Sparkhill Dialysis Unit

Quality Report

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Date of inspection visit: 30 May and 12 June 2017
Date of publication: 27/09/2017

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

Overall summary

Sparkhill Dialysis Unit is operated by Fresenius Medical Care Renal Services Limited. The service has 24 dialysis stations including four isolation rooms. There are three consulting rooms and one meeting room. Dialysis units offer services, which replicate the functions of the kidneys for patients with advanced chronic kidney disease. Dialysis provides artificial replacement for lost kidney function.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 30 May 2017, along with an unannounced visit to the unit on 12 June 2017.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate. Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

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

We found the following issues that the service provider needs to improve:

- The process of incident reporting, investigation, escalation and learning from incidents was not consistent with a lack of understanding of the process.
- The unit did not meet the duty of candour requirements.
- We found medicines management processes including patient identification were not in line with safe medicine standards and national guidance.
- There was not a formal process to detect deteriorating patients and those with signs of sepsis to safely and appropriately manage them in line with best practice guidance and national standards.
- We found variable staff competency to correctly perform aseptic non-touch technique. There was insufficient action taken to reduce the risk of infection and monitor compliance with infection prevention and control procedures.
- We found staff training records to be incomplete and clinical outcome data such falls and infection rates to be conflicting.
- We found that staff did not understand and correctly follow safeguarding procedures and comply with the Mental Capacity Act and Deprivation of Liberty Safeguards.

Summary of findings

- The risk register did not identify all the unit risks and therefore not appropriately managed or action taken.
- The overall leadership and governance of the unit required strengthening to improve.

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

- Staffing levels were maintained in line with national guidance to ensure patient safety.
- Nursing staff had direct access to a consultant who was responsible for patient care. In emergencies, patients were referred directly to the local NHS trust and the emergency services called to complete the transfer.
- Overall, the unit achieved effective outcomes for their patients.
- All patients at the unit received high flux dialysis. High flux dialysis is the most effective type of haemodialysis; it is better quality dialysis with shorter dialysis times.
- Flexible staff worked over their hours when needed for the interests of patients.
- Staff were overall caring and friendly who knew their patients well and looked after them with compassion and understanding.

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 four requirement notices with details are at the end of the report.

Post-inspection, the provider provided an action plan in response to our findings to demonstrate action to address our concerns.

The action plan referred to improvements for the following:

- Mental capacity assessment
- Detection of the deteriorating patient
- Sepsis management
- Falls assessments
- Central venous access device assessments and escalation
- Infection prevention and control practices
- Monitoring of patients at high risk of infection (including those with central venous access devices).

Full information about our regulatory response to the concerns we have described in this report will be added to a final version of this report we will publish in due course.

Heidi Smoult

Summary of findings

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

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

Summary of findings

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Background to Sparkhill Dialysis Unit

Sparkhill Dialysis Unit is operated by Fresenius Medical Care Renal Services Limited. The service opened in 2011. It is a private unit delivering NHS care in Sparkhill, Birmingham.

The unit primarily serves the communities of the surrounding local areas. It also accepts patient referrals from outside this area, if required.The main referral point is from University Hospital's Birmingham NHS Foundation Trust.

The unit operates two dialysis sessions, morning and afternoon, Monday to Saturday.The registered manager has been in post since December 2015.

The service is registered for the regulated activity of diagnosis and treatment of disease.

Our inspection team

The team that inspected the service comprised a CQC lead inspector Stacie Davies, one other CQC inspector, and a specialist advisor with expertise in dialysis nursing. The inspection team was overseen by Tim Cooper, Head of Hospital Inspection.

Information about Sparkhill Dialysis Unit

Fresenius Medical Care Renal Services Limited ('Fresenius') is contracted to provide dialysis to local patients with kidney failure under the care of two nephrologists from University Hospital's Birmingham NHS Foundation Trust. All patients attending Sparkhill Dialysis Unit ('the unit') receive care from a named consultant at the hospital, who remains responsible for the patient. Fresenius has close links with the 'commissioning' NHS trust to provide care between the two services. To achieve this, the service has support from the local NHS trust to provide medical cover, satellite haemodialysis unit coordinator support, pharmacy support, and regular contact with a dietitian. This team attend the unit regularly and assess patients in preparation for monthly quality assurance meetings.

The unit is open between 7am and 6.30pm, Monday to Saturday. It is currently providing treatment for 96 NHS patients, aged 18 and over. The service does not treat privately funded patients. There are two dialysis session day patterns for each patient; either Monday, Wednesday and Friday or Tuesday, Thursday and Saturday with two sessions per day, with 24 patients in the morning 24 patients in the afternoon. The usual times for dialysing patients are between 7am and 12pm, then between 12pm and 6pm.

During the announced and unannounced inspections, we spoke with 21 staff including; the registered manager, the deputy manager, registered nurses, health care assistants, the area head nurse, the business manager, two satellite co-ordinators and an access nurse. We spoke with 15 patients and one relative. We also received 35 'tell us about your care' comment cards which patients had completed prior to our inspection. We reviewed 13 sets of patient records.

There were no special reviews or investigations of the unit on-going by the CQC at any time during the 12 months before this inspection. The unit has been previously inspected once in December 2012 and was the services first inspection since registration with CQC, which found that the service was meeting all standards of quality and safety it was inspected against.

Summary of this inspection

Activity

- Utilisation of capacity was 92-96% during December 2016 and February 2017.
- The total of haemodialysis sessions undertaken in the previous 12 months was 14, 634.
- The average number of dialysis sessions delivered each month was 1220.
- There were no cancelled or delayed dialysis sessions for non-clinical reasons in the past 12 months.
- There were no patients on a waiting list to receive dialysis.
- There were 20 patients transferred from the unit to another service during the previous 12 months.

The unit currently employs 13 registered nurses including one clinic manager and one deputy clinic manager, five health care assistants and one part time secretary. All staff worked long day shift patterns (from open until close).The unit did not keep controlled drugs. The registered manager was the medicines management lead.

Track record on safety (June 2016- May 2017)

- No never events.
- Fourteen clinical incidents between June 2016 and May 2017; eleven low harms (79%) and three moderate harms (21%).
- One serious incident.
- Two unexpected patient deaths in 2016.
- Ten patient falls.
- No incidences of healthcare acquired Methicillin-resistant Staphylococcus aureus (MRSA) in the previous 12 month period.
- Eight incidences of healthcare acquired Methicillin-sensitive staphylococcus aureus (MSSA).
- No incidences of healthcare acquired Clostridium difficile (C.diff).
- No incidences of healthcare acquired E-Coli.
- Six formal complaints.

Summary of this inspection

Services accredited by a national body:

There were no services accredited by a national body, however the 'ISO 9001 quality management system' and 'OHSAS 18001 health and safety' accreditation were in place from October 2016 until September 2018.

The ISO 9001 quality management system is a standard based on a number of quality management principles including a customer focus and continual improvement.

OHSAS 18001 is an occupational health and safety assessment. It is an internationally applied British standard for occupational health and safety management systems.

Services provided at the unit under service level agreement:

- Cleaning services by an outsourced company.
- Facilities contracts with various companies managed by Fresenius procurement department.
- Medical equipment servicing and calibration.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

We found the following issues that the service provider needs to improve:

- We were not assured that the registered manager fully understood the categorisation of incidents. Governance processes required strengthening, including more robust investigations of serious incidents and duty of candour regulation compliance.
- We found evidence that the unit was non-compliant with duty of candour requirements.
- We saw that mandatory training records had gaps in the data and therefore we could not be sure if training was completed or not.
- The registered manager had not received a higher level of adult safeguarding training to be able to support staff in the event of safeguarding concerns as the safeguarding lead for the unit.
- Infection prevention and control practices were below expected standards including variable standards for aseptic non-touch technique.
- The unit reported 11 healthcare acquired infections during April 2016 and May 2017.
- Medicines administration practices did not follow national standards for best practice. Staff did not routinely check patient identity prior to medicine administration. Medicine and dialysis prescriptions were not consistently updated as per provider policy.
- The unit did not have a hoist or back-up weighing scale for emergencies.
- There was no safety process in place to ensure patients who deteriorated would be managed safely and appropriately in line with national guidance. There was no sepsis policy and staff had not received training to recognise or manage this life threatening condition.
- Staff did not consistently escalate deviations of central venous catheter device risk assessment scores as per provider policy for medical review. Other risk assessments were not consistently updated as per provider policy.
- The unit did not assess patient risk for falls despite 10 recorded falls and a serious injury following a fall.
- Evidence we saw did not assure us that audits were effective such as observation of aseptic technique and documentation.

Summary of this inspection

However, we found the following areas of good practice:

- Staff understood their role and responsibility for reporting clinical incidents and were aware of what required reporting.
- Staff were diligent in checking dialysis machine alarms and patient call bells before cancelling the alarms.
- Staff worked flexibly to ensure safe staffing levels with the rota planned to ensure patient needs were met.
- Post-inspection, we received an action plan to demonstrate the actions the provider was taking to address safety concerns.

Are services effective?

