

Clatterbridge NHS Dialysis Unit Quality Report

Clatterbridge Hospital Clatterbridge Road Wirral, Merseyside CH63 4JY Tel: 0151 3462950 Website: http://www.freseniusmedicalcare.co.uk/

Date of inspection visit: 8 June 2017 and 22 June 2017 Date of publication: 13/10/2017

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

Ratings

Overall rating for this location

Are services safe? Are services effective?

Are services caring?

Are services responsive?

Are services well-led?

Overall summary

Clatterbridge NHS Dialysis Unit is operated by Fresenius Medical Care Renal Services Ltd. The unit has 10 dialysis stations in the main ward and two side rooms.

The service provides dialysis services for people over the age of 18, and does not provide treatment for children.

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.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 8 June 2017, along with an unannounced visit to the unit on 22 June 2017.

Summary of findings

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 therapy services but we do not currently have a legal duty to rate them when they are provided as a single specialty service. 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 processes to control and prevent the risk of infection. We saw that the environment appeared clean and audits of the environment took place to provide assurance.
- All dialysis equipment was approved and compliant with relevant safety standards. This was in accordance with the Renal Association guidelines.
- We saw there were appropriate processes to support those patients with blood borne viruses (BBV). There were two side rooms and there was routine blood testing for BBV.
- We observed that patients' fistulas or central venous catheters were assessed pre and post dialysis for infection, with any variances recorded via the electronic system.
- The Fresenius service had developed a Nephrocare standard for good dialysis care based upon standards of best practice.
- The service had a multi-disciplinary approach to patients' care and treatment.
- 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.
- 100% of patients were receiving Hi Flux dialysis. This is considered a better form of dialysis for patients.
- All patients we asked reported the staff were caring and respectful and they were happy with their care and treatment.

- Every patient had an individualised treatment prescription to ensure effective dialysis treatment.
- There was no waiting list for treatment. This meant that there were no patients waiting to start treatment.
- We observed that managers were visible and approachable on the unit and provided support to staff as required.

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

- The service did not have a policy or provide training for nursing staff with regards to identification or process for sepsis management.
- We observed one occasion where staff did not confirm the patient's identity prior to commencing dialysis.
- Dialysis assistants were not dialysing patients in line with the Nephrocare standard for good dialysis care or the safety bulletin dated 12 May 2017. Dialysis assistants were unable to access the trust prescribing system which would enable them to utilise saline during the cannulation process.
- We found that patient records had incorrectly completed or incomplete DNACPR forms stored in them.
- The service did not have or maintain a Workforce Race Equality Standard (WRES) action plan or publish data with regards to monitoring staff equality.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with one requirement notice(s) that affected dialysis services. Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals

Summary of findings

Contents

Summary of this inspection	Page
Background to Clatterbridge NHS Dialysis Unit	5
Our inspection team	5
Information about Clatterbridge NHS Dialysis Unit	5
The five questions we ask about services and what we found	7
Detailed findings from this inspection	
Overview of ratings	10
Outstanding practice	29
Areas for improvement	29
Action we have told the provider to take	30



Clatterbridge NHS Dialysis Unit

Services we looked at Dialysis services

4 Clatterbridge NHS Dialysis Unit Quality Report 13/10/2017

Background to Clatterbridge NHS Dialysis Unit

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the registered provider was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

The service provides haemodialysis treatment to adults. The Clatterbridge dialysis unit opened in 2008 and primarily serves the Wirral area population, with occasional access to services for people who are referred for holiday dialysis. The registered manager (clinic manager) was available for the announced and unannounced CQC inspections. Fresenius Renal Health Care UK Ltd has a nominated individual for this location.

The clinic is registered for the following regulated activities - Treatment of disease disorder or injury.

The CQC have inspected the location previously in 2013 and there were no outstanding requirement notices or enforcement associated with this service at the time of our June 2017 inspection.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector and two other CQC inspectors. The inspection team was overseen by an Interim Head of Hospital Inspection.

Information about Clatterbridge NHS Dialysis Unit

Clatterbridge dialysis unit is operated by Fresenius Medical Care Renal Services Ltd. The unit opened in 2008 and primarily serves the Wirral area.

The Clatterbridge dialysis unit is located within the Clatterbridge hospital in Bebington. It provides treatment and care to adults only and the service runs over six days, Monday to Saturday. There are no overnight facilities. There are two dialysis treatment sessions per day starting at 7am and 1pm. The service did not offer any twilight dialysis sessions.

The clinic has 10 stations in the main treatment area and two side rooms that were accessed from the main ward area. Access to the service was through the hospital main entrance. There was no allocated parking for the unit, but patients had access to free hospital parking, with a pass the unit provided. A security system was in place to access the unit. Patients were referred to the unit by Wirral University Teaching Hospitals Trust. The trust provided the unit with two consultant nephrologists, a dietician, a pharmacist, a specialist vascular access nurse and a specialist anaemia nurse.

The unit had service level agreements with the hospital trust in which it was located, for example fire safety, water supply, and medical emergency response.

In the past year the unit had provided 2408 treatment sessions to adults aged between 18-65 and 3327 treatment sessions to adults over 65. No services were offered to people under the age of 18. There were 41 people currently using the service.

During the inspection of Clatterbridge dialysis unit, we spoke with a range of staff including, registered nurses, dialysis assistants, reception staff and senior managers. We spoke with five patients. We also received 10 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed 10 sets of patient records.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. The most recent inspection took place in June 2013. The June 2017 inspection was the clinic's first comprehensive inspection against the new methodology.

The dialysis unit has one ward and is registered to provide the following regulated activities: Treatment for disease, disorder and injury.

In the reporting period March 2016 to March 2017 there were 5735 day case episodes of care recorded at the unit; of these 100% were NHS-funded.

At the time of inspection 41 people received care and treatment at the unit. 15 people were aged 18 to 65 and 26 were aged over 65.

The service employed eight staff members. There was five nursing staff including the clinic manager, two dialysis assistants and a clinic secretary in reception.

Two consultant nephrologists from the local trust attended the clinic. Multidisciplinary meetings were held monthly alongside the clinic manager, with a dietician, a pharmacist, a specialist vascular access nurse and a specialist anaemia nurse in attendance.

- There were no reported never events.
- Two in-patient deaths occurred at the unit in the past 12 months. The deaths were classed as unexpected and reported to the CQC.

- There were no incidents that were classed as moderate or above that triggered a duty of candour process.
- There were three patient falls reported in the past 12 months.
- There was one incidence of healthcare acquired Methicillin-resistant Staphylococcus aureus (MRSA).
- There was one incidence of healthcare acquired Methicillin-sensitive staphylococcus aureus (MSSA).
- There was one incidence of healthcare acquired Clostridium difficile (C.Diff) and one incidence of healthcare acquired E-Coli.
- There were no complaints made by patients at the unit.

Services accredited by a national body:

The clinic is accredited against ISO 9001 quality management system.

Services provided at the unit under service level agreement:

- Water supply
- Hospital 2222 service
- Fire safety
- Building maintenance
- Waste management (domestic and clinical waste)
- Cleaning services

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, where these services are provided as an independent healthcare single speciality service.

We found the following areas of good practice:

- There were processes to control and prevent the risk of infection. We saw that the environment appeared clean and audits of the environment took place to provide assurances.
- We observed equipment stock used for dialysis treatment was CE marked.
- We saw there were appropriate processes and facilities to support those patients with blood borne viruses (BBV).
- We observed that patients' access sites were assessed pre and post dialysis for infection, with any variances recorded via the electronic system.
- We saw evidence that chemical contaminants in water used for the preparation of dialysis fluid was monitored.

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

- The service does not have a policy or provide training for nursing staff with regards to identification or process for sepsis management.
- We observed one occasion where staff did not confirm the patient's identity prior to commencing dialysis.
- Dialysis assistants were not dialysing patients in line with the Nephrocare standard for good dialysis care or the safety bulletin dated 12 May 2017. Dialysis assistants were unable to access the trust prescribing system which would enable them to utilise saline during the cannulation process.

Are services effective?

We do not currently have a legal duty to rate dialysis services, where these services are provided as an independent healthcare single speciality service.

We found the following areas of good practice:

• 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.

