Blackburn Dialysis Unit

Quality Report

Royal Blackburn Hospital
Haslingden Road
Blackburn BB2 3HH
Tel: 01254 736545
Website: www.freseniusmedicalcare.co.uk

Date of inspection visit: 26 April 2017
Date of publication: 22/09/2017

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

Blackburn Dialysis Unit is operated by Fresenius Medical Care Renal Service Limited. It has been operating since April 2013. Patients are referred by their local trust to the specialist renal and dialysis services provided by Lancashire Teaching Hospitals NHS Foundation Trust, the service's commissioning trust. The unit functions as a satellite unit for the dialysis services provided by the commissioning trust, and treats patients in the Blackburn and Accrington areas.

The unit is a nurse led unit, comprising of a manager, deputy manager, a team leader and three registered nurses. The manager, deputy manager and team leader also provided clinical care. It has six haemodialysis stations and provides three treatment sessions per station per day (108 sessions per week). The unit is temporarily housed in a suite of portacabins in the grounds of the Royal Blackburn Teaching Hospital. Facilities include a patient waiting area with a disabled access toilet, a patient treatment and weighing area, office, clean utility, waste utility, staff changing room and kitchen, storeroom, and water treatment plant.

The unit provides haemodialysis treatment to adults aged 18 years and over, who have non-complex needs. Currently the unit provides treatment to 13 patients between the ages of 18 and 65 (2885 sessions between February 2016 and January 2017) and to 23 patients aged over 65 years (2733 sessions in the same period). The unit does not support patients on home treatment.

We inspected this unit using our comprehensive inspection methodology. We carried out the announced part of the inspection on 26 April 2017, along with an unannounced visit on 8 May 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.

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:

- There were reliable systems and processes in place to keep patients safe. These included staff training,

Summary of findings

incident reporting, infection prevention and control, water quality monitoring and treatment, disinfection and maintenance of equipment, and screening procedures for blood borne viruses.

- The unit's layout, and staff use of equipment including prompt response to machine alarms, kept people safe. Patient records were managed appropriately. Medicines were stored and managed safely. Staff followed the provider's medicines management policy, and a process was in place for review of patient medicines by the medical team when required.
- Patients were assessed for suitability for treatment to ensure the service was able to accommodate their care needs. The multidisciplinary team reviewed individual treatment prescriptions monthly. Patients' vascular access sites were regularly monitored.
- Patients were assessed for risk of deterioration and processes were in place to request urgent medical assessment or resuscitation. Dietitians provided advice monthly to each patient, and there was access to psychological and social work support if needed.
- Staff rarely cared for patients with dementia or learning disabilities, but staff received training in and were aware of the principles of the Mental Capacity Act and the Deprivation of Liberty Safeguards.
- Appointment slots were allocated to patients taking into account their individual needs and staff worked to accommodate requests to change appointments as required. Staff supported patients to go on holiday through co-ordinating care at other clinics in the UK, Europe and other countries.
- Care and treatment was evidence based in line with appropriate guidance. Staff were competent to provide the right care and treatment, and competencies were regularly reviewed. New staff were supported through an induction and mentoring programme.
- There were no written complaints in the reporting period; but there was evidence of shared learning from complaints and incidents that occurred in the provider's other clinics.
- A named nurse for each patient helped to ensure continuity of care. The annual patient survey indicated patients felt staff were caring, treated them with dignity, and explained things in a way they could understand.
- Staff supported families who were bereaved and ensured attendance at patient funerals.
- A clear management and reporting structure was in place. The clinic manager and deputy manager had the appropriate skills, knowledge, and experience to lead and engage effectively with their staff and patients.
- The unit's clinical governance strategy supported the provider's strategic aims; effectiveness against this was monitored through clinical and governance benchmarking audits.

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

- Access to the treatment area was secure; however, there was unlocked access to the clean and waste utilities, the water plant and staff rooms.
- There were sufficient staff to care for patients; however, the unit reported a high number of shifts covered by bank or agency staff. This was due to staff sickness and one nurse vacancy.
- We were concerned that not enough was done to adequately communicate with those whose first language was not English. For example, although the patient guide was available in Punjabi, Urdu and Hindi and staff had access to telephone interpreter services, one staff member told us that sometimes 'hand gestures' were used to communicate with patients who did not speak English. The unit did not have access to information in other formats such as easy-read or braille.
- The risk register, which identified clinical, operational and technical risks, had only recently been introduced and did not include details such as who was responsible for managing each individual risk.

Following this inspection, we told the provider that it should make improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals North

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
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.

Summary of findings

Contents

Blackburn Dialysis Unit

Services we looked at
Dialysis Services

Summary of this inspection

Background to Blackburn Dialysis Unit

The Blackburn Dialysis Unit has been operated by Fresenius Medical Care Renal Service Limited since April 2013. It is a privately operated satellite unit to provide haemodialysis (dialysis) services commissioned by a renal specialist trust. It primarily serves the communities of Blackburn and Accrington, and it will accept holidaying patients when capacity permits. The unit is located in the grounds of the host trust.

The current registered manager (also the clinic manager) has been in post since December 2016.

We last inspected this unit in October 2013. The unit met all the essential standards of quality and safety inspected and did not identify any areas of concern or areas that required improvement.

Our inspection team

The team that inspected the unit comprised a CQC lead inspector and one other CQC inspector. The inspection team was overseen by an Inspection Manager.

Information about Blackburn Dialysis Unit

The Blackburn Dialysis Unit is operated by Fresenius Medical Care Renal Service Limited. It is a six 'station' mixed gender dialysis treatment unit and is registered to provide the following regulated activity to patients over the age of 18 years:

- Treatment of disease, disorder, or injury.

The commissioning trust provides the multi-disciplinary team, including the consultant nephrologist, who support the unit in providing the dialysis service. It primarily serves communities in and around East Lancashire.

The unit is situated in a standalone building on the grounds of the local NHS hospital in Blackburn. Dialysis is provided for patients six days a week from Monday to Saturday. There are no overnight facilities. Three dialysis sessions run each day starting at 7am, 1pm and 6pm.

The unit has six treatment stations offering haemodialysis but not peritoneal dialysis. Home dialysis services are not provided by staff at this unit.

Access to the unit is outside with car parking for two cars. An additional carpark serving the hospital's main site is located a short walk away. Entry to the reception and waiting area is via a secure door bell.

The main referring unit is the specialist renal centre based at the commissioning trust, which provides an associate specialist (doctor) who visits each week.

There are six registered nurses (three of which held renal dialysis qualifications) employed by the unit. No healthcare assistants or dialysis technicians were employed.

Between February 2016 and January 2017 the unit provided 5618 session to adult patients with an average of 480 sessions provided each month. All of these treatments were NHS funded. Services are not provided to children or young people under the age of 18 years. Currently, 36 patients receive dialysis treatment at the unit.

During the inspection, we spoke with six staff including; the area head nurse, the clinic manager, the deputy clinic manager, the team leader and two registered nurses. We spoke with four patients. We also received 19 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed six sets of patient paper and electronic records.

There were no special reviews or investigations of the unit ongoing by the CQC at any time during the 12 months

Summary of this inspection

before this inspection. The most recent inspection took place in October 2013, which found that the unit was meeting all standards of quality and safety it was inspected against.

- Between February 2016 and January 2017 there were no reported patient deaths, never events or serious incidents.
- No incidents occurred which triggered the Duty of Candour process.
- One patient fall was reported.
- There were no reports of pressure ulcers, urinary tract infections or venous thrombo-embolism (VTE).
- There were no cases of methicillin-resistant staphylococcus aureus (MRSA), blood borne virus, Clostridium Difficile (C.Diff) or other bacteraemia reported as having occurred in the service. However two cases of methicillin-sensitive staphylococcus aureus (MSSA) were identified by staff.
- No complaints were received within this time period.

Services accredited by a national body:

- ISO 9001 accreditation for the integrated management systems.
- OHSAS 18001 accreditation for the health and safety management system.

Services provided at the unit under service level agreement:

- Clinical and non-clinical waste removal
- Interpreting services
- Pathology
- Fire safety
- Water Supply
- Building maintenance

Summary of this inspection

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. However, we found the following areas of good practice:

- An incident reporting procedure in place, which staff were aware of and used; however, there were no serious incidents in the reporting period.
- There were reliable systems and processes in place for staff training, infection prevention and control, water quality monitoring and treatment, disinfection and maintenance of equipment, and screening procedures for blood borne viruses.
- The unit was housed in a suite of temporary portacabins; however, its layout and staff use of equipment, including prompt response to machine alarms, kept people safe.
- The minimal medicines held were stored, labelled, and administered appropriately. Staff followed the provider's medicines management policy, and a process was in place for review of patient medicines by the medical team when required.
- Patient electronic and paper records were managed appropriately, and regular record audits were undertaken with actions taken to address issues as required.
- Patients were assessed for risk before, during and after treatment and processes were in place for requesting urgent medical assessment of patients, or resuscitation if needed. The unit did not have an isolation room but staff were aware of processes to follow for screening patients with infection and blood borne viruses.
- Staff were aware of the major incident plan, and undertook regular evacuation exercises to maintain their knowledge.

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

- Access to the unit and the treatment area was by secure doors; however, there was unlocked access to the ancillary areas including the clean room and waste room, storage and utility, water plant and staff rooms.
- There were sufficient staff with an appropriate skill mix to care for patients at the time of the inspection; however, the unit reported a high number of shifts covered by bank or agency staff. This was due to staff sickness and one nurse vacancy.

Summary of this inspection

Are services effective?

We do not currently have a legal duty to rate dialysis services. However, we found the following areas of good practice:

- Care and treatment was evidence based and provided in line with the provider's Nephrocare Standard Good Dialysis Care. The policies and procedures took into account professional guidelines, including the Renal Association Guidelines and research information.
- Data relating to treatment performance was submitted to the commissioning trust for inclusion in the renal registry, and the service was benchmarked against the provider's other units across the country.
- Patients' had individualised treatment prescriptions that were reviewed monthly by the multidisciplinary team, which included the renal consultant, associate specialist in renal medicine, dietitian and the clinic manager. There was access to psychological and social work support if needed.
- Patient's vascular access sites were regularly monitored, and patients were appropriately assessed before, during, and after dialysis.
- Patient's nutrition and hydration needs were monitored, and the dietitian provided face to face advice every month to each patient.
- Staff were competent to provide the care and treatment patients' required. A competency programme was in place and regularly reviewed. New staff were supported through an induction and mentoring programme.
- All staff were trained in basic life support, with four senior nurses trained in immediate life support. A service level agreement was in place with the host trust for emergency resuscitation care.
- A process was in place to check patient identification and staff had access to the information they needed to provide good care to patient.
- The unit rarely cared for patients with dementia or learning disabilities; however, staff received training in and were aware of the principles of the Mental Capacity Act and the Deprivation of Liberty Safeguards (DoLS).