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

We found the following areas of good practice:

- The unit monitored key performance indicators monthly as recommended by the Renal Association.
- The unit provided haemodiafiltration treatment for 100% of patients, which is the most effective treatment for kidney failure.
- In the 12 months leading up to our inspection, 100% of patients received high flux dialysis, meaning better quality dialysis.
- From February to April 2017, we saw 97% of patients who attended three times a week were dialysed for the prescribed four hours treatment time. This is better than the minimum standard of 70%.
- All registered nurses were up-to-date with their annual competency re-assessments.
- All staff were up-to-date with their annual appraisal.
- The unit had an integrated IT system with the commissioning NHS trust meaning all healthcare professionals could coordinate care effectively and communicate with one another easily.
- The dietitian reviewed patients' nutritional status regularly and provided specialist advice.

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

- Provider guidance and policy management was unclear with missing expiry and review dates.
- The unit was below expected ranges for patient blood levels for haemoglobin and albumin.
- Staff lacked understanding regarding mental capacity assessments, best interests and deprivation of liberty

Summary of this inspection

safeguards. We saw examples of two patients where these applied but staff had not implemented these effectively. Post-inspection, we received an action plan to demonstrate the actions the provider was taking to address these concerns.

Are services caring?

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

We found the following areas of good practice:

- The Fresenius 2016 patient survey showed 92% were likely to recommend the unit to a relative or friend and 100% said the unit was a happy one with a friendly atmosphere.
- Overall, patient comments were complimentary of the service and staff with comments such as 'excellent care', 'friendly' and 'professional'.
- Staff treated patients with dignity and respect.
- Staff and patients described a 'family atmosphere'.

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

- We received patient feedback that certain members of staff were rude and we observed that some staff members were not empathetic in their approach.
- We heard two staff members using the word 'demented' when describing patients living with dementia.

Are services responsive?

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

We found the following areas of good practice:

- The unit endeavoured to accommodate patient preference for dialysis date and time with patients helping each other for social or religious events.
- The unit had a high proportion of both patients and staff of minority ethnic backgrounds, meaning staff could speak 10 languages to communicate with their patients. The unit displayed posters and leaflets in several languages.
- Staff could refer patients to a renal social worker if required.
- The staff utilised individualised care plans to plan care for patients with complex needs such as dementia.
- There was no waiting list for treatment and there had been no cancellations of treatment in the 12 months before our inspection.

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

Summary of this inspection

- Data collected by the unit showed that afternoon patients were below the 90% target of receiving treatment within 30 minutes of the treatment time due to transport issues.
- There was no transport user group despite continued issues with untimely collection from the unit.
- Patients told us they did not always feel listened to when they raised concerns.
- Although the registered manager monitored complaints, not all actions and completion dates were recorded on the complaints log.
- There was no process to ensure that people who have a disability, impairment, or sensory loss were provided with information that they could easily read or understand so they could communicate effectively with staff.

Are services well-led?

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

We found the following issues that the service provider needs to improve:

- The registered manager lacked adequate knowledge and understanding of governance processes such as categorisation of incidents and duty of candour requirements.
- We were not assured there was an effective governance framework in place. Systems were not in place to effectively manage risk and safety. There was a lack of understanding by senior staff and corporate processes had not been put in place or maintained. Identified risks were not on the risk register such as the unit infection rate.
- Staff told us there was a lack of visibility of senior managers and we saw no evidence of one-one meetings with the registered manager and head nurse.
- There was a lack of awareness and oversight of safety issues such as poor medicines management and infection prevention and control practices.
- The unit did not look outwards for ways to challenge standards or to improve.
- The unit could not evidence regular team meetings or one-one meetings with the head nurse.
- The unit did not provide us with evidence of a replacement programme for dialysis machines in line with the Renal Association standards.

However, we found the following areas of good practice:

Summary of this inspection

- There appeared to be a positive working relationship between the unit and the commissioning NHS trust with staff describing effective communication and teamwork.
- Staff were positive about the registered manager and although they described the culture as 'busy', they also said the unit was friendly.
- Overall, patient and staff engagement surveys showed positive results.
- The unit had won awards in previous years for high-ranking key performance indicators across Fresenius.

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

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

- Fresenius categorise incidents as either clinical or non-clinical. Patient falls were categorised as non-clinical/ health and safety incidents. Non-clinical incidents were logged differently on a paper-based log, which did not contain full incident details. We were not assured incidents such as falls were appropriately categorised or investigated. In addition to this, there was a system of reporting any clinical variance from the care pathways. These were known as treatment variance reports or TVR's.
- Clinical incident data provided to us showed there had been 14 clinical incidents between June 2016 and May 2017; 11 low harms (79%) and three moderate harms (21%).
- The three moderate harms included two serious infections and one hepatitis C infection post-holiday return.
- There were 10 non-clinical incidents reported during June 2016 and May 2017, 100% of these were patient falls. Out of the 10 falls, three were level 1 (30%), Four level two (50%), one level three (10%) and one level four (10%). The categorised level increased with the level of associated harm however, they were not detailed in the incident reporting policy and the manager could not explain what they meant during the inspection.
- Staff reported incidents directly to the manager who then completed the clinical incident report (CIR). The chief nurse and the health and safety officer were responsible for analysis and investigation of all serious incidents in the Fresenius group.
- The unit had a clinical awareness file for clinical incident learning bulletins, which were developed and sent out by the central clinical incidents team. These were shared across Fresenius and sent out when it was considered necessary but there was no evidence of lessons learnt shared locally for all incidents reported.
- We saw that all staff were required to sign to say they had read the bulletins and staff could tell us examples of learning from the folder. Staff gave an example of recent learning from an incident, which meant that staff could no longer carry and use scissors for dressings. We did not observe any staff using scissors and the manager told us they carry out spot checks to ensure no scissors were used on the unit.
- The unit reported emergency transfers to the clinical incidents team with the reason for transfer. This team decided whether an incident report was required. This meant that there were potential missed opportunities to learn from these incidents.
- There were no never events reported from April 2016 to April 2017. Never events are wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers.
- There were two reported unexpected patient deaths in the previous 24 months prior to the inspection, February and April 2016. Both occurred whilst the patients were at home and were cardiac related.
- We were concerned about the categorisation of incidents because the manager was uncertain about the difference between moderate harm and when an incident would be classed as a serious incident.
- We saw the clinical incident reporting policy, which was updated March 2017 on the intranet. The manager told us that the definitions were unclear and unhelpful.

- There were no governance meetings held locally with the registered manager to discuss clinical incidents. The manager told us that incidents could be discussed at the monthly quality assurance meeting but there was no audit trail of such discussions.
- The manager told us that the consultants and satellite co-ordinator were informed of all clinical and non-clinical incidents via email. The satellite co-ordinator confirmed that they were informed of all incidents reported.
- We viewed four investigation reports for three moderate harm incidents and one death. The root cause analysis and investigation process was brief and did not include evidence of interviews with involved staff members. We could not be assured that actions were appropriate in view of the limited information collected. The manager had received training in root cause analysis and clinical risk management in April 2015.
- Clinical incidents were not an agenda item at unit team meetings. We were provided with minutes from two meetings that occurred in November 2016 and May 2017 and they confirmed this. The manager told us incidents were discussed during daily handovers but there was no evidence to support this.
- Providers are required to comply with the Duty of Candour Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. 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 manager told us that the clinical incidents team decided whether duty of candour applied to incidents. The previous clinical incident report form did not refer to duty of candour but the form was revised recently and included a duty of candour prompt. We viewed recent incidents on the new form and it was evident that knowledge and understanding of duty of candour lacked both locally and at the clinical incident corporate team level because duty of candour was not carried out for any of the moderate harm incidents.
- Nursing staff understood their responsibility to be open and honest with patients when things go wrong.
- We reviewed four incidents that were moderate harm or death and all of these did not meet the duty of candour regulation. The form reported that duty of candour was not relevant because “no notifiable safety incident associated with this event”. The manager told us the trigger for duty of candour was severe harm however, the trigger is moderate harm. The manager was not familiar with the contents of the incident reporting or duty of candour policies.
- We saw training records that showed the registered manager had received duty of candour training in April 2017. No other staff received this training.

Reliable systems, processes and practices

- All staff were required to complete a programme of mandatory training appropriate to their role. Training was divided into several categories dependent on the staff group and whether the modules were once only or reoccurring. Subjects were completed either during face-to-face training or via an electronic learning programme.
- We were provided with the annual timetable of training for the staff working on the unit which was colour coded, for example showing red where training was overdue, amber if the training was due soon, and green if the training was within date.
- Overall, at the time of our inspection, mandatory training rates were high but there were some missing data in the training matrix for some mandatory modules for some staff and therefore some low compliance rates. The highest was 94% (basic life support) and the lowest 0% (treatment variances case studies for less frequent events).
- We asked the manager what the target compliance rate was for mandatory training but they were unsure but told us 100% was expected.
- The registered manager and deputy manager had completed the mandatory annual NephroCare standard ‘good dialysis care’ in 2016. This meant that the rest of the staff (16 out of 18, 89%) were not up-to-date with this module. This module was fundamental to the role of staff delivering dialysis treatment. We were told post-inspection that all staff completed the NephroCare standard ‘good dialysis care’ online module and were up-to-date. Training records did not reflect this.
- Basic life support and defibrillator training compliance was 94% (17 out of 18 staff) and anaphylaxis training was 72% (13 out of 18).

