B. Braun Avitum UK Limited

Gloucester Royal Hospital Renal Units

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Inadequate
Are services safe?	Inadequate
Are services well-led?	Inadequate

Summary of findings

Overall summary

We rated this service as inadequate because:

- The maintenance of facilities, premises and equipment within the provider's remit did not always keep people safe.
- Staff did not consistently manage infection prevention and control risks and fire safety was poor.
- Governance processes had not effectively contributed to improved safety and risk management.
- Service standards did not always meet national best practice, including in relation to the management of chemicals and with regards to confidentiality.
- There was a lack of provision for patients with mental health needs.

However:

- The service operated with a staffing level agreed in advance with the referring NHS trust and consistently met this.
- Staff were trained in renal care to a high standard and patients received treatment in line with national standards.
- The staffing team was highly experienced and dedicated. They delivered good quality, safe care within their abilities despite the deteriorating state of clinical facilities.

As we found the provider breached the regulations, we took action to ensure they improve. Following our inspection, we have served two Warning Notices under Section 29 of the Health and Social Care Act 2008. We notified the provider that they failed to comply with The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014; the provider failed to comply with Regulation 12(2)(d)(h)(i), Safe care and treatment, and Regulation 17(1)(2)(b), Good governance. The provider is required to achieve compliance with the relevant requirement within the timescale set in the Warning Notices.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Dialysis services	Inadequate 	We rated this service as inadequate. See the overall summary for more information.

Summary of findings

Contents

Summary of this inspection

Background to Gloucester Royal Hospital Renal Units

Gloucester Royal Hospital Renal Units is operated by B. Braun Avitum UK Limited. The service provides haemodialysis to NHS patients over the age of 18 under a contract with Gloucestershire Hospitals NHS Foundation Trust. The service operates 50 dialysis bays across 3 units on the site of Gloucestershire Royal Hospital. Cotswold and Severn units are satellite clinics on the hospital grounds. The service also operates a dialysis bay and side room on ward 7B of the main hospital.

Cotswold and Severn units operate from 7am to 6.30pm on Tuesdays, Thursdays, and Saturdays, and from 7am to 12am on Mondays, Wednesdays, and Fridays. The unit on ward 7B operates from 7.30am to 7pm 6 days a week for planned care and the service provides 24/7 on-call dialysis for emergency cases.

The provider registered this location in 2012. A registered manager is in post and the service is registered to carry out the following regulated activities:

- Diagnostic and screening procedures
- Treatment of disease, disorder or injury

We undertook this inspection as part of a random selection of services which have had a recent Direct Monitoring Approach (DMA) assessment where no further action was needed to seek assurance about this decision and to identify learning about the DMA process.

We last inspected the service in 2017. At that inspection we did not have a duty to rate and instead published a narrative report. We found 2 breaches of the Health and Social Care Act (2014) in relation to regulation 12 and regulation 17 and issued requirement notices to the service. At this inspection we found the service had made some improvements and addressed some of the issues that contributed to the previous breaches of regulation. However, there were still areas for improvement.

How we carried out this inspection

We carried out an unannounced, focused inspection of the service on 25 August 2022 and 2 September 2022. Our inspection team consisted of a lead inspector and a specialist advisor with clinical experience of renal services. We included all three units located on the site of the Gloucester Royal Hospital in our inspection.

As part of our inspection we spoke with staff from the host NHS trust to understand how safety systems and governance worked in partnership between the two organisations. While the trust does not form part of our report or judgement, we refer to them because renal services are delivered from premises for which they are responsible.

After our inspection we carried out a remote interview with a member of the senior provider team and asked the provider to send us additional evidence of working standards and practices.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Summary of this inspection

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a service SHOULD take is because it was not doing something required by a regulation, but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

- The service must ensure that good fire safety practices are followed at all times. (Regulation 12)
- The service must ensure breaches of safe medicine storage temperatures are acted on appropriately. (Regulation 12)
- The service must ensure safeguarding practices are uniformly understood and applied across all staff groups. (Regulation 12)
- The service must ensure staff maintain consistent standards of cleaning and infection prevention and control. (Regulation 12)
- The service must ensure governance processes are used to their fullest extent to escalate facilities and estates risks to staff and patient safety. (Regulation 17)
- The service must establish meaningful lines of communication with the host NHS trust to the extent their senior team develop an understanding of the urgent need for repairs or substantial maintenance. (Regulation 17)
- The service must establish a standard operating procedure that incorporates risk management and confidentiality for the use of the audio monitoring device in ward 7B. (Regulation 17)

Action the service SHOULD take to improve:

- The service should ensure staff fully understand the principles of good sepsis management and application of the Sepsis 6 pathway.
- The service should implement effective capacity management protocols in the Cotswold unit waiting area.
- The service may wish to consider a review of audit processes to ensure they are effective.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Dialysis services	Inadequate	Not inspected	Not inspected	Not inspected	Inadequate	Inadequate
Overall	Inadequate	Not inspected	Not inspected	Not inspected	Inadequate	Inadequate

Inadequate

Dialysis services

Safe	Inadequate
Well-led	Inadequate

Are Dialysis services safe?

Inadequate

We rated safe as inadequate.

Mandatory training

The service provided mandatory training in key skills to all staff and made sure they completed it.