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

- Permanent staff reflected to us that they had little time to undertake mandatory training or development during working hours.

Summary of this inspection

Are services caring?

We do not currently have a legal duty to rate dialysis services. However, we found the following areas of good practice:

- A named nurse for each patient helped to ensure continuity of care. All patients we spoke with knew who their named nurse was.
- We observed staff interacting with patients in a compassionate and caring manner. This was reflected in comments made to us by patients during the inspection and in comment cards completed by patients.
- The annual patient survey indicated patients felt staff were caring, treated them with dignity, and explained things in a way they could understand. A patient guide was given to each patient, which included a range of helpful information about dialysis care and external sources of information.
- Staff understood the importance of building a strong and friendly rapport with patients, and the unit supported staff to provide care in line with the 6 Cs of nursing.
- Staff supported families who were bereaved and ensured attendance at patient funerals.
- Staff supported patients to go on holiday through co-ordinating care at clinics abroad.

Are services responsive?

We do not currently have a legal duty to rate dialysis services. However, we found the following areas of good practice:

- The service specification was defined and agreed with the commissioning trust to meet the need of local people, and took into account the trust's policies.
- The unit met the department of health's Health Building Note 07-01: Satellite Dialysis Unit guideline.
- The unit was accessible with designated patient parking, access ramps, and secure but automatic doors. Arrangements were in place for patient transport and there was a positive relationship with the local taxi firm contracted by the patient transport service provider.
- The patient guide was available in Punjabi, Urdu and Hindi and staff had access to telephone interpreter services provided through the commissioning trust. One staff member had skills to help translate if needed.
- Patients were assessed for suitability for treatment to ensure staff were able to accommodate their care needs in a safe and effective way.

Summary of this inspection

- The unit opened six days a week and provided 108 individual treatment slots per week, and accommodated requests for holidaying patients where slots were available.
- Appointment slots were allocated to patients taking into account their individual needs and, although flexibility was limited due to the small size of the unit, staff worked to accommodate requests to change appointments as required.
- There were no written complaints in the reporting period; however, we saw evidence of shared learning from complaints and incidents that occurred in the provider's other clinics.

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

- We were not assured the service was doing everything possible to reduce the risk associated with language diversity. One staff member told us that sometimes 'hand gestures' were used to communicate with patients who did not speak English. The unit did not have access to information in other formats such as easy-read or braille.

Are services well-led?

We do not currently have a legal duty to rate dialysis services. However, we found the following areas of good practice:

- There was a clearly defined management and reporting structure. The clinic manager and deputy manager had the appropriate skills, knowledge, and experience to lead effectively.
- The provider had a clear strategy and vision, which was supported by a set of core values. Staff were aware of these although they were unable to discuss them in detail.
- The unit had a clinical governance strategy document, which supports the provider's strategic aims. Effectiveness against the strategy was monitored through monthly benchmarking audits.
- A clinic audit programme was in place.
- The unit held a risk register, which identified clinical, operational, and technical risks, scoring each appropriately to determine the impact and likelihood with mitigation actions identified.
- The service scored highly on both the employee and patient national surveys, and both groups appeared to be engaged with the unit and the care and treatment provided.

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

Summary of this inspection

- The risk register was very new and some details were missing. For example, the register named the person who had identified each risk but not all risks had been assigned an owner to take responsibility for managing them.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

- The provider had a clinical incident reporting policy, which set out staff responsibilities, definitions of clinical and serious incidents including near misses, and the provider's clinical incident reporting requirements and timescales. The policy detailed the provider's external reporting requirements, including to the CQC, coroner, police, local safeguarding boards, and Public Health England. It also set out specific reporting requirements for a range of incident types such as, but not limited to cardiac arrest, medical device incidents, medicines errors, safeguarding, and seroconversion. Staff we spoke with were aware of the policy requirements, how to report incidents, and the escalation process. No serious incidents or patient deaths were reported between February 2016 and January 2017.
- The unit had no never events between February 2016 and January 2017. A never event is a serious, wholly preventable patient safety incident that has the potential to cause serious patient harm or death, has occurred in the past and is easily recognisable and clearly defined.
- There were no reported incidents of pressure ulcers, urinary tract infections, or hospital acquired venous thromboembolism (blood clots) for the same period. However, one fall was reported during this time. We reviewed the incident report for this fall, which identified the cause of the controlled fall, the impact on the patient, and the likelihood of a recurrence.The overall risk rating score for the incident was calculated, and actions were taken by staff to increase observation of patients in order to minimise the risk of a similar event occurring in the future. The incident report was reviewed and signed off by the clinic manager and the corporate health and safety officer.
- There were no incidents within the unit that required statutory notification to CQC within the same period. However, the unit had three clinical incidents; one needle dislodgement, one central venous catheter disconnection, and one medicine error.
- All staff had access to the incident reporting system. Staff were aware of the type of incidents that should be reported, including near miss incidents. The 2016 staff survey showed that all staff who had last witnessed an incident or near miss that could have caused harm to staff or patients either reported it, or witnessed a colleague report it.
- Incidents were discussed with the clinic manager before the incident report was forwarded to the provider's central clinical incident reporting team; the area head nurse was also informed. The reporting team graded and investigated each incident, and developed appropriate action plans to address any issues. Any incidents involving the death of a patient were referred to the executive board for review and sign-off.
- All staff we spoke to told us that learning from incidents within the unit were discussed with any individuals involved and in monthly staff meetings. Lessons learnt from clinical incidents, serious incidents and safety alerts from all the provider's clinics were also shared through colleague update bulletins, and within staff meetings. The clinic manager was responsible for reviewing each update to check if it applied to the unit. Staff were required to

sign to confirm they had received and read the relevant update bulletins.We viewed copies of the sign-off sheets for a range of updates, which confirmed compliance with this process.

- Learning was also shared with the provider's clinics through quarterly regional clinic managers' meetings. The clinic manager also attended, and shared information with staff from, the bi-annual Nephrocare conference.
- Two staff members shared an example of an update relating to a change in the type of closure cap used with central venous catheters to prevent leakage from the catheter.
- The duty of candour is a regulatory duty that relates to openness and transparency and requires the organisation to notify the relevant person that an incident has occurred, provide reasonable support to the relevant person in relation to the incident and offer an apology.
- The unit reported no incidents of moderate or severe harm or death between February 2016 and January 2017 that triggered the duty of candour. The duty of candour was referred to in the clinical incident reporting policy and in the being open and duty of candour policy.
- Senior staff were aware of the legislative requirements of the duty. Operational nursing staff we asked were able to describe the principles of the duty of being open and honest following incidents where moderate or severe harm or death had occurred.

Mandatory training

- Mandatory training was delivered through a mix of classroom and online training. A training matrix was held which identified which groups of staff required training for each module. The training matrix was updated every three months, and was overseen by the area head nurse. The clinic manager had the flexibility to train additional staff in a subject area not identified as applicable to their group.
- Mandatory training for staff included a range of subjects mandated by legislation and by the provider such as, but not limited to, the NephroCare Standard good dialysis care; basic life support and use of the automated external defibrillator; safeguarding adults; infection prevention and control; hand hygiene; practical moving and handling; and, fire safety.
- The mandatory training rates for the unit were high. At the time of the inspection, staff had completed 93% of mandatory training modules. This figure reflected one staff member who was on a long-term absence and one module of training on data security that all staff members had yet to complete. Dates were scheduled for staff to attend training that had not yet been completed.
- Bank staff were supplied from the provider's in-house flexi bank directorate. Mandatory training for bank staff was monitored by the flexi bank administrators who held the training records centrally. Where training had lapsed, bank staff were suspended from shift allocation until proof of mandatory training completion was provided. This meant senior managers at the unit were assured that bank staff had completed all relevant mandatory training before arriving on site.

Safeguarding

- The unit only provided treatment to patients aged 18 and above.
- Staff were aware of the provider's safeguarding adults and children policy.
- Safeguarding vulnerable adults training formed part of the mandatory training programme for all staff. As patients in the unit rarely had visitors or carers in attendance during treatment, training on safeguarding vulnerable children was offered to level one.
- At the time of the inspection, all staff members but one had completed safeguarding adults level two training and safeguarding children level one training. The remaining staff member had not completed this due to long-term absence. Staff had contact details for the local safeguarding adults and children's boards to obtain further advice, and an electronic link to the pan Lancashire and Cumbria Safeguarding Adults Boards Procedures Manual was available on the unit's computers.
- The clinic manager was the safeguarding lead for the unit. At the time of the inspection, the manager was

not aware if they had received additional training beyond that provided to all staff. However, following the inspection, the manager completed level three safeguarding adults training provided by the local safeguarding adults board.

Cleanliness, infection control and hygiene

- We observed all areas of the unit including the waiting and treatment and clinical areas, staff and ancillary areas. All areas were visibly clean. We reviewed the cleaning rotas for April 2017, which had been completed and signed daily by the housekeeping staff each day the clinic was open. A cleaning audit was carried out in February 2017 that indicated 97.7% compliance with cleaning standards. Patients also commented to us on the cleanliness of the unit.
- We observed staff carrying out their duties in line with the infection prevention and control requirements set out in the provider's Nephrocare hygiene plan.
- Staff wore appropriate personal protective equipment, such as aprons, gloves and visors when cleaning the equipment, and when undertaking the insertion and removal of dialysis needles. Each staff member had their own visor and wore disposable paper uniforms, which could be easily removed if contaminated. This reduced the risk of cross contamination between patients.
- We observed staff following hand hygiene protocols, including 'arms bare below the elbows', in line with the organisation's Nephrocare Standard Hygiene and Infection Control policy. One patient comment card, received during the inspection said, "Each time they see a patient, they wash their hands and gel." Posters explaining the World Health Organisation's 5 Moments of Hand Hygiene were also displayed which helped make sure patients, staff and visitors adopted effective hand washing techniques.
- Antibacterial gel dispensers were located in the waiting room, throughout the treatment area, and at each patient chair. Hand washing facilities were also located in the waiting and treatment areas with clear instructions displayed on the correct hand washing techniques.
- We observed that patients were given gloves to wear during the process of removing the needles, which reduced the risk of infection at the exit site.
- Between January 2016 and December 2016, the unit achieved an average of 95% compliance with hand hygiene procedures. This average dropped to 90% compliance in the first four months of 2017; however, it remained well above the unit's target of 80% compliance. However, clear action plans were recorded monthly and staff were informed of any areas of non-compliance
- A full infection prevention and control audit was carried out each month. This looked at a range of risks in all areas of the unit, including the treatment area, staff areas, toilets, staff practice, and cleaning staff duties. Between January 2016 and December 2016, the unit achieved an average of 98% compliance. In the first four months of 2017, average compliance had increased to 99%.
- The unit did not have an isolation facility. This meant that patient with identifiable infections were not treated at the unit. However, the provider's Nephrocare standard hygiene and infection control policy process set out the steps to be taken to minimise the risk of infection from blood borne viruses such as hepatitis B and C, and HIV, and from bacteriological infections such as methicillin-resistant staphylococcus aureus (MRSA) and methicillin-sensitive staphylococcus aureus (MSSA).
- Patients were screened quarterly for hepatitis B and C and annually for HIV in line with the policy requirements. Patients who had hepatitis C that was under control were checked every three months. Patients with active infections were referred back to the commissioning trust's unit.
- Staff received hepatitis B immunisation, which reduced the risk of staff contracting the infection.
- Patients were screened for MRSA/MSSA every three months. Staff told us that if there was more than one positive result, this was investigated to understand if there might be a particular cause, for example if the patients were treated in the same chair or were in chairs next to each other.