- Manual handling training compliance was 89% (16 out of 18) and fire training compliance was 89% (16 out of 18). Slips, trips and falls training was E-learning and the training matrix was missing data for four (22%) staff out of 18, therefore 78% were up-to-date.
- The annual infection prevention and control assessment and hand hygiene training was up-to-date for 94% of staff (17 out of 18) respectively.
- Data was missing from training records for 10 out of 18 staff (56%) for equality and diversity training. Seventy-two percent of staff (13 of 18) had received radicalisation training.
- Other mandatory modules and compliance rates included: water treatment testing: 82% (14 of 17 staff), blood borne virus training: 77% (10 of 13 registered nurses), preventing medicine errors: 62% (8 of 13 registered nurses), 'an introduction to dementia for health and care professionals': 89% (16 of 18 staff), vascular access: 77% (10 of 13 staff), haemodialysis filtration online module: 83% (15 of 18 staff), treatment variance report training: 23% (3 of 13 registered nurses, this meant that 87% of nurses did not have this training including the registered manager and treatment variances, case studies for less frequent events: 0%
- It was unclear from the training matrix that was sent to us post-inspection if the gaps meant staff had not completed the training module or whether records had not been updated.
- Mandatory training for agency staff was monitored centrally through the Fresenius Flexibank.

Safeguarding

- Records at the time of the inspection showed 94% (17 out of 18) were up-to-date with safeguarding adults training and 89% of staff (16 out of 18) were up to date with safeguarding children training. No children were treated at the unit and were not allowed in the treatment areas.
- There was a Fresenius safeguarding policy in place dated May 2015, which specified the process and responsibilities, however there was no review date. The policy did not specify the level of training required for staff or detail how to detect domestic abuse or female genital mutilation and actions to follow, if detected.
- The service lead for safeguarding vulnerable adults and children was the registered manager however, they received the same level of training as all other staff. This meant that the service lead did not have a higher level of training to support unit staff. The manager told us they had not done a referral before and would need support to do so if the need arose.
- Safeguarding contact details were displayed in the manager's office and staff knew where to find them if required.
- Staff told us that safeguarding concerns would be identified by the commissioning NHS trust and actioned by them. We felt there was a sense of complacency within the unit around safeguarding issues because of reliance upon the commissioning NHS trust to identify and action issues.

Cleanliness, infection control and hygiene

- There were clear infection prevention and control policies and hygiene plans for staff to follow. All staff we spoke with told us they were aware of the procedures.
- An external company provided daily cleaning every day the unit was open. The supervisor from the cleaning company visited the centre once a month to check the standard of cleaning. We were told a health care assistant would do any additional cleaning in the day, if needed.
- On our announced inspection, the unit was visibly clean, tidy and clutter free. However, on our unannounced inspection, we found several pieces of disposed packaging on the floor in the main clinical area. The comment card responses we received were mixed regarding cleanliness and hygiene of the unit. Two highly praised cleanliness and hygiene but five said this could be improved.
- We saw hand-sanitising gel available at every entrance, nurses' station and treatment areas. We saw staff using hand gel before and after patient contact and patients told us staff used hand gel.
- There was a hand washbasin for every isolation room and one between every few chairs within the main treatment area. All hand wash basins on the premises were operated by non-touch sensors, and had paper towels and soap. We saw signs at basins to remind staff of the World Health Organisation (WHO) '5 moments for hand hygiene' steps.
- Hand hygiene compliance was audited monthly and records showed that results ranged from 86% (June 2016) to 100% with an average of 94% between April

2016 and May 2017. Results were consistently below 90% between April and November 2016 but have been above the target compliance of 95% since December 2016 with 100% compliance in April and May 2017.

- There was a hand hygiene audit action plan in place as we saw that during poor compliance months, staff missed several '5 moment' opportunities and staff with poor compliance were informed.
- The registered manager conducted a monthly hygiene and infection control audit of the unit and we saw records that showed that between January and May 2017, results ranged between 98-100%. We saw the associated action plan with appropriate actions with completion dates however; our observations found several concerns and therefore questions the effectiveness of this audit.
- We saw that staff adhered to the uniform policy by not wearing jewellery; arms were bare below the elbows and wore name badges.
- We saw staff using personal protective equipment (PPE) such as gloves, aprons and each staff member had their own face shields and we saw that there was adequate supply for staff to use.
- There were four isolation rooms that were predominantly used for blood borne viruses such as hepatitis C and HIV. Patients with hepatitis B were treated at the commissioning NHS trust. The isolation rooms were also used to treat holiday patients or those returning from high-risk countries. There were designated machines for holiday patients.
- The unit routinely screened all patients for MRSA and blood borne viruses but not for other organisms such as Methicillin-sensitive staphylococcus aureus (MSSA).
- Pre-inspection data reported that during January 2016 to December 2016, there were 14 patient infections, three MRSA, six MSSA and five classed as 'other'.
- Post-inspection data the unit provided reported that during the 12-month period April 2016- May 2017, there were 11 healthcare associated infections. Eight of these were MSSA and three were classed as 'other'.
- We observed two nurses undertaking poor aseptic non-touch technique (ANTT) and one nurse who followed best practice technique when connecting patients to, or disconnecting them from dialysis machines. ANTT is the use of sterile techniques designed to prevent contamination from microorganisms to minimise the risk of infection.
- The examples of poor ANTT practice included touching the sterile field with non-sterile gloves, discarding of needles on the sterile field instead of the sharps bin and used saline ampoules placed on the sterile field. We also saw use of gloves after touching non-sterile equipment, which made them unsterile.
- The manager told us that their objective was to reduce unit bacteraemia rates however, they were unaware of variable ANNT practice and therefore we felt this was a risk to patients.
- The registered nurse 'annual dialysis unit staff re-assessment record' has a self-declaration for staff to declare that they were familiar with the requirements of the 'NephroCare Standard Good Dialysis Guide' (C-UK-CI-09-03), which states that aseptic technique should be maintained throughout connection and disconnection procedures to reduce the risk of infection.
- Staff told us and we saw disinfection of dialysis machines between each patient and at the end of each day. Single use consumables such as blood lines were used and appropriately disposed of after each treatment. We observed staff cleaning the chairs and changing disposable items such as pillow coverings.
- Each dialysis chair space had disposable curtains and we saw that these had dates of when they were last changed. Staff told us they were changed six monthly or when they became soiled.
- Fabric tourniquets were in use on the unit, which makes keeping these clean to remove any potential bacteria difficult.
- There was no system in place to show equipment was cleaned and ready for use. There were no stickers or signs to indicate equipment was clean.
- Staff carried out daily water tests to monitor the presence of chlorine in the water in line with the UK Renal Association clinical practice guidelines. We saw records that confirmed this and no variances were recorded between January and May 2017.
- Staff were able to describe the management of the water systems for the presence of bacteria and PH levels and were explain to explain the procedures that were required should a water sample test positive.
- Records confirmed that the unit carried out monthly water microbiology tests with no deviations reported between January to May 2017.

- The unit used a bar coded system for sharps bins to ensure they were labelled appropriately. We saw one sharps bin that was soiled with blood on the exterior, which was cleaned when we told one of the nurses.
- The unit appropriately separated clinical and domestic waste with designated storage for large waste bins and a designated exit door for when the waste was collected. Staff appropriately segregated waste in clinical areas.
- The unit had a two-yearly legionella risk assessment by an external company. We saw the 2015 report and the recently reported 2017 assessment. The recent rating was 'high' with an action plan in progress to address the issues found. The actions were required to be completed by March 2018.

Environment and equipment

- The main entrance of the unit was secured by intercom access and was fitted with automatic opening doors. The waiting area and the receptionist desk were immediately accessible upon entrance to the unit.
- The door to the dialysis treatment area was secured with a coded key pad. Staff would open these doors at the beginning of dialysis sessions to allow patient access. Other restricted access areas included the water treatment plant, technician's room and equipment storage rooms.
- The unit had three consulting rooms, a meeting room, toilets for staff and patients, staff changing rooms, a staff kitchen a dining area and a patient kitchen to prepare drinks.
- The nursing station was situated so that all dialysis treatment areas could be seen in an open plan design. The isolation rooms and the two treatment bays (with four dialysis chairs) had glass frontages so that patients could be seen externally. The main treatment area (12 chairs) was in the middle of the unit, directly opposite the nursing station with the four isolation rooms to one side and the two bay rooms (four chairs each) to the other.
- Each dialysis chair had adequate space to manoeuvre and to ensure privacy with curtains around. The isolation rooms were spacious with their own designated toilet contained inside.
- Every treatment station had a nurse call button. When a call button was pressed, an audible alert sounded and a light above the station was illuminated. We saw dialysis machine alarms were used appropriately and not overridden; when alarms sounded, we saw nursing staff check the patient and lines before cancelling the alarm.
- There were six spare dialysis machines for the use of patients with blood borne viruses or holiday patients, stored within a designated store room. There was also a designated area assigned to storing spare machines when in use for a particular day.
- We saw evidence of yearly portable appliance testing to ensure electrical equipment was safe to be used. The unit's dialysis machines were serviced annually on site by the manufacturer's technicians and all machines we viewed had an in date service. Staff told us they contacted the technical services helpline during working hours and there was an on call team out-of-hours if required. Emails were sent for less urgent technical issues. Staff told us the reporting process had improved and the technical support was effective and responsive.
- Fresenius had an in-house facilities management team managed by the procurement department. When repair or maintenance was required, facilities would sub-contract companies to undertake the work.
- We saw the unit's maintenance plan for all equipment detailing when the equipment was last serviced and when the next one was due including dialysis chairs.
- Dialysis machines should be replaced every seven to ten years or between 25,000 to 40,000 hours of use, according to the Renal Association guidelines. The unit did not keep a replacement programme for dialysis machines and a senior manager told us this was held by the technicians. This was not provided to us to see.
- There were two non-gender specific toilets in the waiting area and two in the main treatment area.
- New stock was organised and labelled clearly and stored off the floor on shelving. All staff we spoke with told us that there were adequate supplies of equipment and received good support from the maintenance technicians.
- The unit had three wheelchairs for use if a patient required assistance following treatment.
- The unit did not have a hoist but staff told us they could request one if required by a patient.
- Resuscitation equipment was located next to the nursing station and therefore accessible for any patient. Resuscitation equipment included appropriate equipment such as a defibrillator and a full oxygen cylinder. Records showed that the trolley was checked