 100% of patients were receiving Hi Flux dialysis. This is considered to be a better form of dialysis for patients. Four out of five of the nursing staff had a renal dialysis qualification. The service had three link nurse roles (infection control, information management systems and health and safety) and a patient transplant coordinator role. However, we also found the following issues that the service provider needs to improve: A competency for one member of staff had been incorrectly signed off when the competency did not form part of their role. 	
Are services caring? We do not currently have a legal duty to rate dialysis services, where these services are provided as an independent healthcare single speciality service.	
We found the following areas of good practice:	
 We observed that nurses had close and positive working relationships with patients. All patients told us the staff were caring and respectful and treated them with dignity and respect. There was a variety of books available on a bookcase in reception that patients could use whilst on dialysis. 	
However, we also found the following issues that the service provider needs to improve:	
• Patients had a named nurse to provide their care and treatment. However, some of the patients we spoke to did not know who their named nurse was.	
Are services responsive? We do not currently have a legal duty to rate dialysis services, where these services are provided as an independent healthcare single speciality service.	
We found the following areas of good practice:	
 Every patient had an individualised treatment prescription to ensure effective dialysis treatment. Patients were offered hot and cold drinks and sandwiches whilst receiving treatment. Patient information was provided in English, however could be obtained in other formats if required There was no waiting list for treatment. This meant that there were no patients waiting to start treatment. 	

Are services well-led?

We do not currently have a legal duty to rate dialysis services, where these services are provided as an independent healthcare single speciality service.

We found the following areas of good practice:

- There was a clear leadership structure from unit level to senior management level.
- All staff told us they had a good relationship with their managers and felt they were not asked to complete any work outside of their job roles.
- We observed that managers were visible and approachable on the unit and provided support to staff as required
- The service followed a clinic environmental plan to monitor and reduce its environmental impact.

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

- The service did not have or maintain a Workforce Race Equality Standard (WRES) action plan or publish data with regards to monitoring staff equality.
- We found that the service had completed environmental and clinical risk assessments; however, we saw that 15 of the risk assessments were required to be reviewed between January and June 2017. We saw no evidence to support that these had been reviewed.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Notes

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

- The service had a clinical incident reporting policy (UK-CI-14-01) that clearly set out: definitions of clinical incidents, corporate reporting requirements and timescales, external notification processes and escalation processes for different incidents. The accountability and responsibilities of staff were clearly defined in the policy.
- We saw there was an electronic incident reporting system that captured details regarding clinical, non-clinical and treatment variance incidents.
- Treatment variances were recorded using an electronic patient record system. An example of treatment variance included when a patient decided they did not want to receive the full dialysis session as per their prescription. We saw that patients were required to sign a document to consent to not receiving the full treatment, and this was also documented on the electronic patient record.
- In the period January 2016 to December 2016, 2143 treatment variances were recorded to have taken place.
- Between January 2016 and January 2017 the service reported there were three non-clinical incidents, which were patient falls.
- Between January 2016 and January 2017 the service reported eleven clinical incidents, this included five needle dislodgements, four cases of bacteraemia and two cardiac arrests.
- Of the four cases of bacteraemia, one case of MRSA had been recorded as severe harm and one case of MSSA had been recorded as moderate harm. All cases of bacteraemia were fully investigated, regardless of the severity recorded.
- The service had a clinical incident reporting folder where the paperwork relating to incidents was stored.

We reviewed root cause analysis (RCA) documents for the four bacteraemia and the two cardiac arrests on the unit. Correct reporting and notification processes had been followed for these incidents and action plans had been put in place.

- All staff we spoke with had a good understanding of the reporting system and could access the system.
- The clinic manager told us that if she was absent when an incident had taken place, a member of staff would start the reporting process, which had helped the team.
- The clinic manager told us that following an incident, the team got together and reflected on what had happened to share any learning.
- Following a cardiac arrest on the unit, a nurse from the local NHS hospital who responded to the crash call and a paramedic who had been involved in the resuscitation and transfer process came back to the unit. They took part in an informal collaborative reflective learning meeting with the team. We saw evidence that clinical incidents were discussed at team meetings and actions were cascaded to staff.
- We saw evidence that trends had been identified with the needle dislodgements happening in the winter months. The clinic manager told us that patients had told them how they had dislodged the needle and she put a poster in the reception area advising patients not to cover their vascular access site with blankets or clothing. The unit did not provide blankets for patients.
- The service reported no 'never events' from March 2016 to March 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.
- Staff told us they were aware of their duty of candour regulatory duty and that duty of candour training was available through on line learning as part of the fundamental nursing skills training.

- The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- The clinic manager, area head nurse and regional business manager had oversight of any incidents that occurred within the unit. Once the incident form had been completed, the clinical incident forms were sent to the clinical incident team for triage. This team screened the incident to ensure the detail and quality of the incident report was sufficient. If required a safety bulletin could be produced to share across the organisation to aid learning.
- Non-clinical incidents were reported to the health and safety team. We were told that they could also produce a safety bulletin to aid shared learning.
- We saw evidence safety bulletins were shared and staff were encouraged to read and sign to confirm they had understood the changes. For example, a bulletin dated 12 May 2017 had been sent outlining the preferred cannulation process for dialysing a patient and staff confirmed they had seen this.
- The area head nurse told us safety bulletins were a good way of cascading learning across the organisation and the team were not complacent and realised that incidents could happen in any unit.

Mandatory training

- Mandatory training was available to all staff. Mandatory training was delivered in a blended approach which included e-learning and classroom sessions. E-learning sessions could be undertaken around work commitments, at a time to suit the staff.
- Mandatory training included fire training, moving and handling and adults and children's safeguarding.
- We saw evidence of a live training monitoring tool that detailed which staff had completed mandatory training. The matrix was colour coded in a red, amber, green system which highlighted whether staff were up to date with their training (green), approaching renewal (amber) or overdue (red).
- The training monitoring tool showed staff were up to date with their mandatory training in all areas apart from children's safeguarding, where two staff members needed to complete this training.

- The service operated a 'skills passport' for staff that had been used in the NHS. This enabled them to transfer over any relevant mandatory training from their previous employment if it was still valid and up to date. We saw evidence this had been used by some staff.
- The clinic manager had oversight of the training monitoring tool to monitor staff completion and remind staff to renew training when it was close to expiring.

Safeguarding

- The clinic manager was the safeguarding lead for the unit.
- The service had a safeguarding adults and children policy (UK-CI-09-47) that clearly set out accountability and responsibility for identifying and reporting safeguarding concerns.
- Staff were aware of the process to follow to raise a safeguarding concern.
- Staff undertook level two safeguarding adults training as part of their mandatory training. 100% of staff had completed safeguarding adults training.
- Safeguarding children training rates were 75% as two staff members had yet to complete the training.
- There were no services delivered for persons under the age of 18 years. However, staff received this training as the provider recognised that staff may come in to contact with children, parents and carers in the course of their work.

Cleanliness, infection control and hygiene

- The service had an infection prevention and control policy (UK-CI-09-22) to maintain a safe environment for patients, visitors and staff.
- The service used the local NHS trust's policy for Methicillin-Resistant Staphylococcus Aureus (MRSA) screening which operated on a monthly basis.
- Between March 2016 and March 2017, the service reported one case of MRSA and one case of Methicillin-Sensitive Staphylococcus Aureus (MSSA).
 MRSA and MSSA are infections that have the capability of causing harm to patients. MRSA is a type of bacterial infection and is resistant to many antibiotics. MSSA is a type of bacteria in the same family as MRSA but is more easily treated. Both cases had been reported as clinical incidents.

- We reviewed the root cause analysis (RCA) documents and these determined that the cases of MRSA and MSSA had not been acquired on the unit, but had been identified in the patients whilst on the dialysis unit.
- In February 2016, the service reported one healthcare acquired bacteraemia, which when tested was confirmed as E. Coli that was acquired off the unit. We saw evidence that the incident had been investigated and reported and actions taken. Actions included retraining staff on the clinical record keeping policy (UK-CI-05-06).
- In July 2016, the service reported another healthcare acquired bacteraemia, which when tested was confirmed as Clostridium difficile that was acquired off the unit. We saw evidence that the incident had been investigated and reported, and it was determined that the patient had cross contaminated their exit site.
- All staff were trained and used an aseptic non touch technique technique when accessing fistulas and dialysis lines. This minimised the occurrence of infection transmission between patients. We observed that staff used appropriate personal protection and sterile fields were used on the dialysis trolleys to minimise cross contamination.
- We observed staff cleaning and decontaminating dialysis machines, beds, trays and trolleys between patients to ensure good levels of hygiene and minimise the risk of cross contamination. Staff also cleaned medical devices, for example the blood pressure monitors and thermometers between patients. We saw competencies in staff files to show that staff were trained in cleaning procedures for the dialysis machines.
- The service had a contract with an external cleaning contractor to provide cleaning services in the early evening. Cleaning equipment was colour coded and kept in a locked cleaning cupboard. The clinic manager told us she had a good working relationship with the cleaning supervisor who did regular audits to ensure standards were maintained.
- Staff on the unit complied with the arms 'bare below the elbow' guidance. Staff used the appropriate personal protective equipment (PPE) such as visors, colour coded aprons, masks, goggles and gloves in line with the infection prevention and control policy (UK-CI-09-22).
- The clinic manager had a level 2 food safety certificate and five other staff had a level 1 food safety certificate.
 Food was prepared and stored hygienically and the fridge temperatures taken and recorded daily.

