Stratford Dialysis Unit

Quality Report

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

Ratings

Overall rating for this location

Are services safe?	
Are services effective?	
Are services caring?	
Are services responsive?	
Are services well-led?	

Overall summary

Stratford Dialysis Unit is operated by Fresenius Medical Care Renal Services Limited. The service has 12 dialysis stations. Facilities include two isolation rooms.

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

The service provided over 8,700 dialysis treatment sessions per year and had 59 patients.

All the patients were over 18 years old:

- 44% of patients were aged 18 to 65 years.
- 66% of patients were over the age of 65.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 3 May 2017, along with an unannounced visit to the unit on 10 May 2017.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Summary of findings

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

Services we do not rate

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

We found the following areas of good practice:

- The unit and equipment were visibly clean, with evidence of effective cleaning regimes and schedules in place. Staff were observed using effective precautions to maintain patient safety and reduce the risks of infection.
- There were systems in place for recording and escalating incidents both internally and externally.
- Equipment was maintained according to the manufacturer's guidance, with an adequate supply to cover maintenance or breakages.
- There were processes in place to ensure that medicines were ordered, stored, and used, in line with guidance.
- Patients' records were held securely, and staff had access to all relevant information.
- At the time of our inspection, 100% of staff had completed their mandatory training.
- Nursing staff were aware of their roles and responsibilities in the escalation of safeguarding concerns. However, the units' safeguarding lead had not completed training in line with national guidance.
- Nursing staffing levels were maintained in line with national guidance and there was a structured handover process between shifts.
- Medical advice was available during opening times, with direct access to the consultant or renal team at the NHS trust.
- Staff were aware of their roles and responsibilities to maintain the service in the event of a major incident.
- Staff completed a detailed competency assessment on commencement to post and were reassessed annually. At the time of our inspection, 100% of staff had received their annual appraisal.
- Patients received regular support regarding nutrition from the renal dietitian from the NHS trust.
- There were effective processes in place for gaining patient consent for treatment.
- Patients who required dialysis were assessed by the parent NHS trust staff for suitability to dialysis in a satellite unit and then referred to this unit.
- The unit provided three dialysis sessions per day including a twilight session. Staff supported patients changing dialysis days and or times as far as possible to accommodate external commitments, appointments or social events.
- Patients were treated in a calm, caring and friendly manner. This was reflected in the positive local annual patient satisfaction scores and patient feedback we received during the inspection. Nursing staff gave patients time to ask questions during treatment.

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

- We found a patient receiving medicine from a transcribed unsigned prescription. However, the service took action to rectify this concern and staff received targeted training regarding this aspect of medicine management.
- Staff were using a cannulation technique called 'dry needling'. This was not in line with the provider's policy, which stated that 'wet needling' was the recommended technique. The service and provider took immediate action to ensure that staff complied with this policy.
- While patients were observed closely during treatment, the service did not use the national early warning score system for monitoring a patient's risk of deterioration.
- Some risks identified on this inspection had not been fully recognised by the unit leaders. Patients' individual risk of falling was not formally assessed by the nursing staff.

Summary of findings

- The provider was not responsible for the building where the service was delivered, and the facilities were established prior to the Health Building Note 07, 01: 'Satellite dialysis unit' (2013) guidance. However, they did not meet all aspects of this guidance including, lack of space in reception for patients, lack of reception desk, dedicated consulting or exam room, treatment and training room. There were no risk assessments regarding this.
- We found that some items were stored inappropriately, for example sterile items in the dirty utility room. There were no risk assessments regarding this.
- We found that some governance systems were not fully established. For example, the unit's patient concerns' register and risk registers were recently commenced. This meant that there was not a fully embedded risk management process to capture risks and drive improvements.

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 two requirement notices. Details are at the end of the report.

Edward Baker

Deputy Chief Inspector of Hospitals

Central Region

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. • Staffing levels were maintained in line with national guidance and all staff were compliant with their mandatory training requirements and had received an annual appraisal. • Patients were positive about the service they received and staff aimed to meet their individual needs. • The service was based in a unit that predated and did not meet Health Building Note 07 01: Satellite dialysis unit (2013) guidance. We did not see governance systems in place related to this such as local risk assessments. • Systems were in place to keep patients safe including, infection prevention and control and quality assurance meetings. However, there were areas for improvement including, safeguard lead training, compliance with clinical policy and risk management processes.

Summary of findings

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Background to Stratford Dialysis Unit

Stratford Dialysis Unit is operated by Fresenius Medical Care Renal Services Limited. The service opened in October 2004. It is a dialysis unit in Stratford upon Avon, Warwickshire. The unit primarily serves the communities of Warwickshire. It also accepts patient referrals from outside this area.

The unit has a registered manager, who has been registered with the CQC since January 2017.

The service has been previously inspected in April 2013, when it met all standards relating to:

- Consent to care and treatment.
- Care and welfare of people who use services.
- Cleanliness and infection control.
- Requirements relating to workers.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector, and another CQC inspector.

Information about Stratford Dialysis Unit

Stratford Dialysis Unit is a stand-alone 12-bedded unit that provides dialysis for patients with chronic renal failure.

The unit is registered to provide the regulated activity of treatment of disease, disorder or injury.

Fresenius Medical Care Renal Services Limited (Fresenius) is contracted to provide dialysis for patients under the care of nephrologists at University Hospital Coventry and Warwickshire NHS Trust. All patients attending Stratford Dialysis Unit (the unit) receive care from a named consultant at the trust, who remains responsible for the patient. The provider has close links with the trust to provide care between the two services. To achieve this, the service has support from the NHS trust to provide medical cover and regular contact with a dietitian. Members of this team attend the centre regularly and assess patients in preparation for monthly quality assurance meetings.

The provider is responsible for the staffing, dialysis equipment, consumables and stationary. The building where the unit is located remains the responsibility of the NHS trust.

During the inspection, we visited the unit. We spoke with 11 staff including registered nurses, health care assistants, and senior managers. We also spoke with two members of trust staff. We spoke with three patients. We also received 26 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed seven sets of patient records.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time from April 2016 to the time of the inspection in April 2017.

Track record on safety in the previous year:

- No never events.
- No incidences of healthcare acquired MRSA.
- No incidences of healthcare acquired Methicillin-sensitive staphylococcus aureus (MSSA).
- No incidences of healthcare acquired E-Coli.
- The provider received five complaints.

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 areas of good practice:

- The unit and equipment were visibly clean, with evidence of effective cleaning regimes and schedules in place.
- There were systems in place for recording and escalating incidents both internally and externally.
- All staff were observed using effective precautions to maintain patient safety and reduce the risks of infection.
- Equipment was maintained according to the manufacturer's guidance, with an adequate supply to cover maintenance or breakages.
- There were processes in place to ensure that medicines were ordered, stored, and used, in line with guidance.
- Patients' records were held securely, and were completed accurately.
- At the time of our inspection, 100% of staff had completed their mandatory training.
- Nursing staff were aware of their roles and responsibilities in the escalation of safeguarding concerns. However, the units' safeguarding lead had not completed training in line with national guidance.
- Nursing staffing levels were maintained in line with national guidance and there was a structured handover process between shifts.
- Medical advice was available during opening times, with direct access to the consultant or renal team at the NHS trust.
- Staff were aware of their roles and responsibilities to maintain the service in the event of a major incident.

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

- The provider was not responsible for the building where the service was delivered, and the facilities were established prior to the Health Building Note 07, 01: 'Satellite dialysis unit' (2013) guidance. However, they did not meet all aspects of this guidance including, lack of space in reception for patients, lack of reception desk, dedicated consulting or exam room, treatment and training room. There were no risk assessments regarding this.
- Patients' individual risk of falling was not formally assessed by the nursing staff.

Summary of this inspection

- We found a patient receiving medicine from a transcribed unsigned prescription. However, this was rectified following the inspection and staff received targeted training regarding this aspect of medicine management.
- Staff were using a cannulation technique called 'dry needling'. This was not in line with the provider's policy, which stated that 'wet needling' was the recommended technique. The unit and provider took immediate action to ensure that staff complied with the policy.
- While patients were observed closely during treatment, the national early warning score system for monitoring patient's risk of deterioration was not in use at the unit.

Are services effective?

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

We found the following areas of good practice:

- Policies and procedures were based on national guidance.
- The unit measured patients' outcomes and used them to make improvements.
- Staff completed a detailed competency assessment on commencement of post and were reassessed annually.
- At the time of our inspection, 100% of staff had received their annual appraisal.
- Staff had access to the relevant information to provide patient care and treatment.
- Patients received regular support regarding nutrition from the renal dietician from the NHS trust.
- There were effective processes in place for gaining patient consent for treatment.
- There were local audits completed against an audit schedule at the unit.

Are services caring?

