	Published D&C summary	Annually	Care group 3 performance review group	Annually
3.d Organisational factors	Review operational plans to manage capacity to achieve the above to ensure quality and safety of dialysis delivery	Head of Operations Care group 3	April 2025	In progress	Published SOP	Annually	Unplanned care divisional Board	Annually

Area for Improvement 3: Demand and Capacity modelling within dialysis services								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool/ measure**	**Measurement frequency**	**Responsibility for monitoring/ oversight**	**Planned review date**
3.e. Organisational factor	Urgent review of how to create short /medium / long term available dialysis stations within the current state, considering current risk appetite.	Clinical Director and Deputy Chief Operating Officer	Nov 2024	Dec 2024	Published agreed optional appraisal	N/A	TMG	Annual care group work plan
3.f. External factors	Discussion with NHSE specialised commissioners for financial pressures for 2024/25	Director of Finance	Jan 2025		Documented outcome form commissioning/ partnership conversation	N/A	TMG	
3.g. External factors	On receipt of confirmed funding details from NHSE for 2025/26,	Deputy Director of Finance and	Jan 2025		Agreed published financial	N/A	Divisional Board	N/A

Area for Improvement 3: Demand and Capacity modelling within dialysis services								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool/ measure**	**Measurement frequency**	**Responsibility for monitoring/ oversight**	**Planned review date**
	undertake planning review and implications	Head of Clinical Services Chronic Care Group			agreement			
3.h External factors	Long term regional capacity modelling work and strategy across East of England dialysis services	EoE Renal Network with NHSE /specialised commissioners	April 2025		Agreed modelling delivery plan	N/A	TMG and Divisional Board	N/A
3.i Organisational factors	Review of dialysis nursing workforce for service delivery needs	Care Group 3 head of Nursing	March 2025	In progress	Published agreed establishment	Annually	Divisional Board	Annually

Area for improvement 4: Risk Management Oversight								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool/measure**	**Measurement frequency**	**Responsibility for monitoring/ oversight**	**Planned review date**
4.a Organisational factor	Review performance of governance against quality governance standards framework	Director of Quality	Quarter 4 24/25		Governance maturity matrix balance score card	Annually	Chair Audit and Risk Committee	Annually
4.b Organisational factor	Embed new risk management policy and processes within new organisational operational model	Associate Director of Quality Governance	October 2024	In progress	Audit and Risk Committee governance maturity deep dives	Quarterly	Chair of Risk management Group	Annually
4.c Organisational factor	Audit and monitor RMG processes against policy.	Internal Auditor: RSM UK Risk Assurance Services LLP	December 2024	In progress	Audit and Risk Committee governance maturity deep dive	Monthly	Chair of Audit and Risk Committee and Deputy CEO	As per guidance

Area for improvement 4: Risk Management Oversight								
	Safety action description	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool/measure**	**Measurement frequency**	**Responsibility for monitoring/ oversight**	**Planned review date**
4.d Organisational factor	Review Trust wide provision for integrated risk management, including risk management training needs analysis	Associate Director Quality Governance and Head of Corporate Governance	Initial benchmarking review completed September 2024. Further Trust wide TNA due Jan 2025.		Integrated Risk management organisational structure change proposal options appraisal	N/A	Chair of Risk Management Group	Annual TNA process

Complete	Partially complete	Not complete	Not Due