- The service had an infection control link nurse who undertook the additional infection, prevention and control duties alongside their substantive nursing role. We saw the infection control link nurse job description in the relevant staff member's file.
- All staff had completed their annual infection prevention and control assessment (UK-CR-18-145).
- The service completed hand hygiene audits on a monthly basis. Results from 2017 showed 100% compliance in January, February, March and May and in April results showed 80% compliance. The clinic manager told us that she had determined why the results had dipped in April and those staff responsible were retrained.
- We saw hand hygiene was discussed at team meetings and actions cascaded. One example was for staff to remind patients to use hand gel when entering the unit and to wash their hands after dialysis.
- The service completed infection control audits on a monthly basis. Results from May showed 86.06% compliance. Findings included some areas that were found to be dusty, a member of staff wearing a ring that did not comply with the infection control policy and some equipment that was hard to clean due to needing replacing. We reviewed the action plan and actions included providing the regional business manager with a list of equipment that needed replacing and cleaning staff being informed of the areas where dust was found.
- Results from the 2016 patient survey showed that 98% of the patients who responded felt the treatment rooms were well maintained and clean and we found that the unit appeared clean, tidy and well maintained.
- The service had a blood borne virus policy (UK-CI-09-76). The service screened patients monthly for blood born viruses (BBV) such as Hepatitis B, C and HIV.
- Those patients identified as having a BBV were dialysed in a side room using their own dedicated dialysis machine. The side rooms also had their own dedicated equipment trolley with devices such as blood pressure monitors for sole use in the side rooms to avoid cross contamination.
- There were processes for patients who chose to have dialysis away from base (holiday dialysis). Patients who went on holiday to areas at higher risk of BBV transmission were dialysed in isolation for three months on their return to ensure the possible risk of transmission was mitigated. The clinic manager told us that this had happened with a patient recently.

- We saw evidence that chemical contaminants in water used for the preparation of dialysis fluid were monitored. Chlorine levels in water were tested daily and other contaminates such as nitrates tested monthly to ensure the quality of the water used. This testing was in-line with the Renal Association guideline 3.3 – HD: Chemical contaminants in water used for the preparation of dialysis fluid. We saw that records of compliance and a standard operating procedure was in place for staff to follow to ensure the procedure was completed accurately.
- We saw that dialysis fluid was produced by the mixing of treated water, acid (dialysate) and bicarbonate concentrates to provide ultrapure dialysis fluid, free from microbiological contaminants. This was in-line with the Renal Association haemodialysis guideline 3.5. We saw evidence that an audit programme was in place and contaminants were monitored. We saw that the chemical contaminants within the water had been tested in April 2017 and met the relevant international standards organisation (ISO) 13959 standard.
- The service had two side rooms per 12 dialysis stations for patients who carried infection or were at risk of infection. This was in line with the health building note 04-01 supplement A – isolation facilities in acute settings.
- We observed that all dialysis lines were pre-packed and were for single use only. Once dialysis treatment was completed, we saw that all used lines were disposed of in clinical waste bags and any needles placed in sharps bins.

Environment and equipment

- The unit appeared clean and tidy and areas were kept free of clutter
- All doors were unobstructed and fire escapes were clear.
- In the reception area, we saw that there were easy clean chairs for patients to use whilst waiting for treatment. Chairs had arms to aid patients to stand with mobility difficulties.
- All corridors were wide to provide ample access to the main ward treatment area and were suitable for wheelchair use.
- All areas of the unit flooring were easy clean surfaces in case of spillages and appeared free of dirt and staining.
- Access to the unit was controlled. Patients and visitors were required to press a call bell to gain access.

- All storage areas, including the dirty utility room were well organised and tidy. Stock was placed on shelving and we observed that stock was rotated.
- We saw that equipment stock in the storage areas was CE marked. For example, dialysis needles and accessory kits. This ensured that all dialysis equipment was approved and compliant with relevant safety standards and met the Renal Association guidelines. Guideline 2.2
 HD: Haemodialysis equipment and disposables. We saw that all dialysate was CE marked in accordance with the Renal Association guidelines. Guideline 3.1 - HD: Concentrates for haemodialysis. This ensured that the dialysates used met the required standards for safe patient treatment.
- We saw that the water treatment plant was organised and appeared clean and tidy.
- We observed that spare dialysis machines were kept on site. The unit had two spare dialysis machines in case a fault developed on any of the machines on the main ward and two additional machines that the technician could use for parts. We saw that the spare machines appeared clean and ready for use.
- There was adequate space between dialysis chairs to allow for privacy, but also space for staff to be able to attend to patients. This met the recommendation of a preferred minimum of 900mm between stations is set out in Health Building Note 07-01 – Satellite dialysis unit.
- The nurses' station was located centrally to the ward area, so that staff were able to maintain visual contact with patients. However the side rooms were behind the nurses station and they were not floor to ceiling glass, so viewing these rooms was not as easy. Staff told us the rooms had alarms that sounded different to the alarms on the machine, to alert staff to any issues.
- We observed that a nurse call bell system was in use; however, there was no process in place to test the call bells on a regular basis to ensure they worked.
- We observed staff responding appropriately to alarm guards on the dialysis machines and patients did not override the alarms when they sounded.
- We observed that a program of maintenance for the equipment was place to ensure continuity of service. Technicians that visited the unit carried out maintenance. Staff we spoke with reported that technicians provided a good service and attended quickly if a fault developed.

- We saw from staff files that competencies were in place for all medical devices. This included the use of the dialysis machines and safety equipment. For example the defibrillator.
- We saw evidence that electrical safety testing was being completed across the service. We reviewed five items of electrical equipment including computers and scales and saw that they had been tested and safe for use and were due to be tested again in October 2017.
- Emergency equipment was checked daily, with items appropriately packaged, stored and ready for use. The resuscitation trolley was provided by the trust. All items were present and within their expiry date. If the trolley required replenishment, the clinic manager told us they requested this from the trust and the items came the next day.

Medicine Management

- The service had a corporate medicines management policy (UK-C-09-05) that was available to all staff through the service intranet. Staff were aware of where to find it should they need guidance.
- All staff completed training in preventing medication errors and completed annual competency declarations that included medicine management competencies.
- We saw that every patient had an individualised treatment prescription. Any requests to change prescriptions, where the nephrologist was not available, were made to the senior house officer at the local trust via the on call bleep system. The requested change was then made electronically.
- The NHS consultant completed all medication prescriptions. We saw that the prescriptions were kept on the electronic system and dialysis prescriptions were printed out into the paper patient records.
- The clinic manager was the lead responsible for the safe and secure handling and control of medicines, and was available on the unit to provide support and guidance. There was also a deputy clinic manager to provide guidance if required.
- The nurse in charge held the keys for the medicines cabinet. We observed that the medicines cabinet was kept locked.
- We saw that all medicines in the medicines cabinet were within expiry dates and records kept of expiry dates.
- The unit did not store or administer any controlled drugs.

- The service did not use any patient group directions (PGD's) and none of the nurses were trained in non-medical prescribing.
- The service stored medicines which needed to be refrigerated in a locked fridge. Records indicated that staff completed daily fridge and room temperature checks, in line with their corporate policy, to ensure that medicines were kept at the correct temperature so they were still effective.
- Staff had access to pharmacy support from the local NHS trust pharmacy for additional advice relating to dialysis drugs and the service head office had pharmacy support for staff to access.
- We observed that nursing staff administered medication following the NMC standards for medicines management. Staff checked identity of the patient against the prescription and signed the prescription form immediately. However, on one occasion we observed that staff did not confirm the patient's identity prior to commencing dialysis. We saw no medication was left unattended.