- The unit reported two MSSA skin colonisations in 2016. These were for the same patient, where it was determined the colonisation was localised to an area under a patient's dressing at the central venous catheter site. This meant there was minimal risk to other patients in the unit. Staff initially identified the infection as a result of redness to the patient's skin. The patient was treated with body wash, topical ointment and antibiotics in line with the provider's policy and pathway on the treatment and eradication of MSSA infection. The clinic manager told us a separate pathway was in place for MSSA nasal infections.
- Existing patients returning from holiday in the UK or Europe were able to resume their treatment at the unit. However, patients returning from holiday in countries outside the UK and Europe were referred back to the commissioning trust for a period of three months to ensure any risk of infection was minimised. These patients were screened for infection prior to return to the unit.
- Records were in place to indicate that daily checks were carried out between January and May 2017 on the unit's water system with samples taken appropriately. These checks included, although was not limited to, the daily levels of chlorine in the water, the raw water pressures and the filtrated water pressures.
- We also saw several examples of the water treatment plant service reports for 2015 to 2016. Microbiology samples were taken monthly between January and April 2017. The records showed that staff immediately reported increased levels of endotoxins in a sample taken in early April 2017. Samples were subsequently taken to confirm the effectiveness of the disinfection procedure before recommencing the supply.
- The unit held sufficient supplies of saline to be used as a fall-back for online haemodiafiltration if the main water supply was interrupted.
- The unit also held certificates for chemical analysis of the water from May, August and November 2016 and February 2017.
- A legionella risk assessment was carried out on 6 April 2017. The overall risk score indicated the unit was at high risk and a remedial action plan was recommended. However, the report recognised that given the susceptibility of the patients in the unit, it was unlikely the overall risk would reduce to below medium risk even if the remedial action plan was completed in full. Following the inspection we were informed a meeting had been undertaken in June 2017 to discuss and put into place the actions required to meet the plan. This work was ongoing.
- Weekly flushing of all taps in the unit was carried out. This reduced the risk of development of bacterial infections in water supplying sinks in the unit. We viewed the log, which confirmed the flushing had been carried out weekly between January 2017 and April 2017.

Environment and equipment

- The unit was located in a suite of well-maintained portacabins in the grounds of the host trust. This was a temporary measure until a permanent site was identified and built. A business case was in progress, and planning permission had been received for a new site at the time of the inspection; however, staff were unaware of the timescales for moving the unit to the new site.
- Access to the unit and to the treatment area was via secure automatically locked doors. However, the remaining staff areas were accessed via an unlocked door at the end of the treatment area. On the day of the inspection, none of the rooms in this area were locked; this included the water treatment room, the clean and waste utilities, the store room, and staff kitchen. In most cases only staff or patients were permitted within the treatment area and one staff member was required to be present in the treatment area at all times. However, this meant there remained a small risk that a patient or other unauthorised person could potentially access all the rooms in this area including equipment stored within them.
- The water plant room met the building notes requirements; however, there was no separate maintenance room and, as such, the unit's spare dialysis machine was stored within the water plant room. However, there was no impact to patient safety as a result of this.
- A resuscitation trolley was located within the treatment area. The trolley was owned, supplied, and

stocked by the host trust, who held a service level agreement with the unit to respond to cardiac arrest emergencies via the bleep call system. This meant staff attending the unit in an emergency situation were able to quickly locate the emergency equipment needed. The trolley was sealed with tamper tags, which were replaced after the trolley had been opened; a tamper tag identification log was held and completed appropriately.

- A registered nurse checked the equipment on top of the resuscitation trolley and oxygen cylinder daily; the whole trolley is checked weekly as per trust policy. We reviewed the check logs, which confirmed full checks had been carried out between 13 March 2017 and 26 April 2017. We also checked a range of equipment held in the resuscitation trolley, which was all within the manufacturers' recommended expiry dates. An oxygen cylinder was held with the trolley, and was within the recommended expiry date.
- The defibrillator was checked weekly which included removal and reinsertion of the battery in line with the hospital's policy. We reviewed the check logs, which confirmed the defibrillator checks had been carried out between 17 March 2017 and 24 April 2017.
- The anaphylaxis box was sealed and within expiry date. The team leader told us that pharmacy staff from the host trust replaced the anaphylaxis box when required.
- Since January 2017 facilities management was provided by a dedicated in-house team consisting of a facilities manager and two helpdesk co-ordinators. Contractors were allocated to attend the unit to undertake reactive and planned maintenance work, for example to a blocked toilet or failed lighting, as necessary and according to the priority assigned to the incident. Staff told us the facilities management team and contractors were responsive to requests, particularly when responding to dialysis machine failures. All facilities or contractual staff attending the unit to effect repairs to equipment were required to sign a risk assessment record.
- The unit had a maintenance and calibration schedule and records for each dialysis machine, patient treatment chairs, water treatment and other auxiliary clinical equipment including patient thermometers, blood pressure monitors and weighing scales. The schedule recorded equipment by model and serial number. All records were up to date.
- Dialysis machines, chairs, beds, and the water treatment plant were maintained by the provider's technicians. The remaining additional dialysis equipment was maintained and calibrated under contract with the individual specialist equipment providers. The refrigeration and air conditioning systems had been tested and the relevant certificates were up to date.
- We reviewed the maintenance and calibration records used in the unit. The clinic had seven machines in total; six in use at the treatment chairs with one spare machine. The spare machine was ready for use and stored within the water treatment room. Four of the dialysis machines had undergone maintenance and calibration in January and February 2017. The remaining three machines were scheduled for maintenance and calibration in December2017.
- The unit's dialysis machines were purchased in April 2013 and it was expected these would be replaced in 2020 based on an average running time of 16,000 hours.
- In the event of a patient cardiac arrest or death, a process was in place to take the dialysis machine out of service and to store it until the relevant data could be downloaded from the machine. Any consumables used in the treatment were also retained, labelled and stored for further analysis.
- Equipment within the water treatment room was clearly labelled with the last maintenance check and next maintenance check dates. All the equipment, including the power system, had been checked and maintained during the appropriate dates. The filter last and next change dates were also displayed next to each filter. All the filters had been changed during the appropriate dates.
- Portable equipment was routinely tested in line with the annual testing schedule. A portable appliance test register was held on site was checked as part of the annual health and safety audit. We reviewed the register, which showed that all portable electrical

equipment had been tested, and passed, on 7 April 2017. This was supported by the test record sticker on all the equipment we observed. Testing records were also held at the unit for 2013 to 2015.

- The treatment room was laid out so that staff were able to see all patients. Two of the treatment chairs were located behind a partition wall, which reduced the opportunities for these patients to talk with others in the room. However, all chairs included a nurse call button for patients to alert staff to any needs.
- The dialysis machines sounded audible alarms to alert staff for a range of reasons during treatment such as issues relating to patient movement, leaks, or other changes. We observed staff responding to audible alarms from the dialysis machines in a timely manner. We did not observe alarms being overridden inappropriately. Transparent guards were in place at the front of the machine to reduce the likelihood of the machine being tampered with. The clinic manager told us it was theoretically possible for a patient to override an alarm but we did not observe this occurring.
- We observed staff respond rapidly but calmly to an emergency alarm which had been activated. Alarms were also sounded to alert staff to any self-test failures or other errors.
- Each machine underwent a heat disinfection cycle at the end of each treatment session, which was confirmed by a machine self-test at the end of the cycle. We observed staff cleaning the treatment chairs and associated equipment, and decontaminating each dialysis machine between patient treatments.
- There was sufficient space between the treatment chairs to enable patients to mobilise easily into and out of the chair, and for staff to attend to the patient during treatment or emergencies. This was in line with the Department of Health's Health Building Note 07-01: Satellite Dialysis Unit guideline.
- A disposable curtain was available around each chair to be used to provide privacy for patients if required. All the curtains had been replaced within the previous two months, which reduced infection risk.
- There were two trolleys within the treatment area that held ancillary equipment such as specimen tubes, needles, syringes, dressings and tape. We checked a range of items stored in both trolleys. All items we checked were within the manufacturers' recommended expiry dates.
- Dialysis needles and lines were single use only and were appropriately disposed of as clinical waste after use.
- Sharps boxes were available throughout the treatment area, including on equipment trolleys used by nurses when setting up or attending to patients. All the sharps boxes we observed had the date of construction completed and were part closed when not in use. This meant the risk of injury was reduced.
- Boxes of equipment used for dialysis, such as the single used dialysis needle packs, and citric acid for cleaning of the dialysis machines, were held in the store room on shelving off the floor. All stock was clearly labelled with, and stored by, the received date. This ensured effective stock rotation and meant that the oldest equipment was used first. All equipment we checked within the store room was within the manufacturers' recommended expiry dates.
- Hazardous materials were stored within lockable cupboards in the water treatment plant and in the waste utility. However, we observed two containers of hazardous disinfectant concentrate stored in the open area under the sink in the unlocked waste utility room, along with personal protection gloves. This could potentially pose a safety risk to any personnel who could access the room.
- External disinfection of dialysis machines was carried out with a prepared solution of strong disinfectant. The solution was made up each day from concentrate, using appropriate personal protection. Each batch was recorded by staff on a daily checklist.
- Clinical waste was appropriately segregated, transferred and disposed of through a service level agreement with the host trust in line with the unit's waste separation policy. Logs were kept for the transfer of hazardous and clinical waste, including sharps, to the host trust for disposal. An audit of medical care waste was carried out in January 2017. This indicated that staff were fully compliant, and no recommendations for improvement were identified.