daily and we saw completed daily checks for March- May 2017. The trolley contained emergency resuscitation drugs that staff were not trained to use and staff confirmed that they had not used them before. All consumables were in date except one, which was removed by staff after we found it.
- There was an eyewash and first aid kit located at the nursing station.
- The unit had one weighing scale and did not have a backup. Senior managers were unable to describe what would happen if the scale failed and therefore unable to assess patient weight, which is essential for effective and safe dialysis treatment.

Medicine Management

- The unit did not use or store any controlled medicines. The registered manager had overall responsibility for the safe and secure handling and control of medicines.
- On a daily basis, the nurse in charge was responsible for the medicines cupboard keys.
- The lockable medicines cupboard was stored within the clean utility room. The cupboard was locked on both inspection days. The medicines stored within the cupboard were within their expiry date.
- The door to the clean utility room was not routinely locked and we found normal saline ampoules stored in an unlocked cupboard. At our unannounced visit, the cupboard had been fitted with a new lock but the lock was broken and therefore ampoules were accessible. The lock was reported to facilities and the door to the utility room was locked for the interim period.
- Medicines requiring refrigeration were stored in a fridge; the fridge was locked and the temperatures were checked on a daily basis and we saw records that confirmed this.
- Within the fridge, we saw 44 flu vaccines from the previous flu season. They were due to expire the month of our inspection. We highlighted this to senior managers who confirmed they were aware of them and they would ensure appropriate disposal.
- We did not see any Patient Group Direction's in place at the unit and the unit did not have any nurse prescribers. We saw that the consultants reviewed patient prescription charts in the monthly quality assurance meetings.
- We saw that consultants sent GP's medicine updates following monthly patient reviews.
- Medicines administration processes did not follow the medicines management policy or the Nursing and Midwifery Council (NMC) standards. We saw that nurses took out medicines in batches and did not check patient identities prior to medicine administration. This increases the potential for patient harm of medicine errors.
- We viewed five patient medicine and dialysis prescriptions. Four out the five did not have updated medicine prescriptions with two-dated December 2016. Four of the five had recent updates to dialysis prescriptions within the previous month.
- There were no arrangements for a pharmacist to visit the unit and the unit did not conduct pharmacy audits. Pharmacy support was available from the local NHS trust pharmacy for advice relating to dialysis drugs. Staff also had access to the company pharmacist at head office.
- We asked for data for the number of medicine errors during April 2016 and May 2017. We were provided with two; one related to incorrect intravenous administration against provider policy and the other was an omission of intravenous antibiotics with a patient following discharge from the acute NHS trust who was treated for sepsis.
- We looked at the training matrix held by the manager and the nursing annual re-assessment documentation and did not see that nursing competencies for the administration of intravenous medicines were re-assessed. Staff told us that they were not re-assessed.
- There was a detailed medicines management policy dated June 2016. There was no guidance to support audit of practice to provide assurance that standards of practice were monitored and reviewed by pharmacy or senior staff. The registered manager confirmed the audit programme did not include medicines management.

Records

- The unit used a combination of paper and electronic records. Data was shared between the electronic database of the unit and the commissioning NHS trust including all blood results. This meant that all staff caring for the patient had access to the patient records at all times.
- Paper records were stored in individual patient folders with the patient name and named nurse on the front. These were held at the chair side during treatment and

in a lockable cabinet behind the nursing station during non-treatment times. The cupboard was not locked during our visits. We were told it was locked when the unit was closed.

- Patient folders holding paper records contained dialysis summary form (patient observations during treatment), the dialysis prescription, medicine charts, nursing assessments such as anaemia and consent forms. We also saw several clinic review letters from the consultant that were sent to the GP and or nursing home if relevant.
- Treatment was mainly electronically recorded and we saw nurses updating electronic records at the end of treatment sessions.
- We saw evidence of recently completed individualised care plans for patients with anaemia, diabetes and one patient with schizophrenia.
- Assessment of patients with central venous catheters (CVC's) was required every treatment session. We viewed CVC assessment documentation of four patients and all were completed appropriately. However, we noticed that three out of the four did not follow provider policy of escalation to the consultant. The policy was if the score was one or more, the nurse was required to contact the consultant for advice on the management.
- The manager held a risk register for the 35 patients with a CVC to monitor care and management of these in view of the increased risk of infection. We saw that this was updated regularly.
- We viewed eight-skin pressure care and manual handling assessment records and found two skin pressure area assessments and one manual handling assessment were not up-to-date.
- The registered manager or deputy manager conducted monthly nursing documentation audits to ensure assessments and prescriptions were updated as required. We saw audit records for January to May 2017 and found that all had omissions in documentation but there was no overall compliance rate specified for each month's audit. There was evidence of actions when omissions identified and action completion.
- The unit submitted documentation audit results as part of their monthly performance data and this reported 'error rates'. The average percentage of active patient records audited was 19% during January and May 2017. The average error rate was 10% with a range of 0-3 records containing an error.
- The documentation audit did not assess if records were legible, signed, dated and contemporaneous as recommended by NMC standards. We found some written nursing documentation to be illegible when reviewing patient records.

Assessing and responding to patient risk

- Staff told us that only medically stable patients could receive dialysis at the unit. The commissioning NHS trust assessed patient suitability for satellite unit care. If a patient became acutely unwell at the unit, they were transferred via ambulance to the commissioning NHS trust. If a patient was deemed unsuitable for satellite care provision, their care would be provided at the commissioning NHS trust, to ensure patient safety.
- Dialysis patients are at a higher risk for sepsis due to a lowered immune response, presence of invasive devices (direct access to the blood stream) and multiple healthcare contacts. Sepsis is a life-threatening illness caused by the body's response to an infection.
- Staff and senior management confirmed that Fresenius did not have a sepsis management policy or pathway and staff were not trained to recognise or manage sepsis. This was not in line with the National Institute for Health and Care Excellence guideline (NG51) for recognition, diagnosis, and early management of sepsis. We saw that this was placed on the risk register in January 2017 with a planned completion date by June 2017.
- We were concerned that the lack of sepsis knowledge and awareness combined with observation of poor aseptic non-touch technique that patients were at risk of infection.
- The manager confirmed there was no formal process or documentation for assessing patient risk of falls but considered the manual handling assessment to be sufficient. We noted that patient who recently had a fall post dialysis did not have a formal or documented risk assessment in place to prevent future falls. We did see during our unannounced visit that a nurse advised this same patient to take care and offered a wheelchair.
- Patient falls were recorded as part of the treatment variance record (TVR) system. Between January and May 2017, there were six patient falls recorded. This data varied from incident data reported at the time we visited.
- There was no formal process or policy in place to positively identify patients prior to commencing dialysis

treatment. It was routine for the patients at the centre to take their own treatment card from the nursing station on arrival and weigh themselves pre-treatment. Nursing staff did not confirm patient identity against the dialysis prescription. We saw an example of a relative taking a treatment card for a patient and inserting the card in the scales and we were concerned this could be a potential cause of error.

- Observations of vital signs such as blood pressure and pulse were recorded before, during and after dialysis treatment. We saw staff checking on patients during their treatment.
- There was no formal process to recognise and manage a deteriorating patient such as the use of the national early warning score (NEWS) system. Staff told us they felt they could identify when their patient was deteriorating but this lacked the effectiveness of NEWS to detect a deteriorating patient before they became acutely unwell. Post inspection, we were told there was a 'management of complications during dialysis pathway' however, staff did not show us how this was utilised.
- Staff recorded clinical care variances, known as TVR's, during dialysis patient records for example, falls risks, mobility post dialysis, weight recording and changes in vital signs measurements. This data was submitted monthly to the commissioning NHS trust.
- The staff on the unit carried out 'handover rounds' each dialysis session, every day. We observed one round and saw this was an opportunity to discuss how each patient was on that day and a chance for all staff to be aware of all the patients on the unit. The manager told us this would be an opportunity for them to share safety bulletin updates received from Fresenius corporate governance team. These rounds were not formally recorded and therefore no audit trail.

