

## Frome Renal Unit

#### **Quality Report**

Frome Community Hospital **Enos Way** Frome Somerset BA11 2FH Tel:01373 473235

Website: www.bbraun.avitum.co.uk

Date of inspection visit: 6 June 2017 and 14 June 2017

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

#### **Overall summary**

Frome Renal Unit is operated by B.Braun Avitum UK Limited. The service has 12 dialysis stations for patients and operates two shifts of sessions daily between 7.00am and 7.00pm. The service is open six days a week and operates 144 sessions for a caseload of 48 patients. Facilities include 11 dialysis stations, one isolation room and machine, one storeroom, one plant room and an office and kitchen.

Dialysis units offer services, which replicate the functions of the kidneys for patients with advanced chronic kidney disease. Dialysis is used to provide artificial replacement for lost kidney function.

The service is a nurse led unit and is supported by the renal unit at Southmead hospital which is run by North Bristol NHS trust.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 6 June 2017 and further unannounced inspection on 14 June 2017.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well led?

Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

The main service provided by this unit was dialysis. Where our findings on dialysis – for example, management arrangements – also apply to other services, we do not repeat the information but cross-refer to the dialysis core service.

#### Services we do not rate

We regulate dialysis services but we do not currently have a legal duty to rate them. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

We found the following areas of good practice:

- The service had a good incident reporting culture and staff were using data to improve services.
- The service demonstrated good practices for effective infection control and prevention.

- The environment complied with national guidance for satellite dialysis units and the unit was clean and tidy.
- Staff adhered to recommended practices for infection control such as the use of personal protective equipment and the use of aseptic non-touch techniques, when connecting patients to dialysis machines.
- All equipment was regularly serviced and maintained, and consumables were all in date and well managed.
- There were safe nursing staff levels to ensure safe and efficient patient treatment.
- There were good working relationships between the unit and the consultant nephrologist who was responsible for patients' treatment.
- Staff completed contemporaneous documentation about care and treatment given to patients including evidence of discussion around risks.
- The unit had a clear procedure for identifying patients receiving blood and blood products.
- The service had effective contingency plans in the event of adverse conditions.
- Policies and procedures reflected current evidence-based guidance and practice.
- The unit had a comprehensive annual audit schedule with clear actions taken as a result.
- The service monitored key performance indicators and these demonstrated the service performed similarly to other dialysis centres in most categories.
- Dietitians saw patients regularly and patients felt they had a good amount of information to manage their diets.
- Dieticians used screening tools to identify patients at risk of malnutrition.
- Staff had the skills, knowledge and experience to ensure safe patient care.
- There was effective multidisciplinary working and a close working relationship with the supervising NHS trust involving specialist link nurses.

- There were effective processes to ensure consent was obtained at the beginning of and throughout patient treatment.
- Staff treated patients with respect and compassion.
- · Patients were complimentary about the care and treatment they received at the unit.
- There were processes to assess patients' emotional needs.
- The unit had a well-attended patient forum and invited outside speakers to attend.
- Staff took care to maintain patient dignity and when carrying out care and treatment.
- Staff showed a considerate and holistic approach to delivering information to patients.
- There was a good end of life pathway with involvement from the supervising NHS trust, which followed national guidance and best practice.
- The service met the needs of the local population and the needs of individuals attending for dialysis.
- The building met national guidance for satellite dialysis units.
- There was good provision for support to patients going on holiday and the unit welcomed patients from other parts of the country to receive dialysis while on holiday.
- There were processes to support patients who missed their dialysis.
- The unit had received no complaints in the last 12 months.
- Leaders had the knowledge, skills and experience to manage the service.
- Staff felt valued and there was a positive culture. We observed team working and respect for others.
- All patients and staff were positive about the service and the service used forums to engage with patients and their relatives.

However, we also found the following issues that the service provider needs to improve:

- The service did not have a sepsis policy/standard operating procedure to follow if patients displayed signs of sepsis. The service did not use a recognised early warning tool to alert staff to deterioration in their condition during dialysis.
- Staff did not routinely receive feedback form incidents reported.
- Not all staff were up to date with mandatory training including safeguarding and aseptic non-touch technique.
- · Not all patients felt involved in their care and treatment.
- Patients did not always feel their privacy was maintained when holding discussions about their care or treatment.

- Not all governance processes were effective to ensure a robust approach to managing quality and performance. There were no formal action plans from patient review meetings.
- There was not an effective process to monitor risks and understanding of efficient risk management processes were unclear.

Following this inspection, we told the provider that it should make some improvements, even though a regulation had not been breached, to help the service improve.

#### **Edward Baker**

Deputy Chief Inspector of Hospitals South West region

#### Our judgements about each of the main services

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**Dialysis** Services We regulate this service but we do not currently have a legal duty to rate it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary

#### Contents

Summary of this inspection	Page
Background to Frome Renal Unit	7
Our inspection team	7
Information about Frome Renal Unit	7
The five questions we ask about services and what we found	9
Detailed findings from this inspection	
Overview of ratings	13
Outstanding practice	40
Areas for improvement	40
Action we have told the provider to take	41



## Frome Renal Unit

Services we looked at:

Dialysis Services.

#### **Background to Frome Renal Unit**

Frome Renal Unit is operated by B.Braun Avitum UK Limited. The service opened in 2008 and provides haemodialysis to patients from the local areas of Wiltshire, Somerset and Bath and north east Somerset. This was in response to a request from a local NHS trust to provide a dialysis unit within a specified area.

The hospital has had a registered manager in post since 2008. The current registered manager had been in post since 2012.

The service is registered for the regulated activity of treatment of disease, disorder or injury, and screening and diagnostic procedures.

The service had previously been inspected in both October 2011 and November 2012.

#### **Our inspection team**

The team that inspected the service comprised a CQC lead inspector, Louise Couzens and one other CQC inspector. The inspection team was overseen by Catherine Campbell, inspection manager and Mary Cridge, Head of Hospital Inspection

#### Information about Frome Renal Unit

Frome renal Unit is a 12 bedded unit that provides dialysis for patients with chronic renal failure. The unit was opened in 2008 following the increased demand for dialysis in the Somerset area.

B.Braun Avitum Ltd is contracted to complete dialysis for local patients under the care of nephrologists at a local NHS trust. All patients attending Frome renal unit ('the unit') receive care from a named consultant at the supervising NHS Trust, who remains responsible for the patient. B.Braun has close links with the trust to provide seamless care between the two services. To achieve this, the service has support from the nearby NHS trust to provide medical cover, pharmacy support, and regular contact with a dietitian. This team attend the centre regularly and assess patients in preparation for monthly quality assurance meetings.

The centre is open between 7.00am and 7.00pm, Mondays to Saturday. It is currently providing treatment for 48 patients, 33 aged over 65 years of age and 15 aged between 18-65 years of age. The centre is registered to provide the following regulated activity:

- Treatment of disease, disorder, or injury.
- Screening and diagnostic procedures.

During the inspection, we spoke with ten staff including registered nurses, health care assistants, reception staff, medical staff, and senior managers. We spoke with nine patients and we reviewed seven sets of patient records and associated documents.

There were no special reviews or investigations of the service on-going by the CQC at any time during the 12 months before this inspection.

In the reporting period June 2016 to January 2017, the unit provided 4789 haemodialysis sessions to its own patients and 10 sessions to temporary patients (usually patients on holiday in the area). All sessions were provided for NHS-funded patients. The unit did not support patients who completed their dialysis at home or

received peritoneal dialysis (dialysis where the peritoneum in a patient's abdomen is used as membrane). These patients were supported from dialysis centre in a nearby NHS hospital.

The unit employed 7.7 registered nurses, 2.5 care assistants and one clerical assistant.

Track record on safety in the previous year:

- The unit reported no never events in the reporting period from February 2016 to February 2017.
- The unit reported no clinical incidents in the reporting period from February 2016 to February 2017.
- The unit reported no serious injuries in the reporting period from February 2016 to February 2017.
- The unit reported no incidents of hospital acquired methicillin-resistant Staphylococcus aureus(MRSA) or hospital acquired methicillin-sensitive Staphylococcus aureus (MSSA) bacteraemia from February 2016 to February 2017.
- The unit reported no incidents of hospital acquired Clostridium difficile (C. diff). or incidents of hospital acquired E-Coli from February 2016 to February 2017.

• The unit had received no complaints in the reporting period from February 2016 to February 2017.

Services accredited by a national body:

- Investors in People accreditation (reaccredited in 2016)
- ISO 9001:2008 (accreditation given to organisations, which fulfil a set of quality management standards). This accreditation has now been replaced by ISO9001:2015. The service were aware of this and were due to submit evidence for re-accreditation.
  - Services provided at the unit under service level agreement:
- Clinical and or non-clinical waste removal
- Maintenance of medical equipment and environment
- Pathology and histology
- Maintenance and service of dialysis chairs
- Water treatment system maintenance

#### The five questions we ask about services and what we found

We always ask the following five questions of services.

#### Are services safe?

We do not currently have a legal duty to rate dialysis services.

We found the following areas of good practice:

- The service had a good incident reporting culture and staff were using data to improve services.
- The service demonstrated good practices for effective infection control and prevention.
- The environment complied with national guidance for satellite dialysis units. The unit was clean and tidy.
- Staff adhered to recommended practices for infection control for example the use of personal protective equipment and the use of aseptic non-touch techniques, when connecting patients to dialysis machines.
- All equipment was regularly serviced and maintained. Consumables were all in date and well managed.
- There were safe nursing staff levels to ensure safe and efficient patient treatment.
- There were good working relationships between the unit and the consultant nephrologist who was responsible for patients' treatment.
- Staff completed contemporaneous documentation about care and treatment given to patients and recorded evidence of discussion about risks.
- The unit had a clear procedure for identifying patients receiving blood and blood products.
- The service had efficient contingency plans in the event of adverse conditions.

However, we also found the following issues that the service provider needs to improve:

- The service did not have a sepsis policy/standard operating procedure to follow if patients displayed signs of sepsis. The service did not use a recognised early warning tool to alert staff to deterioration in their condition during dialysis.
- The service did not always ensure visiting staff understood their role and responsibilities whilst working on the unit, and we saw missed fridge temperature checks on days when visiting staff had worked.
- · Not all staff were up to date with mandatory and annual training updates, including safeguarding and aseptic non-touch technique.

• Staff did not consistently or routinely receive feedback from incidents they reported.

### Are services effective? Are services effective?

We do not currently have a legal duty to rate dialysis services.

We found the following areas of good practice:

- Policies and procedures reflected current evidence-based guidance.
- The unit had a comprehensive annual audit schedule with clear actions taken as a result.
- The service monitored key performance indicators. These demonstrated the service performed similarly to other dialysis centres.
- Dieticians saw patients regularly and patients felt they had a good amount of information to manage their diets.
- Nutrition screening tools were used to identify patients at greatest risk of malnutrition.
- Staff had the skills, knowledge and experience to ensure safe patient care.
- There was effective multidisciplinary working and a close working relationship with the supervising NHS Trust involving specialist link nurses.
- There were effective processes to ensure consent was obtained at the beginning and throughout patient treatment.

However, we also found the following issues that the service provider needs to improve:

 The service did not always ensure patients were aware of all types of pain relief available to them at the beginning and throughout their treatment.

## Are services caring? Are services caring?

We do not currently have a legal duty to rate dialysis services.

We found the following areas of good practice:

- Staff treated patients with respect and compassion.
- Patients were complimentary about the care and treatment they received at the unit.
- There were processes in place to assess patients' emotional
- The unit had a well-attended patient forum and invited outside speakers to attend.

- Staff took care to maintain patient dignity and confidentiality when carrying out care and treatment.
- Staff showed a considerate and holistic approach to delivering information to patients.
- There was a good end of life pathway with involvement from the supervising NHS trust, which followed national guidance and best practice.

However, we also found the following issues that the service provider needs to improve:

- Not all patients felt involved in their care and treatment.
- Patients did not always feel their privacy was maintained when holding discussions about their care or treatment.

### Are services responsive? Are services responsive?

We do not currently have a legal duty to rate dialysis services.

We found the following areas of good practice:

- The service met the needs of the local population and the needs of individuals attending for dialysis.
- The building met national guidance for satellite dialysis units.
- There was good provision for support to patients going on holiday and the unit welcomed patients from other parts of the country to receive dialysis while on holiday.
- There were processes to support patients who missed their dialysis.
- The unit had received no complaints in the last 12 months.

