

Oldham Dialysis Unit

Quality Report

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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

Oldham Dialysis Unit is operated by Fresenius Medical Care Renal Services Limited. Nephrocare is the service brand of Fresenius Medical Care. The unit is situated close to an acute trust hospital site in Oldham. The unit is a satellite unit to the renal unit of Salford Royal NHS Foundation Trust located elsewhere in Greater Manchester.

The unit has 22 dialysis stations in the main treatment area, two bays, four side rooms and a self-care room.

The service provides dialysis services for adults from 18 to 65 and adults who are over 65 years of age. There are no services provided to children and young people.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 25 April 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.

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

Summary of findings

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 was run with appropriate staff numbers, equipment, medicines and records management, and infection control processes.
- Patients were assessed for risk before during and after treatment and there were processes in place to evacuate patients safely in the event of an emergency.
- Care and treatment at the unit was evidence based and provided in line with the provider's Nephrocare Standard Good Dialysis Care.
- There was a comprehensive competency programme in place and staff were competent to provide the care and treatment that the patients required.
- Care was delivered to patients by staff who were caring and compassionate and patients indicated that they were treated with dignity and respect.
- There was a clearly defined management and reporting structure and the clinic and deputy clinic manager had the appropriate skills, knowledge and experience to lead the service effectively.

- There was adequate auditing in place and strategic aims and objectives were measured and benchmarked.

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

- The unit did not undertake a Workforce Race Equality Standard evaluation in accordance with the NHS standard contract.
- The service needed to reduce the risks associated with language diversity and other protected characteristics.
- There was a new risk register that needed to be embedded within the organisation.
- There was no sepsis care pathway in place.

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

Ellen Armistead

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Dialysis Services

Rating

Summary of each main service

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

Summary of findings

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Oldham Dialysis Unit

Services we looked at

Dialysis Services

Summary of this inspection

Background to Oldham Dialysis Unit

Oldham Dialysis Unit is operated by Fresenius Medical Care Renal Services Limited. The service opened in February 2014. The service primarily serves the communities of Oldham and the surrounding area and occasional access to patients who are referred for dialysis whilst they are on holiday in the area. The service is a satellite unit of the renal unit at Salford Royal NHS Foundation Trust. This trust provides the unit with access to the renal multi-disciplinary team, with a consultant nephrologist visiting the dialysis unit four times per month along with a dietitian.

The service provides haemodialysis and haemodiafiltration (HDF) treatment to adults. The clinic is registered for the following regulated activities: - Treatment of disease, disorder or injury. The clinic manager was reasonably new in post and has now been registered with the CQC as the Registered Manager.

The CQC had not inspected the location previously. There were no outstanding requirement notices or enforcement associated with this service at the time of our inspection in April 2017.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector and an inspection manager. The inspection team was overseen by Tim Cooper, Head of Hospital Inspection.

Information about Oldham Dialysis Unit

The Oldham Dialysis Unit was a standalone unit, located in a purpose-built building that was close to the site of the local NHS acute hospital.

The unit provided dialysis treatments for adults and the service ran from Monday to Saturday each week. There were no overnight facilities.

There were two dialysis treatment sessions per day, starting at 07:15 and 13:00. Patients were generally split into four groups with two groups attending the unit on Monday, Wednesday and Friday and two groups attending on Tuesday, Thursday and Saturday. There were around 20 patients dialysed in the morning and 20 in the afternoon on each day. There were no twilight dialysis sessions.

Patients were referred to the unit by Salford Royal NHS Foundation Trust. A contract was in place with the trust for the unit to deliver dialysis treatments to their patients.

There were 22 dialysis stations in the unit in a main treatment area; two four-bedded bays; four side rooms that were partitioned with glass and a self-care room that

was not generally used. The unit delivered an average of 910 treatment sessions per month. In 2016, the unit delivered 6804 treatments to adults aged 18-65 and 4468 treatments to adults over 65 years of age. They did not provide services for children or young people. There were 77 patients using the service at the time of our inspection.

The service employed six full time and two part time qualified nurses (7.62 whole time equivalent). Three full time and one part time dialysis assistants were in post (3.77 whole time equivalent). There were also two full time healthcare assistants. In the previous 12 months, three staff had left the service and three had joined. The staff numbers included the clinic manager and deputy clinic manager. There was also a unit secretary.

During our inspection of the unit we spoke to a range of staff, including, registered nurses, dialysis assistants, reception staff and senior managers. We spoke with four patients and one carer. We left "Tell us about your care" comment cards at the unit but none were completed by patients. We also reviewed five sets of patient records and five sets of staff training records.

Summary of this inspection

Services accredited by a national body:

- The clinic is accredited against ISO 9001 quality management system.
- OHSAS 18001 accreditation for the health and safety management system.

Services provided at the unit under service level agreement:

- Clinical and or non-clinical waste removal
- Cleaning services
- Interpreting services
- Pathology
- Fire safety
- Building maintenance

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

- There was an incident reporting procedure in place and staff were aware of and knew how to report incidents. There were no “never events” reported in the 12 months prior to our inspection and the one serious incident reported had been handled appropriately and duty of candour had been applied.
- The unit had reliable systems and processes in place for staff training, infection prevention and control, water quality monitoring and treatment, disinfection and maintenance of equipment, and screening procedures for blood borne viruses.
- The unit was clean and hygiene and infection control policies and procedures were being adhered to.
- Equipment was safe, checked, calibrated and maintained effectively.
- Medicines were stored and dispensed appropriately.
- Records were managed appropriately and regular record audits were undertaken.
- Patients were assessed for risk before, during and after treatment and processes were in place for requesting urgent medical assessment of patients, or resuscitation if needed.
- The unit was appropriately staffed.
- Staff were aware of the major incident plan, and undertook regular evacuation exercises to maintain their knowledge.

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

- The service does not have a policy or provide training for nursing staff with regards to identification or process for sepsis management. This was not in line with the NICE guideline (NG51) for recognition, diagnosis, or early management of sepsis. (Sepsis is a life-threatening illness caused by the body's response to an infection).
- Staff had not received Safeguarding Children Level 2 training, as recommended by the intercollegiate guidance document published by the Royal College of Paediatrics and Child Health.

Are services effective?

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

Summary of this inspection

- Care and treatment at the unit was evidence based and provided in line with the provider's Nephrocare Standard Good Dialysis Care. The unit's policies and procedures took into account professional guidelines, including the Renal Association Guidelines and research information.
- Data relating to the unit's treatment performance was submitted to the commissioning trust for inclusion in the renal registry, and the unit was benchmarked against the provider's other units across the country.
- Patients' had individualised treatment prescriptions that were reviewed monthly by the multidisciplinary team, which included the renal consultant, associate specialist in renal medicine, dietitian and the clinic manager. The unit had access to psychological support if needed.
- Patient's vascular access sites were regularly monitored, and patients were appropriately assessed before, during, and after dialysis.
- Patient's nutrition and hydration needs were monitored, and the unit's dietitian provided face to face advice every month to each patient.
- Staff were competent to provide the care and treatment patients' required. A competency programme was in place and regularly reviewed. New staff were supported through an induction and mentoring programme.
- All staff were trained in basic life support, and the unit met the requirements for at least one member of staff per shift to be trained in immediate life support.
- Staff had access to the information they needed to provide good care to patient.
- The unit rarely cared for patients with dementia or learning disabilities; however, staff received training in, and were aware of the principles of the Mental Capacity Act 2005 and the Deprivation of Liberty Safeguards (DoLS).

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

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

Are services caring?

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

However, we found the following areas of good practice:

- The unit had a named nurse for each patient, which helped to ensure continuity of care. All patients in the unit knew who their named nurse was.