Staffing

- The unit had 13 whole time equivalent (WTE) dialysis nurses, 2 WTE HCAs, and two part time HCAs in post. One full time HCA was due to commence post in July. The staffing numbers was calculated to accommodate for annual leave.
- There was one part time dialysis nurse vacancy, which was actively advertised.
- The registered manager worked five days per week with 80% time allocated to management and staff supervisory time and 20% clinical time.
- On our inspection days, there were six nurses and two healthcare assistants (HCAs) on duty. Staffing levels met patients' needs at the time of the inspection. We saw that the nursing rota confirmed staffing numbers were consistent and maintained the appropriate one nurse to four patients (1:4). This ratio was based on national guidance as recommended by the British Renal Society.
- Senior management monitored staffing levels and compliance with the 1:4 ratio. We saw records that showed for April 2017, 96% of shifts (48 out of 50) were compliant for registered nurses. Due to the HCA vacancy (due to commence post), compliance for HCA staffing levels was 52% (26 out of 50) compliant. For May 2017, 83% of shifts for registered nurses were compliant and 78% of shifts for HCAs. These records were submitted monthly to the commissioning trust.
- The average sickness rate for the period June 2016- May 2017 was 6% with a range of 1-15% with the highest being in August 2016. For the month of the inspection, the sickness rate was 12%.
- The average agency staff usage rate for the same period was 2% with a range of 0-8%. The highest rate of 8% was during the month of the inspection due to sickness.
- When staff shortages were identified, staff were flexible and covered extra shifts. If staffing levels could not be maintained by permanent staff, requests were made to FMC Renal Flexibank, who arranged for cover. When Flexibank could not cover shifts, approved external nursing agencies were used.
- An HCA shortage was a consistent concern raised during our inspection by staff, patients and from comment cards (five out of 35). The manager explained that HCAs could not be sourced from an agency, which could leave shifts with one HCA. There was a full time HCA commencing post in July and staff told us this would alleviate the strain.
- The unit did not employ medical staff. The commissioning NHS trust provided medical care. Two dedicated nephrologists attended weekly to review dialysis patients. Staff told us that the consultants made cover arrangements for when they were on leave.
- The commissioning NHS trust provided daily consultant cover and the unit could contact them via email or by telephone as required. Staff told us that accessing a consultant was never a problem.
- The commissioning trust provided dietetic and social work support and both visited several times per week to ensure access to all patients.

- Although staff wore names badges, it was unclear who the nurse in charge was unless patients looked at the board behind the nursing station. All nursing staff wore the same colour uniform and were identifiable by role by their name badges.
- A comment card suggested that it would be beneficial to have a board with staff photos and names on for new patients to the unit.

Major incident awareness and training

- The emergency officer was the registered manager. We saw a location specific emergency preparedness plan (EPP). This detailed the plans for the prevention and management of potential emergencies, such as fire, loss of electricity or water leaks.
- Each patient had a 'personal emergency evacuation plan' (PEEP) and we saw that the manager held a spreadsheet record for all patients electronically. The policy was for the PEEP to be reviewed at least annually or as often as required if circumstances changed. We saw six PEEP records and found the registered manager had recently updated all of them. Two of the forms of patients living with dementia stated that assistance was required for evacuation, but did not specify what assistance. We found these to be unpersonalised to the individual.
- The unit did not have a back-up power generator. Staff told us the dialysis machines had a 15-minute battery back-up so in the event of a power cut, the patient's own blood could be recirculated and returned to them.
- Staff told us they took part in bi-annual fire evacuation drills.

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

Evidence-based care and treatment

- We saw that Fresenius developed policies and procedures in line with guidance and standards from National Institute of Health and Care Excellence (NICE) and the UK Renal Association, and was incorporated into the organisations 'NephroCare standard for good dialysis care'.
- Fresenius adopted an International Standards Organisation (ISO) accredited integrated management system (9001) which ensured all policies and procedures support best practice evidence. This worked alongside an annual review requirement, which was stated as providing assurance that the evidence used was current.
- We looked at five policies, which detailed the date they became effective but did not indicate when the policy expired or review date.
- Arteriovenous fistula's (AV fistulas) are specially created blood vessels in the arm to aid transfer of a patient's blood to the dialysis machine and back to the body. An AV fistula is a surgically created (at the commissioning NHS trust) by connecting an artery to a vein, which makes the blood vessel larger and stronger. AV fistulas are regarded as the best form of vascular access for adults receiving haemodialysis. This is because they last longer and have less risk of complications than other types of vascular access.
- Vascular access was monitored every treatment, audited on a monthly basis and reported at monthly quality assurance meetings. Patients with CVC's were risk assessed at every dialysis session and were on a unit CVC risk register.
- The UK Renal Association's clinical practice guideline on vascular access for haemodialysis recommends 80% of all long-term dialysis patients should receive dialysis treatment through 'definitive access' such as an AV fistula or graft. At the time of the inspection there were 96 patients receiving dialysis with 64% (61) of those with an AV fistula or graft and 36% (35) with a central venous catheter (CVC). The vascular access nurse told us that the commissioning NHS trust monitored CVC access and was usually because of either patient choice or an AV fistula was not possible.
- Staff assessed patients' weight, blood pressure, pulse and temperature pre and post treatment and we saw nurses completing these assessments during our visits. Documentation audits showed that staff occasionally missed temperature assessments and this was an area to improve.
- The unit did not participate in any national audits.

Pain relief

- The unit stocked paracetamol and prescribed as required by patients. The unit did not stock or administer any other pain relief medicines. If patients needed pain relief, they brought their own medicines.

- Patients told us it could be painful when the needles were first inserted into to their fistulas, but the pain went away quickly. Patients told us that some staff were more careful inserting needles than others were.

Nutrition and hydration

- Patients who have renal failure require a strict diet and fluid restriction to maintain a healthy lifestyle.
- Essential to accurate dialysis treatment was ascertaining patient's weight pre and post dialysis. We saw patients weighed themselves before starting dialysis and on completion of treatment.
- The unit provided tea or water and biscuits. Patients told us that this was insufficient both during the inspection and through the comment cards.
- Patients could bring in their own food but were not allowed to heat food up on the premises due to food safety standards.
- The commissioning NHS trust provided dietician support two to three times a week to ensure all patients were reviewed. We saw the dietician in attendance on both of our inspection days.

Patient outcomes

- The UK Renal Registry is part of the Renal Association and provides independent audit and analysis of renal replacement therapy in the UK. The unit did not directly contribute data to the UK Renal Registry. The commissioning NHS trust reported this data for all of its patients including those treated at the unit and therefore patient outcomes were benchmarked with the commissioning NHS trust dataset but not as a unit separately.
- Fresenius benchmarked patient outcomes at unit level for 49 UK units. The unit came second top for one key performance indicator (KPI), one within the top 20, one in the middle range and two within the bottom 11.
- The unit provided haemodiafiltration (HDF) treatment for 100% of patients, which is the most effective treatment for kidney failure.
- All patients had monthly blood tests to assess the effectiveness of their treatment in line with the Renal Association Standards. These included tests for haemoglobin (sign of anaemia), albumin (sign of malnutrition or fluid management), renal clearance (how effective the dialysis treatment is), and phosphate/calcium balance (risk of developing bone disease).
- The results show how the unit performed in the achievement of quality standards based on UK Renal Association guidelines. We reviewed results of blood tests for three months from February to April 2017. These comprised of a number of standards, for example: two standards we looked at show how much waste products were removed from the patient and how effective the dialysis treatment was.

1. The rate blood passes through the dialyser over time, related to the volume of water in the patient's body (expressed as 'eKt/V >= 1.2,h'). On average around 96% of patients had effective dialysis based on this standard. This was significantly better than the 70% target.
2. Urea reduction ratio (URR): the average URR for the patients at this unit from February 2017 to April 2017 was 99%. The Renal Association guidelines indicate a target of 65% and therefore the unit was performing better than the target. Patients with these levels of waste reduction through dialysis have better outcomes and improved survival rates.

- Other results that measure the performance of the treatment the unit provided included iron (haemoglobin/Hb) and potassium levels in the blood, against the Renal Association standards. During February to April 2017, the average number of patients with the NICE recommended iron levels (100-120 g/l) was 67% against the 70% target. Anaemia (low iron levels in the blood) can be a complication of renal failure and dialysis associated with increased risks of mortality and cardiac complications.
- During February to April 2017, an average of 5% of patients had high levels of potassium (greater than 6.0 mmol/l). This meant around 95% of patients had potassium levels within acceptable ranges. High potassium levels in the blood can cause serious health problems including heart complications.
- The unit also monitored nutritional and hydration levels as part of their key performance indicators. Nutrition and hydration monitoring and management are crucial in keeping patients with kidney failure healthy. During January to May 2017, over 75% of patient's hydration status was above the 30% target. Low albumin levels indicate malnutrition and performance data for the same period showed the unit was below the 50% target at 25% within the target albumin blood level range.

- The unit had clinic review report detailing what the key performance indicator targets were against the unit performance rates. Where targets were below expected, there were actions in place. For example, for the lower than expected albumin levels, the action was to ensure the dietician reviewed patients. We saw an action in place for consultants to review all patients' Hb levels in the monthly quality assurance meeting and to adjust prescriptions as necessary.
- During February to April 2017, we saw 97% of patients who attended three times a week were dialysed for the prescribed four hours treatment time. This is more than the minimum standard of 70%.
- In the 12 months leading up to our inspection, 100% of patients received high flux dialysis. High flux dialysis is the most effective method for the clearance of the waste products and fluid. High flux dialysis delay long-term complications of haemodialysis therapy.
- The unit monitored treatment variances such as cannulation problems, clotting, high and low blood pressure, changes in procedure, machine malfunctions and patients who did not arrive for dialysis. A treatment variance report (TVR) summary was produced each month with variances categorised as 'most frequent events', 'less frequent events' and 'other'.
- There were 693 treatment variances between January and May 2017 with a monthly average of 139. The manager told us these results were monitored and submitted to the commissioning NHS trust to look at issues and make improvements where possible.