Staff received and kept up-to-date with their mandatory training. The service maintained records of training compliance. However, as records did not include the expected or actual month of completion, it was not possible to identify an accurate overview of level of completion expressed as a percentage across the team. The training link nurse reviewed each staff folder monthly to check training was up to date.

Mandatory training was comprehensive and met the clinical needs of patients and staff. It included up to 69 modules depending on the individual's specific role and location of work. For example, staff who provided care on the ward 7B unit undertook more advanced training that reflected the higher level of patient need. The provider supplemented mandatory training with ad-hoc specialised training, for example, how to help patients experiencing needle phobia feel more confident about their care.

The registered manager and senior practice development nurse monitored mandatory training and alerted staff when they needed to update their training.

Managers of ward 7B invited dialysis unit staff to join team training days to help supplement their mandatory training. This reflected the higher level of acuity of patients in this unit and ward staff said they worked with the dialysis team to ensure their level of emergency care training met patient need.

A senior practice development nurse worked across the provider's clinics. They supported staff to complete mandatory training and helped staff access national vocational qualifications. They supported staff recruited from overseas to complete the objective structured clinical examination to enable them to gain certification to practice in the UK.

Staff undertook practical training in fluid assessment, anaphylaxis and vascular access and were trained in basic life support. Senior nurses were trained in immediate life support.

Safeguarding

Staff understood how to protect patients from abuse although there were inconsistencies in understanding of escalation processes. Staff had training on how to recognise and report abuse and they knew how to apply it.

Staff received training specific for their role on how to recognise and report abuse. The designated safeguarding lead was the provider's UK operations manager. While they were named as such as in the safeguarding policy, only the

registered manager and senior provider staff demonstrated knowledge of this. Staff we spoke with had different levels of understanding about the provider's safeguarding policy and procedure. All 3 units were based on the site of the NHS hospital, which had a full safeguarding team in place. Patients treated in the B. Braun unit on ward 7B were on care pathways operated by the trust.

Staff on ward 7B said if they had safeguarding concerns about a patient, they would contact the trust's safeguarding team. However, trust staff, including the duty safeguarding lead were unfamiliar with the B. Braun service and said while their team would always respond to requests for support, there was no formal agreement in place. After our inspection, the registered manager told us their team were instructed during safeguarding training to contact the trust's team for support and referrals. This was a discrepancy that meant safeguarding protocols were not clearly understood.

Staff completed safeguarding training for adults and children to level 3. The service did not provide treatment to children and young people and staff maintained up to date training as good practice in case young people accompanied patients.

Staff could describe how to identify adults and children at risk of, or suffering, significant harm. However, none of the staff we spoke with other than the registered manager knew about the service's 1 safeguarding referral in the previous 12 months. There was a lack of clarity about how they worked with other agencies to protect patients, which was a potential risk in light of the high levels of vulnerability with which some patients presented.

The service provided care to patients living with complex mental health needs, including dementia. Some patients who lived in a nursing home required one-to-one care from a mental health nurse (RMN). RMNs worked for the patient's nursing home but were not always able to support patients due to demands on the service. Although the service treated patients with complex needs who were highly vulnerable, none of the staff we spoke with could give examples of safeguarding referrals or escalations. This meant dialysis unit staff were required to carry out additional observations to keep patients safe, including those with conditions they were not trained to support. The registered manager said they liaised with NHS hospital renal consultants and senior emergency care staff to help provide support.

The provider told us a recent audit by a head office team highlighted inconsistency amongst staff in their understanding of safeguarding processes and contacts. A senior member of staff told us the provider subsequently issued single point of contact information for staff to contact their internal safeguarding lead. However, none of the individuals we spoke with were aware of this and printed contact information for safeguarding staff differed between units. In addition, the registered manager told us this was incorrect, and that staff should contact the NHS trust's safeguarding team in the first instance as they were based on the hospital site.

While staff knowledge was variable, the registered manager provided evidence of good collaborative working between B. Braun and the NHS trust safeguarding teams to protect a patient with a severe learning disability from harm. However, this was not reflected consistently, and incident records indicated challenges with securing safeguarding support. One incident report noted a patient who experienced an exacerbation of a diagnosed mental health condition deteriorated and waited in the unit for 8 hours without specialist support. The NHS hospital teams noted there were no renal consultants available to attend and the safeguarding team said they were too busy to attend. The patient left the unit of their own accord. This reflected a significant gap in safeguarding processes between the provider and the trust. Staff documented the patient left the site safely and of their own accord but there was no evidence of a safeguarding report.

The clinic provided short-term dialysis for patients on holiday in the region. The patient coordinator ensured the patient's home NHS trust provided contact details for their duty safeguarding service, which local dialysis staff could use in the event of a concern.

NHS safeguarding contacts were supplementary to the provider's own safeguarding process although there was a lack of assurance staff proactively contacted either team.

Cleanliness, infection control and hygiene

The service did not consistently control infection risk.

The estates and facilities were provided by and remained the responsibility of the NHS trust.

Clinical areas were visibly dirty in places. Flooring around dialysis beds in some areas of Cotswold unit, as well as some doors, walls, and other fixtures and fittings were visibly dirty. In Severn unit, the patient's kitchen, which was connected directly to the dialysis area with a fire door that was propped open, was visibly dirty. The hot water boiler was caked in hardened limescale, which was also dirty. The sink, dish storage rack, and cupboards were stained and visibly dirty.