### Are services well-led? Are services well led?

We do not currently have a legal duty to rate dialysis services.

We found the following areas of good practice:

- Leaders had the knowledge, skills and experience to manage the service.
- Staff felt valued and there was a positive culture. We observed team working and respect for others.
- All patients and staff were positive about the service

However, we also found the following issues that the service provider needs to improve:

 Not all governance processes were effective to ensure a robust approach to managing quality and performance. There were no formal action plans from patient review meetings.

• There was not an effective process to monitor risks and understanding of efficient risk management processes were unclear amongst some management.

## Detailed findings from this inspection

#### Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Dialysis Services	N/A	N/A	N/A	N/A	N/A	N/A

Safe	
Effective	
Caring	
Responsive	
Well-led	

#### Are dialysis services safe?

We regulate this service but we do not currently have a legal duty to rate it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

#### **Incidents**

- The unit had a good safety record. There had been no never events at the unit between January 2016 and January 2017. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
   Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- The unit reported no serious incidents between January 2016 and January 2017. Serious incidents include acts or omissions in care that result in unexpected or avoidable death or unexpected or avoidable injury resulting in serious harm.
- Staff understood their responsibilities to raise concerns, to record safety incidents, concerns and near misses, and to report them internally and externally. Staff gave us examples of incidents and near misses they had reported. Staff also told us they reported patient transport delays through the electronic reporting systems, which was currently being collated and shared with the supervising NHS trust to highlight an ongoing problem with patient transport.
- The unit had a robust reporting system, and all adverse incidents, affecting patients and staff, were reported through the APO (adverse patient occurrence) or EHS (environmental health and safety) systems. The unit manager reviewed these reports before being reviewed

- and closed by senior management. Falls and bacteraemia were also documented on a timeline report, to ensure all relevant information was captured should an incident require further investigation.

  Between June 2016 and February 2017, the unit reported 115 APOs. Performance was similar when compared to other units operated by B.Braun. The most frequently recorded reason for an APO was 'other'. Staff explained this covered all incidents that were not formally categorised. We saw the senior managers recorded all APO incidents including preventative actions, and discussed them at the monthly managers meetings.
- Safety goals had been set, and a monthly report listing and reviewing all EHS events was compiled and distributed by the operations manager. Safety targets, linking to infection, falls, water quality, needle stick incidents and vigilance reporting were recorded in the monthly management review. The most recent falls data showed the unit had reported no patient falls since January 2017, and one fall between January 2016 and December 2016. This was better when compared with other similar units.
- Staff told us there had been an increase in aggression and violence towards staff across all B.Braun units. In partnership with local NHS trusts, the corporate leads had developed a zero tolerance policy in line with that used in NHS trusts to help identify, report and reduce these incidents. Staff told us they were reporting all incidents of aggression towards them, which were addressed by the unit managers in line with policy.
- When things went wrong senior managers reviewed incidents and carried out timeline investigations. For example, we saw a timeline report from a needle stick injury, which involved the manager reviewing and discussing needling techniques with the affected staff member. Following these investigations, the manager

14

updated staff through informal discussions at handovers and on a one to one basis. However, staff said they did not get formal feedback from incidents they reported.

- When things went wrong, lessons were learnt, and action taken was taken as a result of investigations.
   Senior staff told us that analysis of APO and EHS data had identified an increase in needle dislodgment during dialysis. As a result, the way the needles were secured with tape was examined and changes to techniques were made. Staff confirmed this and showed us the new technique and how it was different from the previous technique. Staff said this change had been communicated to them through a safety alert generated by the senior management team through an email. Staff also told us safety updates were communicated through a diary, and staff signed a front sheet to say they had read the alert.
- Safety alerts were received and acted on. We saw an alert displayed in relation to the battery unit on the defibrillator. The manufacturer had identified a potential problem with the battery on the portable defibrillator unit, and had issued guidance to replace the battery on a weekly basis. The unit had a checklist to show these additional checks were being carried out, and we saw the checklist was complete with no gaps. Staff explained how they now checked both the battery in the machine and on charge as part of their daily checklist. All records we saw were complete and up to date, and we saw a new defibrillator had been ordered, and staff were in the process of updating their training to use the new machine.
- Staff were aware of the duty of candour and could explain their responsibilities under it. Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 is a regulation introduced in November 2014. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- The operations manager for B.Braun Avitum was the lead for duty of candour, and when an incident occurred in the unit, they completed the investigation, issued the

apology and gave actions to prevent it from reoccurring. If an incident occurred in the trust, or was reported to the supervising trust, it was dealt with by the trust but in collaboration with B. Braun.

#### **Mandatory training**

- Not all staff were up to date with their mandatory training, which meant they were not compliant with their corporate policy and local target for 100% of staff to have completed their mandatory training. The registered manager told us all staff were up to date with their mandatory training requirements, however, the training records submitted did not support this and contained a number of errors and missing data. Not all staff had completed all mandatory annual updates required by B.Braun, and no member of staff had completed all five required annual updates at the time of our inspection. For example, all staff were required to complete an annual aseptic non-touch technique update, and data submitted showed this had only been completed by three out of 12 staff. One out of 12 staff had completed bacterial water sampling. Oral drug administration had been competed by five out of 12 staff, and venous dislodgement had been completed by two out of 12 members of staff.
- No member of staff had completed the mandatory updates for all required annual training and all members of staff had yet to complete mandatory training in one or more subjects. Four members of staff were yet to complete the annual face-to-face update in basic life support and manual handling for 2017 but we were told these staff members were on long term sick, maternity leave, or had just joined the organisation. Senior managers told us the system for monitoring training compliance was due to be updated, and the current database had not been updated to reflect actual training compliance, however, no data to support this was submitted.
- Staff were given time at the end of shifts to complete their mandatory updates, and senior managers told us staff were allocated time, every shift, which allowed them to complete their training. Staff were also offered study time for learning and development outside of work. However, some staff told us there was often not enough time at the end of shifts as most modules took an hour to complete.
- Staff undertook basic life support training as a minimum and updates every year in order to deal with

emergencies, however, in two out of the four training files we looked at; we saw front sheets for staff to sign to indicate they had read a policy update. The resuscitation policy had been updated three times, and in January 2017 seven out of 12 staff had not signed the front sheet, March 2017 seven out of 12 staff and May 2017 10 out of 12 staff had not signed the front sheet. The provider told us these front sheets were not policy updates, but were in fact a record of basic life support training, however the sheets made no reference to this.

#### **Safeguarding**

- The service had processes to ensure staff were trained to recognise vulnerable adults at risk of abuse and there was a standard operating procedure to provide guidance. Staff were aware of signs of abuse and knew how to report concerns. They completed mandatory e-learning updates in both child protection and adult safeguarding at level two every three years however, this training did not include information about female genital mutilation. Training records showed that eight members of staff had completed both safeguarding training modules and five members of staff had one or more modules yet to be completed, including clerical staff
- B.Braun had a corporate safeguarding lead trained to level two, but there was no one with a higher level of safeguarding training at the unit. Senior staff told us level three training was planned for two members of the senior manager's team in July 2017.
- We saw a reflective account from one nurse, who had received a phone call from a patient to cancel their dialysis session on the morning of the session. The nurse felt the patient was not themselves, so they followed the safeguarding guidance.
- The service carried out disclosure and barring service (DBS) checks for clinical staff, every three years in line with their corporate standing operating procedures. DBS checks help employers to make safer recruitment decisions and prevent unsuitable people working with vulnerable people. We reviewed four staff records and found that all staff had had a DBS check within the last three years. Managers were also assured staff would report anything, which may affect their DBS status because they were registered nurses and bound by the Nursing and Midwifery Council (NMC) code of conduct.

#### Cleanliness, infection control and hygiene

- Standards of cleanliness and hygiene were maintained through a series of monthly audits. The audits monitored compliance with aseptic non-touch technique (ANTT) and hand hygiene, as well as housekeeping. Environmental health and safety walk rounds were completed by the unit manager and reported to the quality and operations manager monthly, and feedback was given to staff as appropriate. The latest data from the audits showed then unit had an overall compliance of 93.5%. Three members of staff had scored 85% or lower and confirmed verbal feedback had been given to them following the audit along with advice to help them improve their compliance with both hand hygiene and ANTT.
- There were reliable systems in place to prevent and protect people from healthcare-associated infections.
   Staff applied infection control measures efficiently when dealing with patients. The service had a standard operating procedure (SOP) for infection control to provide guidance. Staff had access to and wore appropriate personal protective equipment such as gloves, aprons and full-face shields. We observed staff wash their hands before and after patient contact.
- Decontamination of medical devices, including dialysis machines was carried out efficiently. Staff cleaned the dialysis machines after each session in accordance with corporate and manufacturer guidance. There was an internal decontamination schedule after each patient use and once a week the machines were programmed to carry out an extended internal cleaning and decontamination process. Each dialysis station was cleaned with an anti-bacterial solution after each dialysis session. Solutions were prepared and dated according to recommendations. All equipment-cleaning records we looked at were complete and up to date with no omissions.
- We saw staff cleaning equipment thoroughly between patients, using antibacterial wipes, and all areas we visited were visibly clean and free from clutter. We saw cleaning checklists for the main dialysis area, isolation room, kitchen and patient toilet that showed between 96%-100% compliance in May 2017. The cleaning checklists also contained an action log recording feedback given to cleaning staff, and actions taken.
- All clinical staff we saw were bare below the elbow and had long hair tied back in line with infection prevention control and uniform policies.

- The service had effective processes for screening patients for blood borne viruses. All patients were screened every three months and patients who returned from holiday had to be screened when they got back.
   When patients returned from holiday to a high risk area, they received dialysis in a side room until screening showed they did not have any transmittable infections or viruses. There were standing operating procedures to guide staff in additional infection control measures if required.
- There were procedures in place to assess patients as carriers of blood borne viruses (BBV) such as Hepatitis B and C as part of the patient's initial assessment upon commencement of treatment at the unit. If a blood borne virus was identified, the unit had one isolation room, which was in line with the national guidance. These rooms were used to maintain effective isolation processes or could be used if patients preferred to receive their treatment in a single room facility. For example, we saw the room used to accommodate a patient who was undergoing chemotherapy in addition to their dialysis. The unit also had two surplus machines, which were allocated to a named patient if an infection risk was identified.
- The service reported few dialysis related infections.
   There had been no reported cases of Clostridium difficile (C. diff), methicillin-resistant Staphylococcus aureus (MRSA) or methillin-sensitive Staphylococcus Aureus (MSSA) bacteraemia at the unit between January 2016 and January 2017.
- Dialysis patients were swabbed frequently for MSSA.
   Patients with central venous catheter (CVC) access were swabbed fortnightly, those with fistula and grafts were swabbed three monthly. Patients with MSSA discovered through these regular swabs were offered treatment, as per the supervising trust's infection control policy and were classed as community acquired infections.
- There were effective processes for infection control screening in accordance with the corporate standard operating procedure for infection control. There was an MRSA protocol with action cards to provide guidance for staff about screening. All patients were screened when commencing dialysis treatment at the unit and every three months thereafter. If patients had been on holiday or admitted to hospital, they received their dialysis treatment in the isolation room until screening

- processes showed they were clear of MRSA. All new patients were also screened for blood borne viruses and there was guidance for staff to follow if patients tested positive as carriers for these viruses.
- Patients had their own blood pressure cuff, which they
  wore for the duration of their dialysis treatment, and this
  was replaced every three months.
- All staff had completed the B.Braun hand hygiene e-learning modules for hand hygiene. Training records showed that ten out of 13 staff had completed the annual mandatory e-learning update in infection control, as required by the NHS trust, at the time of our inspection.
- The unit had set a lower limit for hand hygiene compliance of 80%. Data submitted showed that between June 2016 and January 2017, hand hygiene compliance varied between 80 to 100%. One member of staff had achieved a score of 66.67% compliance in January 2017 and had received feedback about areas that needed to improve, and subsequently achieved 100% when re-audited in March 2017.
- Staff we observed were trained and competent in an aseptic non-touch technique for the management of dialysis vascular access, and we saw evidence of training and updates stored in the four sets of staff training records we looked at. We observed four patients having cannulas inserted and nurses followed correct procedures in line with policy and best practice guidance in all cases.
- There was evidence of bacteriological surveillance of haemodialysis fluids, and the service had effective water testing procedures in the water treatment plant area. Staff carried out checks in the morning and repeated them before the afternoon sessions started. Records between January 2017 and May 2017 demonstrated 100% compliance. If the test results showed variances, staff called in engineers who attended within four hours. Recently staff had identified the chlorine levels in the water were slightly raised, and had been monitoring them. Engineers attended and advised the water was safe to use but some filters needed to be replaced which were ordered.