Summary of this inspection

- We observed staff interacting with patients in a compassionate and caring manner. This was reflected in comments made to us by patients during the inspection.
- The annual patient survey indicated that patients felt that staff were caring, treated them with dignity, and explained things in a way they could understand.
- Staff understood the importance of building a strong and friendly rapport with patients, and the unit supported staff to provide care in line with the 6 Cs of nursing.
- Staff supported families who were bereaved.

Are services responsive?

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

- The unit service specification was defined and agreed with the commissioning trust to meet the needs of local people.
- The Department of Health building guidance relating to the design and layout of renal dialysis units was met.
- The unit was appropriately accessible to patients in the local area, including those with disabilities and adequate patient transport was provided.
- Dialysis slots were limited but allocated as far as possible to meet the needs of the individual patient and slots were available to accommodate patients who were on holiday in the local area,
- Staff supported patients to go on holiday through co-ordinating care at clinics abroad.
- The number of complaints about the unit was very low.

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

- The unit was not doing everything possible to reduce the risk associated with language diversity. There were no staff members who spoke languages, other than English, and there was a reliance on family members to pass on important information to non-English speaking patients. The unit did not have access to information in other formats such as easy-read or braille.

Are services well-led?

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

Summary of this inspection

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

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

- The risk register had only recently been developed and needed to be embedded within the organisation.
- The unit did not undertake a Workforce Race Equality Standard evaluation in accordance with the NHS standard contract.

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

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

- There were no 'never events' reported by the service in the last 12 months. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic barriers, are available at a national level and should have been implemented by all healthcare providers.
- There were nine clinical incidents recorded between 1 January and 31 December, 2016, including one serious incident.
- We reviewed eight clinical incident reports and found most were completed appropriately, with a summary of the incident, outcome and any recommended actions for future practice.
- Two incidents where the patient had died had not been followed up appropriately, to ensure the death was not related to the dialysis treatment. In one instance the cause of death was unknown at the time that this decision was made.
- There was an incident reporting policy in place and the process of reporting CQC notifications was clear.
- There had been one serious incident, involving a new patient. This had been reported to the commissioning trust. We reviewed the investigation report and paperwork around this incident. The investigation highlighted poor recording of information on the electronic patient information system and a lack of competency reassessment on a nurse's use of the ultrasound machine. An action plan had been put in place to reduce the risk of such an incident happening again.
- There was clear evidence of learning from the incident. Systems had been put in place so that treatment of a new patient would not commence without all the required information in place.
- We saw that the service followed their duty of candour policy following this incident where moderate harm and above had resulted. We saw from the paperwork that meetings had occurred with the patient and an apology letter from the clinical director had been sent. 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.
- When a clinical incident report (CIR) was completed it was forwarded to the centrally based clinical incident team and to the NHS hospital trust's governance team.
- The clinical incident team, led by the chief nurse, decided whether or not an investigation was required. If an investigation did take place, this was sent to the clinical service director for discussion at board level.
- There had been no incidents of pressure ulcers, urinary tract infections of hospital-acquired venous thromboembolism (VTE) (blood clots).
- Clinical incidents were monitored centrally with clinic updates and learning bulletins distributed by the chief nurse to support lessons learned across the organisation.
- Incident reporting fed into the clinical governance framework and local clinic review process.
- The service had different systems in place for monitoring incidents. As well as the clinical incident reporting system they had 'treatment variation

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reports' for reporting any incident related to a patient's treatment, for example if a patient had to use a different machine due to their regular machine having a major fault.

- There were also 'non-clinical' incidents, which included falls, and 'unit variation reports' which related to environmental incidents. There had been ten falls recorded from July 2016 to April 2017. They were recorded as non-clinical incidents. No harm was recorded to any of the patients who had fallen.
- Patient safety alerts were distributed centrally from head office and reviewed by the clinic manager for relevance to the local patient group. There had been none so far this year that applied to this clinic.
- Learning bulletins were disseminated across the organisation when there were lessons to be learned from clinical incident reports. These were discussed at daily handover, and a copy was recorded in the clinic awareness file at the nurses' station with a read and sign sheet for any staff who were not present. These sheets were monitored by the nurse in charge and the manager checked that they were completed.

Mandatory Training

- There was a training matrix in place that identified which training was mandatory for each staff role. This meant that staff undertook training appropriate for their position, for example the clinic manager had to either complete training or have awareness of all training listed on the matrix, whereas it was not necessary for healthcare assistants to undertake training for complications in dialysis or blood transfusion.
- Clinical staff, at all levels, were required to undertake training in the Nephrocare Standard Good Dialysis Care. This defined best practice requirements regarding quality standards of patient care, technical procedures and training needed to perform daily activities in a dialysis clinic.
- All staff, including non-clinical staff, were required to complete a range of other training, including the Nephrocare standard hygiene and infection control training.

- There was a training and education plan in place, with courses and available dates for classroom training for staff to book onto. There was a 'red, amber, green' monitoring tool which showed the status of mandatory training for each member of staff.
- Information provided by the service in March 2017 showed that all staff at the unit were up to date with their mandatory training and course dates were showing as green.
- Mandatory training records for bank staff were retained centrally and were monitored by the flexibank administrators. Where bank staff were not up to date they were suspended from shift allocation until evidence of completion was received.

Safeguarding

- The unit provided treatment to patients aged 18 and above. Safeguarding vulnerable adults and safeguarding children's training formed part of the mandatory training programme for all staff.
- At the time of the inspection, all staff members had completed safeguarding adults level two training and safeguarding children level one training.
- Staff had not received Safeguarding Children Level 2 training, as recommended by the intercollegiate guidance document published by the Royal College of Paediatrics and Child Health.
- The unit had clear systems and processes in place to keep patients safe from potential and avoidable harm.
- Staff were aware of their roles and responsibilities for escalating safeguarding concerns. Staff were knowledgeable about how to deal with and raise safeguarding issues and were able to give us examples of when it would be appropriate to do so.
- There was a Fresenius Medical Care policy on safeguarding adults and children. This policy was easily accessible and there were also quick reference guides for key safeguarding contacts displayed prominently in the clinics offices.
- The unit had reported one safeguarding concern in the 12 months prior to our inspection that involved the suspected neglect of a patient in their home environment.

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- The information had been escalated appropriately, the local authority safeguarding team, social workers and renal consultant were involved and the patient was supported as an inpatient in hospital until they could return to a safe environment.