Furnishings in many areas were damaged and poorly maintained. Flooring throughout Cotswold unit was stained and discarded clinical items, such as used gloves, were present in some areas. In some areas the floor was sticky. Infection prevention and control (IPC) processes were inconsistent.

On Severn unit, hand towels were left out in their paper packaging rather than being stored in a dispenser. This increased the risk of contamination. After our inspection the provider told us the trust's housekeeping team refilled hand towels overnight and they were responsible for correct storage, which the provider had no control over. This meant the provider had limited control over some areas of IPC in their clinical environment and systems were not in place to correct issues and errors such as this. Hand hygiene guidance posters at sinks was significantly out-of-date and related to information current in 2009. Patient chairs could not be cleaned effectively because old repair tape was in place to cover damage.

Despite our findings during the inspection, audits indicated the service performed well for cleanliness. While cleaning records were up-to-date and demonstrated that all areas were cleaned regularly, this was not clearly reflected during our inspection.

Staff carried out a monthly environmental cleaning audit in each unit. This included monitoring of facility cleanliness and condition, such as dialysis treatment areas and staff rooms and toilets. In Cotswold unit in the previous 8 months, the audit identified 96% compliance with expected standards.

It was not evident staff acted on audit results to improve standards. Audits showed many repairs were months overdue. The registered manager identified issues for repair and reported them to the trust estates team, who were the responsible body for maintaining the premises. Repairs were not completed in a timely manner and we were told the provider questioned the length of time it was taking for the repairs to be completed. There was no evidence the senior provider team continued to chase the delays with the trust estates team. However, we also found a lack of action from the local B. Braun team in response to immediate risks within their control highlighted by the audits. For example, staff noted ripped fabric on dialysis chairs. Although they documented action had been taken, comments were vague, and our findings did not indicate the audits resulted in significant improvement. For example, we found staff in Severn unit were using a dialysis chair with ripped fabric. The team had noticed the rip but had failed to act and instead continued to provide care normally. The same audit in ward 7B found 95% compliance and in Severn unit 96% compliance.

Staff used personal protective equipment in line with best practice and maintained good standards of hand hygiene during our observations.

Staff audited correct use of the aseptic non-touch technique (ANTT). In the previous 6 months audit results demonstrated 97% compliance with expected standards. In the same period, the hand hygiene audit showed consistently good practice, with 100% compliance. The provider had updated ANTT guidance in line with recommendations from the Association of Aseptic Practice.

NHS trust cleaning teams carried out overnight cleaning in each unit as part of a contractual agreement.

Staff audited safety processes and acted on the results to improve practices. For example, the service recently implemented a new key performance indicator for the management of venous needle dislodgements and the outcome monitoring of central venous catheter and fistulas. The provider had a target of fewer than 0.4 instances of bacteraemia infection per 1000 catheter days. In the previous 8 months, the service had moved closer to the target, with a steady reduction from 0.54 instances in January 2022 to 0.45 instances in August 2022.

The service had a good track record in relation to managing central venous catheters. In the previous 6 months there were no reported unit-acquired infections.

Environment and equipment

The maintenance of facilities, premises and equipment within the provider's remit did not always keep people safe. Staff managed clinical waste well.

The estates and facilities were provided by and remained the responsibility of the NHS trust. However, the general state of repair was poor. Floors were damaged, with broken lining and failed impervious seals, which presented a significant risk of bacteria growth and infection to patients. A kitchen in Severn unit used for staff and patients was visibly damaged, including a hot water urn caked in thick, solid limescale. The condition of the environment meant Cotswold and Severn units were not fully operating in line with national guidance; Department of Health and Social Care (DHSC) Health Building Note (HBN) 00/09 in relation to clinical environment design or HBN 00/10 in relation to infection control in the clinical environment. The registered manager reported and escalated these concerns to the NHS trust using contract monitoring meetings and to the hospital estates team although very little action had resulted.

Audits indicated a profoundly deteriorating environment across all 3 units, with buckled shelving and doors, chipped and cracked paint, damaged fire exits that hindered rapid exit, and damaged flooring. The registered manager documented repeated escalation to the trust in audits but there was very little evidence of corrective action.

Patients could reach call bells and staff responded quickly when called. The design and size of Severn and Cotswold units meant staff could not see all patients from the nurse station and the registered manager increased staffing levels to reflect this.

The service had enough suitable equipment to help them to safely care for patients. The service offered pre-planned treatment and staff allocated equipment in advance. Equipment manufacturers provided training and updates to staff to ensure they maintained up-to-date practice.

The service used a programme of planned preventative maintenance to ensure dialysis machines were serviced in line with manufacturer guidelines. They had extended maximum allowable service gaps by 6 months to reflect a shortage of engineers during the pandemic.

Staff carried out daily safety checks of specialist equipment. Documentation was consistently good, and nursing and dialysis support staff undertook advanced training on clinical equipment management.

Staff disposed of clinical waste safely and in line with DHSC Health Technical Memorandum (HTM) 07/01 (2013) in relation to the safe management and disposal of healthcare waste. The provider had a national programme of waste streaming in place designed to reduce unnecessary disposal and improve recycling.