#### **Environment and equipment**

 The dialysis unit was designed, maintained and used in a way that kept people safe. The dialysis area was purpose built, and met Department of Health: Health Building Note: 07-01 guidance. There was sufficient

- space around dialysis chairs for two people and they could be accessed from either side. The flooring was intact and easy to clean. The area was airy with natural light from windows.
- The unit maintained and used equipment in a way that kept people safe. The service had effective processes to ensure all medical devices were regularly serviced and maintained in line with manufacturer guidance. The unit held a log of all medical devices, which showed when regular service was required. Staff were aware of processes to report faulty equipment. When equipment was awaiting collection, it was taken out of use, clearly marked as faulty and stored away from the clinical area.
- The unit had a set of standing weighing scales which patients used to weigh themselves before and after their dialysis sessions. These scales were calibrated annually and had a cleaning schedule which was complete and up to date. The unit also had a sitting set of weighing scales which they could use in the event of the main scales failing.
- The service had effective process to deal with clinical waste. There were a sufficient number of waste bins, which staff emptied before they were overfilled. Staff used sharps boxes appropriately and closed these between usages to avoid accidental needle stick injuries. There was a dirty utility area, which was clean and tidy, and staff separated clinical and non-clinical waste in line with national recommendations.
- There were safe systems in place for the classification, labelling, storage and transportation of clinical specimens. We saw nurses taking swabs and blood cultures from a patient with a suspected infection. All samples were labelled at the patient's side, and were sealed in plastic bags that were also labelled at the patient's side. All samples were kept in a locked refrigerator until the dedicated courier arrived, when they were transferred to coloured bags to indicate which samples were hazardous.
- Staff accessed standard operating procedures, policies and protocols through the company online electronic system. All policies we looked at were in date, and staff told us they did not print polices, as it would not guarantee they were looking at the most up to date policy. When B.Braun policies were printed, an expiry date and time was printed on the front sheet that lasted 24 hours from the time of printing.

- All dialysis sets were single use, the unit keep a record of all lot and/or batch numbers of all the dialysis set components used, including the fluids, and medications administered, which was recorded on all of the five dialysis prescriptions we looked at.
- Up-to-date staff training was carried out on the use of specific medical devices, and we saw specific training documents in staff folders containing competency based training and assessments, which were all complete and up to date.
- The unit was situated in a community hospital, and there was a service level agreement (SLA) with the company responsible for the hospital maintenance. Planned preventative maintenance (PPM) was carried out as per the hospital maintenance schedule, which included ensuring emergency lighting, generators and fire equipment were in proper working order. This company also performed Legionella prevention checks for the unit. Technical services, part of B.Braun, performed PPM on all the dialysis machines annually and performed any repairs required, and we saw a separate internal SLA covering this arrangement. An external engineering company attended annually to perform safety checks and maintenance on all other medical equipment, and attended at six monthly intervals to perform the hoist service in line with Lifting Operations and Lifting Regulations 1998.
- Staff responded quickly to alarms on the dialysis machines and we saw these alarms were assessed appropriately and not overridden. Staff told us they had experienced a dislodged needle in the past and were aware that detection of dislodged needles at the earliest opportunity was essential to preventing significant blood loss or cardiac arrest.
- The unit had a resuscitation trolley that had been stocked in line with national resuscitation council guidance for community hospitals. Staff checked the trolley on a daily basis and all of the records we saw were complete and legible. Staff told us a new defibrillator had recently been purchased following a safety alert for the existing one. At the time of our inspection, one member of staff had been trained on the new machine; however, guidance from the manufacturer, of the original machine, had been issued so staff could continue to safely use the old machine until training on the new one could take place.
- There was an equipment replacement programme and processes to alert managers when equipment was due

to be replaced. All dialysis machines were due to be replaced every ten years in line with the Renal Association guidance. There were two spare dialysis machines in case any of the other machines developed a fault. Senior staff told us the machines were eight years old, and were due to be replaced at the same time the current contract ended. The unit manager was unsure what plans were in place for this as the current contract had only recently been finalised. However, they told us B.Braun had a stock of used machines from other units that could be sent if necessary. Senior staff told us that since the contract had been renewed, a strategy for machine replacement was being finalised for the unit.

- The unit was assured technical staff maintaining the equipment had appropriate training. Technical services formed part of B.Braun, and performed all planned preventative maintenance on all the dialysis machines annually and performed any repairs as required. The unit manager had access to the training competencies for technical staff to ensure they were performing maintenance in line with manufacturer and company polices.
- All treatment stations had a nurse call system, and staff said all stations were in clear sight of the nurses' station and higher risk patients were always identified and stationed closer to the nurses' station.

#### **Medicine Management**

- The centre had processes in place for the safe management of medicines. Patients attending received prescribed medicines as necessary for their dialysis or continuing treatment only. Ongoing prescribed oral medicines were taken by the patient at home or at the unit but were not administered by nursing staff.
- Medicines stock was stored in a large storage room, which was secured with a keypad access door, and behind the nurses' station in locked cupboards and a fridge.
- There were a small number of medicines routinely used for dialysis, such as anti-coagulation and intravenous fluids. The centre also had a small stock of regular medicines such as EPO (erythropoietin – a subcutaneous injection required by renal patients to help with red blood cell production). Controlled drugs (requiring extra security of storage and administration) were not used or available on site.

- Nursing staff completed weekly orders of medications and medicine stock level audits every three weeks when the amount and expiry dates were checked, however, checks and rotation also took place on a weekly basis when stock deliveries arrived.
- There were processes in place to ensure prescriptions for dialysis treatment were available. The consultant nephrologist prescribed treatment for each patient for one month at the time. Staff printed off dialysis prescriptions for patients for each session, which meant it was the most up-to-date prescription for patients booked for treatment. Prescriptions contained information about the haemodialysis filter to be used, length of treatment time and dry weight (weight after dialysis treatment). We saw staff checking the prescription against the parameters set on the dialysis machine prior to the start of treatment, and in one case, the staff altered the amount of fluid the patient was having removed because their blood pressure had been quite low during the treatment set up.
- Medicines came directly from the supervising NHS trust.
   Ordering of medicines occurred on a weekly basis, when
   stock levels were assessed. A specialist drug company
   courier completed delivery. Upon arrival at the centre,
   the registered nurse checked the medicine against the
   order form to confirm it was correct. A stock form was
   then completed, signed and faxed to the supplier to
   confirm delivery.
- The centre did not have a dedicated renal pharmacist.
   Pharmacy support was provided through the supervising NHS trust as part of the service level agreement. The renal consultant prescribed all patients' medicines, which were reviewed at each quality assurance meeting for each patient. We saw that prescription charts were clearly written, showed no gaps or omissions and were reviewed regularly.
- Medicines that were temperature sensitive were monitored closely. We saw that the fridge and stock room temperatures were recorded daily, and had been maintained within the recommended parameters. However, we saw one day where the fridge and stock room temperature had not been recorded. Staff said there had been a member of staff from another unit working that day. All staff were aware of the escalation process for a temperature spike, and guidance was printed on the bottom of the daily record sheet. We

- spoke with staff who told us that changes in temperature were escalated to the nurse in charge who discussed the medicines with the renal pharmacist to determine if they could be used.
- All patients had a prescription chart, which had been provided by the supervising NHS trust. It contained all routine medicines used during dialysis including the strength, dose, route, reason for use and duration of use for each medicine listed. In addition, patients who had specific individual medicines, had charts for each medicine, which were signed as and when they were used. We looked at four sets of patients records and saw the medications prescriptions were up to date, legible and contained no omissions.
- During the inspection, staff raised concerns about a
  patient with a suspected infection. Staff explained they
  could administer intravenous antibiotics upon receipt of
  a signed prescription, provided they had provided B.
  Braun with evidence of competencies gained in the
  administration of intravenous antibiotics.
- Staff received training on the safe administration of oral medicines, and training data showed three out of eight staff had yet to complete their annual update training in the administration of oral medications. We did not see any evidence of training undertaken in the safe administration of intravenous medications. Senior staff told us this was undertaken as part of an assessment by the registered manager when they started, and staff provided evidence of previous courses attended.
- Staff followed guidance from the Nursing and Midwifery Council when administering intravenous drugs. A registered nurse held the keys to medicines cupboards however; healthcare assistants collected anti-coagulant intravenous medicines from the medicines cupboard and put this out ready when preparing dialysis stations for the next patient. The registered nurses delegated this task to healthcare assistants who were knowledgeable about how to carry out the task safely, and had completed competency based training. They had a list of patients and equipment needed for individual patients attending for dialysis that was checked against each patient by the registered nurse responsible for that patient before treatment started. Registered nurses administered the anti-coagulant as prescribed and in line with national recommendations.

 When changes were made to a patient's prescription, the changes were communicated to the GP by the lead consultant in the form of a letter, which summarised the changes and reasons why they had been made.

#### Records

- Individual patient dialysis records were written in a manner that kept patients safe. Staff completed paper records and entered information about dialysis sessions on a renal database. This information was shared with the consultant who was responsible for patients' dialysis treatment. Staff entered information onto the hospital renal database following dialysis treatment. This included information about patients' vital signs before, during and after dialysis, patients' pre and post dialysis weights and blood test results.
- Staff completed paper care records in line with their corporate operating procedure. We reviewed four patient records and found them all to be organised and legible. Patients had a folder that contained their dialysis records and their care and treatment pathways. The service used a 90-day care pathway for new patients commencing dialysis at the unit. This pathway included information about infection screening, patient education programme and assessment of parameters at different points during the first 90 days of patient dialysis. Once the dialysis was well established, staff used a continuing care pathway which was re-assessed every three months and ensured on going care followed evidence-based guidance.
- The unit had access to the dedicated renal database used by the supervising NHS trust, which allowed for central storage of patient information. All dialysis information was inputted onto the database to record treatment activity. The system allowed staff to access blood results, medication lists, recent clinic letters, multi-disciplinary team planning and demographic and identity information necessary to provide safe care.
- The unit held regular continuous quality improvement meetings with the trust, where the unit's clerical assistant communicated all medication changes to the GPs. Records from these meeting showed changes to patients' prescriptions and medications were recorded on a written sheet; however, no formal minutes of these meetings were taken.

- All nursing notes were kept in the unit until the patient
  was no longer dialysing, and all records were locked in
  the office over night to maintain confidentiality. When a
  patient was discharged from the service, the nursing
  records were sent back to the trust for storage.
- Records were monitored for patients that self-needled and the unit currently had one patient competent to do this. A named nurse was allocated to the patient to support them in completing the training and education package for self-needling patients. Staff told us they tried to establish a buttonhole site for patients, which could take two to three weeks to establish (a buttonhole site is created by cannulating the same site each time, creating a track which can then be cannulated for future dialysis sessions using blunt needles to reduce pain for the patient). Staff continued to assess and record the condition of patient's fistula before every treatment, but only connected the patient to the machine once the patient indicated they were ready.
- Staff carried out documentation audits once a quarter.
   The results demonstrated each nurse's thoroughness when completing patient records. We reviewed the results from audits carried out between January and April 2017, which showed two members of staff had achieved below the corporate target of 80% compliance, although one had later improved. Results from this audit were sent to the quality manager each quarter. A dialysis nurse, who gave feedback to the staff member involved, completed this. Recent actions identified in the audit included clear instructions on what had been missing during the previous two audits, however we did not see any actions to help improve compliance in future audits.