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

We found the following areas of good practice:

- Patients were treated in a calm, caring and friendly manner. This was reflected in the positive local annual patient satisfaction scores and patient feedback we received during the inspection.
- Nursing staff gave patients time to ask questions during treatment.
- Patients could be referred by staff to access to support such as a social worker or psychologist if required.

Summary of this inspection

Are services responsive?

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

We found the following areas of good practice:

- Patients who required dialysis were assessed by the NHS trust staff for suitability to dialysis in a satellite unit, and then referred to the unit.
- Staff supported patients' changing dialysis days and or times as far as possible to accommodate external commitments, appointments or social events.

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

- Some patients complained about delays encountered with patient transport. This service was not the responsibility of the unit but senior managers frequently liaised with the renal transport provider to seek to address these issues.

Are services well-led?

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

We found the following areas of good practice:

- Leaders had the appropriate skills and knowledge to manage the service.
- Staff had effective working relationships with staff from the NHS trust, for example, the renal consultant.
- There were monthly quality assurance meetings to assess and monitor the effectiveness of treatment and tailor individual patient's dialysis plans.

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

- We found that some governance systems were not fully established. For example, the unit's patient concerns' register and risk registers were recently commenced. This meant that there was not a fully embedded risk management process to capture risks and drive improvements
- Some risks identified on this inspection had not been fully recognised by the unit leaders.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Notes

We regulate this service but we do not currently have a legal duty to rate it.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

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

Incidents

- There was a clinical incident reporting policy that guided staff regarding reporting pathways. The unit had a system in place for recording, investigating and monitoring incidents. Staff were aware of their roles and responsibilities in the recording of incidents, both internally and externally.
- In the 12 months ending December 2016, there had been one statutory notification to the Care Quality Commission, which was regarding an unexpected death of a service user. The patient had been dialysed without incident and seen by the renal consultant prior to unexpectedly dying at home. The case was referred to the Coroner.
- There were no serious incidents or never events reported from March 2016 to March 2017. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- There were four types of incident reports used in the service: treatment variance reports, non-clinical and clinical incidents and unit variance reports.
- Treatment variances were used to record when there had been a change from the expected dialysis treatment. We saw that any incidents or changes to the patient's normal dialysis session were recorded on treatment variance records (TVR). For example, we saw that when a patient had changed their dialysis slot and they had to use a different dialysis machine a TVR was completed. The change of dialysis machine resulted in no harm: however, this was a reporting requirement of the provider. These treatment variances were documented electronically and formed part of the patient's dialysis record.
- We saw another TVR, which had initially been categorised as a 'needle dislodgment'. This is when a venous needle accidently comes out during dialysis, which is a potentially life threatening incident due to blood loss. There was evidence that the clinic manager had reviewed the record and made an amendment, as this was not an actual dislodgement but an infiltration incident. This is when blood leaks outside of the fistula or graft into the surrounding tissues. There was also evidence that the patient was reviewed by the clinic manager regarding this prior to the next dialysis treatment.
- Non-clinical incidents were those that related to health and safety. A health and safety incident form would be completed and sent to the provider's health and safety manager. We saw that this process was followed and the health and safety manager reviewed and signed off the incidents and considered any changes that may be required to risk assessments.
- There were four patient falls reported by the unit in the 14 months ending February 2017. The provider categorises a patient fall as a non-clinical incident. We reviewed three of the incident reports, which detailed the falls. The incidents were reported as resulting in minor harm. Two of the patients fell while in the unit's reception area. Actions taken following the incidents included changing the allocated place for storage of the wheelchairs in this area to reduce the trip hazard. We saw during inspection, that a sign on the wall

identified the allocated wheelchair storage area. However, the reception area to the unit was small and therefore it was difficult to accommodate wheelchair storage and provide adequate seating.

- Clinical incidents included, for example a bacterial blood infection. Clinical incident reports were completed and emailed to the area head nurse and Fresenius chief nurse. We were told that clinical incidents were monitored centrally with clinic updates and we saw that learning bulletins distributed by the chief nurse, to support lessons learned across the organisation.
- A unit variance report would be completed if there was an issue encountered that affected the whole of the unit's ability to provide a service. For example, a failure of the unit's water treatment plant.
- Staff we spoke with at the unit were able to describe the different types of incident. Staff told us the majority of incidents that were reported related to patients' reactions to the dialysis session, for example, a period of hypotension (low blood pressure). These were noted to be common side effects of treatment, but were recorded as incidents to alert staff to any issues with treatments.
- Incidents and any learning arising from them were shared across the team at team meetings and at the staff handovers. We saw minutes from meetings, which evidenced feedback to staff regarding local incidents and actions to be taken. The renal consultant from the NHS trust overseeing the service was aware of incidents that occurred, as they were informally discussed during monthly quality assurance meetings.
- Providers are required to comply with the Duty of Candour Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The Duty of Candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain notifiable safety incidents and provide reasonable support to that person. There was policy relating to duty of candour, which outlined actions to be taken when something went wrong. All staff had completed training in Duty of Candour and the steps to follow when something goes wrong. Staff were aware of the thresholds for when Duty of Candour was triggered. Nursing staff told us that as patients attended the unit frequently, they had an open relationship, so always discussed anything that may affect patient care and treatment.
- Patient safety alerts were distributed centrally from the Fresenius head office to the clinic manager for sharing with the team.

Mandatory training

- All the staff at the unit had to complete mandatory training. This included annual updates regarding infection prevention and control, anaphylaxis, basic life support, fire training, and manual handling. This was in addition to three yearly training in safeguarding adults and children, slips, trips and falls training, practical manual handling and fire marshal training. There were e-learning modules that were also completed including legionella, control of substances hazardous to health regulations (COSHH) and disability discrimination.
- Face-to-face training was provided at a local centre, and staff were rostered into attending sessions. Compliance with training was reviewed at annual staff appraisals and monitored by the deputy clinic manager and the clinic manager. We saw that there was a spreadsheet maintained to facilitate this. At the time of our inspection, there was 100% compliance with mandatory training.
- All unit staff had access to an electronic safety learning platform. This held details of the mandatory training that was required to be undertaken.

Safeguarding

- There were systems, processes and practices in place to keep patients safe from avoidable harm. Staff were aware of their roles and responsibilities for escalating safeguarding concerns.
- Nursing staff told us they had not had to report or escalate any safeguarding concerns but were able to talk through scenarios and were clear about their responsibilities.
- There was a corporate policy to guide staff regarding their responsibilities regarding safeguarding. This contained flowcharts to advise what actions to be taken.

- The clinic manager was the location lead for children's and adult safeguarding. However, they had not completed adult safeguarding training to the required level (three). This meant that we were not assured the clinic manager was trained to the appropriate level for their role in order to protect the adults they were caring for, from abuse.
- The unit did not treat patients under the age of 18 years. However, staff had all completed (level one) safeguarding children training.
- 100% of staff at the time of our inspection had completed safeguarding adults level two training.

Cleanliness, infection control and hygiene

- We observed that staff wore appropriate personal protective equipment for interactions with the patients. This included facemasks for the connection and disconnection of dialysis catheters, to protect staff from blood sprays. We also saw that patients wore facemasks when being disconnected from lines.
- We saw staff washing their hands and using hand-cleansing gels appropriately to maintain patient safety. This included before and after any patient contact. Hand hygiene training had been completed by 100% of staff at the time of our inspection (May 2017). The infection and prevention link nurse told us that they focus on the importance of hand washing not only for staff but for patients too. One of their key roles was to educate patients regarding the importance of hand hygiene. We saw that there were hand-cleansing gels available at each dialysis station to encourage compliance.
- Staff used appropriate aseptic techniques to attach patients to their dialysis machines. This was completed through either the insertion of large bore needles into an arteriovenous fistula/ graft or central line.
- A fistula is a special blood vessel created in a patients arm, called an arteriovenous fistula (AV fistula). The blood vessel is created in an operation by connecting an artery to a vein which makes the blood vessel larger and stronger. This makes it easier to transfer the patients' blood into the dialysis machine and back again. 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.
- Grafts (AVGs) are strong artificial tubes inserted by a surgeon underneath the patients skin. One end of the tube connects to one of the arteries, and the other end connects to one of the veins (in the same limb).
- Central lines are larger cannulas that are inserted for long periods for dialysis.
- The infection prevention and control link nurse was responsible for completing monthly local audits. Results from January to April 2017, were on display in the reception area of the unit. The compliance with unit hygiene was 97%, with hand hygiene at 98% overall. There had been no patients with MRSA or blood borne infections during this time.
- Unit staff were required to undergo an infection prevention and control, annual competency assessment. Records showed 100% compliance with this, at the time of our inspection.
- Equipment was cleaned between patients. Dialysis machines completed a disinfectant wash cycle in between patients. A specific disinfectant was used by staff to clean the dialysis machines; we saw that there was a daily checklist signed by staff for the preparation and disposal of this solution.
- Water used for dialysis needs to be specially treated to prevent risks to patients. There was a large water treatment room, which was monitored In the event that a result showed an anomaly, staff would contact the engineers for an urgent review.
- Water testing was completed monthly for microbiology, to ensure that water used during dialysis was free from contaminants. The water was also tested quarterly for full chemical analysis. This was in line with guidance on the monitoring the quality of treated water and dialysis fluid. We saw the record log that recorded the testing and the results. Staff were aware of the processes for obtaining samples, and actions to take if results showed some contaminants.