The registered manager carried out fire drills twice annually in Severn and Cotswold units. The trust was responsible for carrying out fire drills in the ward 7B unit and staff who worked there demonstrated good understanding of local emergency procedures.

On Severn and Cotswold units we saw it was common practice for staff to wedge open doors marked 'Fire door, keep closed'. This included storage areas that contained flammable material. On Cotswold unit the door to a workshop labelled as 'Fire door – keep locked' was blocked open with a metal bin. A fire exit was partially blocked with a disused patient bed on Severn unit that would have prevented rapid exit. On Cotswold unit, large amounts of clutter were stored in an exit corridor and a wheelchair was stored next to a nurse station that blocked a fire exit. There was a general lack of care and attention to fire safety processes. The cluttered, disorganised nature of equipment and consumables in units would further complicate a safe evacuation. We spoke with the registered manager who provided assurance that they had been addressed after our inspection.

The most recent fire risk assessments were dated June 2022. They did not reflect any of the risks we identified during our inspection. For example, they noted fire escape routes were free from clutter or obstruction and that furniture was in a good state of repair. The fire risk assessment for ward 7B noted the dialysis bay was free from clutter and trip hazards. However, we found the unit was excessively cluttered with all available space used for storage.

Patient waiting areas were in a better condition, with visibly clean and well maintained seating.

Management of chemicals subject to the Control of Substances Hazardous to Health Regulations 2002 (COSHH) was inconsistent and did not always keep patients and staff safe. During our inspection of Cotswold unit, we saw chemical products stored on the floor in an unlocked room with a fire door wedged open. In all units we found bottles of surface disinfectant placed in patient areas, including at least 6 bottles, next to patient beds and chairs. This product is toxic and is subject to COSHH management standards, including the need for locked, secure storage, and use only in well-ventilated areas. Staff did not routinely follow these standards. We raised this during the inspection. The registered manager told us the solution used was diluted by 100 times, which meant there was a reduced risk of harm. We saw the provider had prepared guidance for this process and it was standard practice across their network. However, there was no documented evidence of when the dilution process had taken place and the product packaging still noted it was a hazardous chemical that needed controls in place. This meant it was not possible to verify that bottles in the clinical area presented a reduced risk for use.

After our inspection the registered manager told us they had instructed staff to change the way in which they used the product, to reduce the risk of harm to patients. For example, they said staff would spray the bottles only cloths in sinks to reduce the spread of droplets. However, this was not an adequate resolution since the bottles were still labelled as toxic and storage did not meet COSHH requirements.

The service was compliant with DHSC HTM 07/01 and the Health and Safety Executive Health and Safety (Sharps Instruments in Healthcare) Regulations 2013 in relation to sharps waste.

Spill kits were stored in key locations and included equipment to help staff contain bodily fluid spills and other similar risks.

Provider staff carried out regular water flushing of all outlets in the service as a strategy to reduce the risk of Legionella build-up. This approach reflected good practice and meant the service was compliant with DHSC HTM 04/01 in relation to the management of safe water in healthcare premises.

An external organisation managed the water treatment systems under a contract with the provider. During our inspection the water system on Severn unit had failed. The team used a business continuity policy to safely transfer patients while the team awaited an engineer, who arrived over 3 hours later. This unit had a history of water issues, including Legionella outbreaks identified during water testing in the previous 12 months. Staff mitigated the risk of recurrence by using point of use filters attached to taps. While patients experienced disruption such as moving to other units for dialysis during water failures, there had been no patient harm as a result.

The main dialysis bay on ward 7B was very cluttered, with chemical storage boxes flush to the side of 1 patient bed, and cardboard boxes stacked up behind patient beds. There was very little room to move freely in the unit and mobile trolleys blocked much of the floor space. Staff had to use a handwashing sink top area to complete records and store consumables due to the lack of space. A shelf had partially buckled due to the amount of material stored on it. The shelf had been identified at environment audits and repeatedly raised with the trust.

The waiting area in Cotswold unit was not large enough for the volume of patients. During our inspection, we saw the waiting area was overcrowded with patients having to stand and patients in wheelchairs blocking the exit and the manager's office. Healthcare assistants triaged patients in this area, and we saw some patients become agitated and aggressive due to the congestion. Staff did not enforce the trust's no smoking policy and we observed ambulance staff escort patients into the unit through a cluster of patients and those accompanying them smoking in front of the main entrance. After our inspection the registered manager told us the trust security team had told their staff they did not have the authority to enforce the no smoking policy. Trust security staff were not usually present in this area, which meant the problem was unmitigated.

Stock control of consumable items was not fully effective. We found glucose chews in an emergency hypoglycaemia box and urinalysis sticks that were past the expiry date.

Each unit was equipped with emergency equipment including an automatic external defibrillator (AED), oxygen, and breathing support equipment. In the event of a clinical emergency, the trust provided cover from the on-call resuscitation team. The dialysis team had access to ward emergency resuscitation equipment as part of a service level agreement.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and minimised risks. Staff identified and quickly acted upon patients at risk of deterioration.

Staff responded promptly to any sudden deterioration in a patient's health. Incident reports indicated staff acted quickly when patients' needs changed. Patients received care on a long-term basis and staff maintained an up to date understanding of their health needs.