#### Assessing and responding to patient risk

- Comprehensive risk assessments were carried out for people who used services and risk management plans were developed. We saw falls risk assessments completed in all four of the patient records we looked at, which were reviewed every three months by the patient's named nurse, as part of a care plan review. We saw conversations about risks took place before, during and at the end of every dialysis sessions, and we saw evidence of these discussions recorded in the patient's notes.
- The unit did not employ any medical staff, which meant there was no immediate access to medical staff in the

- event of a medical emergency. The service had processes to follow which included calling an ambulance for emergency transfer to the local NHS hospital.
- Staff identified and responded appropriately to changing risks to people who used services, including deteriorating health and wellbeing. One patient attended with visible bruising and told staff they had fallen. Staff assessed the patient and recorded their observations in the patient's record, but also informed the patient's GP of their concerns through a phone call.
- The service had a corporate operating procedure for staff to follow in the event that an urgent patient transfer was required. This included information about who to contact regarding the transfer, organising the transfer and ensuring information was shared with patients' next of kin.
- Patients were weighed on arrival to the centre at each visit. This was to identify the additional fluid weight that needed to be removed during the dialysis session. This varied from patient to patient.
- Some patients were observed weighing themselves prior to dialysis, and inputting this into the dialysis machine. Nursing staff told us that all patients were encouraged to participate in their treatment to different levels.
- Staff monitored patients throughout their dialysis treatment. Prior to commencement of the treatment patients had their general health, weight and blood pressure recorded. Throughout the treatment, staff monitored patients' blood pressure and pulse every 30 minutes and vital signs were documented every 60 minutes. Patients were encouraged to rest in the dialysis chair for a little while post dialysis to ensure there was no bleeding from the fistula and that they did not feel unwell/light headed. However, the service did not use national recommended early warning systems to alert staff to patients not being well. We saw one patient who was driving themselves home, complain to staff that they were feeling lightheaded. Staff decided to do both standing and sitting blood pressure readings before letting the patient go, in line with the unit policy. Another patient had low blood pressure at the beginning of their treatment, so staff switched from hourly to 15-minute observations to monitor the patient.
- There were protocols for patients to wear a name badge when they received blood transfusions. Staff said this

21

was to ensure the correct blood was given to the right patient. Staff told us identification checks were carried out on patients using their date of birth before identification badges were placed on patients, in line with company policy.

- Staff did not confirm the identity of patients before commencing dialysis treatment. Staff explained that they knew patients well. If there were new patients or patients on holiday receiving dialysis, nurses followed guidance from the Nursing and Midwifery Council known as the five Rs; this included checking it was the right patient, the right medicine, the right dose, the right route and the right time.
- The service did not have a sepsis policy or guidelines to follow. Staff phoned the consultant nephrologist if patients demonstrated signs of infection, who gave a verbal prescription for nurses to administer antibiotics, and sent through an electronic copy as well. If sepsis was suspected staff arranged for an ambulance transfer for the patient to be admitted to the local NHS hospital for further assessment and treatment. We saw a patient attend the unit with a suspected infection, and upon the advice of the renal registrar, the nurses modified the patient's treatment time and arranged for the patient to be transferred to the hospital once the treatment had finished. They also took blood samples and cultures and sent them via courier to the hospital for analysis.

#### **Staffing**

- The unit had staffing levels which were in line with The Renal Workforce Planning Group (2002) and the Renal Association (2009) recommendations. Actual staffing levels were equal to the planned levels of staff, which ensured the unit was staffed to care for and treat patients in line with their needs. The unit employed 7.7 full time equivalent nurses and 2.5 healthcare assistants. One member of staff had left the service in the last 12 months. At the time of our inspection, there were no vacant posts.
- The unit was staffed with one qualified nurse to four patients, and there was also a healthcare assistant on duty on every shift. Staff worked long shifts from 7.00am to 7.00pm. We checked rotas between January and May 2017; these rotas demonstrated there was always three registered nurses on duty and that there was a senior nurse on duty every day. When the senior nurses were on holiday, another senior nurse from a nearby B.Braun dialysis centre came to cover the unit.

- The unit had processes to cover for staff sickness. Between February 2016 and February 2017, there had been 2% sickness. Staff working extra hours covered shifts. The unit did not currently use any agency staff, and extra shifts were covered through overtime. There were arrangements in place, centrally, to ensure any agency staff coming to work in any B. Braun units had a competency document completed. The registered manager kept information sent to them by the agency, which confirmed their training, competence and disclosure, and barring checks. The unit used a basic general health and safety induction, which the agency nurse signed when completed. This included emergency procedures, fire equipment, layout of the building, basic renal information about dialysis prescriptions and how to operate essential equipment such as the dialysis chair.
- There were effective arrangements for handovers and shift changes that kept people safe. Once the patient had been put onto the machines, all nursing staff gathered and discussed each patient for that session including any risks identified. Handover information was also recorded in the unit diary to ensure all staff were aware of discussions held during handover and any actions taken.
- The unit had link nurses for falls and pressure ulcers, and had access to the supportive care nurse at the supervising NHS trust for end of life support. Staff also had access to a renal dietician for nutritional advice and a renal psychologist, if a patient needed further support, both through the supervising NHS trust. The renal dietician also attended the unit on a weekly basis to reassess patients either in the unit, or in clinic in the outpatient department nearby.
- There were no medical staff on the premises, which meant staff called an ambulance in the event of a medical emergency. A consultant nephrologist visited the unit every week on a Wednesday. This meant patients were reviewed once a month by the consultant, or more often if there were concerns about a patient's renal treatment or condition. Staff had access to the consultant nephrologist at other times via the telephone. Although all patients were under the care of one consultant nephrologist, the team of consultants at the supervising NHS hospital offered support it they were not available. Staff told us it was easy to get hold of one of the consultants if they had concerns about patients.

- The clinical lead for the unit attended once a week to complete tasks required and discuss any issues relating to patients. At all other times the consultant could be reached via mobile phone or email to discuss patients and gain advice. When the lead consultant was not available, the unit contacted the renal registrar on call for support.
- Once a month a continuous quality improvement meeting was held with the nurse manager, lead consultant and dietician to discuss all individual patient's care and outcomes.

#### Major incident awareness and training

- The unit had equipment for staff to use in the event of emergency. Staff received fire-training updates annually via e learning, which showed 11 out of 13 staff had completed the training., The two staff who not received the training had been sick or maternity leave. There were fire extinguishers and fire exit displayed throughout the unit. We asked some patients if staff had told them how to disconnect themselves from the dialysis machine in the event of a fire. The patient records demonstrated that patients had been told how to do this and signed an agreement to acknowledge this. However, one patient we spoke with could not remember how to disconnect. Staff told us they knew which patients required assistance in the event of an emergency.
- There was an emergency folder kept in the unit. This contained all emergency contingency plans available for staff to access should it be necessary. Contingency plans were reviewed annually, unless a change was required. This folder also contained the evacuation plan for the hospital, in which the renal unit was situated and the hospital procedures for power failures. A list of emergency numbers was in place at the nurses' desk to allow for immediate access. The unit manager had attended two recent hospital business contingency planning meetings to highlight the renal unit's processes and requirements within the larger hospital setting. The manager said this had been very worthwhile as some hospital managers were unaware of the implications of power or water loss for the dialysis unit. Staff we spoke to were aware of these plans and felt confident to carry out the advised actions quickly and effectively.
- Potential risks such as adverse weather, were taken into account when planning services. Patients were prioritised following review of fluid levels and bloods

results and contacted by phone to establish who could and could not get into the unit for dialysis. If a patient was identified as requiring urgent dialysis and could not get to the unit, staff told us they spoke to units closer to the patient's home to see if they could be accommodated as an emergency. In the case of IT failure, staff told us dialysis prescriptions were printed and all pre- and post-dialysis checks were recorded on paper records to be entered on the hospital system when repaired.

## **Are dialysis services effective?** (for example, treatment is effective)

We regulate this service but we do not currently have a legal duty to rate it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

#### **Evidence-based care and treatment**

- Treatment was managed in accordance with national guidance. There was a 90-day treatment plan, which was followed by a continuing treatment pathway. These pathways were evidence-based on national guidance from the Renal Association haemodialysis guidelines (2009) and the National Institute for Health and Care Excellence (NICE, 2015): Renal replacement therapy for adults.
- The unit set key performance indicators (KPI) based on Renal Association and B.Braun Group guidelines. Each month, all patients had pre and post dialysis bloods taken to monitor dialysis adequacy and efficiency, and staff ensured changes to treatment were made where necessary. The unit manager collated this data and a report was generated, using these results, to assess the effectiveness and quality of the treatment and any variances. This was further discussed at the continuous quality improvement (CQI) meeting, held each month with the lead consultant, unit manager and dietician. Examples of changes made during the CQI meeting included actions for one patient who was prescribed a medication infusion for a number of dialysis sessions following a change in their blood results.
- Staff followed evidence-based guidance when carrying out checks before patients' dialysis treatment. Patients weighed themselves before entering the dialysis unit.
   Staff checked their vital signs: blood pressure, pulse and

temperature before commencing dialysis treatment. During treatment, staff checked patients vital signs hourly or more often if there were concerns or identified trends of any abnormality. At the end of the dialysis treatment, patients weighed themselves again and reported their actual weight to the nurse to be compared with their target 'dry' weight (their weight after excess fluid had been removed through the dialysis treatment). This weight helped staff assess the effectiveness of the dialysis session.

- Staff monitored patients receiving dialysis in line with Renal Association Haemodialysis Guidelines (2009). For example, the service did not meet guideline 1.3: 'Patients travel less than 30 minutes for dialysis treatment'. However, it was patients' choice and they told us they were pleased with the location of the unit and did not mind travelling a little further for their treatment.
- The dialysis unit was internally audited each year, against ISO 9001, CQC and B.Braun quality management requirements. A timeframe was in place to review all audit findings and to document they had been actioned and closed appropriately. For example, it had been noted that some services were provided to the unit by another branch of B.Braun, and it was felt service level agreements (SLA) should exist for those services. We saw this had been actioned and saw one of the new SLAs for maintenance of the machines.
- The unit underwent an annual audit programme conducted by the senior managers which covered many areas including cleanliness, documentation and incident reporting. The audit took place over a day, and the unit managers received a report from the senior managers highlighting three categories of advice, recommendations, minor non-compliance and non-compliance. In 2016, Frome renal unit received seven minor non-compliance notifications and six recommendations. These notifications were further rated to show if they were closed, in progress or open and were given were given a red, yellow or green rating. The 2017 audit identified three recommendations and three minor non-compliance deviations, and all were rated green and were open. Managers had one week to return an action plan to the senior management team, outlining how these recommendations were going to be addressed. For example, some equipment was identified as not being

- within service date, and the actions showed the manager had contacted the person responsible for this equipment to arrange electrical safety testing, which had been completed.
- The unit used the B.Braun quality management system (QMS) to ensure all policies and procedures were reviewed and amended within agreed timescales. All policies were available for staff to access through the integrated management system. All standard operating procedures had an allocated reviewing manager who oversaw all reviews and amendments were distributed to all managers, who then circulated these to the staff.
- Staff monitored and recorded patients' vascular access in line with NICE Quality Statement (QS72) statements 8 (2015): 'Haemodialysis access – monitoring and maintaining vascular access'. The majority of patients (72% to 78%) between June 2016 and January 2017 had an arteriovenous fistula (AVF) as their vascular access. An AVF is a surgical created vein used to remove and return blood during haemodialysis. Patients were referred to a local NHS hospital for formation of vascular access. We saw individual care plans for those AVFs that were difficult to cannulate. If patients' fistula were difficult to cannulate this was undertaken by more experienced staff. The AVF was the most common of type of vascular access for the patients on the unit. In January 2017, 35 out of 48 patients had an AVF, 11 had a CVC and two had a graft.
- The service followed national guidance for end of life care and followed recommendations set out in the National Service Framework for Renal Services part two. Staff told us they used the term supportive care, as patients felt very distressed when staff mentioned end of life, especially as there were some younger patients currently receiving treatment on the unit. Staff identified when patients may need additional support through use of a screening tool. A series of questions helped staff flag up patients who may wish to go onto the supportive care register. The screening tool clearly set out who could use it and when, and actions to be taken depending on the answers patients gave to the questions outlined on the tool.

#### Pain relief

 Patients' pain relief needs were assessed and managed appropriately at the start of their treatment. Patients did not routinely receive oral analgesia during their dialysis sessions; however, local analgesia was available for

cannulating the patients' arteriovenous fistula or graft (AVF/G). Needling is the process of inserting wide bore dialysis needles into the AVF/G, which some patients find painful. However, after reviewing care records and speaking with patients, it was not clear if discussions or assessments around pain took place at any other time during the patients' treatment.