- The trolleys used during the connection and disconnection of dialysis lines were cleaned at the start of the clinical shift and in between patients.
- From March 2016 to March 2017, the centre reported no cases of healthcare acquired infections such as MRSA or Methicillin-sensitive staphylococcus aureus (MSSA).
- In the twelve-month period ending January 2017, there were two patients with episodes of bacteraemia (presence of bacteria in the blood). Patients had blood tests taken and clinical advice had been provided.It was unclear if this was related to care provided at the unit.
- Two side rooms were available for patients identified as being at risk or those with potential infectious conditions. Rooms were observable from the main workstation, on the open plan unit. There were not separate bathroom facilities for the isolation rooms so these were not suitable for those patients with for example diarrhoea.
- Staff followed the NHS trust sepsis guidelines, with any patients thought to be unwell being referred directly to the NHS trust for an urgent medical review.
- Effective infection control procedures were in place. The unit was visibly clean on inspection. The cleaning of the unit was subcontracted to an external provider.
- We saw that cleaning schedules were maintained with evidence of regular cleaning documented.

Environment and equipment

- The provider did not own the building where the unit was located; this was leased from the NHS trust.
- The Department of Health provides best practice guidance for the design and planning of new healthcare buildings and the adaptation or extension of existing facilities, via health building notes. Stratford Dialysis Unit facilities predated and were not in line with all aspects of Health Building Note 07 01: 'Satellite dialysis units' (2013). These included a lack of space in reception for patients, no reception desk, no allocated consulting or exam room (the secretary office doubled as consulting room with no couch to examine patients), sterile consumables stored in dirty utility due to lack of space and no treatment room or training room. We saw evidence of escalation of these estates issues to the NHS trust via contract meetings and emails. While we did not find evidence of patient harm due to the unit not meeting this guidance, the unit did not document any risk assessments related to estates' issues.
- Some of the estates were tired and in need of repair or decoration. For example, we found that in the dirty utility room there was lots of flaking paintwork on the walls above the sinks. The metal storage shelving racks in this room were rusty and the sluice sink was also rusty. This was discussed with the clinic manager, who explained that the shelving unit replacement had been ordered. However, they had been escalating estates issues to the trust and had requested that they attend the unit for a walk round visit, as there were many areas that needed repair. We were provided with examples of when the unit had escalated environmental concerns to the trust.
- The Control of Substances Hazardous to Health (COSHH) cupboard was rusted and although it did close, this was not easy. The clinic manager explained that a new cupboard had been ordered. However, we found that this had not been replaced at our unannounced inspection.
- The centre provided 12 dialysis stations, including two isolation rooms. The main unit was open plan, which provided nursing staff good visibility of the patient receiving treatment. Each dialysis station had a dialysis machine and a nurse call bell,
- Each patient was allocated a set area or station for their treatment; this would remain the same for each session attended. To assist the staff, the patient locations were displayed on a white board above the work station. This detailed station number and patient initials. Any changes to the seat allocation were discussed with patients on arrival to the unit.
- The unit reception area was accessed by a locked door, which had an intercom system for visitors. We were told that patients were given the code to the door to enable them to enter the building early in the morning to prevent them standing outside. They could also use the intercom system for access.

- The reception room for the unit was small. Patients remained in the waiting area until the whole unit was ready for the next session. This meant that the reception area was busy between each session.
- The unit had two side rooms that could be used for isolating high-risk patients. During inspection, we saw that these were used for routine patients, and the doors were left open. The side rooms were observable from the workstation, in line with guidance.
- Equipment and environmental checks were completed daily. Staff maintained a checklist, which was signed by staff member completing the tasks. For example, checking of monthly first aid kit, electrical equipment and defrosting the fridge. Weekly task lists included the checking of storeroom, trolleys and visors. Daily checks of water supply, glucometer and resuscitation trolley. Three times weekly checks of water taps and oxygen cylinders. Checklists we reviewed showed good compliance.
- The unit had a small storeroom, which was accessed directly off the main unit. Stores were delivered weekly. Staff told us that there were sufficient supplies to meet demands for an additional three to five days if delivery was postponed or not available.
- We saw that there was some additional stock kept in the dirty utility room. These were sterile single use dialysis items in closed cardboard boxes stored on open shelves. We raised this during the inspection and the clinic manager explained that due to lack of storage space this had been accepted as a low risk solution. One of the mitigations in place was that stock would be kept to a minimum. We saw evidence that this had been discussed this during internal infection control audit in 2013. However, there were no more recent updates and no formal risk assessment in place for this.
- There were five handwashing sinks available within the main unit area, which provided adequate facilities for patients and staff.
- The unit had four spare dialysis machines that could be used in an emergency or as a replacement while maintenance was taking place. These were stored in the technician's room ready for use.
- We saw the maintenance log for dialysis machines. This detailed dates of machines being reported and date of service.
- There were systems in place to monitor and manage the maintenance of equipment for the service. This included the dialysis machine, dialysis chairs and other clinical equipment. There was also a helpdesk provide that the service could access to raise any issues. All equipment we checked during the inspection had been electrical safety tested. The nursing staff received training on the equipment in use. We saw that equipment training records showed 100% compliance.
- The unit had a water treatment facility, which was monitored daily by nursing staff. We were told that this was checked by the first member of staff attending the unit in the morning. This made sure that the water supply was appropriate before the dialysis machines were switched on for treatment. Technicians were available through a 24 hour on call service. Any incident was reported and logged to the head office, and then technicians were contacted by the head office. This meant that the head office had an oversight of the maintenance issues in each unit.
- The unit had equipment to be used in case of a clinical emergency. The resuscitation trolley was located in the main unit. The resuscitation trolley was not sealed though it was easily observed by staff. There was minimal risk that it could be tampered with. Medicines on the resuscitation trolley were kept in a tamper evident sealed box. The trolley contained single use equipment, which were sealed. All resuscitation equipment was checked daily and found to be in date. All single use equipment was labelled accordingly, and disposed of after use.
- Waste was managed appropriately with the segregation of clinical and non-clinical waste. Bins were not overfilled and were emptied regularly. We were told that filled bin bags were stored in secure units awaiting collection.
- We saw that the patients' fridge for milk and cold drinks was checked daily to ensure that the temperature was appropriate.

Medicine Management

- The unit had processes in place for the safe management of medicines. Patients attending would receive prescribed medicines as necessary for their dialysis or continuing treatment only. Ongoing oral medicines were taken by the patient at home and not administered by nursing staff.
- Controlled drugs (those requiring extra security of storage and administration) were not used or available on site.
- We saw that when medicines were administered, two nurses completed a patient and medicine check. This was in line with the corporate medicines policy, which was based on the nursing and midwifery council standard.
- The nurse in charge of the unit was the key holder for the medicines cupboards on a day-to-day basis.
- Medicines were stored in the treatment room, which was located off the main unit. We saw that this was not locked meaning that there was a potential risk, albeit low, that anyone could access the area unobserved. All cupboards inside this room were locked preventing unauthorised access to medications. There was also a direct line of sight from the nurses' station to this treatment room.
- The medicine fridge temperature was recorded daily. We saw that the temperature was maintained between 5 to 7 degrees Celsius. The record detailed what actions to take if the temperature was outside this range.
- Medicine charts were stored separately to the patient records. These were both locked in the notes cupboard when not in use.
- During the inspection, we reviewed six medicine charts. We saw that they included the patient's weight and allergy status. All medicines were signed by two nurses routinely.
- We found that some medicines had been originally prescribed in May 2016, with no evidence of review. However, we attended the monthly quality assurance meeting during the unannounced inspection and we saw that the patient prescription charts were checked. This was to ensure that the prescribed medicines were appropriate and reviewed for example in light of the most recent blood results. This meant that we were assured that there were systems in place to check that medicines prescribed were appropriate and reviewed at least each month.
- The prescriptions were signed by the consultant from the NHS trust, detailing dose, time and any parameters for administration.
- One medicine was noted as being administered without a signed prescription. This was from a transcribed prescription for a routine medicine, which the patient received on each attendance to the unit. We brought this to the attention of the clinic manager during the inspection, who stated they would take action immediately. During the unannounced inspection, we found that the prescription had been signed by the prescriber and other actions had taken place. These included trained nursing staff signing two summary training records; five staff had signed that they had been trained in the use of the medicine management policy regarding transcribing and understood it fully. Six staff had signed a similar record following receiving training in the Nursing and Midwifery Council standards for medicines' management.
- Any medicine changes made by the renal consultant during the quality assurance meeting or patients' clinic appointments were communicated to the patients and their GP.
- The unit did not have a dedicated renal pharmacist. The renal consultant from the NHS trust prescribed patients' medicines and these were reviewed at each quality assurance meeting for each patient. We were told that advice could be accessed via the local NHS pharmacy or the pharmacist at the corporate head office should this be required.
- We saw that the ferritin protocol used by the unit. This stated that iron should not be administered if the patient's haemoglobin (Hb) was greater than 12.5 grams per decilitre. However, nationally Hb is recorded in grams per litre and not grams per decilitre. This meant that the Hb recording on the protocol was not in line with national standardisation.