Records

- The dialysis unit used a combination of electronic and paper records. Data was uploaded daily from the electronic record to the referring trust database in order for data sharing. This ensured that consultant nephrologists had access to the patient records at all times.
- Staff were competent in the electronic record system and all had received training in order to effectively use it.
- We found that four patient records had incomplete DNACPR forms stored in them. One DNACPR form was signed by the clinician, however, had no patient name, date of birth, NHS number and where the DNACPR decision was initiated. We asked three staff members what they would do if the patient suffered a cardiac arrest and all three confirmed they would proceed with CPR as the form was incomplete.
- Other DNACPR forms had information missing or inappropriate answers, for example 'co-morbidities' as the circumstances for instigating the DNACPR form. We escalated this issue to the clinic manager, area head nurse and the deputy divisional director for the trust. When we returned on the unannounced inspection, all DNACPR forms had been appropriately completed by the consultants.

- We found that post dialysis temperatures had not been recorded in four out of ten patients' files. Pre and post dialysis temperatures were taken from patients with a central venous catheter, to provide a baseline to monitor for potential infections.
- The records contained all patient demographics including height, weight as well as the patient prescription and blood results.
- Any variances to treatment required staff to complete a treatment variance record. This included if the patient wished to terminate dialysis prior to the required treatment time. We saw that the patient also signed an early termination report. This was also recorded in the electronic record to inform the nephrologist.
- Prior to treatment, any variances from the previous treatment session needed to be acknowledged by staff prior to commencement of a new session. This ensured that staff were aware of any specific issues relating to care and treatment.
- As the electronic system was used across the organisation, this enabled other dialysis units to share information if a patient moved area to access treatment.
- We saw that a referral form was completed by the trust for all new patients requiring treatment. The referral form included patient demographics, treatment required and a quality of data check to ensure that all fields of the referral were completed prior to the commencement of treatment. This ensured the unit had the necessary information regarding the patient to ensure their needs could be met.
- All patients had a care plan and risk assessments in order to provide staff with the necessary information to provide safe care and treatment.
- Staff completed a patient concerns record that was shared electronically with the nephrologist. The record highlighted any problems encountered in treatment and further advice and support required. We saw that patient concerns were discussed within the monthly clinical governance meeting.

Assessing and responding to patient risk

- Patients were clinically assessed on each visit and any issues highlighted to the clinic manager and to the nephrologist. The staff told us that the unit was nurse led and they escalated any issues immediately as they did not take risks with patients.
- Patients had their vascular access sites assessed prior to treatment. We saw evidence that the clinic manager had

told staff in a team meeting that patients with difficult access sites must be seen by permanent staff members and not agency or bank staff as there had been occurrences of patients being sent home without dialysis because agency/bank staff could not cannulate their access site.

- We saw that prior to dialysis needle insertion; the registered nurses primed the needles using a syringe with saline. This is considered best practice and we observed that this process was outlined in the Nephrocare standard for good dialysis care procedures for the staff to follow. We also saw that this had been raised in a safety bulletin dated 12 May 2017, to ensure that staff followed this process.
- However, the dialysis assistants at the unit were unable to access saline due to the level of access they had to the trust's prescribing system. Dialysis assistants were using a 'dry needling' technique. Dry needling is a technique that has been used previously in dialysis units but has been replaced by 'wet needling' as best practice, to minimise the risks of an air embolism.
- We escalated the saline and 'dry needling' issue to the clinic manager and area head nurse as this practice went against the organisational policy, a recent safety bulletin and best practice. The clinic manager told us that this issue was on the local risk register, had been escalated internally so the Fresenius clinical services director was aware. It had been escalated within the trust to the renal matron and deputy divisional director and that the dialysis assistants had undergone competency based training, so were able to perform the procedure proficiently.
- When we returned on the unannounced inspection the 'dry needling' practice was still ongoing, however we saw evidence that the unit was working with the trust to rectify this. The clinic manager told us that this issue was linked to the use of the trust prescribing system and the level of access the dialysis assistants had to the system. It was not a choice taken by the staff it affected, as they recognised that best practice and company policy favoured 'wet needling'. We saw evidence of the dialysis assistants' competencies and that the issue was on the unit's risk register and had been escalated appropriately.
- We observed staff following processes for patient identification, which met the NMC standards for medicine management.

- Staff routinely asked patients for their names and date of birth, prior to commencing dialysis and issuing medication. However, we observed one occasion when staff failed to ask for the patient's name and date of birth prior to starting dialysis. The patient was later asked to confirm their name and date of birth on the medicine round, prior to issuing medication.
- We observed that each dialysis machine had an alarm guard so that significant risks such as detection of a dislodged needle could be identified to prevent significant blood loss. We saw nursing staff attended promptly when the alarm sounded to ensure the safety of patients.
- Patients used nominated dialysis machines to aid tracking and traceability.
- We observed that patient fistula's or central venous catheters were assessed pre and post dialysis for infection, with any variances recorded via the electronic system.
- We observed that for patients with a central venous catheter (CVC), a multi-racial visual inspection catheter tool (Mr Victor) was used. This guide provided nursing staff with a consistent and recognised description of the condition of the CVC using a score of 0-4. The assessment tool provided nurses with pictures and guidance on the assessment and monitoring of CVC's to quickly highlight signs of infection.
- From the records, we observed that the electronic system recorded information with regards to vascular access (VASACC). The records we reviewed showed that nurses assessed the vascular access site prior to any treatment and recorded their findings.
- Patients used their electronic card, which was picked up on arrival in the waiting area, to record their weight. Prior to commencement of the treatment staff checked patient identity and prescription. The dialysis machine also prompted staff to confirm the patient identity. This process ensured that patients received the correct treatment, as the machine would not progress until the identity had been confirmed and a button pressed on the dialysis machine.
- Patients were monitored throughout their dialysis treatment. Mid-treatment reviews were completed and documented by the nursing staff. We saw evidence of this in patient records and observed practice.
- Although there was not a formal early warning score system in place, staff told us that mid-treatment reviews could be increased for patients who were not feeling

well, who visibly looked unwell and were deteriorating or patients who were higher risk due to co-morbidities. All staff we spoke with confirmed that they checked to ensure patients remained stable and explained the process to follow if a patient deteriorated.

- The dialysis unit was situated in an NHS hospital, but there was no accident and emergency department so deteriorating patients were transferred out to another NHS hospital via ambulance. A process was in place with the host hospital if a patient suffered a cardiac arrest, nurses from the hospital would attend the emergency bleep and clinic staff would dial 999. Staff we spoke with were aware of the process to follow.
- All staff had completed immediate life support training (ILS) including the clinic secretary. This training provided staff with the knowledge and skills to be able to respond to patients requiring resuscitation.
- The unit did not have a policy or training for staff with • regards to identification or process for sepsis management. This was not in line with the NICE guideline (NG51) for recognition, diagnosis, or early management of sepsis. Sepsis is a life-threatening illness caused by the body's response to an infection. However, staff had a good understanding of sepsis and patients could be transferred via ambulance to the accident and emergency department at another local hospital should sepsis be identified. Managers we spoke with were looking at a process to support staff with sepsis management that included the possibility of adopting the referring trust's sepsis process. We saw this was on the risk register, however we did not see that a formal risk assessment at the dialysis unit had been completed.
- Between March 2016 and March 2017 eight patients had been transferred out of the service and into the care of another health care provider.

Staffing

- Staffing levels and skill mix were planned and reviewed so that patients could receive safe care and treatment at all times. The unit was contracted to provide a staff to patient ratio of 1:4 staff ratio with a skill mix of 67% nurse staff and 33% dialysis assistants. The ratio was established to ensure there were always two trained nurses on shift during dialysis sessions.
- We observed that staffing rotas were based upon the numbers of patients requiring treatment to ensure there were adequate staff to the numbers of patients. We

were informed that the clinic would not start unless there were two trained staff on shift to maintain patient safety. Staff confirmed this process and staffing rotas we looked at confirmed there were always two trained nurses on shift.

- The service employed eight staff that included a clinic manager, a deputy clinic manager, team leader, two further dialysis nurses, two dialysis assistants and a clinic secretary on the main reception.
- At the time of the inspection the unit had a vacancy for 1 FTE registered nurse. The unit also had a maternity cover vacancy for a registered nurse, to backfill for the deputy clinic manager who was acting up as clinic manager from July, whilst the clinic manager was on maternity leave.
- From January 2017 to March 2017, the service reported there had been 35 shifts covered by bank staff and 21 shifts covered by agency workers; to ensure the skill mix and numbers of staff were appropriate to provide safe care and treatment for patients. Managers reported that sickness was monitored monthly and the sickness rate for the period was 0%.
- The service used Fresenius' in-house nurse agency, Renal Flexibank. Renal Flexibank staff undertook an induction programme with a training shift and competency assessment with the same standards and procedures as full-time staff. Job functions mirrored those of full time employed staff. Flexibank staff were given a short induction to local working practices. Mandatory training records were monitored by the Flexibank administrators, to ensure training was up to date. If training lapsed, staff were suspended from shift allocation until evidence of completion was received.
- External agency staff were required to undertake a health and safety temporary worker induction checklist, which included emergency equipment. Agency nurses allocated to cover shifts were required to have renal experience and, where possible, have a renal qualification.
- Duty rotas were completed eight weeks in advance and forwarded to the regional business manager for approval. Annual leave was included in the rotas.
- We observed that the rotas were completed using an electronic system that highlighted how many staff were required per day dependent on the number of patients attending for treatment.