- Local analgesia was prescribed as a 'to be administered as necessary medication', which enabled it to be used at each attendance to the centre.
- Staff told us they offered the use of a local anaesthetic cream prior to cannulation of the fistula if patients found this process uncomfortable or painful, and most patients were appreciative of how staff considered their comfort during dialysis, however two patients we spoke to said they had not heard of the cream, or been offered it.
- Staff did not administer regular analgesia to patients receiving dialysis. Patients attended on an 'outpatient' basis and would take their own medication as prescribed. If patients complained about pain during treatment, nurses would assess possible reasons and consult with the consultant nephrologist if required.

#### **Nutrition and hydration**

- The unit addressed patient's nutritional and hydration needs which was recorded in the patient's care plan.
- Patients in renal failure require a strict diet and fluid restriction to maintain healthy lifestyle. We were told that patients were reviewed by the dietitian monthly, who assessed their medical history and their treatment plans to advise patients on the best diet for them.
- Patients and staff at the unit had access to specialist
  dietary advice through the renal dietician from a nearby
  healthcare organisation. The dietitian visited the unit
  every week on alternate days to ensure they saw and
  reviewed all patients regularly. The dietitians wrote up
  their records and spoke with staff about any changes on
  the same day, before leaving the unit. The dietitian
  reviewed patients' monthly blood test results remotely
  and therefore monitored patients every month
  in-between face to face visits. If slight amendments were
  required to nutrition because of tests, these were
  actioned immediately.
- Dieticians visiting the unit used a subjective global assessment pathway (SGA) to help identify patients at risk of malnutrition. A series of questions around protein intake, skin condition, body mass index and weight loss

- gave each patient a score, which in turn was categorised as red, amber or green. The SGA pathway gave clear advice for patients depending on their colour category, which included the addition of high calorie diet supplements for patients at greatest risk.
- We saw that patients were provided with written information and guidance relating to their diet and fluid management, which patients told us was very good and helped them understand their diet and fluid intake.
- Patients had access to food and hydration whilst undergoing their dialysis, and we saw the morning patients were offered a hot or cold sandwich provided by the hospital kitchen. Patients placed their order when they arrived and community hospital kitchen staff delivered the items mid-morning for patients to eat during their session. Staff also did a tea and biscuit round for patients during their session. The sandwich run had been brought in, in response to patient feedback, as the morning patients were in the unit very early, and frequently missed breakfast.

#### **Patient outcomes**

- The unit collected data, which was submitted, to the UK Renal Registry by the local NHS trust. This allowed the service to compare treatment outcomes to similar outcomes from other services in England. The service collected data about ten haemodialysis key performance indicators. These included data about dialysis frequency, treatment time, blood pressure recordings and blood test results such as haemoglobin, phosphate and calcium levels.
- The service's performance indicators were similar to the country average for all key indicators. For example, dialysis frequency data showed that the average number of weekly treatments for patients was three sessions per patient between June 2016 to January 2017. This was in line with the recommended frequency of three treatments per week for each patient. The unit reported that 94.9% of patients received three dialysis sessions per week, which was lower than the national average for other B.Braun units for five out of eight months in the same time period. The unit reported diastolic and systolic blood pressure values which had been consistently higher than the B.Braun country average between June 2016 and January 2017, which meant the centre was performing better when compared to other similar B.Braun services. The unit reported that only 2.2% of patients who received

- dialysis treatments in any given week had less than nine hours treatment, which was the same as all other country wide B.Braun units between June 2016 and January 2017.
- The unit set key performance indicators (KPI) based on Renal Association and B.Braun Group guidelines. Each month, all patients had pre and post dialysis bloods taken to monitor dialysis adequacy and efficiency, and staff ensured changes to treatments were made where necessary. The unit manager collated this data and a report was generated, using these results, to assess the effectiveness and quality of the treatment and any variances.
- The service had a calendar with details of when different performance reports should be completed and sent to the corporate operational manager for review. This included a monthly 'management plan' and a quarterly 'outcomes and explanation report'. The management plan held information about KPIs, which was reviewed against set targets, as agreed with the local NHS trust. Data from January to April 2017 demonstrated the service met all KPIs. The management plan also presented information in relation to other performance indicators such as infection control, water testing, mandatory staff training and information about staffing levels.
- Each month, the unit completed a document recording all patient bloods and returned it to the quality manager. This document audited the percentage of patients who had achieved the standards set by the Renal Association. Parameters audited included: haemoglobin, phosphate, calcium, dialysis adequacy, treatment time, albumin and the type of access used. This data formed part of the CQI meetings with the lead consultant, and highlighted where prescription changes were required. For example, outcome data was also reviewed at the quarterly B.Braun Avitum managers meetings. Data from all units was compared and discussions held and also formed part of the analysis presented at the supervising NHS trust's dialysis meeting. The most recent discussions surrounded haemoglobin levels, where outcomes from Frome renal unit had achieved its local target for 58% of patients to have over 12 g/dl post dialysis. This was better than all other renal units supervised by the trust. One reason the unit had discussed for this was the water quality or the automatic reinfusion used when returning patient blood post treatment.

- Staff followed evidence-based guidance when carrying out checks before the dialysis treatment. Patients weighed themselves before entering the dialysis unit. Staff checked their vital signs such as blood pressure, pulse and temperature before commencing dialysis treatment. During treatment, staff checked patients vital signs hourly or more often if there were concerns or identified trends of any abnormality. At the end of the dialysis treatment, patients weighed themselves again and reported to their weight to the nurse. This weight helped staff assess the effectiveness of the dialysis session.
- We saw patients care plans were reviewed monthly or sooner if required. The basis of this was the monthly bloods taken from all patients. The care pathway document covered all aspects of patients care, and other assessment tools were also used to provide a holistic approach and any variances were accounted for within the patient's notes.
- The unit had an internal audit schedule which covered many areas including hand hygiene, documentation, housekeeping and patient satisfaction. As part of the 2016 patient survey, patients were asked if they felt involved in their treatment, and if they had received sufficient information to understand their condition. Of the responses, 74% of patients stated they were satisfied with their care, which was just below the local target of 75%. As a result, the unit undertook a shared care audit to try to establish what additional support patients needed or wanted in order to feel more involved in their own care and treatment. Senior staff told us the audit did not identify significant numbers of patients who wished to participate further in their care, but actions taken as a result of the audit, included introducing a target for 25% of patients to wash their hands and fistulas prior to treatment.

#### **Competent staff**

Staff had the right qualifications, skills, knowledge and experience to do their job, and if they did not have the correct skills upon starting their employment, a training matrix appropriate to their job role was used to identify gaps in skills and knowledge. Mandatory training was completed in the first quarter of the year and included training to be completed annually, once only or to be revisited every three years. The quality manager collated all training records, with a report distributed to the unit managers monthly. Training completed was reviewed

and reported to the operations manager each month by the unit manager. Data submitted, showed a number of staff were not up to date with all mandatory and required training, including aseptic non-touch technique and safeguarding, which was not in line with the local target for 100% compliance.

- All new staff members had a six-month probationary period, during which a competency document was be completed. Their progress against this document was assessed through one, three and six month reviews. All new dialysis nurses completed a nurse development programme, specifically surrounding renal failure and dialysis. Once through probation, all staff members received six-month appraisals in which they gave examples to show they were continually meeting various competencies linked to clinical care and the requirements of the business. Where staff were unable to demonstrate their ongoing competency, or if any other concerns arose, any shortcomings were discussed with human resources (HR) to formulate a performance management plan.
- New and visiting staff were inducted using a staff checklist which included the awareness of safety procedures (fire safety, resuscitation equipment), equipment training (dialysis monitor, infusion pumps, and glucometers) knowledge of governance policies, patients data requirements and uniform policy. We saw that the induction checklist was completed by staff at every attendance to the centre and signed by a substantive member of staff.
- Staff had been given the appropriate training to meet their learning needs, which included the opportunity to attend the external renal course. Staff told us they were encouraged to develop, and one member of staff explained how they had brought back research and evidence around diabetes to share with the rest of the unit, following attendance on the renal course.
- Of the eight nurses employed at the unit, three held the formal renal nursing qualification, one was training, and another planned to start training later in the year. All staff at the unit had completed the B.Braun renal training package.
- All staff had completed their annual appraisal. Annual appraisals identified any areas for development and an agreed timescale for completion. All staff completed competencies, which were measured against a B.Braun knowledge and skills framework. These were reviewed annually as part of the staff member's appraisal.

- Up-to-date staff training was carried out on the use of specific medical devices, including the dialysis machines and we saw specific training documents in staff folders containing competency based training and assessments, which were all complete and up to date. Staff explained how they could adapt treatments depending on the patient's general heath at the time of the treatment. For example, one patient had a heart condition and nurses adapted their treatment to the patient to ensure their body could cope with the amount of fluid taken off.
- Staff followed evidence based guidance when commencing patient's dialysis training. Nurses used a technique referred to as wet needling, when connecting patients to dialysis machines. They followed clinical care pathways to ensure secure vascular access.
- Staff had an understanding of the principles of the medicines used during dialysis. All staff were assessed annually for medications administration and understanding, however training updates had only been completed by five out of eight qualified staff.
- All staff received yearly face-to-face updates in basic life support training including anaphylaxis training. Records showed that nine out of 13 staff members had had their yearly update in 2017 and the registered manager told us all other staff were planned to attend a training session or were on long-term sick leave or maternity leave
- B.Braun trained nursing staff in dialysis and all staff had completed renal training programmes. Four out of eight staff had completed or were in the process of completing the national renal training course.

#### **Multidisciplinary working**

- There were processes to ensure effective multidisciplinary working. The consultant nephrologist from the supervising NHS trust had the overall responsibility for managing patients' care. Nurses played a vital role in ensuring care and treatment was carried out as prescribed and communicated any deviations to the consultant. Nurses told us their working relationship with the consultant nephrologist was good and that they were supportive.
- The unit held monthly continuous quality improvement meetings with the supervising NHS trust, during which, KPI data was discussed for the unit. Each month, all patients had pre and post dialysis bloods taken to

monitor dialysis adequacy and efficiency, and staff ensured changes to treatment were made where necessary. The effectiveness and quality of the treatment and any variances were discussed in the meeting with the lead consultant, unit manager and dietician. We saw that the meetings followed a set format where patients' current condition, their care plans, most recent blood results and medications were discussed and recorded in the electronic patient record. Each patient review was recorded on a written table, and any changes to patient medication were communicated to the GP in a letter from the consultant.

- There were effective working relationships with regional transplant centres. Patients waiting for a renal transplant received specialist care, including psychological support, from the regional centres. Once patients were accepted onto the renal transplant waiting list, staff obtained regular monthly or three monthly additional blood tests, which were sent directly to the renal centres.
- Patients received regular reviews by a
  dietitian sub-contracted from another healthcare
  organisation. If patients needed input from other allied
  health professionals this would be discussed with the
  lead consultant nephrologist or with the patients GP.
  This included support from a clinical psychologist but
  patients had to travel to the nearby NHS trust to receive
  this support, as the clinical psychologist did not visit the
  unit.

#### **Access to information**

- The unit had access to the dedicated renal database used by the supervising NHS trust, which allowed for central storage of patient information. All dialysis information was in-putted to record treatment activity. The system allowed staff to access blood results, medication lists, recent clinic letters, multi-disciplinary team planning and all demographic and identity information necessary to provide safe care.
- Units requesting holiday dialysis for their patients were sent a document as soon as the request was received, which had to be completed and returned before the request for holiday dialysis was accepted. The information requested ensured the patient was treated safely and effectively. Information requested included details of the dialysis prescription, including maximum fluid removal, any access issues and all treatment parameters. Recent blood biochemistry, haematology

- and virology results were also required within 4 weeks prior to attendance, as well as swab results to monitor infections. The referring unit were also requested to ensure all medications and medical devices required, had been prescribed by the patient's lead consultant. If these details were not received, treatment could not occur. The returned documents were received by the clerical assistant in the unit, and were reviewed by either the unit manager or senior dialysis nurse before the patient was accepted.
- When people moved between teams and services, including at referral, discharge, transfer and transition, all the information needed for their ongoing care was shared appropriately. Nursing staff completed telephone referrals for additional support or specialists. This process was followed by a written letter or email to the relevant service to ensure details had been shared.
- The consultants or dietitians contacted patients' GPs directly with any changes to treatment. We saw that each month, all patients had pre and post dialysis bloods taken to monitor dialysis adequacy and efficiency, and staff ensured changes to treatment were made where necessary. The effectiveness and quality of the treatment and any variances were discussed in a meeting with the lead consultant, unit manager and dietician. Each patient review was recorded on a written table, and any changes to patient medication were communicated to the GP in a letter from the consultant. We were told that information to the GP was shared initially by telephone, and followed up with letters or secure emails.