Cleanliness, infection control and hygiene

- There were appropriate infection prevention and control policies in place and the identified standards were audited on an on-going basis at unit, central and external level. We saw evidence of this, and reviewed the audits submitted from the reporting period between January 2016 and December 2016.
- MRSA (methicillin-resistant staphylococcus aureus) and MSSA (Methicillin sensitive Staphylococcus aureus) screening was conducted prior to patients attending the unit and were processed in the local NHS trust laboratory. Results accompanied the referral letter from the local NHS hospital trust. The unit accepted test results from up to four weeks prior to referral.
- There had been no reported cases of C-difficile, MRSA or other bacteraemia in 2016. There had been two recent cases of MRSA in 2017 and these patients were always dialysed on the same machines, in isolation, which were cleaned using a different chlorine-based solution to ensure the necessary infection prevention and control measures were met. The service had undertaken a deep clean which included the waiting area, to minimise the chance of any cross-infection. There was no set schedule for deep cleans; they were completed as and when required. The clinic manager made a decision based on the risk of infection. There had been one case of MSSA in the reporting period between January and December 2016. MSSA, is a type of bacteria which is usually harmless but can cause an infection if it enters the bloodstream.
- Hepatitis screening was conducted by the Fresenius in house laboratory. Post-admission, routine blood samples were taken monthly. Hepatitis screening took place every three months. If there was a history of positive results for hepatitis B or C this would be undertaken monthly as required. Nurses and support workers were trained and competency assessed to take blood.
- If patients were unwell, a C-reactive protein (CRP) test was taken to check for inflammation / infection. If results showed changes then the patient would be referred for medical advice.
- There was a separate dialysis machine set aside for any patient with hepatitis B. This machine would not be used by anyone else. Patients with certain infections such as HIV or hepatitis C could share machines in accordance with national guidance. There had been no known cases of cross-contamination.
- We observed all areas of the unit including the waiting and treatment areas, the dirty and clean utilities, storage rooms, water treatment room, and the staff room. All areas were visibly clean.
- We observed staff carrying out their duties in line with the infection prevention and control requirements set out in the provider's Nephrocare hygiene plan.
- Staff wore appropriate personal protective equipment, such as aprons, gloves and visors when cleaning the equipment, and when undertaking the insertion and removal of dialysis needles. Each staff member had their own visor. Staff wore disposable clothing, which could be easily removed if contaminated. This reduced the risk of cross contamination between patients. Staff observed aseptic no touch techniques (ANTT) when using equipment such as needles that could cause contamination and key parts, such as needle tips were not touched. We did not see any instances of contamination breaches whilst on the unit.
- We observed staff following hand hygiene protocols, including 'arms bare below the elbows', in line with the organisation's Nephrocare Standard Hygiene and Infection Control policy. Posters explaining the World Health Organisation's "5 Moments of Hand Hygiene" were also displayed which helped make sure patients, staff and visitors adopted effective hand washing techniques. The moments of hand hygiene that must be observed are before patient contact; before an aseptic task; after body fluid exposure risk; after patient contact and after contact with patient surroundings.
- Antibacterial gel dispensers were located in the waiting room, throughout the treatment area, and at

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each patient chair. Hand washing facilities were also located in the treatment areas with clear instructions displayed on the correct hand washing techniques. We saw staff using the facilities.

- We examined the hand hygiene audit results for each month from January to December 2016. The target for hand hygiene compliance was 100%. The audits showed that there was an average of 93.1% compliance through this period with five months achieving 100% compliance.
- There was an action plan in place for the hand hygiene audits and this showed that immediate action was taken where 100% compliance was not achieved. Staff who had missed moments of hand hygiene were told what had been observed and reminders were given to all staff at handover meetings to observe the five moments of hand hygiene.
- We observed that patients were given gloves to wear during the process of removing the needles, which reduced the risk of infection at the exit site.
- When a patient finished their treatment they were disconnected from the dialysis machine. As soon as the lines were removed the machine automatically went into a heated disinfect process which included 40 minutes of internal cleaning. Built-in safety mechanisms meant this could not be over-ridden; the touch screen on the machine became unavailable and the machine could not be switched off.
- On Saturdays, the machines were all programmed to carry out a de-grease chlorine disinfection process that needed to be carried out once a week with a 24 hour resting period before the next dialysis patient used the machine.
- Blood lines were drained internally and bagged into clinical waste bags at the point of care, then double bagged again by staff before collection. There was one double bag per clinical area. Clinical waste was appropriately segregated, transferred and disposed of through a service level agreement with the commissioning trust in line with the unit's waste separation policy. Logs were kept for the transfer of hazardous and clinical waste, including sharps, to the commissioning trust for disposal.
- Sharps boxes were available throughout the treatment area, including on equipment trolleys used by nurses when setting up or attending to patients. All the sharps boxes we observed had the date of assembly completed. Most were closed when not in use, reducing the risk of injury and infection. One sharps box had been left open and this was pointed out to the clinic manager.
- The bed space, table and dialysis machine were cleaned with cleaning solution. The electronic system on the machine asked if the cleaning had been done and did not allow staff to close the treatment session until this question was answered. All treatment sessions had to be cleared on the system at the end of every shift. We observed that this cleaning was taking place between dialysis sessions and after patients left at the end of the day.
- Filters were in place to ensure water quality was maintained and daily tests were conducted to monitor for chlorine levels and hardness of the water. These were carried out by a health care assistant every morning. The testing was re-validated every Friday by the technical services department.
- Results from the water tests were entered onto an electronic monitoring tool which colour coded the results. If a problem was identified, the results showed up as 'red'. For example, chlorine content could be high when the temperature was very cold as bacterial content in the water was not high enough to use up all the chlorine put into the water by local utilities companies. If chlorine levels were approaching the limit, they would re-tested.
- If the readings were out of range even after re-testing, staff would call in the technical services team and contact the medical director. There was a protocol in place should this happen, and there were various options available to the team, including sending patients to another unit, using saline instead of the online water system, or sending patients to the hospital trust if necessary. Patients would be assessed to determine who needed to undergo dialysis that day, and who could wait until the following day. This had never happened at the unit.

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- If it was necessary to stop dialysis in the unit because of a problem with the water treatment plant the nurses would carry out an immediate “washback” of the lines with saline solution. Blood samples would also be taken from each patient for testing.
- A “total viable count” (TVC) sample was taken every month from three separate points in the water treatment system and sent to the technical laboratory for testing. A total viable count gives a quantitative idea about the presence of microorganisms such as bacteria, yeast and mould in a sample. To be specific, the count actually represents the number of colony forming units (CFU) per millilitre of the sample.
- Every three months an additional sample was submitted for bacterial and chemical analysis.
- Facilities management was also undertaken in-house, by a team who attended the unit to deal with both reactive and planned preventative maintenance work. There was a system in place to prioritise the urgency of jobs when they were logged.
- A PAT (portable appliance testing) register was kept on-site confirming testing had taken place and this was checked during the annual health and safety audit.
- The renal care Health Building Note 07-01: Satellite dialysis unit (Department of Health, 2013) provides guidance on the design and planning of healthcare facilities. This includes the recommendation that the layout of the multi-station dialysis area should enable patients to talk to one another, and nurses to call for assistance from one station to another, but sufficient space between dialysis stations should be allowed to prevent the risk of cross-infection and for a degree of privacy (a preferred minimum of 900mm between stations is required in this guidance). This recommendation was met in the layout of the clinic at Oldham.

Environment and equipment

- There were eight dialysis machines with chairs in the main area, two bays with four machines in each, four machines in single isolation side rooms and two machines set aside for self-care. All chairs were equipped with a nurse call bell.
- Maintenance of dialysis machines and chairs was scheduled and monitored using a dialysis machine maintenance/ calibration plan which detailed the dialysis machines by model type and serial number along with the scheduled date of maintenance. There was a similar plan in place for dialysis chairs and other clinical equipment for example patient thermometers, blood pressure monitors and patient scales. The maintenance was carried out by Fresenius in-house technicians. Additional dialysis related equipment was calibrated and maintained under contract by the manufacturers of the equipment or by specialist maintenance/ calibration service providers.
- Spare dialysis machines and chairs were available should one need to be taken out of service at short notice. The spare machines were ready for use.
- We looked at a sample of equipment including treatment chairs, a hoist, fridge and dialysis machines. All had current maintenance labels indicating they were up to date with servicing and calibration stickers.
- Records were in place relating to the maintenance and calibration of all equipment used at Oldham renal unit.
- There was a stocked and sealed resuscitation trolley on the unit, with an emergency drugs box provided by the hospital trust. There was also a spare, second emergency drugs box so that when the first box was returned to the hospital to be replenished, there was still a box at the clinic. The boxes were sealed, dated and maintained by the pharmacy at the commissioning trust. We saw evidence that the resuscitation trolley was checked daily to ensure that all equipment was in place, sealed and in date.
- Dialysis sets were single use and CE marked (indicating European conformity), supplied from a central store which recorded all the batch numbers.
- The dialysis machines had alarm guards which were never over-ridden by staff.
- Haemodialysis machines were replaced after seven years or after 40,000 hours usage, whichever was the sooner which allowed for sustainability of the service. All machines were seen to be within range.