- Rotas were reviewed daily by the clinic manager and where unexpected staff shortages were identified, action was taken to rearrange shifts with staff cooperation, or fill the shift with a bank or agency member of staff.
- Bank and agency staff were arranged by a renal flexi bank team to support co-ordinating staff across the organisation.
- The dialysis unit was a nurse led service, with a two nephrologists visiting monthly to review patients. Staff and managers said they could access the nephrologists through the trust if they needed advice and support, and they were contactable via phone or email. A renal consultant was available on a 24 hour basis through the local trust as the 'nephrologist of the week'.
- There were two nephrologists covering two cohorts of patients. One nephrologist covered the Monday, Wednesday and Friday morning and afternoon patients together with the Tuesday, Thursday and Saturday morning patients, whilst the other Consultant was responsible for the Tuesday, Thursday and Saturday afternoon patients.
- The unit did not employ any service technicians. Technicians employed by the provider, completed routine maintenance, and provided both telephone support and on-site support as necessary. Staff we spoke with told us that any queries were quickly dealt with.

Major incident awareness and training

- The service had an emergency preparedness plan (UK-CI-47-20). This highlighted the actions taken in event of an emergency. This included actions to take in the event of a fire, water loss or loss of electricity.
- The unit had a service level agreement with the hospital trust where it was located for fire alarm testing and water supply.
- Staff understood their responsibilities in relation to major incidents and received training in evacuation.
- We saw that the emergency plan contained relevant emergency telephone numbers to contact in the event of an emergency.
- We saw in patient records that a personal emergency evacuation plan (PEEP) was recorded. The plan included any patient mobility issues in order to evaluate the level of help required in the event of an emergency evacuation.

- We saw the unit had fire extinguishers that were secured to the wall and within their service date, and were ready for use in the event of a fire.
- The service backed up their server tapes daily as part of the 'daily jobs list', this ensured that the most recent patient data would be available in the event of a serious IT issue and loss of systems.

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

Evidence-based care and treatment

- Care and treatment was delivered to patients' in line with the National Institute for Health and Care Excellence (NICE) guidelines. For example, we saw that all patients receiving treatment had their vascular access site monitored and maintained prior to dialysis. We observed nurses monitoring the vascular access site and recording this on the EuCliD patient database system under the VASACC tab. A patient concerns record was also used to raise any issues with the nephrologist. This was in line with the National Institute for Health and Care Excellence (NICE) QS72 statement 8.
- The service had developed a Nephrocare standard for good dialysis care based upon standards of best practice. The standards 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 staff with a standard working instruction to ensure best practice was followed and all staff completed treatment the same way to the same standard. Staff were aware of the guidance.
- Policy and procedures were linked to the Nephrocare standard for good dialysis care. The Nephrocare standard set out procedures for staff to follow with a rationale for the process in place. For example, the standard provided information to perform hand hygiene, put on a plastic apron and wear a visor. This was linked to a local hygiene policy (UK-CI-09-04) with the rationale to prevent contamination risks. We observed that staff followed this practice.
- Patients receiving care at the unit were carefully accepted to ensure their needs could be met. As the unit was a nurse led unit with two nephrologists visiting the

unit monthly, the referring trust renal unit treated patients with complex comorbidities and difficult access sites. This ensured that patient care needs were planned and delivered safely.

• We saw evidence that the service had an audit schedule to ensure compliance with the corporate policies. For example, audits were undertaken with regards to infection control, records and hand hygiene.

Pain relief

- Pain relief medicines were not routinely stocked at the unit. If patients were experiencing severe pain, they would be transferred to the referring hospital.
- The service did not prescribe paracetamol as PRN (as needed) pain relief. If patients required pain relief, such as paracetamol, they were required to bring their own.
- There were topical anaesthetic sprays held in the medicine cabinet that could be applied prior to the patient being cannulated for dialysis, if requested.

Nutrition and hydration

- A dietician visited the unit on a twice weekly basis and patients told us they could see the dietician when they required. The dietician was also involved in the monthly MDT meetings at the unit, where each patient was reviewed.
- We saw evidence of dietetic booklets, posters and leaflets in the clinic waiting area.
- Patients were offered hot and cold drinks, sandwiches and biscuits during treatment.
- Sandwiches were stored in a fridge and use by dates were checked prior to them being given to patients.
- We saw that patients were offered hot and cold drinks and sandwiches whilst receiving treatment.
- Patients were able to bring their own food and drink to the unit, for example a flask of tea, if they preferred. They were able to take their sandwich home with them if they decided not to eat it whilst receiving treatment, one patient told us they preferred to take their sandwich home and have it for their lunch.

Patient outcomes

• The unit audited patient outcomes via the EuCliD data management system. Outcomes audited included: achievement of quality standards (Renal Association Guidelines), patient observations, dialysis access specific data, treatment variances and infection control interventions.

- Patients' blood results were monitored each month as per a defined schedule dictated by the NHS trust consultant. The bloods were individually reviewed monthly to audit the effectiveness of treatment and define/action improvements and changes to care provision that would improve outcomes. Results and treatment data were captured by the EuCliD database with blood results from EuCliD feeding into the trust system.
- The service operated on a six day service providing two sessions per day. Patients usually dialysed every other day for four hours, three times per week. This was in accordance with the renal guidance. Guideline 5.1 HD: Minimum frequency of haemodialysis per week and Guideline 5.4 HD: Minimum duration of thrice weekly haemodialysis. We saw from the clinical review report for May 2017 that the number of patients receiving their effective weekly treatment time was: March 85.7%, April 79.4% and May 83.7%. The target set for all Fresenius units was 70%.
- Information on how the unit performed against the quality standards based on UK Renal Association guidelines was requested but not provided by the service.
- Submission of the service's data to the UK Renal Registry was undertaken by the parent NHS trust. The unit's data was combined with the parent NHS trust data and submitted as one data set. This data set only included patients under the direct care and supervision of the trust.
- As the UK Renal Registry data is representative of all parent NHS trust patients this does not permit the review of patients and outcome trends specifically treated within Clatterbridge dialysis Unit. Therefore, data specific to the service and available via the electronic database was used to benchmark patient outcomes at clinic level and nationally against all Fresenius Medical Care UK clinics.
- 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, 75% of patients achieved the effective weekly treatment time. This figure had dropped slightly by 1.9% during the six-month period between June and December 2016. For albumin scores 83.3% of patients achieved the required measure in December 2016; this benchmarked Clatterbridge in the top seven clinics across the provider's clinic portfolio for albumin scores.

 Data provided by the service showed that 100% of patients were being dialysed using Hi Flux Haemodialysis. This provides higher rates of removal of small and middle molecules and may lower the risk of developing complications due to dialysis related amyloidosis (a group of diseases in which abnormal protein, known as amyloid fibrils, builds up in tissue). In patients with established renal failure if it was shown in randomised controlled trials to provide better patient outcomes. This was in-line with Renal Association Guideline 4.3 - HD: High flux HD and haemodiafiltration.

Competent staff

- Staff were able to access training internally and externally. There was an online learning system across the organisation where staff could access additional training opportunities. Staff we spoke with reported that they were encouraged and able to access training to improve their knowledge and skills.
- Four out of five of the nursing staff had a renal qualification, with one member of staff yet to complete the training. This training supported nurses to enhance their knowledge and practice in order to lead and deliver care and treatment to patients with a range of renal conditions. The area head nurse told us it was a corporate objective to ensure all nursing staff completed the renal qualification.
- There were three link nurse roles in the service. The link nurse roles covered: health and safety, infection control and information management systems (IMS). The area head nurse told us the roles were to help develop and nurture staff. Each role had a job description that was present in the link nurses' training files.
- New members of staff were given a mentor to support their learning and induction process. The mentor was given two weeks supernumery time to be able to fully support the new member of staff. The two week supernumery support time could be used flexibly as needed and did not need to be a block of two weeks taken at once.
- New staff completed a 12 week induction plan. This included a wide range of essential training such as vascular access techniques, management of intravenous cannulas and dialysis machine use and decontamination. Following the supernumerary period staff commenced a probationary and supervised period that was individually tailored to them.