Staff carried out a monthly falls risk assessment, and a manual handling risk assessment for patients every 6 months, or more often if their health condition changed. The assessments ensured staff provided appropriate support to patients when moving between transport, wheelchairs, and dialysis chairs

Staff completed an individual risk assessment with each patient on arrival. This included a general check of how they were feeling, a check for swollen ankles, feet, and legs, and a check for breathlessness. This reflected good practice and meant staff could modify treatment based on each patients' needs.

Staff carried out a huddle before the start of each shift to plan the service and discuss any issues or pressures. Once treatment commenced, a member of staff carried out a walkaround of the service to provide support if needed.

An on-call consultant nephrologist was available for urgent clinical discussions and referrals while the service was in session.

At our last inspection we told the provider it must implement improved systems for sepsis management. The provider had introduced a sepsis policy that reflected national guidance and mapped the 'Sepsis 6' pathway used by the host NHS trust. Cotswold and Severn units each had a sepsis management box that included emergency equipment and guidance for staff. The team on ward 7B had an agreement in place to use the resources in place on the main NHS ward. While the new policy reflected improved practice, not all nursing staff demonstrated adequate knowledge of sepsis and there was limited assurance training and understanding was sufficient. For example, 2 nurses were unable to explain the warning signs of sepsis or the local escalation and management process.

Staff briefed patients on fire evacuation processes when they first began dialysis. As patients undergoing dialysis had a fistula inserted, leaving the building quickly in an emergency would be slowed if staff needed to remove each patient's medical equipment. The briefing included a demonstration of how each patient could safely detach their fistula to evacuate safely. Staff had prepared large, visual displays in each unit demonstrating the correct procedure to use, including photographs. In an emergency, this would enable staff to assist the most vulnerable patients who could not evacuate by themselves.

The NHS ward 7B manager and their team included the dialysis unit in their risk assessments.

The service offered holiday dialysis for patients away from home as part of national NHS England standards. A dedicated holiday coordinator worked with patient's home medical teams and completed additional risk assessments to ensure staff could provide safe care. In some cases, the host hospital accepted holiday dialysis patients on behalf of the service. The coordinator liaised with trust colleagues to ensure this was a safe process.

Staffing

Staff had the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. The registered manager regularly reviewed and adjusted staffing levels and skill mix, and gave bank and agency staff a full induction.

6ty staff across a range of grades and functions staffed the service. Each unit except Cotswold maintained a 1:4 nurse to patient ratio, which met national standards. Cotswold unit maintained a nurse to patient ration of 1:3.5. Dialysis assistants provided specialist support and healthcare assistants supported the smooth running of each service, including patient triage.

The number of nurses, dialysis support workers, and healthcare assistants matched the planned numbers. The service was recruiting for more 2 registered nurses in the Cotswold unit and was otherwise fully staffed.

The service had low turnover rates, with over 99% retention in the previous 12 months.

The registered manager made sure bank and agency staff had a full induction and understood the service.

The service had variable sickness rates, with absence in the previous 12 months ranging from 3% to 12%.

Staff were highly trained and specialists in their field. Renal nurses completed an intensive 6 to 8-week clinical training programme followed by intravenous medication administration competencies and specialist equipment training before they could deliver care.

Healthcare assistants and dialysis assistants undertook specialised dialysis and renal care training to ensure their skills met patient need. This included a 3-stage programme of renal care followed by equipment and practical training. Training was competency based and staff had to demonstrate their skills before they could provide care themselves as part of the team. Training for dialysis assistants included technical elements such as central venous catheter management and a 6 month clinical package.

The service did not employ doctors. The host NHS trust had a renal consultant on call who provided on-demand support to nursing staff in the units.

Two registered nurses were always on duty in the ward 7B unit, 1 of whom was a deputy manager. The B.Braun nursing team were experienced in high complexity renal care, which reflected the high levels of patient acuity.

An on-call team provided out of hours emergency dialysis in the ward 7B unit on demand.

NHS trust consultants carried out monthly ward rounds of their own patients.

Records

Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.

Patient notes were comprehensive, and all staff could access them easily. The service kept contemporaneous records as part of long-term treatment. These included each patient's latest haemodialysis prescription, blood borne virus test results, and COVID-19 status.

When patients transferred between teams, there were no delays in staff accessing their records, such as when patients received dialysis temporarily while on holiday.

Records were stored securely and encrypted by the provider. The service archived records in hard copy and digitally and used service level access agreements with the referring trust about storage and access.

Staff audited standards of documentation monthly using a comprehensive tool that included clinical, demographic, and other care details. In the previous 6 months the service achieved over 99% compliance with provider standards.

Staff recorded blood results and transmitted them to the NHS trust pathology department who uploaded them to the renal database. It was the trust's responsibility to submit the results to the renal registry.

Two parallel records systems were in place in the units. The NHS trust was responsible for prescribing documentation, including dialysis flow sheets prepared in advance of treatment, and erythropoietin (EPO) and iron injection charts. EPO is a medicine used to treat anaemia, which is common in patients who need dialysis treatment. The provider was responsible for all other care and treatment records.

Medicines

The service used systems and processes to safely prescribe, administer, and record medicines. Storage arrangements did not always follow safe practice.