Medicine Management

- There was a Medicines Management Policy in place and this was accessible to staff.

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- All medicines were stored in a locked cabinet in a clean utility room with key code access. There were no controlled drugs kept at the unit. Medicine stocks were checked weekly by staff and most were ordered from the NHS hospital pharmacy. The exceptions were catheter lock solution (trisodium citrate) and tinzaparin sodium which were ordered directly from the manufacturer.
- The clinic manager was the lead with responsibility for the safe and secure handing and control of medicines. The nurse in charge was the key holder for the medicines cabinet on a day to day basis.
- There had been two medicine errors in the 12 months before our inspection, in May 2016 and February 2017. Clinical incident reports had been completed in both instances and both errors were classed as causing no harm to the patient. There was evidence of learning from these incidents.
- Staff used syringes that were pre-filled with anticoagulants by the manufacturer so did not draw any medicine themselves. Any discarded medicine was returned to the hospital pharmacy for destruction. Qualified nurses drew up and administered intravenous medications (other than anticoagulants) and did so in accordance with Fresenius Medicines Management Policy and Nursing and Midwifery Council Guidelines.
- There was a monthly medicines audit to check all medicine expiry dates.
- New prescription charts were sent by email to the unit to begin immediately, and the hard copy was sent from the NHS hospital trust with the patient transport drivers. The documents were married up to ensure that there was a thorough record.
- We observed staff set up one patient for dialysis. When medicine was given, the type and dose was checked against the prescription and recorded on the medicine administration record by the nurse. This was double checked and signed by a second nurse to minimise the risk of error. The patient's identity was verified and checked against the prescription before medicine was administered.
- When a patient's treatment was completed the dialysis machine delivered an online fluid to rinse the blood back to the treatment that was still in the lines before the lines were removed. If a central venous catheter (CVC) line was in use, rather than needles, the line was flushed with a saline solution and then a locking dose of solution was instilled in the line for the length of the line, and no more, so that it did not reach the patient's bloodstream. As this process was just locking the solution in the lines, not administering it, this could be undertaken by the dialysis assistants. Staff were appropriately trained to flush the lines.
- There were no patient group directions (PGDs) in place. A PGD is a written instruction signed by a doctor and agreed by a pharmacist which can act as a direction to a nurse to supply and/ or administer prescription medicines to patients, using their own assessment of patient need.
- Intravenous (IV) therapy training was identified on the nursing competencies document and was mandatory for all qualified staff. Healthcare assistants (HCAs) and dialysis assistants (DAs) did not administer IV therapy.
- Changes to a patient's dialysis prescription would not be communicated to the patient's GP. Other medication changes agreed at consultant appointments were included in the subsequent correspondence following the appointment and would be sent to the patient's GP by letter. We saw examples of these letters in the case notes we reviewed.
- The nurses liaised with the NHS pharmacy from the hospital trust for additional advice relating to dialysis drugs, for example they sought advice in relation to the storage of drugs when a loss of power had caused the drugs fridge temperature to rise. In addition, Fresenius had access to a pharmacist at their head office should this be required.
- We saw that medicines requiring storage at 2-8°C were appropriately stored in a medicines fridge and fridge temperatures were checked on a daily basis and were within range. Staff knew what to do if they were not within range.
- There was an emergency drugs box, supplied by the commissioning trust, on the resus trolley. A spare box was kept locked away in the clinic manager's office. The boxes were sealed and dated by the trust pharmacy. The boxes were checked regularly by the

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clinic staff and returned to the pharmacy for a new box when the expiry date was getting close or if the seal was damaged in any way. We saw that the boxes were correctly sealed and had not passed the expiry date.

Records

- Patient records were held on paper, on an electronic treatment database, and on the electronic patient record (EPR) for the hospital trust, dependent on what they were. For example, the dialysis summary was recorded on the electronic treatment database, but was also summarised on paper as a backup.
- Dialysis prescriptions were recorded on the electronic database, but were also printed on paper and held in the paper records. Each time there was a change to the prescription, or to the patient's dry weight, a new printout was generated.
- The unit's electronic patient treatment database automatically transferred patient data, including blood test results and treatment outcomes, into the hospital's clinical database system electronic patient record (EPR). This meant they could be accessed by the consultant and the dietitian.
- There was a plastic card (credit card size) kept on the unit for each patient, which provided a link between the electronic database and the dialysis machines. The card was collected by the patient on arrival for treatment. When inserted into the machine the information read from the card directed the machine on the treatment to be provided. The cards would only work on the machines in the Oldham dialysis unit unless the information was sent by staff to another Fresenius unit via the electronic database. The information would have to be sent back to Oldham when the patient returned.
- When not in use the patient cards were stored in a container for the relevant shift, for example all the patients who had their treatment on a Monday, Wednesday and Friday morning had their cards stored together. They were stored securely with their patient records, which were colour coded for each shift.
- Clinic letters were dictated by the doctor and their secretary prepared and forwarded the letters to the GP, advising of any changes to the patient status, any medication changes and any referrals made to other agencies.
- The nursing staff updated the patients' dialysis notes using the named nurse system. The clinic staff could access the letters via the commissioning trust's electronic patient record system.
- When new patient transfer documentation was received at the unit there was a section on the form to confirm that a data quality confirmation check had been undertaken. This was to confirm that the information provided reflected accurate patient details and was cross checked between paper records, the hospital EPR and the Fresenius electronic systems. Any discrepancy and action to rectify was documented as applicable.
- There was a record keeping policy in place which defined the mandatory record keeping requirements for patient files, and which documents the files should contain, for example the electronic prescription print out, consent documentation and appropriate care pathways.

We reviewed five sets of patient records. We found that the records were in line with the expectations of what should be in a patient file, set out in the Fresenius Clinical Record Keeping Policy.
- The records contained details of the patient's named nurse; admission documentation that was fully completed; the dialysis prescription print out; medication prescription records (including patient allergies); a fully signed consent to treatment form; a standard haemodialysis care pathway; a manual handling assessment; pressure risk (Waterlow) assessment and monthly blood test results. Monitoring of the patient during treatment was also on a handwritten form on each file. The data was later transferred to the Euclid electronic patient record system.
- In addition, the patient record files contained care pathways appropriate to the individual patient assessment, such as, renal bone disease; nutritional

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status; management of newly created fistula; anaemia insufficient production of red blood cells or iron deficiency; fluid management; dialysis adequacy or central venous catheter management.

- Patient records included the patient's transplant status, diabetes status and infection status. At the time of our inspection approximately 30% of the unit's patients had diabetes and had their blood sugar levels checked and recorded pre and post dialysis.
- The unit kept a blood screening book where details of patients requiring ad hoc blood tests or swab screening were written to remind staff to carry out the procedure. Any tests required on that day were discussed at the start of each dialysis session. The book was also used to diarise when test results needed to be chased up if they had not been returned.
- During a clinic audit in October 2016, six patient records were reviewed. Issues found were, patient admission forms not being fully completed and some Waterlow and manual handling and care plans were missing from the files. Training gaps were identified and an action plan was drawn up to ensure improvements. We noted that actions on the plan had been completed at the time of our inspection. Patients who did not have fully completed referral admission documents from the commissioning trust were not accepted until the paperwork was fully completed and a judgement could be made on whether it was safe to accept the patient.