#### **Equality and human rights**

The service did not have any knowledge of the NHS
 Workforce Race Equality Standard (WRES) published in
 2016 and was therefore non-compliant with NHS
 England requirements. The Workforce Race Equality
 Standard (WRES) and Equality Delivery System (EDS2)
 became mandatory in April 2015 for NHS acute
 providers and independent acute providers that deliver
 £200,000 or more of NHS-funded care. Providers must
 collect, report, monitor and publish their WRES data
 and take action where needed to improve their
 workforce race equality. WRES looks at the extent to
 which black and minority ethnic (BME) background
 employees have equal access to career opportunities

and receive fair treatment in the workplace. Although these reports may be written at corporate level, there should be data about workforce race equality collected and reported at local level.

- The services had an operating procedure (OP) to ensure patients with protected characteristics were not discriminated against. The OP provided guidance to staff about accessing for example translation services or written information in large-scale print or Braille. The unit was easy for patients with disabilities to access. All treatment areas were on the ground floor and were spacious to accommodate people in wheelchairs. The toilet was specifically designed to provide easy access for patients with either a right-sided or a left-sided weakness. The toilet facilities also had an emergency call bell to summon assistance if required.
- The service did not accept children into the unit at any time and only treated stable patients who were used to dialysis treatment. These were the only 'blanket' restrictions. However, staff acknowledged that some challenging patients would be difficult to manage in the environment and without the support of medical staff.
- Staff obtained information about patients' communication needs in line with the Accessible Standards (2016). The Equality Act 2010 places a legal duty on all service providers to take steps or 'make reasonable adjustments' in order to avoid putting a disabled person at a substantial disadvantage when compared to a person who is not disabled. An assessment of patients formed part of the initial assessment when they commenced treatment at the unit. Staff ensured patients' needs were met wherever possible for example by purchasing specific equipment or facilitating the dialysis treatment in a side/single room if required.
- One member of staff had received an award for work they had done around adapting patient information leaflets. The staff member had simplified language and used pictures to enhance the leaflets. The leaflets were being reviewed by the head office at the time of our inspection to consider implementing them across other B.Braun units.

### Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

• Staff obtained consent and acted in accordance with patients' wishes. Staff obtained written consent from all patients when patients started treatment at the unit.

Thereafter staff obtained verbal consent before treatment and care interactions were commenced. This consent was not documented in patient records. Staff explained that there was also implied consent as patients attended for their treatment. Staff acted in accordance with patients' wishes, which sometimes meant that patients' dialysis session was shortened. When this happened staff explained the potential consequences of shortening the dialysis session but took account of the patients' wishes and disconnected them from the dialysis machine. Staff reported this as an adverse patient occurrence. This had happened between three and five times each month between January and April 2017.

- We saw that each patient completed consent forms for the completion of treatment and for dialysis. This consent form was filed in the patient's paper records upon commencement of dialysis treatment. We looked at four patient records that all contained this information and were signed and dated.
- Patients who were suspected not to have capacity to consent to treatment were discussed with the consultant and a mental capacity assessment completed. In these cases, the consultant would speak with the patient's family, who were asked to consent on the patient's behalf following a best interest decision.
- Patients who expressed that they did not want to continue with treatment were referred urgently to the consultant and supportive care nurse, following the completion of the supportive care screening tool. We were told that a meeting was arranged to identify if there were any specific reasons that affected the patient's choice and where necessary try to resolve them. Patients who continued to withdraw from treatment were supported to understand the outcome and the supportive care nurse arranged help for the palliative stages of their illness.
- Nursing staff told us information leaflets in a variety of languages were available to help patients understand treatments prior to consenting for treatment. We were told the unit had not had a patient whose first language was not English, however a translator could be provided if necessary to ensure consent was understood, and staff told us they would directly approach companies and manufacturers to obtain specific leaflets in the desired language. Recently, B.Braun had translated all of its information materials into Welsh.

#### Are dialysis services caring?

We regulate this service but we do not currently have a legal duty to rate it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

#### **Compassionate care**

- Staff took the time to interact with people who used the service and those close to them in a respectful and considerate manner, and we were told of a patient who had recently attended a wedding. The staff and the patient's family had used the wedding as a goal to help them manage and improve their overall health, and we heard a staff member on the phone to the patient's relative asking the patient to bring in photographs from the day.
- Staff understood patients' personal, cultural, social and religious needs. We saw that these were taken into account when planning treatment. For example, patient's dialysis sessions were planned around their work, social events, hobbies and patients grouped into those with similar interests. Staff told us this could be challenging, as there were a number of younger patients attending the unit.
- Annually patients were encouraged to complete the patient satisfaction questionnaire. This was distributed to all patients, was anonymous and allowed for open and honest feedback. The results of this questionnaire were reviewed at senior level, and the unit manager formulated a response to the patient group. The response included any actions that were taken by the unit to improve patient experiences. The response rate also formed part of the management monthly scorecard. The most recent survey in 2016, showed a 71% response rate, and explained how patient's concerns were going to be addressed, specifically around the unit temperature and involvement in patient's own care. Where issues could not immediately be addressed, the response letter explained why, such as around comfort issues with the current dialysis chairs. An action plan drawn up by the unit showed an additional portable heater was purchased for patients to use if they still felt cold during their treatment.
- The unit had a patient forum that met at least twice a year. Each shift had a patient representative, who acted as an advocate for that group. These meetings allowed

- open discussions between the patient group and unit manager. Any concerns, ideas or requests from the patient group were encouraged to be voiced here and discussed. One action that came out of the patient forum meetings was the introduction of a breakfast sandwich round for the early session patients.
- Staff treated patients with compassion, kindness, dignity and respect. We observed staff interact with patients in a compassionate manner. However, some feedback received both in the patient survey and in the run up to the inspection indicated patients sometimes felt ignored by staff which made them feel unsafe, however, we did not see this during our inspection.
- We saw a folder containing thank you cards from families, which were kept in the unit for staff to read.
- Staff were aware of the importance to provide care for a diverse population and ensured patients' individual wishes and needs were met wherever possible. Staff made sure that people's privacy and dignity was always respected, including during physical or intimate care, and we saw screens were used to surround the entire dialysis station. However, feedback received from patients in the patient survey and in the run up to the inspection expressed a concern that conversations about personal healthcare issues were taking place at the dialysis stations, and patients expressed a wish for them to be given an option to discuss some issues in a more private setting.
- Staff were mindful of maintaining privacy but their individual dialysis stations could not easily be screened off when care interactions took place. However, a consultation room within Frome hospital outpatient department could be used for clinical examinations although staff stated the rooms were rarely used. In the patient survey, 35 (100%) of patients stated they were very satisfied or quite satisfied with privacy during treatment and clinical examinations. Staff maintained patient confidentiality. However, patients expressed concerns that information was sometimes shouted across the unit and staff sometimes did not attempt to speak with patients in a lowered tone to maintain confidentiality. The unit had consultation rooms where patients could speak with staff in private, which patients told us they were aware of.
- We were told that staff had not witnessed any disrespectful behaviour but would escalate any concerns directly with the manager. Nursing staff told us that due to patients attending the centre regularly for

long periods of time, they had formulated effective nurse patient relationships. Staff told us it was often upsetting for them when a patient chose to withdraw from treatment, but staff said they comforted one another, and knew how to access counselling services provided through the company.

There was provision for patient comfort, including the use of dialysis chairs and pressure relieving aids.
 Through the patient survey, patients raised concerns about the comfort of the dialysis chairs. The unit manager's response letter explained dialysis chairs would not be replaced whilst the current contract was under review and hoped this would be resolved by summer 2017. In response the unit ordered extra pillows and a donation from a patient had allowed the manager to purchase pressure-relieving cushions for each chair. Senior managers told us there were plans to refurbish the chairs with memory foam cushions, which had been patient tested across several B.Braun units.

### Understanding and involvement of patients and those close to them

- Staff communicated with patients in a manner that ensured patients understood the information they were given. The serviced used a 90-day clinical pathway that included a patient education programme. Patients received information about the treatment, fluid management, diet, vascular access, medicines, how to adapt to dialysis and information about kidney transplant. We observed staff took time to explain for example blood results and checked the patients had understood the information by asking further questions.
- As part of the patient survey, patients were asked if they felt involved in their treatment, and if they had received sufficient information to understand their condition. Of the responses, 74% were satisfied with their treatment and 26% were not satisfied. In response, the unit had undertaken a shared care audit which staff told us had failed to identify any additional reasons for the survey results. Besides lack of involvement in their care, patients also identified the unit temperature and dialysis chairs as a source of dissatisfaction. The unit manager had responded to patients to inform them that increasing the unit temperature would lead to an increased risk of patients' blood pressures dropping, but had purchased two heaters for patients to use if they needed.

- Nursing staff told us that as they saw their patients frequently they were familiar with their moods and were able to identify when patients were having a bad day or were feeling unwell. This enabled them to spend additional time with the patients as necessary to support them with their treatment or assist with any concerns they may have.
- Most patients spoke positively about the staff and treatment at the centre, and comments we received from patients included 'staff always treat me with the utmost respect and skill' and 'can't fault anything', however, some comments said 'staff sometimes don't speak' and 'health discussions could be done in a more private way'.
- The unit had good links with the supportive care team at the supervising NHS trust. The link nurse liaised with the lead consultant and nurse, and highlighted any patients who had been assessed as requiring increased supportive input or had voiced a need for help. Staff told us the supportive care not only focused on end of life decisions but also pulled together all support services available in the community. This included increased input from carers, assistance from occupational therapy or palliative care.
- On referral to the centre, patients were encouraged to visit the centre for an initial assessment and a look around. On arrival, staff gave patients information packs about the centre, which detailed what to expect from the service and information on haemodialysis. Patients and their relatives were encouraged to spend time with the staff and other patients to ensure that they were satisfied with the centre before agreeing to start treatment at the unit.
- Patients new to dialysis were given additional time and support by staff prior to commencing treatment.
   Information leaflets were used by staff to inform patients of side effects and common risks and benefits of treatment, and were discussed throughout the patients visit to the centre. On the day of our inspection, a new patient was having their first treatment at the unit. Nurses showed an extremely compassionate approach and acknowledged how the patient could be overwhelmed by the amounts of information they received at the start of their treatment. The nurse spent some time considering what to give the patient and explained they would go through things bit by bit over the coming days and weeks.

- Patients and their relatives were encouraged to participate in their treatment. Staff encouraged patients to take responsibility for parts of their treatment, such as weighing themselves prior to dialysis, inputting data to the dialysis matching, preparing needles and connecting dialysis lines. However, some patients told us they did not feel involved in their care plans. Results from the patient satisfaction survey showed not all patients were satisfied with their level of involvement. Actions taken following an audit into shared care included offering patients a variety of activities they could be involved in, such as washing their fistulas, setting up their machines and self-needling.
- Patients we spoke with were aware of the links between other clinical conditions and their renal failure. For example, one patient openly spoke about the management of their diabetes and the impact this had on their renal diet and treatment.
- We saw that patients were fully informed of their blood results at each dialysis session. Patients spoke with the nurses about the impact of their blood results and whether any changes would be made to their treatment.
   We saw that any changes to treatments were written and given to patients to ensure they were informed of the reasons why things had changed.
- All patients were reviewed a minimum of monthly by the consultant and dietitian which enabled discussions about any concerns, medications, treatment changes, and future plans for different dialysis. Following each meeting, patients were given a printed summary of the discussion and any planned changes to treatment. We saw that nursing staff spoke with patients about the discussions and answered any queries relating to the changes.
- All patients were allocated a named nurse who was
  responsible for the holistic care planning and
  management for each patient. Patients were allocated
  to specific nurses if certain skills and expertise were
  required, for example if they had difficult venous access.
  The named nurses reviewed patient blood results and
  care pathways to instigate any changes to prescription,
  in collaboration with the lead consultant or dietician.
  For example, the senior nurse in charge was overseeing
  the care of one patient whose fistula was difficult to
  cannulate, and was attempting to extend the fistula
  using careful needling techniques. The patient
  confirmed this had been explained to them and
  understood what the nurse was doing and why.