Staff followed systems and processes to manage and administer medicines safely. Each patient's renal consultant prescribed anti-clotting medicines and staff administered these locally. They maintained a good standard of documentation, including tracking of stock and batch numbers.

Staff completed medicines records accurately and kept them up-to-date.

Renal consultants based in the NHS trust prepared haemodialysis prescriptions in advance of treatment. The service did not have prescribing staff. If nurses identified a need for a medicine, they contacted the duty renal consultant in the NHS hospital, who would review the patient and issue a prescription. This included for urgent need, such as an emergency medicine for low blood pressure.

Records in Cotswold unit indicated temperatures in the medicines storage area often exceeded the maximum safe limit set by the manufacturer. Staff had escalated this to the site pharmacy team but there was no evidence the trust had taken action to improve ventilation or reduce temperature in the building. During our inspection on Severn unit, a medicines fridge was displaying an alert because the temperature had exceeded the safe maximum limit. We escalated this to the nurse in charge. Staff had not followed the provider's policy for keeping medicines safe during periods of high temperatures. For example, the policy stated to move medicines to another location.

Incidents

The service managed patient safety incidents well. Managers investigated incidents and shared lessons learned with the whole team and the wider service. Managers ensured that actions from patient safety alerts were implemented and monitored.

Staff knew what incidents to report and how to report them, including near misses and incidents involving other services. However, not all staff knew how to use the electronic incident reporting system. One support worker told us they would need to ask a nurse to submit reports on their behalf.

The service used an electronic incident reporting system shared with the NHS host trust. From January 2022 to August 2022, staff reported 43 incidents across the providers' renal services nationally. The most common incidents were patient falls (37%) and aggression or violence against staff (28%). These were key areas of focus for the provider. Although 7 patient falls had been reported as occurring in Cotswold and Severn units, most were analysed overall at a national provider level rather than at a location or individual unit level.

Inadequate

Dialysis services

The provider shared learning with their staff about incidents that happened elsewhere and included the severity of harm to help staff learn from colleagues nationally. Staff said they received feedback about improvements to patient care through monthly briefings and from unit meetings.

At our last inspection we told the provider it must improve incident reporting and management systems. The provider subsequently introduced a new internal reporting system to track adverse events. This supplemented the NHS trust's electronic incident reporting system, to which the service had access, and was called APO (adverse patient outcomes). In the previous 12 months the service reported between 15 and 45 APOs per 1000 dialysis cycles. APOs included 33 pre-defined common incidents, such as difficulty cannulating or a patient fall. The most reported categories were, missed dialysis and treatment time shortened by over 10 minutes. This data reflected care on Cotswold and Severn units; the provider did not supply us with monitoring data for the unit on ward 7B.

As a result of incidents, the registered manager had implemented improved risk management processes for patients living with dementia or a learning disability. For example, they introduced quarterly risk assessments for venous needle dislodgement. This followed instances in which patients had pulled out needles unless cared for one-to-one by unit staff.

The registered manager monitored national patient safety alerts on a weekly basis and implemented policy, practice updates and new risk assessments in response. The NHS trust also? monitored this information and supported the local team as part of a joint process.

Incident reports that involved medical emergencies indicated a well-coordinated response between the unit staff and NHS hospital teams. For example, where a patient experienced a fall in the Cotswold unit, a registrar arranged a head computed tomography (CT) scan and emergency department treatment. This contrasted with incidents that involved patients with a mental health need, in which coordinated NHS hospital response was lacking.

Are Dialysis services well-led?

Inadequate

We rated well-led as inadequate.

Leadership

Leaders understood the priorities and issues the service faced. They were visible and approachable in the service for patients and staff.

The registered manager was the unit manager and held significant experience in renal services and working with the host NHS trust. They planned their week to include at least 1 day at each of the 3 clinics. A team of 6 deputy managers provided support across units.

Staff spoke positively about their relationship with the manager and said they felt supported and looked after. The registered manager had acted to protect staff wellbeing during the pandemic and ensure they were treated with parity with their NHS colleagues.

Senior provider staff regularly visited the units. This included managers from operations, quality, and training. Staff said such visits were regular occurrences and provided an additional leadership presence.

There were limited opportunities for staff progression and development. Staff highlighted this in forums and surveys and the senior team was in discussion to create new team leader roles.

Vision and Strategy

The provider had a vision for what it wanted to achieve. The vision was focused on promoting better health aligned to local plans within the wider health economy.

The provider had an overarching vision that centred on protecting and improving global health. This was underpinned by a mission statement focused on driving standards in system-wide healthcare. Transparency, trust, and recognition were core elements of the provider's values and were prominently displayed in Cotswold and Severn units.

Staff had variable buy-in to the vision and strategy and none of the nursing or support staff we asked knew about it in detail although the provider included it regularly in staff communications. Staff said they had not been involved in its development. The provider did not have assurance the vision and strategy were applied to staff at care delivery level.

Culture

Staff felt respected, supported and valued by the registered manager and were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work. The service had an open culture where patients, their families and staff could raise concerns without fear.

The senior provider team said they felt morale amongst staff was good. The registered manager recognised the dedication of staff in maintaining the service and staff told us they felt valued and respected locally. However, there was a clear feeling of detachment from the provider. Most staff could not articulate how B. Braun, at a corporate or national level influenced or supported local care and understanding of wider work was low. Staff did not have a good understanding of some basic provider-level national policies and contacts, such as for safeguarding.