Medicine Management

- The unit had a medicines management policy, which was supported by staff training in the prevention of medicines errors. The clinic manager was responsible for the safe and secure handling of medicines within the unit.
- There was one medicine error reported at the unit in the period May 2016 to April 2017.
- The unit did not administer or store any controlled drugs. Medicines used in the unit that were not required to be refrigerated, were stored in a locked medicines cabinet. The cabinet was located within the temperature controlled store room, which reduced the risk of extremes in temperature affecting the medicines.The room temperature was checked and recorded daily using a maximum/minimum thermometer. We reviewed the logs, which confirmed that daily temperature checks had been carried out.
- Keys for the cabinet were held by the nurse in charge for each shift. This meant the lead for secure handling of medicines varied with each shift; however, the clinic manager assured us this was always a senior member of staff.
- Medicines were organised to ensure the oldest medicine was used first. We checked a sample of four different medicines stored in the cupboard, all of which were within their manufacturers' recommended expiry dates. The unit did not hold oral liquid medicines. An oxygen cylinder stored in the room was also within the recommended expiry date.
- Medicines that required refrigeration were held in a locked fridge in the clean utility room. The maximum and minimum temperature of the fridge was recorded daily on the logs that we checked. The temperatures recorded were within the appropriate temperature ranges. The medicines held were within the manufacturers' recommended expiry dates, and were again stored to ensure that the oldest medicines was used first. Any medicines that passed the recommended expiry date were returned to the host trust's pharmacy for destruction.
- A lockable fridge for the storage of patient blood samples awaiting collection was located within the waste utility room. The fridge maximum and minimum temperatures were recorded. We reviewed the log and there were no instances when these temperatures were exceeded.
- Nursing staff liaised with the NHS pharmacy at the host trust for any general medicines enquiries. Staff were also able to contact the renal pharmacist at the commissioning trust for more advice on specific dialysis medicine. Additional pharmacy support was available from the head of regulatory and pharmacy services at the provider's head office.
- Any medicines needed were prescribed by the patient's consultant nephrologist.The unit did not use non-medical prescribers. A process was in place to fax urgent prescriptions to the unit with the signed hard copy of the prescription forwarded to the unit within 24 hours (or a maximum of 72 hours for bank holidays and weekends. This was in line with the provider's medicines management policy.
- We reviewed medicine prescription and administration cards held in six patient files. These were clearly written out, legible, and including relevant information such as the dose, frequency of administration, prescriber's signature, and checked by signature, and initials of the staff member administering the medicine. We could see that medicines were administered in line with the prescription instructions, and staff carried out appropriate identification of patients prior to administration of medicines.
- The unit held a log for medical safety alerts, which included alerts for medicines. The clinic manager reviewed each alert to determine if it applied to the unit. We saw evidence that relevant alerts were forwarded to staff, who signed to confirm they had received and read the information.
- Staff told us the unit did not hold any medicines that could be administered under a patient group direction. A patient group direction, signed by a doctor and agreed by a pharmacist, enables an authorised nurse to supply or administer prescription-only medicines to patients using their own assessment of patient need, without referring back to a doctor for an individual prescription.

Records

- All staff were trained in the provider's record keeping policy, which included nursing documentation. The area head nurse told us that a new classroom training programme had recently been launched by the provider for new staff on patient assessment and documentation.
- The deputy clinic manager was the unit's information management systems representative, while the team leader was the unit's representative for the in-house computer system.
- The unit used a mixture of electronic and paper records. Paper records were stored in a locked cupboard located in a corridor within the staff only area, and only moved from the cupboard when treatment was being provided.
- Patient's clinical measurements, vital observations and treatment variations before, during and after treatment were recorded and held within the unit's electronic system. This automatically transferred treatment data to the patient's main electronic hospital record at the commissioning trust. This meant the medical team could access the patient's data off-site. Pre dialysis, post connection, mid dialysis and post dialysis observations were also recorded within the patient's paper records. We reviewed six sets of patient paper and electronic records. All six included records of the observation readings for each patient treatment session.
- Patient blood results were held within the commissioning trust's electronic system which nursing and medical staff at the unit had access to. This meant that the consultant and associated specialist in renal medicine were able to access the patient's blood results when required. Staff in the unit highlighted any abnormal results for review by the associated specialist to review weekly.
- All the paper files we viewed were structured and labelled on each page with the patient's identification details. Handwriting was clear and legible and there were no loose sheets.
- The unit carried out a monthly nursing documentation audit of ten per cent of records (approximately four records per month). Any actions arising from the audits were fed back to the individual named nurse for the patient, who signed to confirm completion of the actions.
- We reviewed the audits for January, February and March 2017 with an average compliance rate of 93%. However, there were recurrent omissions to manually document the vascular access assessment. The unit identified this issue predominantly related to bank staff and actions were in place to discuss this with all permanent and bank staff.
- Clinic letters which advised of any changes in patient status, medicines, or referrals were copied to the patient's GP and to the unit. We saw evidence of such letters in all six sets of paper records we reviewed. The patient's named nurse updated the patient's dialysis records with any relevant information that was received.
- The unit had a mandatory process to undertake data confirmation checks on new patient transfer documentation. This was to ensure the information provided was accurate and cross checked between the patient's paper record, the commissioning trust's patient electronic record including the system for blood results, and the provider's patient record system. This meant discrepancies in the patient information and data were identified and rectified as soon as possible.
- Information about patients on holiday who received treatment at the unit was transferred to the unit's electronic record system prior to attendance. This included ensuring any relevant medicines were prescribed and prepared for the patient's arrival at the unit.

Assessing and responding to patient risk

- Staff undertook a detailed assessment of patients prior to commencement of their treatment at the unit. This reviewed each patient's admission form which included their clinical details, primary and renal diagnoses and vascular access type, past medical history, their existing medicines and current prescription and medicine administration chart, special needs or mobility requirements, information relating to activities in daily life, and the patient's emotional and religious needs.

- Patients were already established on dialysis before attending the unit. However, new patients were given an appointment to see the associate specialist in renal medicine at the next scheduled outpatient's clinic usually within two weeks of starting treatment at the unit.
- Patient's weight, temperature, pulse, and blood pressure were checked before dialysis commenced, after the patient had been connected to the dialysis machine, and after dialysis ended. Additional readings were taken during dialysis if clinically required and if the patient requested this. The readings were automatically transferred to the patient's electronic record. We observed patients and staff undertaking these observations.
- Sepsis is a life-threatening illness caused by the body's response to an infection. The unit did not have a policy or training for staff with regards to identification or process for sepsis management, and did not use an early warning score system to help staff identify when patients' conditions are worsening. This was not in line with the NICE guideline (NG51) for recognition, diagnosis, or early management of sepsis. However, flowcharts for the management of suspected infection were displayed prominently in the staff corridor, and in the treatment area.
- Staff we spoke with described that they could be alerted to a patient's deterioration in a number of ways, including machine alarms, the patient alerting staff, and visual signs of deterioration, including signs of inflammation around central venous catheter sites. Staff told us they used clinical observations to determine how well patients were; we saw these were entered into patient records we reviewed.
- Additionally, each dialysis machine allowed staff to pre-programme the frequency of observations to ensure they were completed as regularly as required. Patients also used call bells to alert staff if they were feeling unwell and we saw this process working during our inspection.
- Staff had a good understanding of the process for transferring patients to the host trust's accident and emergency department if a patient's condition deteriorated.
- Intravenous antibiotics could be administered if, following a blood culture, these were prescribed by the on call registrar in the commissioning trust. The unit accepted faxed prescriptions; however, these were followed by a hard-copy written prescription within 24 hours, or a maximum of 72 hours over a weekend or bank holiday. This was in line with the provider's medicines management policy.
- The service was supported under a service level agreement by the emergency resuscitation team from the host trust with transport from the unit to the main hospital arranged by ambulance. The unit undertook regular resuscitation simulation exercises under the supervision of the area head nurse. There had been no instances in the previous twelve months where the resuscitation team had been required to attend the unit.
- Between February 2016 and January 2017, 17 patients were transferred from the clinic to another health care provider. Any issues with patient transport were fed back directly to the transport service responsible by unit staff.
- Each patient had an individual identification card for use with the unit's equipment. Each card was labelled with the patient's name and was inserted to the relevant equipment to identify the patient, for example on the weighing scales and the dialysis machine. Any measurements or other patient information collected by each piece of equipment was stored on the service's computer system and not on the card. This meant that if the card was lost or misplaced, no patient information could be read from the card itself.
- Prior to commencement of dialysis treatment, staff inserted the patient's identification card into the dialysis machine. The machine automatically required the staff member to confirm the name of the patient by pressing the relevant on-screen button. Staff then cross referenced the electronic information record on the machine with the patient's paper session treatment record. In many cases, staff had known their patients for a long time; however, the process followed meant the risk of mis-identifying patients was reduced.

- We saw evidence that patients were appropriately assessed at the start, during and after dialysis to ensure they were fit to commence treatment and following treatment. Vital observations were automatically recorded on the unit's electronic patient record. Staff assured themselves by reviewing the patient's observations post disconnection and in talking with the patients, that they were fit to leave before they left the unit.

Staffing

- At the time of our inspection, the unit employed six full time staff; the clinic manager, deputy clinic manager, team leader and three nurses. The unit did not employ any dialysis assistants or healthcare assistants at the time of our inspection.
- A minimum of two registered nurses were scheduled for each shift. With six treatment chairs, the nurse to patient ratio was 1:3. This was better than the unit's contracted commitment of a ratio of 1:4, and better than the ratio of 1:5 recommended by the National Renal Workforce Planning Group 2002.
- The clinic manager used a bespoke e-rostering system to schedule staff shift attendance, taking account of annual leave, six to eight weeks in advance. The schedule was approved by the regional business manager. This ensured that all shifts complied with the unit's contracted staffing levels and skill mix.
- The clinic manager reviewed the roster daily to assess staffing levels against expected patient numbers. This meant the clinic manager could rearrange shifts with the co-operation of staff or arrange bank staff cover for unexpected staff shortages. Agency staff were only used if shortages could not be covered by these options and were provided with an orientation and induction to the unit on arrival.
- The unit had one dialysis nurse vacancy (0.6 full time equivalent). Between February 2016 and January 2017, one new staff member joined the unit and two left.
- In the period between November 2016 and January 2017, staff sickness rates were low at 2%. During the same period bank staff provided cover for 51 shifts and agency staff covered a further 28 shifts. This was due to the existing staff vacancy combined with one staff member being on maternity leave.
- The unit did not have any on-site medical staff. However, all patients were reviewed quarterly by the medical team in an outpatient's appointment at the commission trust. The associated specialist in renal medicine attended the unit each Wednesday morning to review and address any issues raised by staff including patient prescriptions. The commissioning trust's renal consultant attended the unit on Fridays as required. Staff were able to seek advice from the renal consultant at the host trust if needed. An on-call system was also available 24 hours a day to the renal registrar at the commissioning trust. Staff were aware of how to obtain advice if needed.
- The unit did not have any on-site technical staff; however, staff were able to request urgent unscheduled visits from the provider's technicians to carry out work on the equipment if needed. The clinic manager told us they had no concerns about the responsiveness of the provider's technicians.