- New staff were given a minimal patient caseload which was gradually increased as they progressed through their training. The clinic manager told us that the mentor set objectives for new staff to work to
- Evidence provided by the service showed that all eligible staff had received an appraisal within the last 12 months. We reviewed that appraisals included a review of current objectives and set future objectives to aid development.
- We reviewed seven staff competency files and saw that course certificates were included, and an integrated competency document with dates and signatures of competencies completed. Competencies included medical devices, cannulation, infection control and medicines management. However, we identified a member of staff that had two competencies signed off that were not part of their job role. We escalated this to the clinic manager and it was identified as a mistake and rectified.
- The clinic manager told us that she had recently undertaken some nursing revalidations. The revalidation process involved going through the paperwork alongside the staff member's training history, working hours, CPD record, feedback and reflective practice. There was also a PIN monitoring tool, this meant the service conducted annual checks to make sure all the nurses were registered with the Nursing and Midwifery Council (NMC) and is considered good practice.
- We observed that an electronic training monitoring tool provided information as to training completed by the staff. The tool included dates that training needed to be completed and any out of date training was highlighted red.
- The clinic manager told us the area head nurse attended the unit and held unannounced BLS simulation resuscitation training in order for staff to practice their skills.

Multidisciplinary working

- The nephrologists had overall responsibility for the care and treatment of their patients on the unit and visited once a month to review their care.
- The clinic manager faxed the GP with the necessary information as to the patient's current treatment. The clinic manager would contact the GP surgery via phone if required, however any urgent referrals would be made by the renal consultant.

- The clinic manager held monthly quality assurance meetings with the nephrologist to discuss patients' treatment plans and any treatment variances. The monthly meetings were attended by the clinic manager, the nephrologists, a vascular access nurse, an anaemia nurse, a dietician and a pharmacist. Any changes to patients' medications were made in the meeting with the input of the multidisciplinary staff. We saw evidence that these meetings were minuted by the clinic manager.
- The vascular access nurse attended the unit twice a week and staff told us the anaemia nurse was able to attend the unit 'almost daily', if needed. The staff reported a good working relationship with the nurses.
- The dietician attended the unit twice a week and patients reported they were able to see the dietician when they required.
- Patients could access psychological services through a referral process to the referring trust.
- Patients could be referred to a renal social worker at the trust and they attended the unit on a needs only basis.
- The service had a nurse who acted as the patient transplant coordinator. Each patient on the transplant waiting list was discussed at the monthly clinical governance meeting. The patient transplant coordinator ensured that cytotoxic antibodies were taken every three months and regularly reviewed patient details on the EuCLiD database to ensure all information was correct.

Access to information

- Staff told us they had access to policies and procedures through the electronic database.
- Patient records were easily accessible via the computer terminals. All staff had secure, personal log in details and had access to e-mail and hospital systems. We observed that no computer terminals were left unattended displaying confidential information.
- We saw that there were standard operating procedures (work instructions) for staff to follow. The instructions provided systematic instructions in areas such as water testing, and good dialysis care the instructions ensured that staff maintained the safety of patients at all times.
- Patient blood results were recorded on the EuCliD database which fed in to the referring trust's database.

- The nephrologist's provided the necessary information for the staff on the unit to be able to provide the correct treatment for each patient through their individual prescription. We saw prescriptions were printed out and kept as a paper record.
- The dialysis unit database uploaded to the trust database daily to ensure the trust had the latest information to support data collection and ensure the nephrologist's received the latest dialysis information for every patient. The server tapes were backed up daily as part of the 'daily jobs list', to ensure that patient information was saved regularly.

Consent, Mental Capacity Act and Deprivation of Liberty

- The unit had a current policy for consent to examination or treatment (UK-C-09-02). This was available for staff on the intranet.
- Seven of the eight staff at the unit had completed training on the Mental Capacity Act and Deprivation of Liberty Safeguards.
- Staff were able to demonstrate their knowledge of consent and mental capacity and staff told us if there were concerns over a patient's capacity to consent, they would seek further advice and assistance from the clinic manager.
- Patient records contained a consent to treatment record. We reviewed 10 patient records and found they had been fully completed including date and signature. Consent forms were required in order to start treatment at the dialysis unit.

Are dialysis services caring?

Compassionate care

- We spoke with five patients and we received 10 CQC comment cards. From our conversations and the comments received, patients informed us that nurses treated them with dignity and respect.
- Comments included 'I could not hope for better care! The staff are wonderful', 'The staff were good to me and treated me with dignity and respect' and 'I had the right care and treatment at the right time'. All comments regarding the care and treatment from nursing staff were overwhelmingly positive.

- Only two of the comment cards had concerns detailed from patients. One patient had concerns about staff shortages and pressures on the staff and one patient wanted to know why the second drinks round no longer took place.
- We observed that nurses had close working relationships with their patients. Interactions were positive, friendly and professional, with a strong rapport between patients and staff.
- The service had disposable curtains around the beds in one half of the ward area. There were mobile screens available for the beds that did not have curtains, to ensure patient privacy, if required.
- Patients told us they felt privacy on the unit was adequate, given the open layout of the ward.
- All patients we asked responded that they felt safe on the dialysis unit.
- Patients were greeted warmly by staff when they entered the unit. Patients and staff had friendly and personable discussions and it was clear from the conversations that staff knew the patients well.
- There were rooms available on the unit for staff and patients to have private conversations, if required.
- Patient survey results were shown on an infographic poster in the reception area, alongside the patient satisfaction results.
- There was a 'you said, we did' patient survey action plan on display, so patients could see what the clinic intended to do to address the survey results. The clinic manager told us that patients had been consulted about when they would prefer their refreshments serving. The patients had decided that 9am was the best time so the refreshment round took place at this time.

Understanding and involvement of patients and those close to them

- We observed that staff spoke to the patients to explain the treatment they were going to receive. We observed a discussion regarding a patient's blood pressure being on the high side due to fluid retention and the nurse advised she would monitor the patient's blood pressure regularly.
- We saw that patients were involved in their care, and weighed themselves before and after their treatment.
- Patients had a named nurse to provide their care and treatment. The named nurse approach fosters good relationships and communication between patients and

staff. However, two of the five patients we spoke to were not sure who their named nurse was, and one patient told us their named nurse had just left and they were not sure who had replaced them.

Emotional support

- Staff we spoke with were able to tell us that extra support was available to patients via the referring trust. This included access to a renal social worker and psychological services.
- The unit had a small inner courtyard garden with shrubs, flowers and seating. Patients were able to sit outside to wait for treatment, weather permitting, or if they wanted some quiet time for reflective contemplation, they could make use of the space.
- Patients were actively encouraged to take part in shared care. We saw that patients weighed themselves upon arrival to the ward. This information was captured on the patient identification card and used to start the dialysis process.
- We observed that staff monitored patients throughout their treatment. Staff provided reassurance to patients when the alarm guards sounded and explained what action they were taking.
- Patients told us they felt supported by the nursing staff and they could speak to them about concerns or worries if they felt they needed to.
- Staff told us they would provide support for the patients if they had witnessed something serious on the unit, such as a cardiac arrest, and they would take time to ensure these patients were okay before they left the unit.

Are dialysis services responsive to people's needs? (for example, to feedback?)

Service planning and delivery to meet the needs of local people

- The clinic manager told us patients commencing treatment at the unit were mobile and stable patients identified by the referring NHS trust. The trust liaised with the service to identify clinic capacity for new referrals.
- The unit followed its corporate patient acceptance criteria and policy (UK-CI-09-26). The policy outlined the

criteria for acceptance to the unit. This included, established functioning access for dialysis, haemodynamically stable, and BBV status. Approval to the unit was completed by the clinic manager to ensure care and treatment could be safely managed.

- Patients were welcome to visit the service prior to commencing treatment there, to familiarise themselves with the unit and the staff.
- Staff recognised when some newly referred patients may not be suitable for treatment at a satellite unit. The clinic manager told us that patients who were initially deemed suitable, but turned out to have additional issues, for example patients with complex mobility needs, would be referred back to the trust with the support of the consultant nephrologist.
- Patient transport was delivered by another provider, contracted by the NHS trust. Transport and journey times were not routinely audited by the service. However, the clinic manager told us they had started recording incidences of transport being late or not arriving, so this could be shared with the transport provider to help improve the service.
- Access to the unit was safe and convenient. The dialysis unit was in the main hospital building, close to the main entrance and was located on the ground floor.
- A full range of dialysis sessions were available for patients, taking into consideration working, cultural needs and family responsibilities. We saw that the service offered two dialysis sessions per day over a six day period.
- There was no dedicated parking at the dialysis unit. A free hospital parking pass could be issued by the clinic secretary, to patients who chose to drive to their sessions. There was disabled parking available close to the service for patients with a blue badge.