Assessing and responding to patient risk

- Patients' clinical care was shared between the consultant nephrologists based at the main NHS renal unit and the nurse-led dialysis clinic.
- Each patient had an individual identification card for use with the unit's equipment. Each card was labelled with the patient's name and was inserted to the relevant equipment to identify the patient, for example on the weighing scales and the dialysis machine. Any measurements or other patient information collected by each piece of equipment was stored on the service's computer system and not on the card. This meant that if the card was lost or misplaced, no patient information could be read from the card itself.
- Prior to commencement of dialysis treatment, staff inserted the patient's identification card into the dialysis machine. The machine automatically required the staff member to confirm the name of the patient by pressing the relevant on-screen button. Staff then cross referenced the electronic information record on the machine with the patient's paper session treatment record. In many cases, staff had known their patients for a long time; however, the process followed meant the risk of misidentifying patients was reduced.
- We observed one patient being set-up for dialysis. The patient was known to staff and we saw that the patient's identification and details were checked with them prior to commencing treatment.
- Staff used a "wet needling" practice when inserting a needle into a patient's fistula using a saline flush before commencing haemodialysis. A dry needle procedure was only carried out by staff when they were drawing blood from a patient.
- There was no early warning score system in place. However, observations were undertaken at the start of treatment, mid-treatment and at the end of treatment as a minimum, and more frequently for those patients who required it. We saw evidence of patient deterioration being escalated to the consultant nephrologists for advice. Clinical staff were able to contact them easily by mobile telephone if they were not at the clinic or could contact an on-call renal consultant if they were unavailable. Patients were transported to hospital by ambulance when deemed necessary.
- A clinical information system directly linked to the dialysis machines was used to monitor medical aspects of patient care through continuous data collection and evaluation, for example a patient's blood pressure. Patients had their personal parameters set on the machines which alarmed if these went out of range.
- The dialysis machines also alarmed if a patient was moving about, if it detected a difference in pressure, for example a drop in pressure if the needle was coming out or if the Kt/V clearance was not meeting the expected target rate. Kt/V is used to measure how

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effective a haemodialysis treatment is. It is based on tests of blood urea, by measuring the levels before and after treatment, to show how much has been removed.

- While we were observing patients on the unit, alarms were sounding very frequently. We saw nursing staff at all levels attending to the patients in a timely manner, and making the necessary adjustments or corrections to resolve the problems.
- When the machines alarmed an alert would flag up, with “possible causes” and suggestions as to what needed checking, for example staff told us they may need to adjust the size of the dialyser next time, review the patient’s access and/ or consider whether clots were forming.
- Mr Victor (multi-racial visual inspection catheter tool) scores were used in the assessment of the central venous catheter (CVC) site where the dialysis entered the body for all skin colourings but was especially useful for darker skin. This guide provided nursing staff with a description of the condition of the catheter using a score of 0-4.
- Patients with CVCs had their temperatures taken before and after treatment. If patients were symptomatic of an infection or became unwell, they would be transferred off site. Staff at the unit were not trained to take blood cultures.
- Patients with fistulas had their temperature taken if they felt unwell or had symptoms of an infection.
- Patients were encouraged to have an arteriovenous fistula made, as opposed to having catheter access to receive dialysis as this reduced the risk of site infection. Some patients were reluctant to have a fistula made as this caused a lump in the arm. Others had fistulas that had failed or had a phobia of needles so preferred catheter vascular access. The unit had a target to get 76% of their patients using fistula vascular access. They used the Vascular Access Team at the commissioning trust to support patients in making an informed choice on vascular access. Audit records showed that in November 2016, the percentage of patients with a fistula was at 73.4% and this had risen from 71.4% from the previous audit. We were told that, at the time of our inspection, 75% of patients now had fistulas.
- Renal Association guidelines recommend that 60% of patients with end stage kidney disease should receive dialysis via an arteriovenous fistula (AVF) or arteriovenous graft (AVG). They recommend that 80% of long-term dialysis patients should receive dialysis via an AVF or AVG or a Tenckhoff catheter. This sort of catheter is used by patients on peritoneal dialysis. This was not carried out at the Oldham unit.
- The service had recently reviewed their practice so that clinical incident reports were completed for all emergency 999/ 222 calls.
- In 2016, ten patients were transferred to hospital following an emergency call from the unit. Reasons for transfer to hospital were varied and included, a patient suffering a seizure; a patient collapsing in the waiting area; poor oxygen saturation; chest tightness; hypertension (high blood pressure) and hypotension (low blood pressure).
- Staff attended a twice daily safety huddle where a clinical handover was completed at the nursing station. This took place at the start of each shift, once all the patients were set up and had begun dialysing and before anyone went for a break. All staff were present at the huddle, however the unit was very busy and during the huddle that we observed there were regular interruptions with dialysis alarms needing attending to, and ringing telephones which had to be answered.
- At the huddle staff discussed outstanding issues from the previous huddle, any updates related to clinical incidents, any tasks that needed doing during the day, blood results that needed checking from previous shift and each member of staff provided a brief update in relation to their patients from the previous and the upcoming shift. This was to make all members of the team aware of any highlighted issues or concerns for the shift. Key documents and any minutes or important messages had a “read and sign” sheet attached.
- A monthly report was generated from the electronic database, which tracked the patients’ progress including targets and actions to be taken. These reports were reviewed by the clinic manager and the area head nurse.

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- The unit did not have a policy or training for staff with regards to identification or process for sepsis management. This was not in line with the NICE guideline (NG51) for recognition, diagnosis, or early management of sepsis. Sepsis is a life-threatening illness caused by the body's response to an infection. However, staff had a good understanding of sepsis and patients could be transferred to an accident and emergency department should sepsis be identified or suspected. The need for a policy on sepsis identification was added to the risk register by the provider.

Staffing

- The unit was staffed by registered nurses, dialysis assistants and healthcare assistants.
- The contract with the NHS trust required the unit to be staffed with one member of nursing staff for every four patients. The skill mix ratio was 60% registered nurses and 40% dialysis assistants. This meant there were five members of staff per shift for 20 patients, with a minimum of three registered nurses on duty and two dialysis assistants. There were enough staff to meet this ratio on each shift.
- There was also a clinic manager, deputy clinic manager and a secretary. The technical team attended as and when required to maintain and mend the dialysis machines.
- The service used an e-rostering system, completed eight weeks in advance by the clinic manager and approved by the regional business manager. This advanced planning enabled the service to effectively manage compliance with the required staffing ratio.
- Annual leave was factored in to the advanced planning, and off duty rotas were reviewed daily by the clinic manager to assess staffing levels based on the actual number of patients attending for dialysis, and for any unexpected staff shortages. The average rate of sickness in the previous three months was 3.5%.
- The service employed six full time and two part time qualified nurses (7.62 whole time equivalent). Three full time and one part time dialysis assistants were in post (3.77 whole time equivalent). There were also two full time healthcare assistants. In the previous 12 months, three staff had left the service and three had joined.
- Dialysis assistants could not administer medication other than Tinzaparin (an anticoagulant) and intravenous (IV) saline flush as these were a routine part of the dialysis process. Healthcare assistants were not permitted to put patients on or take them off the dialysis machines. Their role was to support the other staff, provide refreshments for the patients and perform cleaning duties.
- The staffing shortfall at the time of our inspection was minimal and could not reasonably be expected to be achieved without the service going over establishment. The nursing establishment had a shortfall of 0.21 whole time equivalent (WTE) staff member; the dialysis assistants were under-established by 0.51 WTE and the health care assistants were under-established by 0.14 WTE.
- Where staffing levels could not be maintained by using permanent staff employed at Oldham, staffing requests were made to the Fresenius renal flexibank, or where necessary, external nursing agencies. Bank staff had been required for 115 shifts in the previous three months, but agency staff had been used for only 10 shifts.
- The renal flexibank was a Fresenius "in house agency" and employed staff who had been required to complete the same induction programme, training shift and competency assessment as the permanent staff. This helped to provide continuity of care for patients.
- Medical care was led by two NHS consultant nephrologists and there was an associate nephrologist who supported the consultants. Each patient was seen on a minimum of a monthly basis by the consultant on the unit.
- Clinic staff had email addresses and mobile telephone numbers for the associate and two consultant nephrologists. The hospital had an on-call renal registrar available during the unit's clinic hours who was available to take calls if the medical team could not be contacted.