Records

- Patients' records were held both electronically and in paper format. We saw that the electronic records detailed dialysis sessions by date and time. This meant that any problems occurring during the session and any treatment changes could be easily identified. The unit had an electronic patient treatment database that automatically transferred data into the linked NHS trust's clinical database system.
- There were systems in place to ensure that patient information and data was accurate and was cross checked between paper records and the two electronic systems. For example, on receipt of new patient transfer documentation, it was a mandatory requirement to document to acknowledge that there had been a 'Data Quality Confirmation' check undertaken.
- Each patient had a number of paper records, which contained details of their past medical history, next of kin contact details, GP details, dialysis treatment cards and consent forms. When not in use, these were stored securely in a store cupboard, which was accessed using keys held by the nurse in charge.
- We reviewed seven patient records and found that all contained an observation chart, dialysis prescription, patient consent form, admission assessment form, manual handling assessment and a personal emergency evacuation plan. These were completed by the nurse on referral to the unit and updated at regular intervals depending on the patient. Those seen were completed legibly and accurately.
- Nursing staff told us that they did not keep a stock of patient assessments or paper work and opted to print the assessment templates out, as they were required. This was to ensure that they were always using the most up-to-date version of the assessment template.
- The deputy clinic manager completed monthly audits of patient records. This was completed following a patient allocation to prevent the same records being audited each month. Audits reviewed showed that between two and seven records were reviewed each month. Details of compliance were recorded in an action plan and each nurse informed of the finding. Signed action sheets confirmed that staff had been spoken with.
- When treatment was completed, the patient's record cards were stored securely in a locked cupboard.
- Staff completed information governance training as part of their induction and annually thereafter. Training compliance at the time of the inspection was 100%.

Assessing and responding to patient risk

- Patients were required to verbally confirm their identity prior to treatment and medicines. Patient's details were held on an electronic system and each patient had their own electronic card. We saw that these cards were labelled with the patients details and kept in boxes according to the sessions they attend. When not in use the boxes were stored in a locked cupboard.
- On arrival to the unit, patients would be weighed, and the weight collected on the card. Patients would then be called into the dialysis unit, where the cards were inserted into the dialysis machines. The data would automatically update the patient electronic record at the workstation.
- We saw that patient's identity was checked against the card data and confirmed by the nurse prior to treatment commencing.
- The unit's staff completed manual handling risk assessments and personal emergency evacuation plan for patients. However, they did not complete a formal assessment for patient's individual risk of falling. The lack of falls risk assessments was discussed with the area head nurse. They directed us to a generic health and safety risk assessment regarding treatment of patients and general patient handling. This contained overall mitigations that should be in place to prevent a variety of incidents, including falls. This meant that there while there was an overall risk assessment in place, there was not an assessment of an individual patient's risk of falling and therefore no individualised documented care plan to reduce their risk of falling.
- The service had access to the provider's policy to guide staff regarding patient complications, reactions and other clinical events including, seizures, chest

pain and technical complications during dialysis. It outlined staff responsibility related to training, escalation, and if required emergency transfer of patients.

- Four patients had unplanned transfers from the service to another health care provider in the 12 months ending January 2017. This was discussed with the NHS trust's renal consultant for the service during the inspection. They explained that due to the patient's chronic conditions and end stage renal failure, acute clinical events could not always be prevented. The consultant advised that they would clinically review all the patients who attend the unit at least every three months. Nursing staff were able to give us examples of when patients had been transferred to the NHS trust for a variety of clinical reasons.
- Patients whose condition deteriorated requiring transfer to hospital would be transferred via paramedic emergency ambulance, through calling 999. Staff told us that as they were situated near to the ambulance station, they had not experienced any delays with emergency transfers. An unexpected patient transfer would be reported as a clinical incident. The policy was to inform head office of all 999 calls that happened at satellite units.
- Treatment variance reports were used by staff to electronically record any issues that occurred during dialysis such as low blood pressure. This record could remain open, which would then alert the staff at the start of future dialysis sessions that this has been a problem. This would ensure that staff were up to date with previous episodes and could take any necessary precautions.
- The unit followed the company vertical line of responsibility, whereby where possible the same person was responsible for starting and finishing the patient's dialysis session. This was to ensure that each patient was assessed by the same person before and after treatments to identify any changes in condition.
- The unit had recently begun to use a document called a patient concerns' register. At the time of the inspection, there were four patients included on the register. The clinical concerns or issues raised by staff were detailed followed by progress updates, including escalation details. The clinic manager maintained the register.
- Staff told us that experienced trained nursing staff used a technique called 'dry needling' to cannulate a fistula without a primed needle. However, the unit's current policy ('nephrocare standard good dialysis care') stated that wet needling (primed needle) was the recommended cannulation technique. We raised this during our unannounced inspection and the unit and provider took immediate actions. This included instructing all staff to flush needles with sodium chloride solution prior to cannulation. A subsequent training update in this technique was completed, discussion at handover meetings and senior staff observing compliance.
- The chief nurse for the provider the issued a bulletin to all dialysis clinics, which clarified the requirement for wet needling technique for cannulation. We were informed that the policy was also being revised.
- Patients had clinical observations recorded prior to commencing treatment. This included blood pressure, pulse rate and temperature. The nurse reviewed any variances prior to commencing dialysis, to ensure the patient was fit for the session. Where necessary the nursing staff consulted the consultant for clarification. Although the unit did not use an early warning system, patents were monitored closely before, during and immediately post dialysistreatments. Fresenius had a policy with clinical pathways to guide staff regarding recognition and management of patient reactions andclinical events. This did not include the use of an early warning score system.
- Patients' blood pressures were recorded at regular intervals during their dialysis. Alarm settings were adapted to each patient, allowing any variance to the patients' normal readings to be highlighted to nursing staff. Nursing staff recorded patients' observations and details of any incidents relating to dialysis in the electronic patient record at the beginning and end of dialysis' sessions.
- Patients requiring blood transfusions were treated on the unit. Blood samples were sent to the trust for preparation of the transfusion, and a date and time

prearranged for completion. The trust would provide the unit with blood in time for the transfusion during the dialysis session. Training was provided by the trust according to their local cold chain and blood transfusion policy. We saw records confirming that staff had received blood transfusion training.

- During inspection, we saw that dialysis machine alarms were responded to within a few seconds. Alarms would sound for a variety of reasons, including sensitivity to patient's movement, blood flow changes and any leaks in the filters.

Staffing

- In alignment with the contract with the NHS trust, the unit had a 1:4 nurse to patient ratio and two healthcare assistants per shift.
- Staffing planning took place via an electronic roster system to ensure compliance with staffing ratios. This was completed eight weeks in advance by the clinic manager and approved by the regional business manager.
- We saw from rosters that staffing consisted of three qualified nurses and two healthcare assistants or three qualified nurses, one healthcare assistant and one dialysis assistant. A dialysis assistant is senior role to that of a healthcare assistant and they complete extra competencies to assist with dialysis treatments.
- During inspection, we saw that there were three nurses and two healthcare assistants 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 ratio of four patients to one nurse.
- Nursing staff completed a variety of shifts to provide cover the unit. The service day was 7am to 7pm on Tuesdays, Thursdays and Saturdays, with twilight services until 11pm on Mondays, Wednesdays and Fridays.
- Due to working in an isolated unit, which was not located at the NHS trust, staff were responsible for the management of any untoward incident or emergency. The duty roster was created to ensure that there was always a senior member of staff on duty to ensure that staff had access to a more experienced member of staff.
- We saw the handover between the morning and afternoon staff. This was a well-structured handover where every patient who attended the unit was discussed. Nursing staff were fully aware of all the patients, their history and any changes to treatment. The written nursing handover form contained a small amount of information with the detail being added verbally during the handover.
- Staff were supported by the clinic manager who was supernumerary, working predominantly Monday to Friday. The unit had a nominated nurse in charge for each shift, who was the centre manager, the deputy clinic manager or a senior staff nurse. The role of the nurse in charge was to support staff, patients and ensure the safe running of the unit.
- There were eight full time equivalent (FTE) qualified dialysis nurses and five FTE health care assistants/ dialysis assistants employed by the unit at the time of inspection, with no vacancies and no plans to extend staffing numbers.
- The rosters were reviewed by the clinic manager on an ongoing basis. They assessed daily staffing levels meet the actual number of patients attending for dialysis and covered any unexpected staff shortages.
- The unit employed temporary staff such as bank staff and agency to supplement staffing numbers when necessary. According to the service data, 60 shifts were covered by temporary staff in the three months ending January 2017. This was to cover two staff on maternity leave.
- We were told that bank staff were employed from the provider's own renal trained team. We saw that often the same three members of bank staff had covered recent gaps in staffing. These staff members were trained by Fresenius and familiar with policies, procedures and equipment. The head office were responsible for monitoring the bank staff training and competencies. Agency staff were also accessed as a last resort. Induction processes were in place for agency staff.
- Medical care was provided by the NHS trust. The unit had a dedicated consultant who attended weekly. Outside the normal weekly visit, the consultant was available for telephone advice, and contactable by email. We saw this in practice during inspection.