Major incident awareness and training

- The unit had an emergency preparedness plan for the prevention and management of emergency situations. The plan included define roles and contact details for the emergency, public, and utility services. It also set out detailed instructions for staff to follow in various scenarios including fire, power failure, minor and major water leaks, storm damage, and release of toxic fumes or gases.
- Staff told us that in the event of a major incident which affected the operation of the unit, patients would be referred back to the renal unit at the commissioning trust or to other satellite units within the region to continue with their treatments.
- Staff were aware of their roles in an emergency, and this was tested through evacuation exercises every six months. Patients were included in the exercises so that they knew what to expect and this helped to keep patients calm. As part of this staff checked that patients were aware of the assembly point, and how the refuge area was to be used. The last drill was held in February 2017.

- An emergency evacuation 'grab' box was held in the clean utility, next to the treatment room. This included all relevant equipment needed by staff to manage patients' care safely in the event of an evacuation such as needles, gloves and saline.
- Personal emergency evacuation plans were in place for all patients attending the unit. These included assessment of each patient's individual physical, mobility, and medical needs; identification of any need to use the internal refuge point; and, identification of the number of staff needed to support the patient within the refuge point.
- A central copy of all the plans was held in the unit office. This identified that all patients had been assessed on 27 April 2016. Individual plans were held in each patient's paper record. We were unable to identify the individual plan in one patient file out of the six we viewed.

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

Evidence-based care and treatment

- The provider developed a Nephrocare Standard Good Dialysis Care policy that took into account professional standards, including guidance and best practice from the National Institute for Health and Care Excellence (NICE) and the Renal Association, and research literature from a range of sources. The standard addressed the processes to follow immediately before, at the beginning, during and at the end of haemodialysis treatment, and provided a guide for all staff to follow to ensure safe care and treatment for patients receiving treatment at the unit. The standard provided a framework against which the provider's other policies and procedures were linked.
- Treatment to patients was provided by staff in line with their individual treatment prescriptions. Prescriptions were reviewed and amended by the multidisciplinary team following monthly monitoring of patient's individual blood results. This enabled the medical team to review the effectiveness of treatment and to make improvements or changes to a patients care plan.
- Patient treatment data was recorded by the unit's electronic information management system. The live data was available for review by the clinic manager and the associate specialist in renal medicine, and the system was able to produce customised analysis and reports. This meant that opportunities to improve individual patient outcomes were easily identifiable, and performance against the provider's national standards could be assessed.
- Approximately 86% of patients in the unit received dialysis through an arteriovenous fistula (AV fistula – a surgically created connection between an artery and vein). New patients to the unit, or patients with new fistula access, were connected to the dialysis machines by a senior nurse until they were confident that the fistula was suitable and stable enough to be connected by a less experienced nurse.
- Assessment of patients' vascular access was carried out before and during treatment. However, this had been noted as an area of concern within the records audit, which identified that vascular access assessments had not always been recorded. Continuous monitoring by the dialysis machine meant that nurses were alerted by a machine alarm to any potential issues that could relate to poorly functioning fistula. Fistulas were also monitored every three months using a transonic measuring device; if any problems were identified the patient was referred to the vascular surgeons.
- Vascular access review meetings were held quarterly. These were attended by the renal consultants, a vascular consultant, a consultant radiologist, and a member of the unit's nursing team. The meeting reviewed patient X-rays and vascular access problems for individual patients.

Pain relief

- None of the patients we spoke with told us they had experienced significant pain during their treatment sessions. However, the patients confirmed that paracetamol would be provided by nursing staff if they were feeling mild pain or headaches.

- Topical anaesthetic cream and injectable local anaesthetic medicine was held on site and was prescribed by the medical team for any patients that required additional pain relief before the insertion of the dialysis needles into the vascular access site.

Nutrition and hydration

- The unit provided refreshments, including sandwiches, biscuits and drinks to patients during treatment. Patients were able to choose in advance the type of sandwich they wanted. Patients were able to request changes, but this needed to be done a week in advance.
- Vegetarian options were available to patients that requested these. However, the clinic manager told us there were limited opportunities to provide Halal or Kosher nutrition. Fruit was not encouraged due to its high potassium content.
- A dietitian reviewed each patient once a month to discuss patient's diets and to provide advice. Staff were able to contact the dietitian separately if further advice was needed. The unit had a communications file to enhance communication between the dietitian and staff.

Patient outcomes

- Information about the outcomes of patients' care and treatment was collected and monitored by the service to ensure good quality care outcomes were achieved for each patient. The unit measured and reported on its effectiveness against the quality standards of the Renal Association Guidelines.
- Electronic treatment data collected by the unit's dialysis machines was submitted to the commissioning trust for inclusion in its overall submission to the UK Renal Registry. The registry collects analyses and reports on data from the UK adult and paediatric renal centres.
- The data submitted by the unit was reviewed at the monitoring meetings with the commissioning trust and included patients under the direct care and supervision of the unit. The data did not include information on the unit's patients undergoing dialysis elsewhere during holiday periods.
- The service used standard methods of measuring dialysis dose. Urea Reduction Ratio (URR) is the most widely used index of dialysis dose used in the UK. URR is the percentage fall in blood urea achieved by a dialysis session and studies have shown the URR should be at least 65%. Data provided by the unit showed that between January 2017 and March 2017, an average of 98% of patients achieved the Renal Association target of more than 65% reduction. In the same period, 98% of patients achieved the equilibrated urea reduction value of Kt/V greater than 1.2 calculated from pre-and post-dialysis urea values. This was in-line with Renal Association guidelines. Guideline 5.3 - HD: Minimum dose of thrice weekly haemodialysis.
- Patient blood was tested for potassium, phosphate, calcium aluminium concentrations in-line with the renal association guidelines. Pre dialysis serum potassium in patients' blood was monitored on a monthly basis. Renal Association guidance suggests that pre-dialysis serum potassium should be between 4.0 and 6.0 mmol/l in HD patients. Between January 2017 to March 2017 an average of 74% of the unit's patients maintained their potassium levels within this range. Patient haemoglobin (HB) levels were measured to ensure that they remained within 10.5-12.5g/dl target range. In the same period, an average of 61% of patients remained within the recommended range.
- As the unit's data was combined with the trust's data, the unit was unable to benchmark its outcomes against other providers' clinics. However, the unit benchmarked its patient outcomes against the provider's other UK clinics. This included an audit of patient average connection time, patient observations, dialysis access data, treatment variances and infection control interventions. This data was reviewed by the area head nurse and the clinic manager on a monthly basis to identify and address improvement areas.
- Patient blood was tested for potassium, phosphate, calcium aluminium concentrations in-line with the renal association guidelines. The renal association sets outs guidelines for dialysis units to follow based on evidence and research. The guideline promotes the adoption of a range of standardised audit measures in

haemodialysis; promote a progressive increase in achievement of audit measures in parallel with improvements in clinical practice, to achieve better outcomes for patients.

- Patients' blood results were monitored and available within the commissioning trust's electronic system for review each month by the trust's nephrology team. This enabled the unit to review the effectiveness of treatment and implement changes to patient's prescriptions and care plans to improve outcomes.
- The service was included in the provider's monthly benchmarking audit of performance against other clinics. This looked at effective weekly treatment time, infusion blood volume, single pool Kt/V, vascular access, albumin levels, haemoglobin and phosphate levels by each clinic in the group. It also calculated each unit's percentage change over a six month period. For December 2016, in all but two measures the unit performed within the top 50% of the provider's clinics. For effective weekly treatment time, 66% of patients achieved the effective weekly treatment time. This had remained consistent during the six-month period between June and December 2016; the majority (30%) of cases of shortened treatment time were due to prescriptions of less than four hours. For single pool Kt/V 49% of patients achieved the required measure in December 2016; this was against a six-month improvement of 2%.

Competent staff

- The clinic manager, deputy manager and team leader held renal nursing qualifications. The provider supported opportunities for other staff to undertake renal qualifications.
- Staff underwent annual competency checks, which were signed off by the clinic manager. A number of the checks were undertaken through self-assessment. Self-assessments were signed off by a staff member of at least one grade higher. We reviewed three staff training files which included, an up to date competency record and annual staff reassessment record, infection prevention and control annual assessment, individual training and education plan, and employee notification of risks.
- All staff were expected to have an up to date disclosure and barring service certificate. These were held centrally by the provider's human resources department.
- Existing staff were supported in maintaining their professional development and in revalidation with their professional body. However, one staff member told us they mainly undertake that work in their own time as there was no suitable room available within the clinic to undertake this work.
- New staff members underwent a training and education progression plan. As part of this supervised practice, staff were supernumerary for four weeks under the guidance of a mentor while undertaking their induction and competency checks. Each mentor was supernumerary for two weeks during this period. During the period new staff were able to consolidate their skills and clinical practice
- The clinic was notified of any updated policies and procedures by the corporate training team. The clinic manager reviewed each new policy and, using the training matrix, identified which staff members were required to read the updated document. Staff signed to confirm when they had done so.
- Bank and agency staff were informed of any updates through a different system where the corporate training team notified the relevant organisations. The clinic manager told us it was expected that bank and agency staff had received all updates before arriving at the unit.
- Bank staff were provided by the provider's in-house agency: Renal Flexi bank. All bank staff underwent an induction programme, which included competency assessment to the same standards as permanent staff. Bank staff were provided with key clinical policies and work instructions as part of their induction training. This reduced the time taken to orientate bank staff to the unit and minimised any disruption to patients.
- New bank and agency staff were required to undertake a health and safety temporary worker induction checklist, which included orientation to the unit and the use of emergency equipment. We saw documentary evidence that this has been completed.