Competent staff

- There was a comprehensive training programme available for staff. Registered nurses and healthcare assistants (HCAs) were required to complete a series of mandatory clinical competencies, to support their role and responsibilities.
- All staff were required to complete training to gain competence using the dialysis machines. Out of 18 staff members, 15 (83%) had done so therefore, not all staff had completed the training. Agency staff were also required to have this training to work at the unit.
- All registered nurses were required to complete annual hepatitis B vaccination training and records showed that 11 out of 13 (85%) were up-to-date.
- Staff performed annual self-assessments of competence. This followed company guidance and was intended to highlight training and development needs to discuss in annual appraisals. We viewed five staff files and saw evidence of completion of annual competency declarations accompanied with the manager's declaration of completion.
- Records showed that 100% of registered nurses had an up-to-date annual re-assessment and 75% of HCA re-assessments (3 out of 4).
- The manager told us 100% of staff had an appraisal in the current 12-month period and all 13 registered nurses had an in-date Nursing and Midwifery Council (NMC) revalidation and registration. The training matrix had the revalidation dates of six out of the 13 (46%) registered nurses.
- All staff received basic life support training and at the time of our inspection, 94% of staff were up-to-date (17 out of 18).
- The deputy manager had recently completed the manager/deputy manager induction training in May 2017. There was no date provided on the training matrix for when the manager attended this induction training.
- All staff were required to receive an induction period and complete a 'chronic haemodialysis integrated competency' document (separate one for registered nurses and HCAs). Data was missing from the training matrix to show if all staff had completed the document. The only data present was for three out of the 13 registered nurses (23%) who completed it in February 2017.
- No staff received sepsis training and this was seen on the risk register to action.
- The manager told us that two nurses per year could attend an external course to achieve a renal nursing qualification and two were about to commence the course. The manager told us four nurses held the qualification out of 13, but the training record did not show this data.
- The manager told us they observed staff practice as part of their management time and would offer training as required. We were concerned that they had not identified poor medicines management and aseptic non-touch technique as part of this observation.
- Each nurse had a designated extended responsibility known as a link role. The unit displayed a list of designated link roles behind the nursing station. They included staff education and training, MRSA, medicine control, access co-ordination, health and safety, infection prevention and control officer, anaemia

co-ordinator and transplant co-ordinator. Several staff told us that they enjoyed these added responsibilities but because the unit was so busy, they did not get time during their shift to focus on the role.

Multidisciplinary working

- The renal consultant had overall responsibility for patient care and visited the unit every month to carry out a clinical review of patients. Patients also had a named nurse who would usually see them once a week depending on staffing rotas.
- Two team leaders were responsible for the co-ordination of patient care of the named nurses within their team.
- The nephrologist communicated regularly with the GP's of patients, following their monthly review. We saw copies of these letters within patient records. Staff told us communication to and from GPs was effective. We also saw clinic letters that had been sent to patient's living in care homes.
- The consultant nephrologist, the satellite co-ordinator, the access nurse and the unit staff attended the monthly quality assurance meeting. There were no additional multi-disciplinary meetings held.
- There was no escalation process in place in the event of sepsis. Staff told us they would call an ambulance for transfer to the NHS hospital if a patient were unstable or became acutely unwell.

Access to information

- Staff told us they had the necessary information they needed to look after patients.
- Staff at the unit took monthly blood samples from patients, which were analysed by the laboratory at the NHS trust. Unit staff had direct access to their patients' test results through an integrated IT system, which meant all staff had access to the most recent blood results when updating treatment plans and at the point of care.
- Staff told us and we saw that the patient treatment database sent information to the NHS trust. The consultant then notified the GP of any relevant changes.
- We saw the unit shared information to send with a patient when they went for treatment to another unit whilst on holiday. This was to ensure care and treatment could continue.
- We saw that staff used email as an effective communication method both internally and externally. Staff checked their emails on a day-to-day basis and told us that the method worked well.

Consent, Mental Capacity Act and Deprivation of Liberty

- The unit gained written consent for dialysis treatment for all patients at the beginning of their care. We saw evidence of consent forms in patient records. There was no process in place to update written consent after a period of treatment.
- We saw that staff gained verbal consent from patients when performing tasks such as blood pressure monitoring.
- Training records showed that 94% of staff (17 of 18) were up-to-date with The Mental Capacity Act 2005 and deprivation of liberty safeguards training.
- On the day of our announced inspection, we observed a patient living with dementia and a mental health disorder who became distressed and tried to leave during their dialysis treatment. Staff told us the patient's son usually accompanied them but was not present that day.
- We checked the patient records and found a 'patient authorisation for treatment and data protection consent for a patient unable to consent for themselves' form dated November 2013 and signed by a nurse and the patient's son. We saw there was a mental capacity assessment as part of the consent form but there was no recent review of the patient's capacity or consent form.
- We did not see any evidence of a best interest meeting for the same patient or liaison with their GP or psychiatric carers. Staff tried to calm the patient down but also prevented them from leaving the unit. This patient did not have a deprivation of liberty safeguard in place. Staff lacked awareness or understanding about deprivation of liberty safeguards and situations that required action.
- We spoke with six nurses during our announced visit and all told us that mental capacity assessments were completed by the commissioning NHS trust. We asked staff what they would do if they thought a patient lacked capacity to consent and they told us that they would inform the consultant. We were not assured unit staff

had the necessary level of knowledge or understanding for mental capacity assessment or deprivation of liberty safeguards or in the event a patient's capacity to consent deteriorated, arose.
- On our unannounced visit (12 June 2017), we saw the records of another patient living with dementia who did not have a mental capacity assessment or a best interest's assessment. The patient's son, despite no documented evidence that the patient lacked capacity to consent, signed the consent form dated 25 May 2017.

Are dialysis services caring?

Compassionate care

- Staff understood and respected patient's personal, cultural, social and religious needs. We saw staff taking these into account when planning treatment. For example, patient's dialysis sessions were planned around their work, social events, and cultural/religious events. Staff told us patients were also willing to swap sessions with each other to accommodate one off events.
- We saw staff engaging in friendly conversations with patients and addressing them by their preferred name. We could see that nurses and patients knew each other well.
- Overall, we saw that staff were empathetic towards patients and could see they wanted to improve the quality of life for their patients. We however, also observed that at times, a few staff members were unsympathetic in their tone when talking to patients.
- The unit adopted a 'named nurse' approach to provide continuity of carer. Staff told us that their shifts varied but would usually see their patients at least once per week. Overall, patients said they did see their named nurse but knew all the nurses well.
- Nursing staff told us that as they saw their patients frequently they were familiar with their moods and were able to identify when patients were having a bad day or were feeling unwell. A patient confirmed that when they felt unwell, staff were attentive and provided additional support. One patient described the atmosphere as 'one big family'
- We received 35 comment cards filled in prior to our announced inspection and these were from patients or their relatives. Out of the 35, 17 (49%) were positive, 11 (31%) were mixed positive and negative and seven (20%) were negative comments.
- The positive comment cards included 'caring', 'excellent care', 'friendly', 'safe care', 'professional', 'helpful' and 'treated with dignity and respect'. The negative comments related to poor staff attitude, transport issues, lack of food provision, staffing shortages and uncleanliness.
- One of the healthcare assistants (HCAs) was referred to three times in comment cards for their rude manner towards patients and their observed poor attitude towards the registered manager. Another four comment cards referred to bad staff attitude or rudeness.
- Staff drew curtains around for privacy and patients told us they could request to speak to staff in private.
- We observed that staff were attentive to patient needs during treatment. They responded to patient call bells, machine alarms and verbal calls for help or distress promptly.
- Nursing staff maintained patient comfort with additional pillows, pressure relieving aids and laundry. We saw that many patients brought their own blankets and comforters.
- We observed a patient being rude to a nurse and shouted at them. The nurse told them that shouting was unacceptable and not tolerated. The nurse did not report this to the registered manager.
- In the 2016 Fresenius patient survey, there were 72 respondents, which was an increase from 27 in 2015. Of the 72, 90% said the staff were caring, 92% were likely to recommend the unit to a relative or friend and 100% said the unit was a happy one with a friendly atmosphere.
- The unit displayed the patient satisfaction survey results in the reception area. The poster detailed the overall satisfaction score, details, and actions taken for the lowest scoring questions.
- Staff of the unit spoke 10 different languages and patients told us this was supportive for decision making and enabling them to understand their condition.
- On both the announced and unannounced visits, two staff members used the word 'demented' to describe a person living with dementia.

- Patients described how staff offered help with wheelchairs and if they felt unwell post dialysis. We observed staff offering to transfer patients from the dialysis chair to the waiting area by wheelchair and helped them with their belongings.