- The consultant from the NHS trust attended the unit every Wednesday to complete a review of patients. In addition, the consultant completed outpatient clinics at the site and we were told that they attended the unit briefly on each visit to the site.
- Nursing staff could access the renal team at the NHS trust for additional support or advice. For example, in the event of an emergency nursing staff contacted the on-call renal registrar at the referring NHS trust.
- The consultant completed a monthly review of each patient to monitor and track their condition.
- Out of working hours, patients referred any care problems to their GP. Any clinical emergency specific to their dialysis was referred to the NHS trust.

Major incident awareness and training

- The unit had a tailored 'Emergency Preparedness Plan' (EPP) in place, which detailed the plans for the prevention and management of potential emergency situations. The plan included roles and responsibilities and contact details for emergency services.
- The unit's EPP also included prevention of fire, loss of electricity, loss of computer systems and site evacuation due to possible emergencies. These included; gas and water leaks, storm damage and building collapse.
- The unit was registered as requiring essential utilities, which meant that in the event of a local electrical failure or loss of water the centre would be reconnected as a priority.
- All staff had competed fire safety and evacuation chair training at the time of our inspection.
- During the inspection, we reviewed seven patient records and found that they contained a personal emergency evacuation plan. This included individual risks such as limited mobility.

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

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

Evidence-based care and treatment

- The unit had an International Organization for Standardization (ISO) accredited integrated management system to ensured that policies and procedures supported best practice evidence. The policies and procedures were required to be reviewed annually to ensure that they were still based on assurance current evidence.
- The policies and procedures were developed in line with national guidance, standards and legislation. This included guidance from the Renal Association, National Service Framework for Renal Services and the National Institute for Health and Care Excellence (NICE).
- We saw that the IT systems used enhanced the collection of data and ease of monitoring. This was largely due to the system uploading data collected during dialysis to the NHS trust database. Similarly, staff at the unit were able to access all records at the NHS trust; reducing time spent sourcing blood and test results.
- Staff monitored and recorded patients' vascular access each time the patient attended for treatment. Patients were predominantly dialysed through arteriovenous fistulas. We saw that some patients had less established fistulas and were told that more experienced staff were responsible for cannulating these patients. This was in line with the NICE Quality Statement (QS72) statement 4 (2015): 'Dialysis access and preparation'.
- The centre met the national recommendations outlined in the Renal Association 'Haemodialysis Guidelines' (2011). For example, Guideline 5.7: 'The monthly measurement of dose or adequacy of haemodialysis' and Guideline 6.2: 'Monthly monitoring of biochemical and haematological parameter (blood tests)'.
- The unit was not responsible for any patients who completed their dialysis at home. These patients were managed by the NHS trust.
- The centre did not facilitate peritoneal dialysis (which is a type ofthat uses thein a person's abdomen as the

membrane through which fluid and dissolved substances are exchanged with the blood. It is used to remove excess fluid, correct electrolyte problems, and remove toxins in those with kidney failure).

- The unit had an audit programme to assess their effectiveness. This included healthcare documentation and infection prevention and control, and hand hygiene audits.

Pain relief

- Patients' pain relief needs were assessed and managed appropriately. Patients did not routinely receive oral analgesia during their dialysis sessions: however, local analgesia was available for cannulating the patients' arteriovenous fistula or graft (AVF/G). This included local anaesthetic creams and paracetamol. Needling is the process of inserting wide bore dialysis needles into the AVF/G, which some patients find painful.
- Any issues identified with pain were discussed initially with the nursing staff who escalated concerns to the NHS trust consultant.

Nutrition and hydration

- Patients in renal failure require a strict diet and fluid restriction to maintain healthy lifestyle. We were told that patients were reviewed by the dietitian monthly who assessed their past medical history and their treatment plans to advise patients on the best diet for them.
- The dietitian was employed by the NHS trust and part of their role was to support satellite dialysis units. They attended the unit during the visit and spoke with several patients while they were receiving treatment. Details of the conversations were handed over to the nursing staff.
- We saw that some patients had been prescribed nutritional supplements following assessment and advice from the renal dietician.
- The dietitian attended the monthly quality assurance meeting to advise and support the patient's individual plan. At this meeting, the patients' nutritional, fluids and blood results would be assessed.
- Patients were provided with oral fluids and a snack while on dialysis. This was hot or cold drinks, and biscuits. Nursing staff told us that patients frequently brought their own refreshments to consume while having their treatment.

Patient outcomes

- The patient's treatment plan was defined by their renal consultant, from the NHS trust. The renal consultant providing clinical oversight at the unit was also the responsible consultant for around half of the patients attending the unit. Individualised treatment prescriptions were developed to aim for positive patient care outcomes.
- We attended a quality assurance meeting during the inspection. We saw that the patients' blood results, progress and general condition was considered at these monthly meetings. Any changes to treatment parameters or referrals to other services were co-ordinated by the clinic manager or deputy clinic manager and reported to the clinical staff for further action.
- Outcomes and changes were discussed with patients by their named nurses and dietician. Written information was also provided as standard to ensure the patient had an ongoing record of their treatment outcomes.
- The patients' blood results were monitored each month as per the schedule set by the NHS trust consultant. The blood results and treatment data were captured by the electronic database. This data system provided customised reports and trend analysis to monitor and audit patient outcomes and treatment parameters.
- Electronic patient outcome data was available to the clinic manager and consultant, in order to monitor and audit individual patient performance and identify where improvements could be made.
- The unit monitored outcomes including the renal association quality standards. For example, we saw that two of the three indicators of dialysis adequacy for March and April were above target. This included 77% effective weekly treatment time (against 70% target) and 80% infusion or blood volume (against 70% targets).

- 86% of patients attending the unit were on the renal transplant waiting list (exceeding the 60% target).
- Where the unit's performance did not meet the corporate target, we saw explanation was included along with actions being taken. For example, 70% of patients had vascular access such as arteriovenous fistulas (rather than via lines), which did not met the 76% target. Actions included regular contact with access coordinator at the trust.
- The unit did not directly contribute data to the UK Renal Registry. However, the unit's data was uploaded to the national database from the NHS trust.

- Patients were weighed on arrival to the centre at each visit. This was to identify the additional fluid weight that needed to be removed during the dialysis session. This varied from patient to patient and formed part of their dialysis treatment plan, which was adjusted as required.
- Some patients were observed weighing themselves prior to dialysis, and inputting this into the dialysis machine. Nursing staff told us that all patients were encouraged to participate in their treatment to different levels.

Competent staff

- We saw that there were systems and processes in place to ensure that staff were competent to deliver safe care and treatment.
- The pre-employment of staff was managed by a central human resources' team and progress with pre-employment checks was monitored by the business manager. This included disclosure and barring service (DBS) checks. A start date would not be provided for a new member of staff until all checks were fully completed.
- Staff completed a six to eight week induction programme on commencement of post. This included specialist training in theoretical and practical skills. We were told that new staff started with a smaller number of patients to gain confidence in techniques before building up to four patients. Classroom training was provided to new staff including subjects such as:
  - Introduction to chronic kidney disease, and care and management of the dialysis patient.
  - Vascular access.
  - Infection prevention & control in the dialysis unit.
  - Patient assessment and documentation.
- Temporary staff working on the unit, such as agency staff, received a local orientation to the unit. We saw that a record of the orientation was kept and was signed by the agency nurse and the clinic manager. This form focussed on health and safety and included for example fire evacuation procedures, which was completed in line with the Fresenius policy.
- The dialysis assistants (DAs) worked with the qualified nurse to manage patients care and treatment. The DAs were assessed in clinical skills to assist with the completion of dialysis. This included the needling of patients arteriovenous fistulas (AVFs), programming of dialysis machine and administration of some medicines. The DAs were assessed using competencies to perform these skills, and worked alongside a qualified nurse for each clinical duty.
- The clinic manager and one of the trained nurses had also completed external renal course modules. The Fresenius skills' matrix stated that this was mandatory of all clinic managers and deputy clinic managers.
- Annual appraisals identified any areas for development and an agreed timescale for completion. All staff completed competencies, and these were reviewed annually as part of the staff member's appraisal. 100% of staff had completed their annual appraisal at the time of our inspection. The clinic manager and the deputy clinic manager completed the appraisals for the team.
- We saw that each member of staff had a learning file at the unit. These contained records of the competencies that were required to be completed and records of annual checks. Staff told us that part of this annual review, included senior staff observing them perform key skills such as cannulation of fistulas.
- All staff were required to undertake an annual reassessment of competence. During the inspection, we checked records and found that there was 100% compliance with this reassessment. For example, general trained nurses assessments included: the use

of the dialysis machine, demonstrate skills in assessment and management of patients vascular access and safely demonstrate clinical competence related to 'nephrocare standard good dialysis' guide.