Access and flow

- The service did not have a waiting list. There were no patients waiting to commence treatment at the unit. The service reported there had never been a waiting list since it opened in 2008.
- Patients were prioritised for treatment by the referring trust. Where patients were assessed as medically fit and clinically suitable to receive treatment at the unit, the trust would make a referral.

- The service measured the utilisation of capacity. For the reporting period from March to May 2017, the utilisation capacity ranged from 83.3% in March, 85.4% in April and 89.5% in May. This meant that there were some vacant appointments available for patients.
- The service reported no cancellations to treatment between March 2016 and March 2017.
- The service reported no delays to treatment between March 2016 and March 2017.
- Appointments were available for patients in a morning or afternoon, Monday, Wednesday and Friday or Tuesday, Thursday and Saturday. The clinic manager told us they took in to account patients' lifestyle, social commitments, preference and location when allocating dialysis sessions.
- Staff informed us that they were flexible to change appointment times to meet the needs of the patients, sometimes this may necessitate a dialysis session being relocated to the referring hospital. The patients were always central to any decisions made. For example, there were two patients on daily dialysis who sometimes needed greater flexibility with their appointments.

Meeting people's individual needs

- There was good access to facilities in the unit. The unit was spacious and offered good provision for people with individual needs. For example, corridors and doorways were wide to offer wheelchair access.
 Antibacterial hand gel dispensers were mounted at a suitable level for access from a wheelchair.
- There were two patient toilets available. They were located on a corridor just off the waiting area and offered disabled access for patients with mobility issues.
- We were told that treatment could be suspended and patients taken off dialysis should a patient require the toilet during treatment. The patient could then be reconnected to the dialysis machine to continue treatment.
- The signage on the doors throughout the service featured braille translations for patients who were blind or suffered sight loss.
- There was a patient announcement poster displayed in the patient waiting area that advised patient literature was available in other languages, these included: Arabic, Filipino, Hindi, Urdu, Welsh and Punjabi.

- Seven of the eight members of staff employed at the unit had completed training in equality, diversity and human rights. Staff knew the patients well and respected their religious and cultural beliefs.
- The referring trust was responsible for arranging outgoing holiday dialysis for patients, the service arranged incoming patients. There was a poster displayed in the waiting area with the contact details of the local trust's holiday dialysis coordinator.
- The clinic manager told us that incoming holiday patients could be accommodated if there was capacity and medical clearance had been given. Prospective patients made contact directly with the unit to see if there was space. To enable relevant patient information to be entered into the EuCliD patient database, the incoming holiday patient forms (UK-CR-03-40) were used to ensure all relevant information was gathered relating to the incoming patient, ensuring the holiday patient did not pose a risk to the resident patient cohort dialysing with individual needs (e.g. isolation requirements) and the treatment prescription could be met. The patient would be set up on the EuCliD system by a member of the nursing team and the patient would be allocated a dialysis station and prescription prepared for their arrival at the unit for treatment.
- The clinic manager told us that they could order in a 'holiday' dialysis machine for any incoming patients that may be at higher risk, for example a patient with a blood borne virus.
- We observed that patients were encouraged to participate in their care. We saw that patients weighed themselves prior to treatment and we were told that one patient was able to self-care which involved self-needling, and was working towards home dialysis. The service had a 'patient and carer shared/self-care training checklist for AVF/AVG' (UK-CR-09-54) which was a competency document to be signed off by nursing staff to say a patient was trained and competent at providing self-care.
- Patients had access to television with separate headphones in each bed space, and were able to bring in their own reading material if required or could borrow books from the bookshelf in the waiting area.
- Dialysis chairs were electronically controlled by the patient, for comfort.

- Pressure relieving mattresses were available if patients were identified as needing them. The clinic manager told us she could request mattresses, if a patient was identified as needing one, via the regional business manager.
- There was a variety of books available on a bookcase in reception that patients could use whilst on dialysis. The clinic manager told us that patients brought in and borrowed books and it was an informal service. There were also DVDs that patients had brought in, for other patients to borrow.
- Access to interpreter services was available to those patients whose first language was not English.
- There were no patient representative groups that visited the unit on a regular basis. However, there was literature for patients in the waiting area for if they wished to contact them.
- There were posters displayed in the waiting area with diet specific information, such as a phosphate additives list and information on how to read food labels. There were leaflets available for patients to take with them.
- The dialysis machines were numbered and patients were allocated a specific dialysis machine and the number recorded in their records. Patients used the same dialysis machine on each visit to the unit.
- From 1st August 2016 onwards, all organisations that provide NHS care were legally required to follow the Accessible Information Standard. The standard aims to make sure that people who have a disability, impairment, or sensory loss are provided with information that they can easily read, understand or with support can communicate effectively with health and social care services. We saw that the service was aware that they currently did not fully meet this standard and was listed on the risk register.
- The risk register highlighted the actions Fresenius planned to take which included a full assessment of accessible information criteria, so Fresenius can understand their NHS partner approach, policy, procedures and services.
- The service requests comprehensive details regarding patient requirements pre-transfer to ensure all care needs can be met and transfer to the unit is safe and with full communication with the patient. Interpreter and translation services were accessed via the referring trust.

- The dialysis unit followed their corporate feedback policy (UK-CI-14-02) that covered compliments, comments, concerns and complaints. The policy was available to all staff via the intranet and was known as the 4C's.
- The service received no complaints in the 12 month reporting period March 2016 to March 2017.
- We saw that the service had 'tell us what you think' comment cards displayed in the reception area with a freepost label for patients to complete, if they wished.
- The clinic manager told us she would regularly speak to patients to find out if they had any concerns or issues and the area head nurse visited the unit regularly and would speak to patients on the ward.
- The corporate policy outlined that complaints would be dealt with within 20 working days. The clinic manager and deputy clinic manager had the responsibility of 'initial response and investigation' of complaints, for the service.

Are dialysis services well-led?

Leadership and culture of service

- The clinic manager was responsible for delivering effective leadership, governance and quality management across the unit. We saw that the clinic manager was well supported by a knowledgeable wider management team that included an regional business manager and area head nurse.
- The service had a current registered manager (clinic manager). A registered manager is the person appointed by the provider to manage the regulated activity on their behalf. This is a requirement under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 7.
- There was a clear leadership structure within the service with a clear reporting structure up to senior management. We saw an organisation structure chart that detailed the unit's structure; this included a clinic manager, a deputy clinic manager and a team leader to support the day to day running of the unit.
- Staff relationships throughout the service were friendly positive and professional. Staff had a good rapport with senior managers. Staff we spoke to said they had a good relationship with their managers.

Learning from complaints and concerns

- The clinic manager had been in post for a number of years and staff told us they felt she offered stable and knowledgeable management to the service.
- One member of staff felt the service they were providing to patients was not as good as it could be due to recent staff turnover and what they perceived as, the slow recruitment of replacement staff.
- Staff we spoke to said the service had an open and honest culture and they would not be afraid to raise issues with the manager.
- The regional business manager and area head nurse provided the overarching management to the unit. Roles were distinct in that the area head nurse was responsible for the clinical areas of the business, with the business manager having overall responsibility with regards to the dialysis unit performance and contract management. Throughout the inspection, the management team showed they were knowledgeable and well cited to the performance of the service.
- The clinic manager was visible and approachable on the unit; she had a private office located off the ward area, so was accessible to both staff and patients.
- The clinic manager worked some shifts as part of the nursing team on the unit, so was well informed about the patients and actively spoke to them about the service.

Vision and strategy for service

- The vision of the service was set out in the corporate code of ethics and conduct document and within the employee handbook. The vision set out the business commitments and core values of the business.
- We saw that the mission and values were posted on the wall of the unit to remind all staff of the core values. These included quality, honesty and integrity, innovation and improvement and respect and dignity. Managers were able to describe clearly that they were focused on providing high quality care for all patients and strived for continual improvement through auditing of patient outcomes, development and retention of staff, infection prevention, and environmental savings. For, example corporate recycling contracts that included the recycling of sharps bins.
- In the reception area, we saw there was a clear corporate statement of purpose that set out the core values and what patients could expect during a visit to the hospital. These included the aims and objectives for the patients, staff, shareholders and the community.

• Staff we spoke with understood their roles and responsibilities in meeting the core values of the service.