The provider facilitated a bi-monthly forum to provide space for staff to make suggestions and voice concerns. Staff acknowledged this process but were unable to identify any positive changes that resulted from it. Individuals we spoke with instead felt overwhelmed with work and said recognition from any level above the registered manager was lacking. After our inspection the registered manager told us they felt positively about the provider's recognition of staff, which included vouchers and gifts.

The provider had a clear focus on promoting equality and diversity in the workforce and corporate communications and exercises reflected this. The provider noted diversity as a key element of its business strategy.

Governance

The provider operated governance processes but these were not fully effective. Staff were clear about their roles and accountabilities and had regular opportunities to meet.

The registered manager led local governance for the 3 units alongside comparable processes in the NHS trust. This included regular meetings with colleagues in the trust's renal service and more broadly with trust's medical service managers. The provider coordinated national governance structures for all renal services and the registered manager contributed to this.

The governance structure included bi-monthly contract review meetings with the trust, 6 monthly internal clinical governance meetings, and monthly meetings with NHS consultants. The registered manager joined monthly renal operations meetings with the NHS hospital renal lead, although minutes indicated the team rarely discussed B. Braun services.

A quality manager worked nationally across all units and led the implementation of policies and procedures. They monitored audit outcomes and worked with local teams to support improvement.

Management of risk, issues and performance

Systems in place to manage risk and performance were not fully functioning. Escalated risks were not acted on increasing risks to patients and staff.

There were governance systems in place, although we were not assured that these were effective. The registered manager had regular contract review meetings with the host NHS trust. However, they were not minuted and there was no system in place to track actions. While the registered manager repeatedly documented concerns about the unsafe condition of the clinical environment to the NHS trust and to B. Braun in monitoring meetings and estates requests for maintenance, there was no evidence the provider had taken more effective escalatory action.

Staff used an audio monitoring device in the side room used to care for infectious patients on ward 7B. Staff said the device enabled the team in the main bay to hear if a patient needed help or was in distress since the room was not under continuous observation. Staff told us they obtained verbal consent from the patient for its use. However, there was no signage in place to inform other people using the side room of this device. While it did not record audio, staff could listen to conversations potentially without others being aware, breaching confidentiality.

The minutes of team meetings showed staff regularly discussed risks and safety management. For example, there was evidence the whole team had reviewed the provider's new sepsis policy and had familiarised themselves with emergency equipment. The provider sent monthly clinical governance bulletins that included national trends and themes across services. This recently included a sharp increase in aggression and violence from patients and an increase in needlestick injuries amongst staff. The team discussed these issues to identify opportunities to avoid risk. While this reflected good practice, we did not see evidence staff acted on known risks in specific circumstances. For example, patients were becoming verbally aggressive in Cotswold unit during our inspection due to overcrowding in the waiting area. There was no senior presence and staff were unaware of the escalating situation.

The service had an effective business continuity plan in place to ensure patients received care during service disruption. For example, when the water systems in Severn unit failed, staff worked quickly to transfer patients to other units to maintain their scheduled treatment.

The provider's senior quality team had identified discrepancies in water testing results that led to suspension of some dialysis machines. They changed the laboratory that tested water safety, which resulted in significantly improved reliability through a more advanced testing process.

The provider operations manager was responsible for the risk register. The registered manager escalated issues to this through the operations manager. Staff were required to demonstrate an up to date understanding of risks and the registered manager provided protected time to each individual to help them maintain understanding. This reflected the extent of risks, which numbered 90 at the time of our inspection, and included issues with Legionella in Severn unit and issues with the estate and environment. The risk register did not identify mitigations or accountable officers and some risks had gaps of up to 3 years since being reviewed.

The registered manager was working with the NHS trust to address a risk regarding access to death certification and the mortuary. If a patient died in Cotswold or Severn unit, the service had no staff who could certify their death. The service relied on an ambulance provider to transfer the deceased patient, but staff were unable to transfer the body to the hospital mortuary without a certificate of death. This presented a risk of disruption to the service and a traumatic experience for the person's relatives. The manager was working with the ambulance trust to establish a standard operating procedure.

The service monitored performance based on patient sessions numbers, missed sessions, and compliance with the UK target of weekly dialysis time. From January 2022 to August 2022, the service performed better than the UK target of 86% of patients achieving 12 hours or more of dialysis time per week. The service achieved an average of 88% and exceeded the target in each month. In the same period the missed session rate was 3%. There was no national or provider target for this figure and staff worked to reduce failed sessions through health interventions with patients.

Information Management

Information systems were integrated and secure.

Staff completed training in documentation, data protection, record keeping, and information governance.

Staff shared data with referring NHS trusts using secure systems. They used dual systems for IT and information management as many processes were duplicated between the provider and the host NHS trust. Both organisations provided IT support to local staff.

Posters in waiting areas explained the relationship between the provider and NHS trust and detailed what this meant for information and data management. The information included a data processing statement and contact details for the provider's data protection officer.

Additional data sharing agreements were in place between the provider and the NHS team responsible for ward 7B. This included shared access to incident reporting and complaints records, which reflected good practice.

Engagement

Leaders and staff actively engaged with patients and staff to plan and manage services.