- The provider's specification for agency staff required staff to have renal experience and, where possible, a renal qualification. The provider worked closely with the agency to use nurses who had previously covered shifts at the unit. Staff told us that any concerns about the competency of new bank or agency staff were fed back to, or checked with, the relevant organisations.
- Staff we spoke with confirmed they had received an appraisal in the past 12 months. Records indicated that all five staff who had been in post for longer than 12 months had received an appraisal, with the remaining staff member scheduled for an appraisal in October 2017.
- Checks of the Nursing and Midwifery Council nursing validation registration PIN numbers had been carried out for all six staff at the unit in March 2017.
- All staff had access to the provider's online learning centre, and staff told us the unit supported further development through this. However, one staff member expressed concern that, due to the busy nature of the unit, there was little opportunity to undertake online training and learning during work time.
- Staff in the unit undertook other roles such as the link nurses for bacteraemia, anaemia, dialysis access, and infection prevention and control; education and training co-ordinator; stock control; and, hepatitis B records administrator. Staff we spoke with were clear about their roles in providing care and treatment for patients, and in supporting the unit in their additional lead roles.
- All staff were trained in the provision of basic life support (BLS). Four staff were trained in immediate life support (ILS). We reviewed the staff off-duty rota which showed that at least one member of ILS trained staff was allocated to each shift.
- All necessary multidisciplinary staff from the commissioning or host trusts were contacted by nursing staff at the unit in the event of a patient developing suspected sepsis or central venous catheter infections.

Multidisciplinary working

- Overall care of the patients remained with the renal consultant at the host trust. The associate specialist in renal medicine visited the unit four times each month on a Wednesday to review any issues or concerns raised by staff, including review of patient prescriptions. The renal consultant held quarterly outpatient clinics to undertake reviews for any patient that needed to be seen.
- A communication book was used to enhance communication between the renal specialist and the named nurses for the patients.
- A multidisciplinary meeting (MDT) was held monthly to review each patient's blood results, progress and general condition. This meeting included the associate renal specialist, a dietitian and the clinic manager. Additional psychological and social work support could be accessed by the team MDT if needed, although these individuals did not routinely attend MDT meetings.
- The MDT reviewed the patient's treatment records and care plan. Any changes to patient's care and prescriptions were recorded and subsequently entered into a diary for each named nurse to initiate the agreed actions. Outcomes and changes were discussed with all patients by the named nurses and dietitian, and we saw evidence that written information relating to blood results were provided to each patient to help them understand their care.
- Reports from the MDT meetings were sent to the commissioning trust each month. These included the details of any treatment variances and reasons for the variance.
- Clinic letters were copied to patients' GPs and a copy of letters was kept within each patient's paper records. Staff were able to contact patients' GPs separately as and when necessary, for example to enquire if a patient had been admitted to hospital if they failed to attend their dialysis session.

Access to information

- Staff told us they had access to all the relevant information they needed to provide effective care to patients. This included previous treatment records and current observation records, up to date prescriptions, and patient's clinic letters from the renal team to their GPs.

- Patient's blood results were held on the commissioning trust's electronic computer system, which was accessible by all staff including the renal consultant and the associate specialist in renal medicine. This meant the medical and nursing teams had the latest information available for patients undertaking dialysis.
- Clinic letters from the medical team were copied to the unit and the patient's GP.

Equality and human rights

- Staff were governed by a corporate code of ethics and business conduct which described the company values in relation to equality and human rights. Specifically, the code of conduct prohibited staff from discriminating people on the grounds of race, gender, marital status, age, disability or nationality.
- Patients were seen based on their clinical condition and whether there was space on the unit to accommodate them, irrespective of backgrounds such as race, religion, sexual orientation or marital status.
- Information was published in different languages to help make sure it was accessible to a patients from a range of ethnic backgrounds.
- We saw that members of staff in employment came from different ethnic and religious backgrounds. The staff described this as positive because it helped develop understanding of different circumstances.
- The unit had a policy for patients to request access to their information within their own records. However, we found no evidence to indicate any policies or actions had been taken to ensure the service was able to meet the requirements of the NHS Accessible Information Standard. The standard aims to make sure that people who have a disability, impairment or sensory loss are provided with information in a media or format that they can easily read and understand and with support so they can communicate effectively with health and social care services.

Consent, Mental Capacity Act and Deprivation of Liberty

- All staff received mandatory training in the Mental Capacity Act 2005, the Guide to the Deprivation of Liberty Safeguards (DoLS), and an Introduction to Dementia for Health and Care Professionals. At the time of the inspection all staff had completed, and were up to date, on this training and were able to describe the general principles of it.
- Consent forms were held within all six paper records we reviewed. The form detailed the type of treatment including the risks and benefits, confirmation of any advance directives or do not attempt cardiopulmonary resuscitation orders, confirmation of agreement to data protection and research analysis, and any requirement for interpretation. The name of the professional taking the patients consent and the patient's signature were recorded.
- The clinic manager told us the unit rarely cared for patients living with dementia, as these patients were usually cared for in the commissioning trust. Similarly, there had been no situations where it was necessary to apply for a DoLS order.

Are dialysis services caring?

Compassionate care

- Staff delivered care in line with the '6 Cs' of nursing. These are a set of values focused on placing the patient at the heart of their care and include care, compassion, competence, communication, courage and commitment.
- We observed staff interacting with patients in a compassionate and caring manner.
- The unit had a chaperone policy, which meant patients could request to be accompanied in consultations and during treatment.
- During the inspection, we received 19 comment cards from patients who received care at the unit. Without exception all the comment cards reflected positive comments about the unit and the staff.
- One patient said: "I find all the staff on the renal unit very pleasant and professional and passionate to patients. If you ask them anything they will listen and explain everything to you."
- Privacy curtains were available around each treatment chair. Patients confirmed to us that staff drew the curtains to maintain patient dignity when providing

care, particularly for patients with central venous catheters. One patient commented "The nursing staff that look after me each week in the dialysis unit…are very caring. They treat me with dignity [and] respect…The work that the staff do is very prompt and they are constantly busy and never stop"

- Another patient told us "We are a small unit of six beds. The staff treat us as individuals or as a group depending on the situation. Our privacy is respected. [Although] we have few staff they listen and care." In addition, another patient noted, "The staff here are wonderful, very caring, and sociable" and "if we need privacy staff talk quietly and pull the curtains around us"
- The unit took part in the 2016 patient survey and received 37 responses. Of these, 97% said that unit staff were caring and 89% said that support staff were helpful and friendly. The clinic manager had introduced a comment and compliment card facility.

Understanding and involvement of patients and those close to them

- Of those patients that responded in the 2016 patient survey, all said they were treated with dignity, were well informed in decisions about their care, and staff explained things in a way they could understand.
- Staff encouraged 'self-care' with all patients, and took opportunities to discuss this with patients and their families. However, most patients chose not to self-care. The unit did not have any patients who required support to self-care at home.
- Each named nurse discussed the monthly blood results with each patient to help them understand what each test results meant.
- We spoke with four patients during the inspection, all of whom told us that staff involved them in discussion and explanations about their care, including their blood results. Another patient told us they had received care in various clinics in the past, but this unit "is the best". The patient said there was a great relationship with staff who were 'different to ordinary nurses…they see you at your worst and at your best'.
- One patient noted on a comment card that "I am very happy with the excellent service I am receiving during a difficult time for me and my family where I am receiving dialysis treatment. Staff are excellent and treat with great care and dignity…They are also very good when they need to speak to my family when they need to ask any questions." Another patient commented; "the staff are very good, they always find the answer for me, even if they cannot answer my questions straight away. They use basic details without 'jargon''

Emotional support

- The unit operated a named nurse system and this was clearly noted in the records for each patient. This system helped to ensure continuity of care for each patient. Patients knew who their named nurse was.
- Staff understood the importance of building a strong and friendly rapport with the patients in their care, a number of whom had received care at the unit for many years. Staff were aware of the impact of chronic kidney disease on their patients and how long-term dialysis affected their individual needs.
- The small size of the unit meant staff were able to quickly recognise when individual patients needed additional support. Staff told us that patients "unburden a lot to us" and they felt it was beneficial for the patients to have a consistent team to provide care.
- Staff had direct access to and could obtain advice from the clinical psychology service and the renal social worker at the commissioning trust.
- There was no specific 'quiet room' in the unit; however, the office and/or the staff kitchen could be used for confidential discussions with patients if needed.
- One patient commented "the medical staff have always got a listening ear", while another commented "All the patients are listened to if they have a problem and appropriate solutions are found."
- Staff told us the unit supported them to attend patient funerals. Staff were also invited to the wedding of a patient's family member.
- A multi-faith chaplaincy service was available to patients through the host trust.
- Staff could access advice on behalf of their patients from a psychologist and a social worker if this was

needed. However, patients who required more significant psychological, bereavement support or counselling needs were referred to their GP to access the relevant services.

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

- The service was contracted by Lancashire Teaching Hospitals NHS Foundation Trust to provide dialysis for people who lived in the East Lancashire area. Performance against the contract was monitored through the joint meetings with the commissioning trust and in the submission of monthly renal key performance indicator data.
- We also saw that policies and procedures took into account relevant policies and guidance from the commissioning trust. These included the commissioning trust's guidance on 'do not attempt cardiopulmonary resuscitation' (DNACPR); the management of chronic kidney disease; and parathyroidectomy – management of dialysis patients.
- There was adequate patient parking with the grounds of the host trust; the unit was located next to the main hospital carpark. Two designated dialysis parking bays were also located outside the unit for patients who were able to drive; parking permits were provided. For patients who required transport, this was arranged through the local ambulance service, which contracted the service to a local taxi firm.
- The clinic manager told us that, although patient transport was provided within a 45-minute timescale before and after treatment, delays in the transport service arriving to collect patients were rare. However, staff were able to contact the patient transport service provider to chase delays. The clinic manager told us there was a good relationship with the taxi service, and that drivers would check with staff in the unit if they received an unusual transport request for one of the regular patients.
- The unit was located in an area with a diverse population, including a significant proportion of people whose first language was not English. This was reflected in the range of patients who attended the unit, which included patients of South Asian and Polish backgrounds. Staff reviewed the communication needs for new patients before their first attendance. We saw evidence of this in the patient records we reviewed. The patient guide was available in Punjabi, Urdu and Hindi, although the unit did not have copies of this in easy-read or braille format. However they did display a poster in the waiting area which explained how people could source leaflets on other languages such as Welsh, Punjabi, Filipino, Arabic, Hindi and Urdu.
- Despite this, we were not assured staff doing everything possible to reduce the risk associated with language diversity. This was because, although staff were able to access telephone translation services through the commissioning trust, the clinic manager told us they had never had to use this. One staff member told us they were able to help with translation. One staff member described how communication with patients was, on occasion, assisted through hand gestures. There was a risk relating to effective communication with these patients; however, we did not find any evidence to indicate current patients were disadvantaged in understanding or being involved in their care.
- Staff told us they acknowledged cultural events such as Ramadan and Eid by putting banners up, and accommodated changes to treatment slots for patients who wished to observe fasting during the Ramadan period.
- The design and layout of the unit adhered to the recommendations of the Department of Health's Health Building Note 07-01: Satellite dialysis unit. The physical limitations of the temporary portacabin meant a number of rooms were multifunctional, such as the reception and manager's office, staff room and kitchen, and there were no facility for incorporating a multi-faith prayer room.