- The clinic manager monitored the trained nurse's registration with the Nursing and Midwifery Council, to ensure that staff remained appropriately registered. They told us that in the unlikely event of a nurse working without being registered, they would be immediately suspended form practice while this was investigated.
- The unit had nursing staff undertake had link roles or representatives for specific topics such as infection control or nutrition. There were representatives for:
  - Education and training.
  - Infection prevention and control.
  - Health and safety.
  - Clinic information management systems .
  - Clinic EuCliD (Renal Patient Management System).
- The roles of the representatives (link roles) were to attend regional meetings and bring changes in practice, updates on information back to the centre staff. However, we noted that the health, safety, and information management representatives had not attended their mandatory update in the previous year. The staff were booked to attend future updates and dates were allocated.
- The team at the unit was supported with maintenance of training, by the area head nurse and a training & education manager. Locally at the unit, there was also an education and training link representative.
- In addition to mandatory training, staff completed a number of competencies at their commencement to post.
- The clinic manager kept an electronic record of training compliance including additional training and external courses.

Multidisciplinary working

- We found that the staff from different disciplines and organisations worked well together to provide patients at the unit with effective care and treatment.
- As well as the consultant and dietitian, the unit could contact the NHS trust's pre-dialysis specialist nurse, the renal access nurse and the renal services matron for support and advice. The dietitian told us that the unit staff were friendly and welcoming and they worked well as a multidisciplinary team.
- The trust consultant and the renal dietitian attended monthly multidisciplinary team meetings at the unit. These meetings were also attended by the registered manager or a designated deputy. This was the quality assurance meeting and we attended this during our unannounced inspection. We saw that patients' current condition, most recent blood results and medicines were discussed and recorded in the electronic patient record.
- Patients had access to a dietitian who reviewed each patient monthly, prior to the meetings. This enabled an informed discussion about planned care and treatment.

Access to information

- The information needed to deliver effective care and treatment was available to staff through either electronic or paper records. Paper records consisted of patient risk assessments, consent forms and dialysis and medicine prescriptions. Electronic records, including those from the NHS trust and blood test results, were accessible to staff at the unit.
- The renal consultant accessed records held regarding patients at the NHS trust while attending the unit. For example, clinic letters, blood results, diagnostic examinations were checked during the monthly quality assurance meeting.
- We saw that policies and procedures were available online, although staff reported that they printed out a version locally for ease of reading. Staff confirmed that they were informed when policies were updated, at which point the printed copy was replaced with the new version.
- We saw that staff signed to confirm that they read and understood new policies, procedures and memo's which were shared amongst the team. The unit used a file for updates and information sharing. Some data was seen to remain in the file past the expressed removal date.

- Some policies and procedures were determined by the acute trust. For example, the staff were expected to follow the trusts protocol for the administration of iron intravenously. We saw that the procedure was printed and placed in a file at the workstation for ease of access.
- Dialysis away from base (holiday) patient requests were made via head office to the unit. There were systems in place to ensure that the clinic received the relevant information required to ensure that holiday stays could be managed safety. The clinic manager ensured medical acceptance was also sought. However, due to lack of current capacity at the unit, staff informed us that there were few holiday stays.
- Data collected during dialysis was automatically uploaded into an electronic system. This meant that records were contemporaneous and accurate at the time of review. Staff also kept a paper record of the dialysis treatment, as a backup in case of any computer issues.
- GPs received notification of any changes in the post following the quality assurance meeting.

Equality and human rights

- From 1st August 2016 onwards, all organisations that provide NHS care were legally required to follow the Accessible Information Standard. The standard aims ensure that people who have a disability, impairment, or sensory loss are provided with easy to read information and support to communicate effectively with health and social care providers. We requested details of any easy to read leaflets used by the unit, but none were not provided.
- The unit did not provide care for patients with learning disabilities or those living with dementia at the time of the inspection. However, staff were able to facilitate patients who required additional support by allocating staff accordingly.
- The Workforce Race Equality Standard (WRES) is a requirement for organisations that 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 centre was located in a culturally diverse area and staff employed by the service reflected this. However, the unit had not compiled a WRES report.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- Staff were aware of their roles and responsibilities in relation to the requirements of consent. We saw that patients were asked for verbal consent at the start of each dialysis session and for any treatments or care during their attendance at the centre.
- All the unit staff had completed training regarding consent, mental capacity and deprivation of liberty safeguards. Nursing staff told us that currently they did not have any patients who lacked mental capacity.
- We saw that each patient completed consent forms for the completion of treatment and for dialysis. This consent form was filed in the patient's paper records and updated annually.
- Patients who expressed that they did not want to continue with treatment were referred urgently to the consultant. Patients who continued to withdraw from treatment were supported to understand the outcome and support arranged for the palliative stages of their illness.

Are dialysis services caring?

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

Compassionate care

- We saw that all staff interactions with patients were respectful and considerate. Staff spoke politely to patients and were supportive. We saw that staff were responsive to the patients' needs, including calls for assistance, alarms on dialysis machines and any non-verbal signs of distress.

- The atmosphere on the unit once patients were set up on their machine was calm and generally quiet. Patients told us they appreciated the peace. We saw that patients were spoken with sensitively throughout their treatments.
- Patient's dignity was maintained using screens that could be placed around the dialysis station.
- Nursing staff told us that due to patients attending the unit regularly for long periods, they had developed effective nurse patient relationships. Staff we spoke with told us the best part of working at the unit was the 'extended family feel'.
- We observed that the patients and staff had developed appropriate friendly relationships. There was general chat and appropriate use of humour.
- We saw that staff spent time talking to patients throughout their treatments and their waiting time before and after.
- One patient who we spoke with told us that 'the staff are lovely' and they were happy with the care at the unit.
- Staff understood patients' personal, cultural, social and religious needs. We saw that these were taken into account when planning treatment. For example, patient's dialysis sessions were planned around their work and social life.
- Patients told us that staff were kind, caring and provided excellent care and treatment, and were always friendly and welcoming.
- The service received five written compliments in the 12 months ending January 2017.
- The unit took part in an annual patient satisfaction survey. This was advertised by the use of posters. An external company was employed to analyse and collate the results. They also provided a freepost service and a phone line that could be used by those whose English was not their first language. This helped with the response rate. The last survey for Stratford Dialysis Unit was in November 2016, with a response rate of 73%.
- The results of the patient satisfaction survey included: 88% of patient agreed that the clinic was well organised, 88% of patients would recommend the unit to their friends and family and 85% of patients felt the atmosphere in the unit was happy and friendly. We saw that an action plan was in place for areas to improve.

Understanding and involvement of patients and those close to them

- All the patients at the unit were allocated named nurses. This key role was to provide a specific person for the patient to discuss any issue with and access support. Patients we spoke with during the inspection, knew who their named nurse was.
- The renal consultant stated that is was rare for the unit to have a dissatisfied patient.
- Patients that we spoke with who had attended the unit for many years had no complaints. They found the staff to be very good. Patients' particular commended the leadership of the unit and that the unit was 'well run'.
- We observed patients having dialysis commenced during the inspection. Staff spoke with the patient to ascertain how they were feeling and if there were any issue or concerns prior to commencing the treatment.
- We saw that staff spoke openly about the treatments provided, the blood results and dialysis treatment plans. Many of the patients were observed speaking to staff about their latest blood results and what these meant and staff responded appropriately.
- Nursing staff told us that as they saw their patients frequently they were familiar with their moods and were able to identify when patients were having a bad day or were feeling unwell. This enabled them to spend additional time with the patients as necessary to support them with their treatment or assist with any concerns they may have.
- Staff told us that patients were very much encouraged to be involved in decisions about their care and even participate in self-care.
- The patients spoke positively about the staff and treatment at the unit.

Emotional support

- We saw that during the dialysis session, the healthcare assistant on duty attended to each patient to have a

chat and ask how they were. This gave the patients the opportunity to ask any questions which were then referred to the nurse responsible for the patient for that session.