Governance, risk management and quality measurement

- The service used a clinic communication matrix which showed where information from the unit was to be reported to and by when. The matrix included where incident reports, audits and managerial paperwork were to be sent. From the matrix it was clear that all information relating to the unit was filtered up through the Fresenius corporate management structure and to the referring trust. The matrix provided clear guidance on when, frequency and who was to report the information. We saw that senior managers were cited on information from the unit that confirmed they received this information from the unit.
- We saw that key performance indictors (KPIs) were set for patient outcomes. Patient KPIs were based upon the renal association guidelines for improving dialysis process and outcomes. For example, weekly dialysis time and urea reduction rates. We saw that KPI's were monitored and reported through a quarterly clinic review report. Managers were aware of the report content and a balance scorecard containing patient outcomes performance was posted in the staff area. Where the service had not met the required performance we saw that action plans were developed to improve performance.
- We saw that from the monitoring of the key performance indicators contained within the clinic review report, each service could be benchmarked against all of the other Fresenius dialysis units. We saw that the document provided bar graphs showing all Fresenius dialysis units against a number of patient outcome measures such as effective weekly treatment time scores and infusion/blood volume scores. The benchmarking document also contained graphs of improvement or deterioration so that senior managers could act quickly to rectify poor performance.
- We saw evidence that the service had risk assessments in place. Risk assessments included taking water samples, cleaning of blood spills and cleaning of medical equipment. All risks were rated as low. These were kept on file in the manager's office. We saw that 15 of the risk assessments were required to be reviewed between January and June 2017. We saw no evidence to support that these had been reviewed.

- A risk register had been developed to provide an oversight of risks associated in renal dialysis practice and the dialysis environment. The register was split to contain operational risks, clinical risks and technical risks and the new version we were shown, split out local risks from corporate risks so the service had a better overview of the risks directly relevant to the unit. We saw that risks were RAG rated red to green with current controls in place to support the rating.
- Local risks had been documented on the risk register. The dialysis assistants not having access to the trust prescribing system Millennium, was a key risk as they were unable to sign for saline therefore could not follow company policy and best practice when dialysing patients. We saw evidence this had been escalated to the referring trust and that the trust's renal matron and deputy divisional director were informed. This had also been escalated through the correct channels in Fresenius and the clinical services director was aware of the risk and mitigations put in place.
- Senior managers recognised the need to develop a sepsis pathway, and included it on the risk register. They told us this was something that would be looked at on a corporate level. When we returned on our unannounced inspection, we saw that the unit had the copies of the sepsis pathway from the local trust to see if this was something it could implement. A sepsis pathway provides staff with the necessary steps to take to detect a patient with sepsis.
- We saw evidence that the unit had an audit plan that included patient outcomes, water testing, and infection control. The auditing was systematic and followed renal association guidelines to ensure patients received safe care and treatment.
- We saw evidence that the service had developed clinical work instructions to ensure that staff carried out their duties in-line with corporate policy and legislation. For example, we saw there were comprehensive work instructions for the management of blood borne viruses, complications, reactions and other clinical event pathways such as needle dislodgement.
- The work instructions provided staff with flow diagrams to follow. We saw that staff had signed to say they had read and understood the work instructions. However, we saw that the work instruction documents in the folder did not show when the work instructions had been reviewed as they only showed an effective from date, so it was difficult to establish if the documents

were the most current and up to date practice for staff to follow . However, the clinic manager used coloured tabs to mark the work instructions that had been recently updated, to allow staff to see easily which work instructions required re-signing.

- The regional business manager attended contract management meetings with the trust. The clinic manager told us any issues that came out of the contract meeting were fed back to her by the regional business manager.
- The Workforce Race Equality Standard (WRES) 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 produce and publish WRES report.
- Fresenius did not have or maintain a WRES report or action plan to monitor staff equality. We saw that this was on the risk register and reported that it was part of their wider approach to ensure equality for all employees.

Public and staff engagement

- The service completed a patient satisfaction survey in 2016. Results from the survey showed that 76% would recommend the service to family and friends, 86% felt the clinic was well organised and 90% thought patients were treated with dignity. In the 2015 patient survey there were 8 respondents. In 2016 this rose to 21 respondents giving a response rate of 58% against a Fresenius average of 53%. We saw that the action plan was in a 'you said, we did' format, and was displayed on the wall in reception.
- The service performed annual staff surveys. In the 2016, staff survey the response rate was 29% (2 responses). We saw an action plan had been developed to address the issues raised in the survey that included 'improve staff knowledge and confidence in the reporting and management of concerns', 'improve knowledge in management of violence and aggression' and 'increase staff confidence in the value of their suggestion for team improvement'.
- Staff we spoke with told us that the reason the staff survey results showed these areas for action was

because the survey was not written in a way they could easily understand and the questions had been misinterpreted, there were no issues with violence or aggression on the unit and staff were comfortable raising issues and ideas with the management team.

- We saw that 'tell us what you think' cards were available in the main reception for patients to raise issues or compliments if they did not want to raise them directly with the staff.
- We saw that team meetings followed a structure with set agenda topics that included clinical issues; however we saw team meetings did not occur on a regular basis. We saw evidence in the off duty folder of a meeting in May 2017, but prior to that the meetings minutes we saw had been from February 2017 and September 2016. The unit did use a clinic diary for daily communication which had information documented in it such as patient blood requests and additional jobs on the unit that needed doing.
- There was a 'you said, we did' patient survey action plan on display, so patients could see what the clinic intended to do to address the survey results. Actions included all patients receiving a patient guide and patients being reminded how to complain or raise concerns.

Innovation, improvement and sustainability

• The service had had no plans to replace the current dialysis machines and move to a newer model. Managers told us this was because of the way the interim bridging contract operated. We spoke to a technician that told us machines were replaced after 25,000 hours or 10 years. There were 14 machines at the service, six machines had hours over 25,000 the highest being 31,930. Renal Association guidelines state: "we suggest that machines should be replaced after between seven and ten years' service or after completing between 25,000 and 40,000 hours of use for haemodialysis, depending upon an assessment of machine condition."

- The service followed its clinic environmental plan set out in the corporate environmental policy statement. The policy statement set out what the company will do to reduce their environmental impact and improve environmental performance. For example, general waste was separated from cardboard so could be recycled other than going to landfill. We saw evidence that the service monitored its environmental impact using an environmental impact evaluation sheet. The evaluation sheet covered impacts elements from air, water, people and waste, with current control measure and future improvement planning actions. We saw evidence that environmental factors were included on the clinical review reports for review by the senior management team and actions to improve environmental performance.
- The service used dialysate that was stored in a large central delivery system (CDS). This large tank held dialysate rather than using small plastic drums. This would reduce costs to the service, and reduce the amount of plastic used in the dialysis process.
- The clinic manager told us that the deputy clinic manager weighed clinical waste to monitor usage and we saw evidence that sustainability was discussed at team meetings, with staff being reminded that four small clinical waste bags should be put in one large clinical waste bag. The service was meeting the corporate contaminated waste per treatment target of 0.84.
- The area head nurse told us that the provider ran annual two-day management conferences that clinic managers attended, to help build their management skills and drive innovation and improvement in the units they managed.

Outstanding practice and areas for improvement

Outstanding practice

• The service had an outstanding approach to multidisciplinary care and treatment. Patients had regular access to a dietician, a vascular access nurse and an anaemia nurse. Monthly quality assurance meetings were attended by the clinic manager, the

nephrologists, a vascular access nurse, an anaemia nurse, a dietician and a pharmacist. Changes to medication could be made immediately, once the patient had been reviewed.

Areas for improvement

Action the provider MUST take to improve

• The provider must take action to ensure staff are trained with regards to the identification, process, and management of patients with sepsis.

Action the provider SHOULD take to improve

- Ensure the dialysis assistants' practice reflects the recommended Nephrocare practice for dialysing patients.
- Ensure DNACPR forms are fully and correctly completed.
- Ensure the post dialysis temperatures of patients with a central venous catheter, are consistently recorded in the patients' records.

- Review processes to audit staff competency files to ensure they are correctly completed.
- Ensure patient identity is routinely checked prior to starting dialysis and issuing medication.
- Monitor and publish data in line with the Workforce Race Equality Standard (WRES).
- Ensure unit risk assessments are completed and reviewed within the appropriate specified timescales.
- Ensure that there is a process in place to monitor the age and usage of dialysis machines at the unit, and machines that are identified as over the recommended age or usage are replaced.

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment
	(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.

Enforcement actions

Action we have told the provider to take

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