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Major incident awareness and training

- There was an emergency preparedness plan (EPP) in place for the renal unit, detailing actions required for the management of potential emergency situations. The plan included defined roles and responsibilities, emergency contact details for public services and utilities, key headquarters personnel, and neighbours.
- The plan addressed a number of situations that could arise including fire, loss of electricity, gas leak or damage to the infrastructure of the building and loss of water.
- Every patient had an emergency evacuation escape plan (PEEP). This detailed the patient's age, disabilities, mobility capabilities and what assistance they would require to get out of the building in the event of an emergency.
- Staff awareness of the plan was included in mandatory training and site evacuation drills.
- The clinic was listed as a priority service with the local utility providers. This meant that they should receive support such as water delivered if maintenance was planned, or a generator provided if there was no electricity.
- It was company policy to evacuate if there was a fire in the building. A practice emergency evacuation was undertaken once every 12 months as a minimum.
- If there were adverse weather conditions such as heavy snow which meant patients had problems getting to the unit, the team would discuss with the hospital trust which patients could be postponed and which needed to be prioritised. They would use medical records and historical blood tests to make these decisions.
- Managers told us that in the past they had contacted the local mountain rescue team to bring one patient part of the way to meet the land ambulance crew. They said they had always found a way of either getting them into the hospital or to the unit and if staff had to stay longer then they would do so.

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

Evidence-based care and treatment

- The provider developed a Nephrocare Standard Good Dialysis Care that took into account professional standards, best practice and research literature from a range of sources. The standard addressed the processes to follow immediately before, at the beginning, during and at the end of haemodialysis treatment, and provided a guide for all staff to follow to ensure safe care and treatment for patients receiving treatment at the unit. The standard provided a framework against which the provider's other policies and procedures were linked.
- Patients attended a three monthly consultant review. These were completed off dialysis in the consulting rooms adjacent to the dialysis unit. Information and actions from the reviews were entered in the patient records and on to the electronic treatment database.
- Patients underwent routine monthly blood results as per a defined schedule set out by the NHS trust consultant. The blood test results were individually reviewed to monitor the effectiveness of treatment and identify any required adjustments to care provision in order to improve outcome.
- Results, including blood test results and treatment data were captured by the electronic patient database which fed into the NHS trust's electronic patient record (EPR) system. This provided access for the dietitian and consultant to review these.
- There were systems in place to monitor key performance indicators (KPIs) in the clinic. These included a monthly balance score card and a clinic review process carried out every three months, produced from records on the electronic data base.
- The balance score card included a list of targets related to improving the dialysis process, and improving dialysis outcomes. Next to each KPI was a percentage figure for the current month's performance, the previous month's performance, the target performance, monthly trend and performance history. This meant that managers reviewing the document could see at a glance how effectively the

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clinic was meeting their objectives. Each KPI was given a weighting so that an overall average patient effectiveness score was achieved. The average patient score for 2016 was 65%. For January to April 2017 this figure was 62%.

- The local NHS trust had a kidney patient association which patients attending the unit could access. Patients were informed of this when they were seen by the trust.
- There was an audit programme in place. Record audits were due to be undertaken monthly. Two had been missed at the start of this year when a new manager came into post but actions had been put in place to redress this.

Pain relief

- Patients' pain relief needs were assessed and managed appropriately. Paracetamol was given when required for mild pain, and recorded appropriately in the patient record.
- The on-call registrar was consulted for patients experiencing prolonged pain. Patients with chronic pain symptoms were not admitted to the service.
- Topical anaesthetic cream could be used, if needed, before the insertion of the dialysis needles into the vascular access site. However, this had to be prescribed by the nephrologist or patient's GP.
- Patients expressed no concerns over the pain relief given.

Nutrition and hydration

- A dietitian from the NHS hospital attended the unit two or three times a week. She assessed new patients and managed her own list of patients based on her own reviews of the monthly bloods.
- The dietitian developed diet plans with the patients, and her patient records were entered directly on to the NHS trust EPR which staff had access to. Patients were made aware that minerals such as sodium (salt), potassium and phosphorus that would normally be filtered out by your kidneys could build up to dangerous levels quickly between treatment sessions.

- Patients were offered drinks, biscuits and sandwiches during dialysis and vegetarian options were available to patients who requested these. Patients had to order in advance the type of sandwich they wanted.
- Patients were encouraged to not eat fruit due to its high potassium content.
- Drinks were restricted to two per dialysis session as the amount of fluid intake needed to be restricted and monitored to maximise the effectiveness of the dialysis and meet the excess fluid removal target for patients. Most patients were only able to drink 1000-1500ml (two to three pints) of fluid per day.

Patient outcomes

- Outcomes and changes to treatment were discussed with all patients by the nurses and dietitian. A monthly feedback report was generated from the electronic system and given to each patient, to ensure they had a record of their treatment outcomes.
- Information about the outcomes of patients' care and treatment was collected and monitored by the service to ensure good quality care outcomes were achieved for each patient. This data was monitored via a clinic review report and shared with the area head nurse to be able to support the unit to achieve expected results and outcomes for patients.
- The clinic review report was a review of the clinic objectives, with a red, amber, green rated indicator of the actual performance when compared to the target, and an action plan where targets were not being met. The clinic review report also included other clinic matters such as staff overtime, patient satisfaction and utility consumption. Clinic reviews were undertaken by the clinic manager and overseen by the area head nurse. Every three months, reports were submitted to the regional business manager for monitoring.
- We reviewed the clinic review report from January 2017. The service was meeting their target for vascular access management. This meant they had successfully increased the number of patients with arteriovenous (AV) fistula. The clinic target was for a minimum of 76% of patients to have vascular access via a fistula. Dialysis experts generally agree that the safest and

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longest lasting of the access types is the AV fistula because it is made by connecting a vein to an artery so the vein becomes bigger allowing for increased blood flow.