Understanding and involvement of patients and those close to them

- Most patients told us staff kept them updated with changes made to their treatment plan. However, we did not see this documented in patient notes. One patient told us they had requested to see the doctor because they did not understand the care plan. We saw that the nurse made a request for the patient to see the doctor.
- Overall, patient feedback was positive about feeling involved in their care and felt listened to however, this was not consistent in all feedback we received.
- Two comment cards referred to staff not always speaking English when they are on duty and speaking other languages between themselves.
- We saw evidence of an 'early termination of treatment against medical advice' form in one patient's notes who chose to finish dialysis earlier than prescribed. The risks were outlined on this form.
- The unit did not offer self-care but we observed nurses encouraging patients to be as involved as possible with an example of asking if the patient wanted to take the tape off their arm. Patients were also encouraged to weigh themselves before and after treatment.

Emotional support

- Staff told us because they cared for patients frequently over a period of years, they became familiar with them and could tell when a patient was having an 'off day' or were worried. They said they would spend more time with the patients if they could.
- Staff told us they could refer patients to a psychologist at the commissioning NHS trust as required.
- Patient relatives were able to stay to provide additional support if required. We saw this during the days we inspected.
- Staff were aware of the impact that dialysis had on a patient's wellbeing, and supported patients to maintain as normal life as possible. We observed a nurse's empathetic attitude towards their patient during treatment.
- One patient described how the unit staff had helped them through a stressful time with the threat of eviction from their home.

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

Service planning and delivery to meet the needs of local people

- NHS England commissioned dialysis services. The commissioning NHS trust set the service specification for the unit and the contract runs until 2019. Patients were referred to the unit by the commissioning NHS trust.
- Senior managers met monthly with the commissioning NHS trust for contract meetings where they discussed unit performance.
- The building met most of the Department of Health building requirements (Satellite dialysis units: planning and design HBN 07-01). The whole unit was level access and had separate access for waste disposal and delivery of goods. There was plenty of natural light in the main unit, as well as additional lighting. Sink basins were placed in line with requirements. There was adequate space to permit emergency access and allow for privacy around each dialysis chair.
- Car parking included disabled spaces. There was disabled access into the building and throughout patient areas. The weighing scales were accessible for wheelchair users. There were two mobility scooter parking spaces in the waiting area.
- NICE quality standards (QS72- standard 6) recommend that adults using transport services to attend for dialysis are collected from home within 30 minutes of the allotted time and collected to return home within 30 minutes of finishing dialysis. The unit collected and submitted this data on a monthly basis to the commissioning NHS trust. Records at the time of our inspection showed that 98% of patients attending morning sessions received treatment within 30 minutes and above the 90% target but only 79% of patients for the afternoon session.
- The local commissioning group recently changed the contract with the patient transport provider in May 2017.

Patients and staff told us treatment times and leaving at the end of the day were affected by transport delays. This meant delays in treatment occurred and staff had to stay later until all patients had been collected.

- There was not a transport user group or transport survey for patients to engage with and senior managers told us they encouraged patients to complain directly to the transport provider and the unit raised concerns at the monthly contract meeting.
- Staff and managers told us incident reports were not completed for transfer delays but this data was monitored and sent to the commissioning NHS trust on a monthly basis.

Access and flow

- Referrals for treatment at the unit were co-ordinated by the commissioning NHS trust through the satellite co-ordinator. Patient preferences for treatment days and session (am or pm) were accommodated if there was an available slot. The registered manager told us that sometimes patients swapped to suit each other's preferences or needs.
- If patients were not stable or did not fulfil other requirements of the eligibility criteria, they were cared for at the acute NHS trust.
- Staff told us they were happy to welcome patients to visit the unit prior to commencement of treatment to familiarise themselves with the facilities and routine.
- There was an average of 1188 session per month with 94-96 active patients during January to May 2017.
- The unit operated at an average 95% capacity (June 2016 to May 2017), which allowed some capacity to treat holiday patients staying in the local area.
- Staff told us there was no waiting list for treatment and there had been no cancellations of treatment in the 12 months before our inspection. Patients told us that generally, sessions started on time and treatment never cancelled.
- There were 23 patient emergency transfers to hospital during April 2016 and May 2017. We were not provided with the reasons for these. The manager confirmed that incident forms were not completed for emergency transfers.
- We saw two sources of data sent to us post inspection, which recorded patients who did not attend (DNA) their treatment sessions during January and May 2017. The TVR stated 197 (a monthly average of 39 patients not attending each month) and the performance data stated there were 84 during the same period (an average of 17 per month). We could not be sure which was the correct data.
- Fresenius did not have a DNA policy but the unit staff told us they liaised with the satellite co-ordinator if patients were not engaging in their treatment plans.
- The unit monitored the number of missed treatment sessions due to patients hospitalised and therefore inpatients at the commissioning NHS trust. During January to May 2017, there were 54 days missed with an overall average of 0.87% hospitalisation rate.

Meeting people's individual needs

- The unit was situated in a diverse multi-cultural geographical area of Birmingham and unit staff were mainly from minority ethnic backgrounds. This meant that staff could speak 10 languages, which assisted in patient communication when they were not fluent in English. Patients told us this was an advantage of the unit. We saw a list of the languages spoken by staff in the waiting area on display.
- If translators were required, staff could book these through the commissioning NHS trust.
- We saw a number of patient leaflets and posters in various languages in the waiting area and staff showed us the patient guide that all patients received when commencing care at the unit. These were available in most languages.
- The unit provided individual televisions and headphones for every dialysis chair and wireless internet.
- We saw in two patient records that there were dementia individualised care plans, completed by the manager and included actions such as hourly checks by staff and relative support during treatment.
- There were two toilets in the waiting area and two inside the clinical area and therefore patients could visit the toilet prior to treatment commencement.
- The unit had access to a renal social worker from the commissioning NHS trust that they could refer patients to for additional support.
- The unit did not provide care during pregnancy due to the higher risk to the patient. These patients were treated at the commissioning NHS trust in collaboration with the local maternity unit.
- We asked for evidence how the unit met the 'Accessible Information Standard'. 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 or understand and with support so they can communicate effectively with health and social care services. Senior managers confirmed that they were not meeting this legal standard.

Learning from complaints and concerns

- 'Tell us what you think' leaflets were in the patient waiting area with posters displayed detailing how patients can raise a concern or complaint.
- There was a complaints policy in place and was based upon dealing with the '4 Cs', compliments, comments, concerns and complaints.
- It was the responsibility of the registered manager or deputy manager to ensure all complaints were dealt with within maximum 20 working days.
- During June 2016 and May 2017, there were six formal complaints with one written and five verbal. There were no themes identified but two were regarding staff attitude, two patient-to-patient conflicts, two relating to equipment/environment and one transport issue.
- We saw the complaints and compliments log that the registered manager kept for 2016 and 2017. We found that the details were not always recorded for actions taken and action completion dates.
- The registered manager told us that they informed staff of complaints, concerns and compliments during daily unit handovers.
- Patients told us they did not always feel listened to when they raised concerns. This was also an identified issue in the 2016 patient survey with 18% of respondents saying complaints were not taken seriously. The unit had an action plan to improve this score.
- There were no complaints received by the CQC in the previous 12 months prior to the inspection.

Are dialysis services well-led?

Leadership and culture of service

- The leadership structure composed of a registered manager, area head nurse, the regional business manager, a clinical services director, the managing director and the chief executive of Fresenius overall. The registered manager was unable to tell us what exposure and review the unit received at board meetings.
- At unit level, the senior management team was composed of the registered manager, deputy manager and three team leaders.
- We saw that staff worked well together and were enthusiastic to deliver safe and compassionate care.
- Visibility of the senior management team was limited to the area head nurse and the business manager and this was when audits occurred or when they based themselves at the unit for a day.
- Both unit staff and commissioning NHS trust staff told us that there was a professional and positive working relationship with effective communication and teamwork across both sites.
- The registered manager and the deputy manager had not completed any leadership courses and there were no plans to do so in the immediate future.
- There was a friendly culture, and the manager was visible and approachable, but the unit did not look outwards for ways to challenge standards or to improve.
- Staff used the word 'busy' to describe the culture of the unit and felt there was little time for anything other than patient care, this appeared to be affecting morale. Staff reported wanting time to focus on their designated link roles.
- Overall, most staff felt supported although some staff reported unequal opportunities given to develop their skills. An example of this was for healthcare assistants to gain the registered nursing qualification.
- Although the manager had regular supervisory time each week to support staff and patient care, there were variations in the standards of aseptic non-touch technique. This was not included in the annual nurse competency annual re-assessment.
- Unit meetings seemed to take place ad-hoc and we were only provided with meeting minutes for November 2016 and May 2017. Minute records were vague and lacking details for agenda items. There was an 'actions from previous meetings' space in the records but these were not completed.
- One-to-one meetings between the registered manager and head nurse were not regular or documented and

therefore evidence of discussions could not be evidenced. This was the registered manager's source of escalation for concerns and therefore there was no audit trail of this as part of the governance framework.