#### **Emotional support**

- Staff were aware of the impact that dialysis had on a patient's wellbeing, and staff supported patients to maintain as normal a life as possible. Staff encouraged patients to continue to go on holiday, and participate in the management of their treatment.
- The unit had good links with the supportive care team at the supervising NHS trust. The link nurse liaised with the lead consultant and nurse, and highlighted any patients who had been assessed as requiring increased supportive input or had voiced a need for help. Staff told us the supportive care not only focused on end of life decisions but also pulled together all support services available in the community. This included increased input from carers and assistance from occupational therapy or palliative care.
- The unit had access to a supportive care register, which was led by the lead consultant. The assessments made by the nurses, as part of their reviews, highlighted patients who may benefit from increased support, care planning and discussions surrounding end of life wishes. The unit had a link nurse, who made referrals to this service should a patient wish, or if a clinical need was displayed or identified during consultant review. The supportive care nurse had recently begun attending the continuous quality improvement meetings and the unit and trust were discussing how services could further be improved, by increasing supportive nurse visits to the unit.
- There were processes in place to ensure staff assessed patients' quality of life and emotional wellbeing.
   Patients received information about adapting to dialysis as part of the patient education programme when they started dialysis treatment. Staff asked patients if they felt low in mood as part of the continuing care pathway, which was reviewed every three months. Staff could refer patients to a clinical psychologist at a nearby NHS trust if required.
- We saw that the unit provided details of support networks for patients and their loved ones. This included organisations such as the Kidney Patients' Association who arranged and advertised social events, and support networks for patients and their loved ones.
- The unit recognised that encouraging patients to participate in their care could lead to better outcomes.
   Linking with the supervising NHS trust, shared care audits had been performed to identify which patients

wished to participate in their treatment and to what degree. As part of the shared care process patients were encouraged to access Renal Patient View. This on-line system allowed patients access to their most up to date blood results that they discussed with their named nurse, and in conjunction with the care pathways, encouraged a collaborative relationship.

 Patient education relating to their blood results, as well as, dietary allowances, access and the process of dialysis were offered to patients on admission to the unit. It had been recognised that some patients needed a more simplified approach and the literature had been adapted accordingly to the individual.

## Are dialysis services responsive to people's needs?

(for example, to feedback?)

We regulate this service but we do not currently have a legal duty to rate it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

### Service planning and delivery to meet the needs of local people

- Information about the needs of the local population
  was used to inform how services were planned and
  delivered. B.Braun was contracted to complete a
  programme of work by the local NHS trust. The trust and
  local commissioning group had defined the scope and
  specifications of the service. The unit manager for
  B.Braun reported progress in delivering the service
  against the defined specifications at monthly contract
  review meetings and through the collection of key
  performance indicators and quality outcomes.
- The operational manager told us that B.Braun was asked to run a purpose built renal unit in a local community hospital within a specific catchment area to meet the demand of the local population. Patients in the Somerset, Wiltshire and Bath and North East Somerset areas were travelling to the nearby NHS trust or other dialysis centres a minimum of three times per week. Patients and staff told us this journey time was between 30 and 60 minutes each way and sometimes longer when patients used hospital transport. As demand locally had increased, the local NHS trust

- entered into negotiations with the organisation to provide a service. The unit was located with a purpose built community hospital, and met the standards set out in the Renal Care Health Building Note 07 01(2013): 'Satellite dialysis unit requirements'.
- The services provided reflected the needs of the population served and ensured flexibility, choice and continuity of care. Patients who required dialysis in the catchment area were assessed by the nearby NHS trust staff for suitability to dialysis in a satellite unit, and then referred to the unit.
- The unit consisted of three main areas on one level. The
  reception area and office, dialysis stations and services
  corridor. The unit was open plan, but itself was secure
  and only accessible with an electronic pass. Patients
  arriving in the reception were required to be buzzed in
  through a secure door from a large patient waiting area.
  This area had a camera to enable staff to identify callers
  upon arrival. The key code locked service corridor
  contained all treatment storage, water treatment room
  and maintenance room. Clean and dirty utility rooms
  were located off the main treatment area, and were key
  code locked.
- The patients arranged transport through the supervising NHS trust. Some patients told us that they had regular drivers who were punctual and problems only arose if the regular driver was off work. Patients reported they usually waited a short period for transport to arrive. Other patients from different areas expressed concerns over the punctuality of the transport services provided by the company that held the contract for the supervising NHS trust. One patient told us it often could take up to three hours to return home following dialysis, as other patents were dropped off before them. Staff told us questions in the patient satisfaction survey captured patients complaints about transport, and staff were now recording excessive waits and delays on the electronic incident reporting system. Senior staff told us this data was being compiled and shared with contacts at the supervising NHS trust, and also the transport provider company.
- There was adequate designated parking and disabled parking adjacent to the dialysis area, for patients who organised their own transport to and from dialysis, and patients told us they never had any problems either

- parking themselves, or when transport arrived to collect them. There were two designated bays for dialysis patients and a number of disabled spaces directly outside the unit.
- Where possible, nurses told us they would arrange dialysis sessions to suit their patients. For example, one patient continued to run a business, and had chosen to undertake two sessions of dialysis a week rather than three. Staff aimed to maximise these treatments to support the patient's wishes, whilst also explaining the risk associated with shortening dialysis treatments.

#### **Access and flow**

- The service met the needs of the local population and was well utilised. The unit provided 4789 dialysis sessions per month between June 2016 and January 2017 for its own patients and 10 sessions for temporary patients. This meant the utilisation was 98% to 100%. At the time of our inspection, there were three people on the waiting list for dialysis at the unit. The nurse manager at supervising NHS trust's main dialysis unit referred patients to the unit. Once a space was available, it was declared to the nurse manager. Once the registered manager was informed of the patient, they contacted the patient to arrange the first appointment and this included arrangement of transport to and from the unit. The registered manager invited new patients to visit the unit before starting their treatment to ensure the location met their expectations.
- Patients currently on the waiting list had their care and treatment prioritised by the nurse manager at the supervising NHS trust, in collaboration with the patient's lead consultant, who also discussed all pending patients with the unit manager during the weekly visits. When the unit received referrals from outside the trust, for example when patients moved into the area, they were directed to the lead consultant to assess as a transfer of care.
- The service accommodated patients' preferred times for dialysis wherever possible. One patient and their relative also told us about how staff had helped plan the days of dialysis so that the patient could attend an important family event.
- Patients did not have to wait long for their treatment to start from the scheduled time given. A patient

- satisfaction survey from 2016 showed some patients waited less than 15 minutes. However, 15 (42.8%) patients waited between 15 and 29 minutes after their scheduled time.
- The unit did not cancel appointments unless there were issues with the water plant when treatment and safe dialysis could not be assured. If patients could not attend their regular appointment, staff invited them to attend at a different time for example the next day. If patients missed their dialysis appointment, staff telephoned the patient to check they were well and to arrange another appointment the following day. They also informed the consultant and the patient's GP. Staff reported missed appointments as an adverse patient occurrence on the B.Braun electronic incident reporting system. From June 2016 to end of February 2017, the service reported 21 unscheduled missed dialysis appointments.
- Care and treatment was only cancelled or delayed when necessary, and cancellations were explained to people.
   In the 12 months prior to our inspection, the unit had cancelled no sessions for non-clinical reasons.
- The dialysis service provided flexibility and choice for patients. Most patients attended the unit three days a week and had the choice of available morning or afternoon session to suit their preference. One patient told us the unit had changed their morning slot for an afternoon slot as otherwise they would have had to get up very early, which did not suit them. The unit was open from 7am to 6.30pm between Monday and Saturday.
- All appointments with the consultant or dietitian were scheduled for the same day as patient's dialysis sessions to prevent multiple attendances at the unit where possible.

#### Meeting people's individual needs

- The service took account of patients' individual needs when they received dialysis treatment. The dialysis stations each had a television and patients had their own individual headset. Each station had a table and staff offered hot and cold drinks and a biscuits while patients received dialysis. Some patients brought their own food in as well as books, electronic devices or similar items to help them pass the time.
- When staff planned the daily allocation of patients, various considerations were made to ensure every

- patient's needs were met. Seating positions were allocated depending on patient stability throughout treatment, which meant more unstable patients were treated closer to the nurses' desk.
- Patients all had access to individual ceiling mounted TV units, which had recently been replaced the weekend before our inspection. Patients had complained that the previous TV remote controls were changing multiple TV channels at once, causing some friction between patients. Patients supplied their own headphones, and also had access to free Wi-Fi on the unit, which one patient told us helped them continue to work during their treatment.
- Some patients required more support, due to dementia or learning difficulties. The named nurses for those patients formed strategies with the patients and their families or carers to ensure all education, care and support needs were met.
- The services had an operating procedure (OP) to ensure patients with protected characteristics were not discriminated against. The OP provided guidance to staff about accessing for example translation services or written information in large-scale print or Braille. The unit was easy for patients with disabilities to access. All treatment areas were on the ground floor and were spacious to accommodate people using wheelchairs. The unit had a toilet which was specifically designed to provide easy access for patients with either a right-sided or a left-sided weakness. The toilet facilities also had an emergency call bell to summon assistance if required.
- There were provisions for patients attending for haemodialysis to be able to visit the toilet before dialysis commenced, and nurses were responsive to patients who needed to urinate during or close to the end of the dialysis treatment. At the end of one treatment, we saw a nurse screen off a dialysis station to allow a patient to use a bottle.
- There were some patients who participated actively in their own care. Some patients had obtained access to 'Patient View' that allowed them to review their own blood test results on line. If patients considered a home dialysis option, they were transferred back to the care of the supervising NHS Trust. Patients were taught how to disconnect themselves from the dialysis machine in the event of an emergency. However, some patients had expressed, through the patient survey, that they did not feel very involved in their care.

- The service supported patients with arrangements for dialysis while on holiday and welcomed patients from other regions for dialysis sessions. The staff acted as holiday coordinators and liaised directly with patients, consultant nephrologists and co-ordinators to arrange dialysis for patients going on holiday that required dialysis at a different unit. They also arranged dialysis for patients on holiday nearby. We spoke with patients who had been on holiday both in this country and abroad whilst receiving dialysis. There was also a folder in the unit containing information about treatment centres all over the world, including costs. Senior staff told us dialysis treatment costs had recently changed, and the NHS would now only fund care within the European Union (EU). If patients wished to travel outside of the EU, the costs had to be met by them.
- Units requesting holiday dialysis for their patients were sent a document as soon as the request was received, which had to be completed and returned before the request for holiday dialysis was accepted. The information requested ensured the patient was treated safely and effectively. Information requested included details of the dialysis prescription, including maximum fluid removal, any access issues and all treatment parameters. Recent blood biochemistry, haematology and virology results were also required within 4 weeks prior to attendance, as well as swab results to monitor infections. The referring unit were also requested to ensure all medications and medical devices required, had been prescribed by the patient's lead consultant. If these details were not received, treatment could not occur. The returned documents were received by the clerical assistant in the unit, and were reviewed by either the unit manager or senior dialysis nurse before the patient was accepted.

#### Learning from complaints and concerns

 People who used the service knew how to make a complaint or raise a concern, and told us they were encouraged to do so. Patients felt confident to raise complaints, and also told us they had the patient forum to speak to if they were not happy to raise it themselves. Patient complaint information was displayed on the board in the unit. It identified whom patients could make complaints to and the ways of contacting them.

The first contact was the unit manager, but alternatives were available if the patient felt it was necessary. At the time of our inspection, there had been no patient complaints made in the last 12 months.

- We saw information detailing how patients could make complaints was displayed on the notice board in the patient waiting room. This encouraged patients or families to approach the unit manager as the first point of contact. If patients wished to make a complaint about B.Braun Avitum alternative details relating to the patient advice and liaison service (PALS) at the supervising NHS Trust, and the Specialised Commissioner were also displayed. B.Braun had a complaints policy that explained the processes and timescales responses must be within, which staff were aware of.
- On referral to the centre, patients and their relatives were given a copy of the patient booklet, which contained details of the complaints procedure, detailing how a complaint could be made, the process for investigation and the timescales.
- Staff told us they continually sought the views of their patients through the use of a feedback box, to enable patients to make comments or suggestions anonymously.
- The manager held regular open door sessions where patients could escalate any concerns directly. This was in addition to the patient forum which met twice a year where patients could discuss their concerns and suggestions with the unit manager.