- Nursing staff were observed answering alarms quickly explaining to the patient what the alarm had meant and any changes to treatment or any actions to be taken in response to the alarm.
- Patients were supported by the nursing staff to access support and additional services as necessary.
- Staff were aware of the impact that dialysis had on a patient's wellbeing, and supported patients to maintain as normal life as possible. Staff encouraged patients to continue to go on holiday, and participate in the management of their treatment.
- We saw that the staff in the unit had provided details of support networks that were available in information posters in the reception area, for patients and their relatives.
- Nursing staff were observed giving patients time to talk about any concerns. The manager was clearly well known to patients who talked to them often throughout the day.
- Patients had access to a social worker and psychologist if required for advice and support. We observed during the quality assurance meeting, that some patients had been referred by staff to these services.

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

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

Meeting the needs of local people

- Patients were referred to the clinic for their haemodialysis treatment from the parent NHS trust's renal unit. The service had been established since 2004 and it mainly served the local population in Warwickshire.
- The service specification was defined by the parent NHS trust's renal team, and defined within the contract that Fresenius were asked to deliver against.
- The Department of Health provides best practice guidance for the design and planning of new healthcare buildings and the adaptation or extension of existing facilities, via health building notes. Stratford Dialysis Unit facilities predated and were not in line with all aspects of Health Building Note 07 01: 'Satellite dialysis units' (2013). We saw evidence of escalation of these estates issues to the NHS trust via contract meetings and emails.
- Patients were assessed by the NHS trust staff for suitability to receive dialysis in a satellite unit and then referred to the centre.
- When the patient was ready to be collected following their dialysis, an electronic booking system was used to let transport know. They had an hour window then in which to collect the patient. However, this did not meet NICE quality standards (QS72- standard 6), which indicate that adults using transport services to attend for dialysis should be collected from home within 30 minutes of the allotted time and collected to return home within 30 minutes of finishing dialysis.
- Transport problems or delays were noted in formal complaints and in four patient comment cards completed for our inspection. The clinic manager was aware of the occasional problems with patient transport. They would escalate issues to transport control and liaise closely with the renal transport coordinator.
- During the inspection, we spoke with the renal transport coordinator and they explained that the service provided was often affected by pressures at the local NHS trust. If they were under black alert, they would be diverted to help at the hospital. They admitted frequent disturbance to the transport service. The patients would be kept informed of any delays. The coordinator often attended to unit in person to speak with patients when complaints have been raised.

Access and flow

- Patients were assessed for their appropriateness to attend the centre by the NHS trust.

- Patients with acute kidney disease were treated at the NHS trust and only chronic, long-term dialysis patients were referred to the centre for treatment. Referrals for admission for dialysis at the unit were made by the parent NHS trust, who contacted the unit to inform them they had new patients.
- If the unit had no capacity, patients were placed on a waiting list until a slot became free. On these occasions, patients would receive treatment in an alternative unit on a temporary basis. At the time of inspection, there were no patients on the waiting list for treatment.
- The unit was very busy. Around 180 patient dialysis sessions were provided each week.
- The monthly utilisation rates from November 2016 to January 2017, were between 93% and 96%.
- There were 60 patients under the care of the unit at the time of our inspection.
- There were three dialysis treatment sessions provided daily on Mondays, Wednesdays and Fridays, and two sessions on Tuesdays, Thursdays and Saturdays. There were usually 12 patients for each session.
- The usual treatment sessions' times were 7.30am, 1pm and 6pm for the twilight sessions. The dialysis unit opened from 6.15am until 11pm at the latest. There were on average 730 treatments sessions delivered each month.
- The service had not cancelled any planned dialysis sessions for a non-clinical reason in the 12 months ending January 2017. However, five (out of approximately 8,500) sessions were delayed in this time period due to equipment issues.
- Patients who no longer wished to continue with dialysis, were referred to the NHS trust's renal consultant for review. During the inspection, the consultant gave three recent examples, of when the team at the unit had worked with the patients, family, GP and community services to meet patient's end of life preferences. Providing the planned transfer from dialysis treatment to palliative care at home was seen as one of the unit's strengths by staff.
- When patients did not attend sessions, staff tried to contact them by telephone, and contacted the NHS trust to inform the renal team of the missed session. Staff completed a treatment variance form to record the missed session.
- If patients chose not to attend a dialysis session, staff would explain the risks associated with the non-attendance, and where possible, offer another appointment. During the unannounced inspection, a patient had not attended for their session and we saw that actions were taken, including informing the renal consultant.

Service planning and delivery to meet the needs of individual people

- We saw that patient's allocation for dialysis included a timetable for the commencement of treatment. For example, on Mondays, patients seated in chairs one to four commenced their treatment between 07.30am and patients seated in chairs five to eight commenced treatments at 07.45. This routine meant that all patients commenced treatment in a methodical manner.
- Patients were allocated to seats to meet the dialysis times. For example, those patients who required longer dialysis sessions were seated where they would commence treatment earlier than another patient who required a shorter dialysis time. Staff told us that if patients requested a change to this routine, they could swap times. We saw staff arranging a change to patient's dialysis times during inspection. This was to enable a patient to go on holiday.
- The majority of patients attended the centre for treatment on a morning, afternoon or twilight on set days, for example every Tuesday, Thursday, and Saturday morning. Patients we spoke with told us that they had some choice in when they attended, with one patient swapping from a morning to an afternoon appointment when it became available.
- The unit had a flexible approach to the patient's dialysis sessions and supported changing dialysis days and or times as far as possible to accommodate external commitments, appointments or social events. Staff told us that they try to offer as much flexibility as possible regarding session times. As the unit was

currently nearing capacity, this flexibility had to be between patients, who would ask to swap sessions. A dialysis session being relocated to the referring hospital was also an option if necessary.

- Patients were able to reduce the time they dialysed if they had appointments or family activities. We saw that patients completed early termination forms, consenting to the reduction in dialysis time. We were told that patients were informed that any time taken off a dialysis session was added to the next attendance. We saw one example, where a patient completed their dialysis 45 minutes early, and added 15 minutes to the following three sessions to ensure that they dialysed the correct amount of time.
- Patients who wished to use the toilet during their dialysis were offered the option to use the bathroom, or for gentlemen use a urinary bottle. Staff told us that they encouraged patients used the bathroom for privacy and dignity, however used screens when patients used urinary bottles. Patients often preferred to use bottles while on dialysis rather than extending time of their treatment.
- Patients were encourage to participate in their own treatment and the unit completed a shared care checklist for each patient detailing action taken to teach the patients and when they had been deemed as competent to complete the tasks. Patients who did not wish to complete or were unable to complete any part of their treatment had the same checklist in place, but this detailed reasons why the training had not taken place.
- Patients who used hospital transport were responsible for managing their own bookings. Staff would issue the patients with a time of dialysis completion and then add an additional 20 minutes for those with fistulas, and 15 minutes for those with lines.
- Patients were required to update their transport bookings every three months. Staff told us they supported patients to do this each time to ensure that they were able to attend dialysis sessions. Staff printed reminders for patients and included transport contact details.
- Some patients attended the unit using either private transport or volunteer drivers. We saw that there was a small car park for use by patients and/ or family.
- Patients who were due to commence treatment at the centre were introduced to the team and the unit by the renal community support team. This involved a visit, often on a Saturday, where the patient was able to meet other dialysis patients, the staff and look at the unit.
- We were told that the NHS trust assisted the unit to complete patient activities and provided vouchers/ days out for patients, staff and carers. Staff told us that patients were “like extended family” and therefore days out were well attended and enjoyable.
- The unit did not currently treat any patient with a diagnosis of dementia, and staff confirmed that there was no reason why a patient living with dementia would not be dialysed on the unit. They told us the consultant would be involved with the decision to dialyse and refer to the centre.
- Patients who usually had fulltime carers were encouraged to bring their carers in for dialysis sessions if required. The staff told us that they would work in partnership with carers. They gave examples of when personal preferences were met. There was a patient who preferred to have dialysis in a side room, due to anxiety and this had been accommodated.
- Patients on the unit could have visitors during treatment sessions.
- We saw that patients whose mobility was compromised were assisted to their chairs by staff.The unit provided disabled access and wheelchair accessible toilets.
- The unit did not have a multi-faith room.
- Each dialysis station had a television with remote control. A patient told us that the television at their station did not work and this had been the case for some time. Staff at the unit confirmed that the fault had been reported and the engineers would be contacted again. At the unannounced inspection, we found that the television remained broken awaiting an engineer.

Learning from complaints and concerns

- There was a policy and a process in place for the management of complaints. The clinic manager was the lead for complaints at the unit.

- We saw information displayed in reception providing patients and relatives on how to raise concerns and make a complaint. There were also feedback boxes available, to enable patients to make comments or suggestions anonymously.
- Data showed that there were five formal complaints received by the centre from February 2016 to January 2017. Two of these related to patient transport and were managed jointly by the clinic manager and the transport provider.
- The number of complaints was also being monitored centrally by head office. Each dialysis unit that had a risk profile and the number of complaints was one of the indicators.
- The ward manager was very visible on the unit and available to discuss any arising concerns. Staff were aware of the complaints procedure for the unit.
- Patients we spoke with during the inspection were positive about the unit and had no complaints. Patients were aware of how to make a complaint if they so wished.