- The service was not meeting their targets for effective weekly treatment time, infusion or blood volume and single-pool Kt/V. A number of reasons were identified for this, for example treatment time was affected because several patients declined to increase their dialysis time to the recommended four hours, despite advice to do so from consultants. Actions were in place to improve this, with review dates.
- The service used standard methods of measuring dialysis dose. Urea Reduction Ratio (URR) is the most widely used index of dialysis dose used in the UK. URR is the percentage fall in blood urea achieved by a dialysis session and studies have shown the URR should be at least 65%. Data provided by the service showed from September 2016 and April 2017, an average of 84% patients per month achieved at least 65% reduction. This was not in-line with Renal Association guidelines.
- Results and treatment data were captured by the service electronic system which fed into the trust database for inclusion to the UK Renal Registry.
- Data specific to the unit and available via the electronic database was used to benchmark patient outcomes at clinic level and nationally against all Fresenius Medical Care UK clinics.
- We saw that the electronic system provided reports, trend analysis to monitor patient outcomes and in turn quality of life. Data could be viewed 'live' by the clinic manager and consultant to monitor individual dialysis performance.
- The renal association sets out guidelines for dialysis units to follow based on evidence and research. The guideline promotes the adoption of a range of standardised audit measures in haemodialysis; promote a progressive increase in achievement of audit measures in parallel with improvements in clinical practice, to achieve better outcomes for patients.
- Data provided by the service showed that 100% of patients were being dialysed using Hi Flux

haemodialysis. This provides higher rates of removal of small and middle molecules and may lower the risk of developing complications due to dialysis related amyloidosis (a group of diseases in which abnormal protein, known as amyloid fibrils, builds up in tissue). In patients with established renal failure it was shown to provide better patient outcomes. This was in-line with Renal Association Guideline

- Dialysis treatment times (frequency of haemodialysis) were monitored by the service. Data supplied by the service showing the quality standard 90 days after admission to the unit showed from September 2016 to April 2017, 97% of patients received haemodialysis (HD) three times per week. This was in-line with the Renal Association guidelines.
- Patient blood was tested for potassium, phosphate, calcium aluminium concentrations in-line with the renal association guidelines. We saw that blood results were contained in the electronic records so they could be reviewed by the Nephrologist.
- We saw patients' blood results were monitored each month as per a defined schedule provided by the NHS Trust Consultant. These bloods were individually reviewed monthly to audit the effectiveness of treatment and define changes to care provision to improve outcomes.
- Pre dialysis serum potassium in patients' blood was monitored on a monthly basis. The Renal Guidance suggests that pre-dialysis serum potassium should be between 4.0 and 6.0 mmol/l in haemodialysis patients. Audit data from the quality standard 90 days after admission, showed that from September 2016 to April 2017 the average percentage of patients whose pre dialysis serum potassium within these parameters was 85%.
- Patient haemoglobin (HB) levels were measured to ensure that they remained within 10.5-12.5g/dl target range. Data provided by the service showed from September 2016 to April 2017, the average percentage of patients with a HB within this range was 52%. The target was 70%. There was an action plan in place to increase the percentage by 10% by April 2017. At April 2017 the percentage of patients within the recommended range was above 59%. Reasons for not achieving the target had been identified on the action

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plan. For example there was one patient with sickle cell anaemia; there were five patients who frequently did not attend the unit for their treatment and a high number of patients with uncontrolled hypertension. Patients with low levels of haemoglobin were given erythropoietin stimulating agents (ESA) injections by the commissioning trust consultants. ESA injections stimulate the production of red blood cells.

- The service did not participate in audits of travel time or waiting time pre and post dialysis.
- From March 2016 to December 2016 there were 345 instances of patients not attending for their dialysis treatment slot. In 177 of these instances the patient was dialysing off site, on holiday, hospitalised, transferred elsewhere, was transplanted or had died. In 168 instances the patient simply did not attend for their treatment session.
- We were told that staff would attempt to make contact with the patient or a relative when they failed to attend and they would try to fit the patient in for dialysis as soon as possible. We saw that a treatment variance report (TVR) was completed when a patient did not attend. Reports of who did not attend and how often were highlighted to the consultant nephrologist.

Competent staff

- Of the seven permanently employed registered nurses, three had specialist renal training. Two more had been identified to receive the training in the future. This training supports nurses to enhance their knowledge and practice in order to lead and deliver care and treatment to patients with a range of renal conditions. We were informed that it was proving difficult to motivate staff to undertake this training and no staff had taken the qualification in 2016. However, nurses told us that they felt that they did not have, or were not given enough time, to undertake the additional training.
- All staff substantively employed had received an appraisal within the last 12 months.
- The clinic managers attended appraisal study days so that effective and meaningful appraisals were facilitated with staff. New staff worked through a detailed training and education progression plan. This included a wide range of essential training such as

vascular access techniques, management of intravenous cannulas and dialysis machine use and decontamination. New staff were supernumerary (additional to the shift staffing numbers) for a minimum of four weeks and longer where this was deemed to be necessary. Each new member of staff had a mentor (who was also supernumerary) for a minimum of two weeks.

- We reviewed five staff training files for staff from a full range of roles within the unit. There was also an individual training plan on each file which was an “at a glance” training spreadsheet showing what training had been undertaken or was planned.
- The files showed that staff undertook a wide range of training over and above mandatory training, such as courses on chronic kidney disease, immediate life support, resus training, training on the Fresenius dialysis machines (the 5008 therapy system), anaphylaxis, blood-borne viruses and hepatitis B and good clinical record keeping.
- Clinical staff training files showed that they were completing a chronic haemodialysis integrated competency document, designed to be on an annual basis. This documented their competency skills in health and safety; the quality management system; safe delivery of haemodialysis and haemodiafiltration therapy; single and dual pump dialysis; on line post dilution haemodiafiltration; medical devices; vascular access; infection prevention and control; administration of medicines and records and record keeping. Each competency within the document was signed off by a preceptor who was a member of staff who had observed the skills being carried out competently and who was at least a grade above the member of staff carrying out the skills.
- The clinic manager had received advanced skills training in blood volume; temperature monitoring; body composition monitoring; the water treatment plant and sporotol disinfection. In addition, they had also undertaken a management course in the management of a dialysis unit.
- Renal nurses on the unit were link nurses and each concentrated and received training on at least one speciality. There were link nurses for anaemia; transplant; vascular access and education and training

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coordinator. The clinic manager was the link nurse for Euclid (patient record system) reports and infection control. The deputy clinic manager was the link nurse for health and safety and arranging holiday dialysis.

- Because the unit was not on the site of an NHS trust, if there was a medical emergency, such as a cardiac arrest, they did not have access to a hospital crash team. Because of this, Fresenius required at least one staff member per shift be trained in immediate life support. There were appropriate numbers of trained staff to meet this requirement.
- Staff at the dialysis unit did not carry out blood transfusions, as they had not received the appropriate training. One nurse needed to be trained as a trainer so could train other staff members. We were informed that if a patient required a transfusion this would be done at the commissioning trust. Delivering blood transfusions was the responsibility of the dialysis unit according to the contract and the clinic manager and area head nurse were in discussions with the trust about facilitating the training. The trust was drawing up an action plan but, at the time of our inspection, timescales were unknown. The unit had one patient who required regular transfusions.
- The clinic was notified of any updated policies and procedures by the corporate training team. The clinic manager reviewed each new policy and, using the training matrix, identified which staff members were required to read the updated document. Staff signed to confirm when they had done so.
- There was a new record keeping policy in place with face to face classroom training being rolled out across the organisation. We saw the evidence of the training schedule with available dates.

The clinic manager was responsible for checking that all staff were appropriately qualified and had state registration.

Multidisciplinary working

- The consultant nephrologist from the commissioning trust was the chair of the multidisciplinary team (MDT) and had overall responsibility for the care and treatment of the patients on the unit. They visited the

unit on a regular basis to clinically review the patients and made changes to patient prescriptions as necessary. They also provided the patient's GP with information about their current treatment.