#### Are dialysis services well-led?

We regulate this service but we do not currently have a legal duty to rate it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

#### Leadership and culture of the service

- Leaders had the skills, knowledge and experience to manage the service. A deputy managers/senior dialysis nurse supported the registered manager. The registered manager and the senior dialysis nurse all held a post-registration course in renal nursing.
- B.Braun had an organisational structure, which included a managing director who was supported by an operations manager and a clinical quality manager. This was in addition to financial, commercial and human

- resource's divisions within the company. Each dialysis unit had a registered manager, who was supported by the operations manager, the clinical quality manager and a practice development nurse. The operations manager was present during our inspection. They knew the unit well and it was evident that they visited the unit regularly.
- Nursing staff confirmed that the unit manager was approachable and responded positively to any contact and always spoke with patients when they visited the centre. However, some staff said they rarely saw some of the very senior managers.
- We saw that locally senior nursing staff held or were working towards specialist renal nurse qualifications, held teaching certificates and had completed management courses.
- Locally, the manager showed good leadership and most staff told us that they were a good role model for the nursing team and worked above and beyond expectations.
- All staff reported that the manager was approachable and responsive to any needs, whether that was for assistance with clinical practice or personal support. The unit manager was contracted to work 50% of their time clinically, which they consistently managed to do.
- All staff felt valued and told us that they enjoyed working at the centre. One nurse told us that they had left a large acute trust to work at the unit, and believed the staff carried out good work, and enjoyed developing comradery with patients.
- Throughout the inspection, we saw that staff assisted each other with tasks and responded quickly to service needs. For example, we saw that nursing staff shared patient activity across the unit and were not just looking after their designated patients. For example, we saw that nursing staff helped each other when two co-located patients completed treatment simultaneously.
- Staff had effective working relationships with the nearby NHS hospital. This was confirmed by feedback from the consultant nephrologist. Staff were friendly, knowledgeable and experienced and had processes to support safe delivery of care.
- The organisation obtained an accreditation with 'Investors in People' in 2016 at level two (Silver Award). This accreditation is awarded to organisations who meet their standards for people management. The

organisation was given a list of seven recommendations for continuous improvement. These included: simplifying communication around organisational values and to work with employees to do so, clarity around what high performance looked like and encourage employees to engage and come up with new ideas.

#### Vision and strategy for this core service

- B.Braun's corporate vision was commitment to provide safe patient care and to engage with local communities. In addition, they wanted to reward and recognise good staff. The company had a strategic vision of how to achieve this. It focussed on four elements: clinical care, multidisciplinary working, the importance of additional support for patients and their families outside of the dialysis centre and to have robust governance processes. The company had a strategy to support positive staff experiences. This strategy focussed on four 'P's: prioritize people, practice effectively, preserve safety and to promote professionalism and trust. The corporate contract was reviewed and renewed every five years. Corporate managers oversaw the contracts and held the organisational overview of performances in different localities.
- Staff were aware of their role and responsibilities in providing effective and safe care to all patients. Staff spoke positively about providing safe care in the local area but we did not see the vision or strategy displayed in any of the clinical or staff spaces. However, there was varied awareness about organisational or local vision and strategy amongst the staff we spoke to.
- Progress against delivering the strategy monitored and reviewed using a monthly operational report management plan and a key performance indicator report, which helped staff assess the quality of treatment received by patients.

### Governance, risk management and quality measurement

 There was a governance framework to support the delivery of the strategy and good quality care. Quality assurance was monitored at corporate level through regular audits. The registered manager completed an operational report management plan every month, which was sent to the head office. The management plan was set up as a dashboard and held information for example about key performance indicators, adverse

- patient occurrences and staffing. There were monthly operational management meetings where these were discussed. Recent minutes from April 2017 included discussion around the development of a sepsis 6 information sheet and road closures around another B.Braun unit that may affect accessibility.
- There was a strategy to deliver safe care and treatment to patients. This was underpinned by evidence-based standing operating procedures (SOPs) and policies to provide guidance. Staff were aware of these and how to access them electronically, however, in two out of the four training files we looked at, we saw front sheets for staff to sign to indicate they had read a policy update. One policy had been updated three times, and in January 2017 seven out of 12 staff had not signed the front sheet, March 2017 seven out of 12 staff and May 2017 10 out of 12 staff had not signed the front sheet. The registered manager told us these front sheets were not policy updates, but were in fact a record of basic life support training, however the sheets made no reference to this.
- There was a monthly patient review meeting with the supervising NHS trust, attended by relevant staff from the NHS hospital, the operations manager and the registered manager. B.Braun staff presented information about each patient and discussions were held about changes to treatments if appropriate.. The registered manager did not hold any minutes of these meetings and were not sure if minutes were taken. We requested minutes from this meeting and were shown handwritten grids documenting decisions and reviews for each patient. This meant that we were not assured that there was effective communication to identify opportunities for service improvement. We did not see any evidence of action points to improve service provision or evaluation of if these had been completed.
- There were not effective processes to feedback from quality meetings and contract reviews to all staff. There were monthly staff meetings, which were minuted. The minutes demonstrated that there was a set agenda, which included 'quality management'. However, the minutes reflected that staff were given updates and reminders about operational changes. The minutes did not demonstrate any discussion about patient safety, patient outcomes or adverse patient occurrences. This meant that we were not assured if lessons were learnt and shared from incidents or when key performance indicators were not met.

- There were processes to ensure a systematic approach
  to auditing and monitoring. There was a list of dates for
  registered managers to submit reports to the corporate
  operations manager. These reports included the
  monthly management plan, information about
  treatment time and adequacy analysis, treatment start
  times, staff rotas and management of consumables.
  However, we were not clear how this information was
  used or if feedback was given to the registered manager
  and staff at the unit.
- There were not effective processes to manage risks. The service had a list of local risk assessments and there was a corporate document named 'health and safety risk register'. However, both of these were lists of risk assessments undertaken and did not specifically identify current clinical and operational risks. For example, we asked if the ongoing patient transport delays had been placed on the risk register, but it had not identified as a risk to patient care. The risk assessments included for example general risk assessments associated with taking blood samples. The risks were 'RAG' rated (rated red, amber or green according to the level of risk) but there were no dates of when these had been undertaken. Therefore, this was not a current and 'live' risk register and we were not assured that risk management systems were robust.
- There was some alignment between the recorded risks and what people said was 'on their worry list'. Transport was high on the list for most nurses, however this had not been formally captured as a risk to patient safety or quality of treatment. Data was being collected and shared with both the supervising NHS trust and transport provider, although it was not clear what this data was being used for.

#### **Public and staff engagement**

- The service gathered the views of patients via the annual patient survey. There was also a box in the waiting area where patients or their relatives could submit their views about the service or suggest improvements to the unit. Patients told us they always felt welcomed and respected. Staff were friendly, professional and listened if they had concerns, ideas or suggestions.
- The unit held a patient forum meeting every six months that was minuted, and shared with all staff to keep them

- informed of issues raised by patients. The most recent meeting minutes were circulated, and we saw a front sheet signed by staff to acknowledge they had read the minutes.
- Patients and their relatives, we spoke with, felt engaged and involved in decision-making. However, this was not reflected in the patient survey 2016. The service had identified an action to ask all patients and their relatives which aspects of their care they would like to be involved in. Staff were not aware of any feedback from this and of any changes to how care and treatment was delivered to ensure patient involvement.
- Patients told us they were encouraged to complete a patient satisfaction questionnaire every year, and senior staff told us the results helped them formulate an action plan. Previous issues raised and resolved included the installation of Wi-Fi and provision of food, by the hospital kitchen, for early morning patients.
- Staff and patients felt actively engaged so that their views were reflected in the planning and delivery of services. A specialist commissioner had recently been invited by the unit to speak to patients at a forum meeting. There had been a number of delays in finalising the unit's current contract, and the commissioner was able to explain the delays and reasons to the patients, to help allay any uncertainty around the future of the unit.
- An employee forum met guarterly which provided a link between senior management and frontline staff. Operational and quality updates were shared in the forum meetings and representatives acted as advocates for the staff group, putting forward their own agenda of items they wished to discuss. Minutes from these meetings were then distributed to the staff group. The managing director (MD) and human resources department also held road shows, visiting all units to engage with staff. These gave the opportunity for all staff members to receive information about the business and raise any issues with the MD. One issue resolved through these road shows was the variance in shift patterns across the different B.Braun run sites. Shifts had been standardised to long and short days in line with staff wishes.

#### Innovation, improvement and sustainability

 B.Braun was working towards an accreditation for a senior healthcare assistant role but did not offer skills and competencies for dialysis provision. Healthcare

38

assistant staff could undertake the qualifications and credit framework level three in health and social care, in order to achieve an accreditation for dialysis skills, with conversion to a dialysis support worker (DSW) role, which would be able to dialyse patients under the direct supervision of a qualified nurse, but no medications would be administered.

- The service had plans for a phased replacement of older haemodialysis machines to ensure these were replaced every ten years as recommended by the Renal Association guidelines and manufacturer's recommendations, although the unit manager said these plans had not been finalised as the contract would be up for renewal before the ten-year life spans of the machines. Instead, B.Braun held a stock of used machines that were still within their working lives, which could be sent out to the unit if needed.
- Staff were focused on continually improving the quality of care, and one nurse's improvements to patient

- leaflets had been given an award for innovation by head office. The leaflets were currently under review to assess if they were going to be rolled out across other B.Braun units.
- There were processes and initiatives in place for green nephrology and sustainability that monitored water, electricity and the number of waste bags disposed of. However, the unit manager was unsure what happened to this data.
- Staff told us there were opportunities for development and the unit had a training budget. The unit manager told us staff came to her with suggestions for training, and if they could justify why it would be beneficial to the unit, they would approve funding. Staff had also recently attended a three-day British Renal Society conference as part of their training and preparation for revalidation.

# Outstanding practice and areas for improvement

#### **Outstanding practice**

- The service had arranged for specialist commissioners to meet patients at their regular patient forum meeting to explain the contract and tender renewal processes and help allay patient fears.
- The unit used a subjective global assessment (SGA) tool to identify patients at risk of malnutrition that included actions if patients were identified as being at risk.
- Staff took a holistic approach when giving new patients information that showed empathy towards the impact it would have on the patient's social, personal and professional aspects of life.
- Staff used a formal name badge system for patients who received blood transfusions whilst on the unit, to ensure their safety when administering cross-matched blood and blood products.

#### **Areas for improvement**

#### **Action the provider MUST take to improve**

- The service must develop a sepsis policy/standing operating procedure to ensure potential sepsis is identified and treated in a timely manner.
- The service must improve governance processes to ensure information, actions for improvement and learning is documented and shared efficiently.
- The services must review their risk management processes to ensure current risks are identified and acted upon.

#### Action the provider SHOULD take to improve

 The service should ensure patients are given the option to hold discussions around their care and treatment in a more private setting.

- The service should ensure patients have awareness of all types of pain relief available to them at the beginning and throughout their treatment.
- The service should ensure visiting staff understand their role and responsibilities whilst working on the unit.
- The service should ensure all staff are up to date with their mandatory training and ensure accurate up to date records are held to reflect this.
- The service should ensure staff receive feedback from incidents reported.
- The service should ensure all staff are up to date with safeguarding training.

### 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
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment  Regulation 12(2)(a)  Assessing the risks to the health and safety of service users of receiving care and treatment;
	<ul> <li>How the regulation was not met:</li> <li>The service did not have a sepsis policy or pathway to ensure patients with potential sepsis were identified and treated in a timely manner. Treating sepsis in patients receiving dialysis may differ from usual management intervention.</li> </ul>

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance
	Regulation 17(2)(a)
	Assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of the services users in receiving those services;
	How the regulation was not met:
	<ul> <li>The service did not demonstrate if actions from patient reviews were identified and actioned to improve the delivery of dialysis treatment.</li> </ul>
	Regulation 17(2)(b)

This section is primarily information for the provider

### Requirement notices

Assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity;

How the regulation was not met:

The service did not have a risk register, which meant we could not be assured all current clinical and operational risks were assessed, monitored and actioned to mitigate risks.