Are dialysis services well-led?

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

Leadership and culture of service

- Leaders had the appropriate skills and knowledge to manage the service. Locally, the clinic manager was supported by a deputy clinic manager, nursing staff, health care assistants and an administrator.
- There was an area head nurse, who covered a number of dialysis clinics who provided line management and senior support for the clinic manager. The area head nurse and the business manager were present during the inspection, and it was clear from their interactions and knowledge of staff that they had regular contact with the team. They formed part of the management structure that linked from a local and regional level to a national level for the provider.
- Nursing staff confirmed that the management team were approachable when they visited the centre.
- The clinic manager worked mainly supernumerary, this meant they were free to support the running of the unit. Nursing staff reported that if the unit was quiet, the manager completed some ad hoc training in any requested topic. They also had a deputy clinic manager who worked more clinically.
- Team meetings were held approximately monthly. We saw minutes of these meetings, which included feedback to staff regarding incidents and audit performance. Although staff reported, that as they worked in a small unit, they regularly updated each other with developments as part of their daily working pattern.
- The unit used a named nurse approach to patient care. We were told that the named nurse was responsible for maintaining the patient's records, and ensuring they had a detailed understanding of the patient's condition and treatment. The named nurse was also responsible for the updating of patient risk assessments, either by completing them in person or by requesting an update by the staff member caring for the patient on any given day.
- We saw evidence that staff worked with stakeholders. There was understanding of each role and professional interaction to meet patients' needs. We saw open discussions between centre staff and staff employed by the NHS trust.
- We were told that the manager had an open door policy and saw that staff and patients asked for advice, assistance or information when necessary.
- We saw that staff had effective working relationships with staff from the NHS trust, for example, the renal consultant. Medical staff and specialists confirmed that the working relationships were positive.
- The manager explained that they had a process for staff who returned to work following an absence. There was a return to work interview, this was to be supportive. Staff told us that there was good team work within the unit.

Governance, risk management and quality measurement

- The clinic manager was responsible for monitoring and leading on delivering effective governance and quality monitoring in the dialysis unit, supported by the wider Fresenius management team.
- We were told that there was a clinical risk register for the overall provider. However, this was a new process.
- Locally, the unit had recently started a patient concern register for the unit, capturing clinical concerns by staff. This meant that there was not yet an overall recognisable, effective and fully embedded risk management process to capture risks and drive improvements.
- Some risks identified on this inspection had not been fully recognised by the unit leaders. For example, lack of falls' risk assessments, the lack of an early warning score assessment to monitor for signs of patients' deterioration and lack of compliance with all aspects of Health Building Note 07, 01: 'Satellite dialysis unit' (2013) guidance. There were no risk assessments regarding this. The corporate provider was considering use of an adapted national early warning scores in satellite dialysis units.
- We were informed that performance was monitored through a dashboard. A copy of the clinics dashboard for April 2017 was provided. This showed that performance was plotted against set targets in areas of patient, employers, community and shareholders. It included dialysis adequacy indicators, appraisal rates and use of resources. The document that was provided, did not show how the unit was performing compared with other Fresenius satellite clinics.
- The clinic manager attended Fresenius managers' meetings twice a year. This was a two-day conference to be attended by all managers and area head nurses.
- The unit was required to be audited on a routine basis usually every one or two years by the provider. This included health and safety inspections and the provider's chief nurse conducting unannounced audits of the clinic. Performance with this would be discussed at the provider's clinical governance committee meetings. The provider's system was designed to indicate those clinics which were not meeting the standards expected of the provider, and to strive for continuous improvement in audit results.
- There was a risk assessment document developed by Fresenius Health and Safety Manager to address the treatment of patients and general patient handling. It included, fall slips and trips of patient and staff, fire, needle stick injury, electric shock, infection control and untoward clinical events. It contained details of existing controls that should be in place for all dialysis units. It was due for its annual review (29/04/2017). However, this did not contain details of risk specifically encountered at the unit such as estates' concerns and lack of general storage or reception area space for patients.
- The reception area at the unit was small. Staff did not let patients in, as a station was ready. Instead, patients were called through when the whole unit was ready.
- We were told that contract review meetings took place each quarter for the clinic and the trust to discuss any operational issues. This was also an opportunity for the unit to raise any outstanding estates issues. There have been on-going issues related to estates that were not the responsibility of the provider. However, minutes were provided for two meetings, which took place in January and November 2016 respectively. Estates issues were highlighted in the minutes of the January 2016 meeting. The clinic manager was able to demonstrate with copies of emails and infection control audit actions that estates issues, including, general decoration and air-conditioning have been escalated to the relevant managers at the trust, on many occasions.
- We found that one of the patient's televisions was broken during the inspection. When we returned for the unannounced visit, the engineer had not attended. Subsequently the provider informed us they were not responsible for the televisions, which were provided by the patient trust. Funding needed to be approved by the charity prior to expenditure and an engineer had attended and repairs were underway.
- Operational issues were discussed at quarterly contract meetings with the NHS trust. In the twelve months ending January 2017, there were two contract meetings that took place (one was cancelled due to being non-quorate).

- Audit results were shared with the clinic manager electronically and used as part of the contract review meetings with the trust.
- There were monthly quality assurance meetings, which were attended by the consultant, the manager or deputy clinic manager and the dietitian. These meetings discussed all the current patients and would cover any quality or governance issues that arose. There was not a set agenda and this did not formally cover the governance of the unit generally.
- Data collected by the unit was inputted into the renal registry by the NHS trust. This information was validated.

Public and staff engagement

- The unit sought patient feedback in order to improve the service they provided. This was formally captured through the annual patient satisfaction survey. The latest survey results from November 2016 had a response rate of 73%. Positive results included that patients thought the rooms and treatment areas were well maintained and clean (98%) and they had complete confidence in the nursing staff (90%). Areas to improve included 56% of patients agreed that dialysis usually began on time and 71% felt that patients' complaints were taken seriously. During the inspection, we saw that action plans had been developed and were being monitored to improve these areas.
- Each year the unit invited their staff to provide feedback through an employee satisfaction survey. There was a 100 % response rate in the previous survey, which took place in November 2016. The results were mixed. For example, the following were listed as areas to review and improve upon.
  - 38% of staff agreed that they had gone to work despite not feeling well enough to perform their duties.
  - 33% of staff had felt pressure from their manager to come to work.
  - 38% of staff agreed that senior managers acted on staff feedback.
- During the inspection, we saw that action plans had been developed to improve these areas.
- The unit held monthly team staff meetings at the unit. These were led by the clinic manager or their deputy. They were well attended and structured in to the four key areas of focus, the patient, the shareholder, the employee and the community. General status updates were given and included positive reinforcement regarding areas of good performance, for example successful records audit.

Innovation, improvement and sustainability

- The unit had a stable team and staff completed their training according to the training matrix. This was set at corporate level and ensured that staff were up to date with emerging topics.

Vision and strategy for service

- The corporate vision and priority was to ensure the delivery of safe, high quality care for patients. This linked with their four key areas of focus, which were, the patients, shareholders, the community and employees.
- It was reported that staff were committed to dealing with the four C's (compliments, comments, concerns and complaints) in a sympathetic and understanding way.
- There was a strategy for the delivering of quality care, with policies, guidance and procedures based on national guidelines. Staff understood this strategy.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- To ensure effective governance and assurance systems are in place so that leaders of the unit have an effective oversight of risks in the service, and to use this information to drive improvements in the provision of safe care and treatment.
- To ensure that all risks to individual patients are identified, assessed and monitored consistently.
- To ensure that local health and safety risks related to the estates are assessed, monitored and mitigated and escalated formally.
- The service must bring safeguarding training in line with national guidance, which specifies that designated safeguarding leads should be trained to level three in safeguarding adults to support staff in recognising and reporting potential safeguarding concerns.

Action the provider SHOULD take to improve

- To review systems regarding the prescription of medicines.
- To consider the use of an early warning score system for monitoring patient's risk of deterioration.
- To monitor staff compliance with policies regarding cannulation techniques.
- To ensure protocols and guidance for administration of iron use appropriate haemoglobin reference levels.

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 17 HSCA (RA) Regulations 2014 Good governance How the regulation was not being met: There were not effective, embedded governance and assurance systems in place for the leaders of the unit have effective oversight of risks in the service and to use this information to drive improvements in the provision of safe care and treatment. For example, risk registers had recently been introduced. Some risks identified on this inspection had not been fully recognised by the unit leaders. For example, lack of patient falls' risk assessments, Some environmental and estates risks had not been assessed formally.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment The safeguarding lead was trained to level two in safeguarding adults. This was not in line with national guidance, which recommends that designated safeguarding leads should be trained to level three in safeguarding adults.