- Access to the unit was via a ramp and the entrance door was secured with a remote locking system. The clinic office was located adjacent to the waiting area, and afforded staff good visibility of both the waiting area and the treatment area. However, there was no separate changing area for patients or lockers for patients to store outside clothing; coats were stored in the waiting area. There was no isolation room available and, as such, patients with infection were referred back to the commissioning trust.
- Plans had been developed for a new purpose built unit; however, these remained at an early stage and the clinic manager was unaware of the timescales for building and completion. However, a patient representative from the unit was included in the development meetings for the new unit. This meant that the patients' views and perspectives were taken into account in the planning of the building.

Access and flow

- The unit provided treatment to 13 patients between the ages of 18 and 65, and 23 patients aged over 65. The unit opened six days a week Monday to Saturday between 7.15am and 10.30pm. Three dialysis treatment sessions were scheduled for each treatment chair each day at 7.15am, 1pm and 6pm providing a total of 108 individual treatment sessions per week. Due to the limited capacity of the unit, the clinic manager told us services were not normally affected by seasonal pressures.
- Responsibility for the management, referral and prioritisation, of new patients requiring dialysis remained with the commissioning trust. As such, the unit did not hold a waiting list. The unit was operating to capacity, which meant it was unable to accept new patient referrals at the time of the inspection.
- The criteria for referral and acceptance of new patients were set out in the provider's Patient Referral and Acceptance for Treatment process document. Patients were assessed for suitability prior to acceptance. Patients who did not meet the full criteria could be accepted by exception and with agreement between the clinic manager and the clinic consultant nephrologist.
- The acceptance criteria included, although were not limited to, patients being stable with established and functioning venous access and who were independently mobile. The unit accepted patients with a wheelchair if they could self-transfer themselves to the treatment chair. Patients with blood borne viruses such as hepatitis B and C, and HIV were not accepted for treatment.
- The unit did not have separate treatment beds for patients on holiday. However, patients on holiday were accepted if there was capacity for the dates required. This was subject to approval from the commissioning trust, receipt of fully completed documentation, and medical approval and acceptance. This included consideration of any risk posed by the incoming patient on the resident patient cohort, for example isolation requirements.
- The unit had high utilisation rates in November 2016 at 93%, December 2016 at 99% and January 2017 at 99%. The high utilisation rates, and the low number of treatment stations, meant there were limited opportunities for patients to change their treatment sessions at short notice; however, staff aimed to accommodate patient requests or to co-ordinate swapping treatment sessions were possible. This included adjusting treatment session duration or frequency to accommodate patient requirements if required and if there was capacity to do so.
- Between February 2016 and January 2017, 29 planned dialysis treatment sessions were cancelled. This was due to a midweek interruption to the unit's water supply, and mainly affected patients who had already received dialysis that week. We found no evidence to indicate the service notified CQC of this event. A statutory notification is required where an event stops, or may stop, a provider carrying on a regulated activity safely and properly. This includes an interruption of water supply for longer than 24 hours.
- The associated specialist in renal medicine reviewed all patient records, including blood results to determine what action need to be taken for each patient. Those patients who needed urgent dialysis were referred to the commissioning trust, or to other local dialysis units. Patients whose dialysis needs were not as urgent were contacted on the same day, informed about the incident, and were scheduled to attend their next treatment session.

- There were no cancellations due to dialysis equipment breakdown or failure. There were no delayed dialysis treatment sessions as a result on non-clinical reasons.
- Arrangements were in place to ensure continuity of patient treatment where treatment sessions had to be cancelled. This included opening the unit on Sundays and/or referring patients to use treatment sessions in the provider's other nearby units or NHS dialysis units.
- Seventy-five treatment sessions were missed between April 2016 and March 2017. Of these 27 sessions were missed due to the water plant failure; 13 sessions were missed as patients were admitted to hospital or were dialysing elsewhere; 18 were missed as patients were too unwell to attend; and, 11 sessions were declined by the patient.
- For each session missed, the clinic manager followed the unit's protocol to contact each patient to determine a reason for the non-attendance and, if appropriate, to encourage the patient to come in. Where patients were unable to attend renal advice was given in relation to fluid and diet; this included advice to contact medical services it the patient began to feel more unwell.
- If the clinic manager was unable to contact the patient, a process was available to contact the commissioning trust to check if the patient had been admitted to hospital, the patient's next of kin or the police to seek assistance. One such example occurred during our inspection, and the patient was eventually contacted and persuaded to attend.

Meeting people's individual needs

- The single-storey porta cabin, which housed the unit, was accessible via a ramp for patients living with mobility difficulties or for those using a wheelchair. The entrance to the unit was through a secure, but automatic, door into the waiting area. An accessible unisex toilet was available within the waiting area for patients to use if needed prior to commencement of treatment and we saw three available wheelchairs in the waiting area for people to use if required.
- Access to the treatment area was also through a secure door. There was sufficient space between, and around, the treatment beds for patients and staff to move safely. The treatment chairs included pressure relieving mattresses.
- Staff requested detailed information about patients prior to acceptance of their care. This was to ensure the patient met the admission criteria and that staff could meet their individual care needs in a safe and effective way. Staff were able to accommodate visits by new patients and their relatives prior to the start of treatment. This meant that patients were familiar with the unit, its facilities and the staff.
- Staff told us they provided new patients with a patient guide. The guide included information on how to use the electronic patient record card, health and safety information, safeguarding information, hygiene and infection control advice, understanding dialysis including the various types of venous access, diet information, holiday information, how to complain, and other sources of information.
- The unit's catchment area had a diverse population, which was reflected in the patient group. The high usage capacity of the unit meant there was limited flexibility to accommodate patient's requests to change or swap treatment slots for cultural or spiritual needs; however, the clinic manager told us staff would try to agree changes if possible.
- The allocation of appointment slots for dialysis treatment took into account patient's individual needs. These included any social care or work commitments, the number of hours and days for the prescribed treatment, and the length of the patient's journey to the unit. Staff also aimed to provide daytime slots for elderly and vulnerable patients, or those with more complex care needs. However, the small size of the unit in conjunction with peak capacity usage meant that there was limited choice of initial treatment timeslots.
- The unit provided treatment for patients who had learning disabilities. Staff invited patients and their carers to visit the unit prior to treatment and used hand gestures and pictures to help explain the care they provided.

- The unit could only accept 'holidaying' patients when there was a treatment slot available. Holidaying patients were only accepted upon receipt of complete paperwork and the appropriate records. The deputy clinic manager was responsible for co-ordinating, and preparing the relevant paperwork, for holiday treatment for existing patients. Consultant to consultant agreement for holiday treatment was obtained and patients were screened for infection before confirmation of the treatment.
- Patient treatment session slots were not guaranteed for patients returning from holiday abroad. This meant patients were only able to return to the unit if there was capacity to do so. Where there was no existing capacity in the unit, the commissioning trust co-ordinated referrals to other satellite dialysis clinics within the area. This meant there was a potential that patients who wanted to travel to higher risk countries could feel unable to because they risked losing their place. One patient told us they avoided travelling to their home country (outside Europe) as they did not wish to risk losing their treatment slots at the unit or to be referred back to the main unit at the commissioning trust.
- The unit did not have any patients who received care at home. Staff encouraged patients to be involved in their own care, or to self-care; however, most patients were reluctant to do so but were willing to weigh themselves before and after dialysis.
- A patient and carer shared/self-care checklist was in place. This included three observation opportunities for patients and/or their carers to demonstrate each procedure to the named nurse, who was responsible for signing off each competency.

Learning from complaints and concerns

- A policy set out the process and staff responsibilities for handling compliments, comments, concerns and complaints. Feedback from patients was received verbally, in writing, through the patient satisfaction survey, or through the service's 'Tell us what you think' leaflet. The provider's policy and statement of purpose were displayed within the waiting area. The clinic manager was responsible for investigating complaints.
- The unit received no formal complaints in the period February 2016 to January2017. This meant we could not comment on the unit's timeliness for responding to complaints, or the sharing of learning from complaints. However, this positive absence of complaints was reflected in patient comments during our inspection; a number of which said they had 'no complaints'. One patient commented that a concern, relating to access to the unit, had been dealt with quickly and positively by staff.
- Six compliments were received between January and December 2016. Five of these were cards from patients and relatives expressing thanks for the care provided. The other was an iced chocolate plaque again expressing a patient's thanks.
- The policy set out a 20 working day timescale for complaints and concerns to be responded to, and included a risk assessment to determine the severity of the concern. The assessment level identified which staff needed to be made aware of, investigate, and subsequently approve the response to the complaint. The clinic manager was responsible for ensuring complaints were responded to within the policy's timescales.
- Staff told us they aimed to identify and respond to patient concerns face to face. This meant that concerns were dealt with before they escalated to formal complaints or required formal investigation. This was a positive and proactive approach; however, low-level concerns were not always recorded in a way that would enable the clinic manager to identify trends.

Are dialysis services well-led?

Leadership and culture of service

- The clinic manager was supported by a deputy clinic manager and a team leader. The clinic manager also undertook clinical duties (approximately 44% of their time).
- The area head nurse, who had responsibility for the performance of a number of clinics in the region, reported through the regional business manager to the clinical services director.

- Other corporate teams supported staff in the unit including a clinical incident team and regional training centres.
- The clinic manager had received training in leadership and management within the last three years. Having this training, over twenty years' experience in dialysis nursing and regular clinical duties incorporated into the role, the manager had the capacity, capability and experience to lead staff.
- The manager also had an understanding of the challenges to providing good quality care and was able to tell us how these were being addressed. For example, the manager described space as the primary challenge. This would be addressed when the new building was ready and in the meantime staff were careful to place items in assigned areas such as cleaning or storage cupboards.
- Staff told us that local senior staff were visible and approachable. Three staff members told us they felt supported by their line managers. One staff member said they felt safe as a practitioner because of the support of the clinic manager and area head nurse. Staff were aware of the clinic services director and confirmed he had visited the unit on a number of occasions. Staff said they felt they could contact him if they had any concerns.
- We observed a supportive atmosphere within the unit and this was reflected in comments we received from staff. One staff member told us "we all get on as a really good team; we know how we work as a unit."
- The unit did not report on or have a policy related to the Workforce Race Equality Standard (WRES). This is a requirement for organisations, which provide care to NHS patients. This is to ensure employees from black and minority ethnic (BME) backgrounds have equal access to career opportunities and receive fair treatment in the workplace.
- WRES has been part of the NHS standard contract since 2015. NHS England indicates independent healthcare locations whose annual income for the year is at least £200,000 should have a WRES report. This meant the service should publish data to show they monitor and assure staff equality by having an action plan to address any data gaps in the future.