Vision and strategy for this core service

- Fresenius medical care is a large international organisation and had core values of quality, honesty and integrity, innovation and improvement, and respect and dignity. The strategy of the organisation was to grow as a company, enhance products and treatment and to create a future for dialysis patients.
- Senior staff told us that the main focus of the unit was to improve on the unit objectives but there was no unit specific vision or philosophy of care. Senior staff did not highlight safety or the quality of patient care as part of the vision or strategy.
- Nursing staff told us that patient care was their priority and to put the patient above everything else. They could not describe their role in achieving the aims or strategy of the unit.
- We saw that the unit had defined objectives for 2017 with an action plan for completion. Objectives included patient (clinical outcome performance, reducing patients who do not attend treatment and incident reporting times), employee (appraisals, renal nurse qualification and increased retention), community (reducing water, electricity and clinical waste consumption) and business growth objectives.

Governance, risk management and quality measurement

- The governance framework at unit level consisted of the monthly quality assurance (QA) meetings with the multi-disciplinary team. The registered manager and consultant nephrologist from the commissioning NHS trust were the leads for governance and quality monitoring at unit level.
- We found that the QA meetings were a thorough review of each patient medically and performance relating to clinical outcomes but not specifically relating to safety and risk management. QA meeting minutes lacked detail about incidents, risks such as high infection rates and complaints.
- Senior managers told us that safety alerts were escalated down from the head nurse to the registered manager, who informed the nursing staff at daily hand overs.
- Although email communication appeared to be an effective method, we noted that there was a lack of face-face meetings between unit staff, local and regional managers and head nurse meetings. The unit could not provide evidence of meetings.
- We found the registered managers knowledge and understanding about governance and risk management to be lacking in view of the risks associated with a satellite unit. The manager lacked oversight of poor practice issues such as aseptic technique and medicines management.
- There was a failure to follow infection control policies and procedures. The unit had a high infection rate, we observed variable aseptic non-touch technique practice, and therefore patients were at risk of harm. This had not been identified in staff supervision of practice and this was not part of the annual competency re-assessment.
- Medicines management processes were not in line with internal policies or Nursing and Midwifery Council (NMC) professional standards. For example, staff did not check patient identification prior to administering medicines.
- The unit did not have a process to detect or manage the deteriorating patient and sepsis. This included a lack of policies and training for staff. Additionally, there were missed opportunities to learn from incidents such as emergency transfers because the unit did not submit incident forms for these events.
- We were concerned about the lack of awareness and understanding about mental capacity assessments and deprivation of liberty safeguards. The registered manager was the lead for safeguarding but did not have a higher level of training to support staff.
- We found that the unit did not robustly investigate serious incidents and the duty of candour was not carried out for any of the relevant patient harm incidents. We saw evidence from incident report forms that this lack of knowledge and understanding was from both a local management and a corporate level.
- Policies did not always support the manager to carry out her role effectively. This included the serious incident investigation and clinical incident policies. There was ineffective policy management such as the review date to ensure policies reflected the most up-to-date

- The registered manager and other senior managers told us that a risk register was recently implemented. The manager showed us the risk register and the risks specific to the unit.
- There were three operational risks listed, which included safeguarding lead concerns, information governance and duty of candour compliance in relation to non-clinical incidents. There were four listed clinical risks including the lack of sepsis policies and procedures, use of restricted machines and the risk of cross-infection, lack of patient identification procedures and cross-infection from returning holiday patients from high-risk countries. It was evident the document was still in development with information missing such as assessment dates and mitigation of risks.
- The risk register did not list identified concerns such as higher than expected infection rates, recent healthcare assistant staffing shortages and gaps in staff mandatory training.
- The registered manager told us they regularly discussed unit risks and objectives with the head nurse including escalation of concerns but they could not provide documented evidence.
- There was no process to ensure national legislation in meeting the Accessible Information Standard and this was not on the risk register.
- 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. The unit workforce was predominantly BME staff but senior managers confirmed that this data was not formally collected.

Public and staff engagement

- There was no patient involvement group where patients could make suggestions about the service or care of patents on the unit, or where staff could share information about the service with patients.
- A comment card highlighted that it would be nice for the unit to arrange social trips for patients because the last one was several years ago.
- Staff told us they were involved in the development of the electronic patient record programme and could make suggestions for updates.
- Fresenius undertook annual patient survey results to gain feedback about their experiences. The 2016 survey received a higher response rate than the previous year at 74% (72 out of 97 patients) and results showed that: 100% of patients said the atmosphere of the unit was friendly and happy, 92% of patients would recommend the unit, 91% had complete confidence in the nurses, 92% thought the treatment areas were well maintained and clean and 88% thought that the clinic was well organised.
- The unit displayed a 'you said, we did' action plan in the waiting area with the lowest scoring questions (complaint responses, diet and nutrition advice new patients not given introductory session to the unit) with actions to improve.
- The annual staff survey results for 2016 showed (of 21 respondents):
  - 100% of staff said they felt proud of their work in the unit.
  - 100% of staff were satisfied with the quality of care they give to patients.
  - 100% of staff said they felt trusted to do their job.
  - 95% of staff would recommend the unit to family and friends.
  - 95% of staff would recommend the unit as a place to work.
- The unit had an action plan to address four responses but these not all were the lowest scoring questions. They related to the reporting of incidents that could affect staff, team communication, manager support and bullying and harassment.
- There was a policy and process in place to enable staff to raise concerns at work and outside the organisation. The policy described how poor practice concerns could also be raised.
- We received one comment card that referred to potential religious tensions between patients and or their relatives. We informed senior managers in view of the sensitivity of the comment. At the unannounced visit, the managers informed us that they had considered the right course of action and decided that involving staff and encouraging them to be alert to such tensions. We felt that due to the diversity of patients treated that the unit could be more proactive in the local population engagement on issues such as radicalisation.

Innovation, improvement and sustainability

Dialysis Services

- The unit had won the 'Nephrocare Excellence award' several times with the most recent in 2016. This was for performing third highest in key performance indicators within Fresenius.
- Fresenius had an objective to encourage nursing staff to gain a renal qualification, with the target to increase the number each year.
- The unit was participating in a national research study investigation optimal iron therapy for patients receiving dialysis treatment.
- The unit did not provide us with evidence of a replacement programme for dialysis machines in line with the Renal Association standards.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure governance systems are in place and established effectively in order to assess, monitor, and improve the quality and safety of the services provided to patients. This should include more robust investigations of clinical incidents.
- The provider must ensure compliance with duty of candour requirements.
- The provider must ensure that risks to patients are identified, assessed and monitored consistently, and that action plans in assessments and care plans are updated and contain enough detail to enable staff to reduce those risks effectively.
- The provider must take prompt action to ensure safe methods of medicines management and administration are put in place and embedded into everyday practice.
- The provider must take prompt action to ensure a process is put in place so that deteriorating patients can be identified early and managed in line with national guidance.
- The provider must ensure staff receive sepsis training and know what to do to manage patients with sepsis.
- The provider must ensure staff are suitably skilled and competent to carry out their role.
- The provider must ensure processes are in place so patients who have a disability, impairment, or sensory loss are provided with information they can easily read or understand in line with the legal requirement of the Accessible Information Standard.

Action the provider SHOULD take to improve

- The provider should take prompt action to ensure safe infection prevention and control practices are followed and monitor compliance effectively.
- The provider should take prompt action to reduce infection rates.
- The provider should ensure data collection is accurate for all patient care and outcomes.
- The provider should ensure that all patient concerns are listened to and appropriately acted upon.
- The provider should ensure all staff display supportive and respectful attitudes towards all patients.
- The provider should consider creating a patient involvement group to seek regular feedback and for staff to share relevant information about the unit.
- The provider should review the appropriate level of safeguarding adults training required by all staff in relation to their roles and responsibilities.
- The provider should ensure processes and appropriate training are in place to ensure compliance with the Mental Capacity Act and Deprivation of Liberty Safeguards.
- The provider should ensure the staff training matrix is regularly updated to correctly reflect the level of completion by staff.
- The provider should review nursing annual competency re-assessments to ensure staff are competent to safely carry out their role.
- The provider should consider regular structured staff meetings to foster an open learning culture and to encourage challenge to improve practice.
- The provider should consider the use of stickers or notices to demonstrate equipment has been cleaned and ready for use.
- The provider should ensure all staff have an appropriate level of radicalisation training.
- The provider should consider having a back-up scale and hoist on the unit.
- The provider should consider reviewing the effectiveness of audits such as infection prevention and control practice and documentation compliance.
- The provider should liaise with the external patient transport agency to improve collection times and therefore to meet NICE quality standards and to ensure staff are not working beyond their shift end time.
- The provider should ensure there is a dialysis machine replacement programme according to the Renal Association guidance.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **How the regulation was not being met:** • There were gaps in mandatory training records. • Medicines were not being managed or administered in a safe way, according to professional standards. • The registered manager required a higher level of safeguarding adults training for their safeguarding lead role. • There was no sepsis policy and staff were not trained to recognise or take action for sepsis. There was no formal process for identifying the deteriorating patient. • Risk assessments were not consistently updated as per provider policy. • The unit did not have support in place for patients with sensory loss or impairment.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **How the regulation was not being met:** • The registered manager was not confident in explaining clinical serious incidents. The policies did not support them to understand processes and procedures. • Serious incident investigations were not robust to demonstrate the root cause and actions taken to improve. • There was a lack of oversight for clinical risks for the unit.

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Treatment of disease, disorder or injury

Regulation 20 HSCA (RA) Regulations 2014 Duty of candour

How the regulation was not being met:

- The unit did not carry out duty of candour for four moderate harm incidents and not classified as notifiable safety incidents.