The provider carried out an annual patient satisfaction survey. The most recent data available was from 2021 and reflected a 75% satisfaction rate. Patients persistently noted poor lighting and a lack of temperature control in the dialysis areas as the greatest priority areas for improvement. The registered manager was aware of the feedback and repeatedly escalated these to the trust, but no improvements had been made. The registered manager said staff worked extensively with patients to have an agreement of an ambient temperature. Some patients had requested dimmer switches, but this was not possible due to safety.

The provider was accredited to ISO:9001 standard and recent auditors reflected the deteriorating environment in their reports. The provider senior team had also escalated these to the trust.

The provider's senior team worked with staff to make training and policy updates engaging and directly connected to their work. This was part of a programme to ensure updates and refreshers were motivational by nature and helped staff to deliver high standards of care.

Nurses adopted specialist link roles for areas such as equipment servicing, data protection, and water management. This helped build skillsets and staff built relationships with other teams as part of their work.

The provider carried out an annual employee survey. Results from the most recent staff survey indicated a need for improved development opportunities and a more structured workplace. Staff responded variably regarding their views on the provider as a good place to work.

Staff engaged extensively with patients, which reflected the nature of the long-term, highly structured care provided. For example, visual displays around units reminded patients of the importance of adhering to their renal care plan. Staff prepared displays reminding patients of the dangers of shortening dialysis time, in response to increasing trends for patients to do this.

Each patient had a named nurse or dialysis support worker who worked with them on a long-term basis to monitor their blood results and other indicators of treatment.

A patient advocate worked across the provider's network to provide an active link between staff and patients. The advocate was a current patient of the provider's and understood the challenges faced by staff and other patients in dialysis care.

Learning, continuous improvement and innovation

Staff were committed to continually learning and improving services.

The provider was an international presence in renal care and integrated research.

In recognition of the increasing acuity and complex needs of patients, and the subsequent pressure on staff, 7 individuals had completed accredited training to become mental health ambassadors. This provided staff with a more in-depth understanding of mental health, how to manage it, and how to signpost people to support services.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • The service did not always maintain safe storage of medicines. • The service did not demonstrate consistent knowledge of safeguarding practices amongst staff. • The service did not ensure the safe use of chemical products in line with the Control of Substances Hazardous to Health (COSHH) Regulations.

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The service used an audio monitoring device in a side room used by the dialysis service on ward 7B of the host hospital. There was no standard operating procedure or risk assessment in place to manage consent and confidentiality.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • The service did not have appropriate systems and processes in place to assess the risks to the health and safety of service users of receiving the care or treatment. The service did not do all that was reasonably practicable to mitigate any such risks. • Systems and processes to mitigate risk relating to the environment were ineffective. We saw extensive damage and deterioration of the clinical environment in Cotswold and Severn units, including damaged flooring, warped fire exit doors, and damaged clinical equipment. Routine maintenance requests had been made; however, we found no evidence of escalation of outstanding and delayed addressing of ongoing concerns to the responsible body. • Systems and processes to mitigate risk relating to patients waiting for treatment were ineffective. The waiting area in Cotswold unit and the clinical bay on ward 7B, were overcrowded and presented risks to health and safety. We found the Cotswold waiting area was full and patients in wheelchairs were blocking access to the manager's office and exit routes. Staff did not effectively manage this situation and we saw patient's tempers frayed as a result. • Systems and processes to mitigate risk relating to the clinical environment were ineffective. We found the dialysis bay on ward 7B was cluttered with inappropriate storage of supplies in cardboard boxes stacked up behind patients. We found that staff did not have the space to safely move around the unit to attend to patients. • Systems and processes to monitor and mitigate risk relating to the clinical environment were ineffective. We looked at the most recent risk assessment completed for this area, which failed to identify any health and safety risks.

This section is primarily information for the provider

Enforcement actions

- Equipment was not safely and properly maintained. Staff were using dialysis chairs with tears in the fabric, which presented an infection control risk.
- Systems and processes to monitor cleanliness of the environment were insufficient to reduce infection prevention and control risk. We found multiple areas of risk in the clinical environment. This was caused by breached floor surfaces in which water pooled, dirty clinical areas and the kitchen on Severn unit.
- The provider had not actively worked with others to make sure that care and treatment remained safe for people using services. While the registered manager had reported concerns about the unsafe environment to the host NHS trust, they had not received an appropriate response or action. They had not escalated these concerns or been persistent in their attempts to improve safety standards.

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The service did not have appropriate systems and processes in place to assess, monitor, and mitigate the risks to the health and safety of service users which arose from the carrying on of the regulated activity. • Governance systems and processes were not operated effectively. • Governance systems and processes designed to assure the provider of compliance were in place but were not effectively used. The service had not identified the scope of risk in the clinical environment caused by deterioration and damage. • Systems and processes did not enable the service to identify and assess risks to the health and safety of people who used the service. Risks associated with the deterioration of the environment were assigned to the host NHS trust, but the service did not escalate these concerns and issues to ensure action was taken.

This section is primarily information for the provider

Enforcement actions

- The service did not document and evidence persistent escalation to the responsible body as the risk increased. Contract monitoring meetings were not minuted and the provider did not establish assurance of the level of escalation taken with the responsible body.