Vision and strategy for this core service

- The provider's strategy was to provide safe, effective quality care for adults with end stage renal disease. This was supported by a mission statement, set out in the employee handbook, which detailed the provider's commitment to providing high quality, sustainable services and care practices.
- The provider had three core values of quality, honesty, and integrity; innovation and improvement; and, respect and dignity. The provider's had four objectives focused on patients, employees, shareholders and the community: to improve life expectancy and quality of life for patients; to promote staff professional development; to ensure continuous development of the company; and to reflect social responsibilities, legal and safety standards and contribute to maintaining the environment. The provider's strategy and vision was clearly displayed within the waiting area.
- Staff we spoke with were aware the provider had a strategy and values. Staff were unable to discuss these in detail; however, they were able to describe the objective of improvement life expectancy and quality of life for their patients. Staff were aware of how their roles contributed to achieving this objective.

Governance, risk management and quality measurement

- The unit had a clear staffing structure which supported them at work. This included the clinic manager, deputy manager, team leader and nursing staff. Other corporate teams supported the unit such as a clinical incident team.
- A clinical governance strategy document was displayed for patients attending the unit, and set out the objectives, roles on responsibilities of the clinical governance committee. The strategy document supported the provider's aims to increase life expectancy, professionally develop staff, provide good financial returns for stakeholders and adhere to legal and safety standards which could affect the community.

- The clinic manager was the lead for governance, and was responsible for collating and submitting governance data, reviewing updates in policies and ensuring these were disseminated to staff.
- There was a close working relationship between the unit and its NHS stakeholders; the host trust and the commissioning trust. Monitoring meetings were in place with the trusts to review performance against the unit's contract.
- The provider had achieved ISO 9001 accreditation for its Integrated Management Systems (IMS). The IMS system, which all staff had access to, held current and previous versions of all the organisation's policies and procedures. This meant staff were able to access the most up to date policies. The system also included a document version control facility, which tracked the review of documents including previous versions. Staff had the ability with the system to highlight any errors or issues with documents to the relevant document owner. The review date on some of the hard copy policy documents provided to us was not clear and seemingly out of date; however, we saw evidence on the system that these documents had been recently reviewed and re-ratified.
- An audit of the IMS systems, including patients' electronic records, was carried out yearly. The service had a target of achieving less than 10 minor infractions with no major infractions. The previous audit in June 2016 highlighted six minor and one major infractions. The major infraction related to the temperature of the utility room where medicines had been stored. As a result of this the medicines cabinet was moved to the temperature controlled store room.
- The unit had achieved OHSAS 18001 accreditation for its health and safety management system.
- A risk register had been introduced in January 2017 and held 19 clinical, 11 operational, and 23 technical corporately identified risks. At the time of the inspection there were five clinical risks on the register that had still to be assessed and control measures identified. The provider was in the process of incorporating local risks into the register. However, for those risks that had been assessed, there was no reassessment of risk score/levels after control mechanisms were applied to confirm if the measures were reducing the risk sufficiently. When we spoke to the clinic managers about this they acknowledged the benefits of including this information and agreed that this could be fed back to the senior leadership team.
- The unit also held a risk register for dangerous substances. Separate safety data sheets were held for a range of disinfectant solutions, gels, and wipes.
- Despite the risk register being very new, other risk management tools had been in place for some time. These included using risk assessments to capture existing risks and look at ways to manage or reduce the risk. For example the risk of assigning a patient to the wrong machine was lessened by using technology which alerted staff if the patient identification card did not match the machine being used.

Public and staff engagement

- The clinic manager told us that a patient engagement board was convened at the commissioning trust. This was a national group for 'expert patients'; however, patients were, by choice, not motivated to get involved with this. One patient attended meetings related to the development of the new building.
- The unit carried out an annual patient satisfaction survey. The latest survey data available was for 2015, with the 2016 survey due to be published in October 2017. The 2015 survey had a response rate of 83% with all patients indicating the atmosphere in the unit was friendly and happy. The results indicated that 94% of patients had confidence in nurses, 84% would recommend the unit to friends and family, 90% felt the unit was well organised, and 100% felt the atmosphere in the unit was friendly and happy. However, the survey also identified the need to improve the comfort of treatment chairs and subsequently provided additional cushions for patient comfort. Results of the survey, and the action plan, were displayed in the unit's waiting area.
- Patients were able to provide anonymous feedback through the provider's free-post 'Tell us what you think' leaflet system. Completed forms were sent to the clinic services director for review. In a comment received for our inspection, one patient said "The dialysis unit is run very well by the staff. The patients receive personal care of a high standard."

- The unit did not have any patient user groups; however, this did not appear to have any negative impact on the patients. One patient told us they saw their treatment as a necessary inconvenience and there was no desire for patients within their peer group to socialise outside the treatment environment.
- Staff we spoke with appeared to be engaged with the unit and the service as a whole. They had the opportunity to meet with staff from the provider's other units at staff meetings and conferences. One staff member felt the employee handbook was helpful and another staff member told us they felt supported by the provider during a period of ill-health.
- The staff survey in 2016 indicated that all staff would recommend the unit to family and friends, while five out of six staff said they would recommend the organisation as a place to work. All staff said their manager encouraged them to work as a member of the team and could be relied upon to help with difficult tasks at work. Five out of six staff said the organisation acted on concerns raised by patients. The survey action plan included a reminder to staff to report concerns and to review the staff handbook in relation to raising whistleblowing concerns.
- A staff awards scheme was in place at the unit to support staff attendance. Staff received a £25 voucher if they achieved no sickness absences within three months, and a £100 voucher if staff had achieved no sickness absence for a year.
- Staff told us that the local management team and the clinic services manager acknowledged good work and thanked staff when appropriate. Staff also told us they had received a thankyou from the renal consultant of patient who had been successfully cared for with a central venous catheter for longer than would be expected. The consultant noted that this was "due to good care from the nursing team".

Innovation, improvement and sustainability

- Improvements were implemented when issues were highlighted. For example, the clinic manager was aware of recommendations following an audit of similar units by Public Health England. As a result, documentation was updated to provide assurance and evidence that patients had weighed themselves as part of the pre and post dialysis assessment.
- Staff had agreed to support a research nurse to undertake innovative research into a new medicine for renal bone disease. The research programme was still at a very early stage but it was expected the research nurse would subsequently be seeking patient volunteers.
- The service had an environmental sustainability plan which aimed to reduce the amount of waste produced. This was linked to annual corporate objectives. We reviewed the objectives for 2016 which included reducing electricity and water use by 10% and creating 0.85 kilograms of waste per treatment. However we saw that no actions or updates were included to support whether the objectives had been met. Managers told us this was due to the unit being housed temporarily in a portacabin which was limiting their ability to make changes. They expected to implement positive changes when the new dialysis unit had been built. Senior managers confirmed that planning approval had been granted but no building work had started yet. Once work began, managers expected the build to take 12 months with an anticipated completion date of July 2018.

Outstanding practice and areas for improvement

Outstanding practice

- Staff acknowledged cultural events such as Ramadan and Eid by putting banners up, and accommodated changes to treatment slots for patients who wished to observe fasting during the Ramadan period.

Areas for improvement

Action the provider MUST take to improve

- Review and ensure effective use of interpretation services to reduce the risks associated in communicating with people whose first language is not English.
- Review options for eradicating the limitations in the unit, and for the new building, for patients wishing to travel to higher risk countries who may lose their place in the unit following a period of isolation at another centre.
- Ensure staff are provided with procedures and training in the identification, process, and management of patients with sepsis in line with national guidance. Consider implementing a recognised early warning score system to support the recognition of the deteriorating patient.
- Ensure statutory notifications are sent to CQC as, and when, appropriate.

Action the provider SHOULD take to improve

- Consider how the risk register can be embedded and that individuals responsible for managing risks are identified.
- Consider how to record low-level informal concerns or complaints in a way that could more easily enable the unit to identify trends.
- Consider how it can ensure implementation of the requirements of the workforce race equality standard.
- Consider how it can ensure implementation of the requirements of the NHS accessible information standard.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 9 HSCA (RA) Regulations 2014 Person-centred care Regulation 9 HSCA 2008 (Regulated Activities) Regulations 2014 (Part 3) Person-centred care. (1) The care and treatment of service users must be: (a) appropriate (b) meet their needs, and (c) reflect their preferences. (3) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include- - (b) designing care or treatment with a view to achieving service user's preferences and ensuring their needs are met. How the regulation was not being met: Regulation 9(1)(b)(c)(3)(b) Patient treatment session slots were not guaranteed for patients returning from holiday abroad. This meant patients were only able to return to the unit if there was capacity to do so. This meant patients who wanted to travel to higher risk countries could feel unable to because they risked losing their place in the unit.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 9 HSCA (RA) Regulations 2014 Person-centred care

This section is primarily information for the provider

Requirement notices

Regulation 9 HSCA 2008 (Regulated Activities) Regulations 2014 (Part 3) Person-centred care

(1) The care and treatment of service users must be:

(a) appropriate

(b) meet their needs, and

(c) reflect their preferences.

(3) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include- -

(c) enabling and supporting relevant persons to understand the care or treatment choices available to the service user and to discuss, with a competent health care professional or other competent person, the benefits involved in any particular course of treatment.

(d) enabling and supporting relevant persons to make, or participate in making, decisions relating to the services user's care or treatment to the maximum extent possible

How the regulation was not being met:

Regulation 9(1)(b)(3)(c)(d)

The clinic manager told us that, although staff were able to access telephone translation services, staff had never used this. One staff member told us they were able to help with translation. One staff member described how communication with patients was, on occasion, assisted through hand gestures. The unit did not have access to information in other formats, such as easy-read or braille. There was a risk that not enough was being done to adequately communicate with those whose first language was not English to enable and support them to understand the care and treatment choices available and to participate in making decisions relating to their care or treatment to the maximum extent possible.

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Treatment of disease, disorder or injury

Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment

Regulation 12 HSCA 2008 (Regulated Activities) Regulations 2014 (Part 3) Safe care and treatment

(1) Care and treatment must be provided in a safe way for service users.

(2) Without limited paragraph (1), the things which a registered person must do to comply with that paragraph include--

(h) assessing the risk of, and preventing, detecting and controlling the spread of infections, including those that are health care associated.

How the regulation was not being met:

Regulation 12(1)(2)(h)

The unit did not have a policy, training for staff or early warning score system as recommended in NICE guideline (NG51) for recognition, diagnosis, or early management of sepsis. This meant there was a risk to the safe care and treatment for service users in relation to staff assessing, detecting and controlling the spread of infections.