- The multidisciplinary team was made up of consultant nephrologists, a dietitian, psychologist, specialist vascular access nurses, transplant co-ordinator and the clinic manager. Until March 2017, some MDT meetings had also been attended by renal nurses from the dialysis unit but resourcing issues meant that this no longer happened and the renal dietitian and consultant reviewed the monthly blood results and fed this back to the team at the unit.
- Transplant meetings were held monthly with a designated transplant co-ordinator. The transplant link nurse at the dialysis unit liaised with the co-ordinator at the trust and on occasion, referred the patient to the psychologist at the trust if they did not want to go on the transplant list. This was to ensure that they were able to make an informed choice about their options.
- There was also a bone multi-disciplinary meeting that was held every two months, also with a designated co-ordinator. This was attended by the dietitian from the NHS trust. The purpose of the meeting was to discuss those patients whose condition and diet may be causing bone deterioration.
- There were two vascular access specialist nurses from the NHS trust who attended the unit regularly. All patients were seen by one of the specialist nurses, with the unit access coordinator, every two months. Every patient with a fistula had been assessed by the specialist access nurses and any problems with access performance were discussed.
- Discussions were held between the specialist access nurses and patients who had central venous catheters (dialysis lines) to establish whether they needed referring to a surgeon for vascular access formation of a fistula or graft. The access nurses also supported any referrals for further investigations on poorly performing fistulas. Patients could be referred directly to the access clinic if necessary.

Access to information

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- Staff told us that they had access to all policies and procedures through the integrated management system database. There were standard operating procedures (work instructions) for staff to follow in areas such as water testing and good dialysis care.
- Staff had access to patient records on the Euclid electronic patient record system and they also had access to the commissioning trust's electronic patient record system and were able to access the patients' blood results and correspondence with their GP by the nephrologist.
- The nephrologist provided the necessary information for the staff on the unit to be able to provide the correct treatment for each patient through their individual prescription. Prescriptions were printed out and kept as a paper record on the patient's file.
- Laboratory support to the unit offered admission screening, regular viral screening and haematology (blood sample testing). Results were returned within an agreed timescale and in a timely manner. Screening prior to admission for MRSA and MSSA was carried out by the commissioning trust laboratories. Hepatitis screening was carried out by the Fresenius in-house laboratory.
- However, there had been an issue with referral forms from the trust not containing complete information to enable the unit to register the patient on the Euclid system. All referrals were now reviewed by the clinic manager and any with incomplete paperwork were not accepted and referred back to the trust for further information.

Consent, Mental Capacity Act and Deprivation of Liberty

- All staff received mandatory training in the Mental Capacity Act 2005, the Guide to the Deprivation of Liberty Safeguards (DoLS), and an Introduction to Dementia for Health and Care Professionals. At the time of the inspection all staff had completed, and were up to date, on this training and were able to describe the general principles of it.
- Consent forms were held within all six paper records we reviewed. The form detailed the type of treatment including the risks and benefits, confirmation of any advance directives or "do not attempt

cardiopulmonary resuscitation" (DNACPR) orders, confirmation of agreement to data protection and research analysis, and any requirement for interpretation. The name of the professional taking the patients consent and the patient's signature were recorded. We were told that no one had ever refused to sign the consent form.

- The clinic manager told us the unit rarely cared for patients who lacked capacity, as these patients were usually cared for at the commissioning trust. If someone lacked capacity this would generally be picked up prior to referral to the unit. A best interest meeting, involving the patient's relatives, the patient, clinic manager and consultant would generally be held to determine whether it was safe and appropriate to treat the patient at the satellite unit. The manager told us that they had attended such a meeting to decide what the best way to treat the patient was.
- At the time of our inspection, the unit had one patient who had a DNACPR document in place. This meant that, should they suffer a cardiac arrest in the unit they would not be resuscitated. The fact that this was in place was documented on the patient's consent form. However, the manager advised that staff were also aware that if the patient was not carrying their DNACPR document then it was not enforceable.
- Patients in the unit were not inpatients and it had never been seen as appropriate to apply for a Deprivation of Liberty Safeguards to prevent the patient from leaving the unit. We were told that, if a patient started to display any problems around their mental capacity then the unit would phone the consultant immediately for advice and a decision would be made on whether it was safe to continue treatment at the unit.

Are dialysis services caring?

Compassionate care

- Staff delivered care in line with the '6 Cs' of nursing. These are a set of values focused on placing the patient at the heart of their care and include care, compassion, competence, communication, courage and commitment.

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- We observed staff interacting with patients in a compassionate and caring manner.
- During our inspection we spoke to five patients who were receiving dialysis treatment. All said that they were happy with the care and treatment they received. One patient told us “the nurses are fantastic, the drivers are fantastic and they see you to your door.” “There is never a day when I don’t want to come here; the staff are brilliant and very kind.”
- There was an annual patient satisfaction survey given to patients with a free post return address to the clinic services director. Information about the survey is provided to the patients in the patient guide provided on admission.
- In the 2016 patient survey the unit received responses from 33 (42%) patients. Of these, 74% said they would recommend the service to friends or family in need of dialysis, 74% said they had complete confidence in the nurses and 84% thought the treatment rooms were well maintained and clean. 73% of patients thought the clinic was well organised, and 94% of patients felt the atmosphere in the unit was happy and friendly.
- There was an action plan in place to address some of the issues raised in the survey by patients. Some patients said they did not know how to raise a complaint or grievance and a poster providing these details had since been put up in the waiting area. We saw this displayed in a prominent area. Further actions were on-going to ensure this information was given to all patients.
- Results of the survey were shared with the NHS hospital trust and displayed in the patient waiting area, with the actions taken.
- We left a comment box and cards at the unit for patients to tell us their views of the unit and the care and treatment they received. However, we received no responses.

Understanding and involvement of patients and those close to them

- There was a comprehensive patient information booklet provided to patients on admission to the service. This explained how the clinic worked, health and safety and environmental matters, and detailed

information about understanding haemodialysis and the everyday related issues that patients may have to deal with. Senior managers told us this patient guide could be ordered in Hindi, Punjabi and Urdu.

- Some patients said they did not have an introductory session to dialysis when they first started dialysing on the unit. Actions included all patients being allocated a named nurse before starting dialysis in Oldham. The named nurse conducted an introductory session to dialysis with the patient on their first visit. Wherever possible patients were invited to the unit prior to attending for dialysis.
- One patient told us that the staff had supported them to start some self-care and they had attended the commissioning trust to be trained on how to put the first needle into her fistula. However, they had fainted so could not continue with this. They told us that the staff always made sure that they understood what was happening during their treatment and often drew pictures to enable them to understand the process. They also told us that they had missed their dialysis session the previous day, as they had to attend the hospital for an appointment, so the unit had accommodated them to receive dialysis the following day.
- Self-care was encouraged and a comprehensive training and competency document was available to any patient who wished to follow this path. However, most patients chose not to carry out any level of self-care. The unit had been purpose built with a room for two self-care patients. It was not in use at the time of our inspection.

Emotional support

- The unit operated a named nurse system so that each patient had a named nurse. This helped to ensure continuity of care for each patient.
- Staff understood the importance of building a strong and friendly rapport with the patients in their care, a number of whom had received care at the unit for many years. Staff were aware of the impact of chronic kidney disease on their patients and how long-term dialysis affected their individual needs.

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- The small size of the unit meant staff were able to quickly recognise when individual patients needed additional support and provide that.
- The staff were able to access advice from a psychologist at the trust should this be required.
- Staff told us that patients in the unit supported each other, for example, in the event of a patient death, and often contacted each other outside of the unit.
- A patient, who had been attending the unit for two years, told us that staff on the unit had arranged for them to receive dialysis at another unit on several occasions when they went on holiday and they were very supportive in this.
- There was no formal framework in place within the unit to refer patients to external support groups or online forums should they request additional support.

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

Service planning and delivery to meet the needs of local people

- The unit's contract, and service specification, was defined and agreed directly with commissioning trust renal team. As such the unit had no direct link with the commissioners in planning its services. However, performance against the contract was monitored through the joint meetings with the commissioning trust and in the submission of monthly renal key performance indicator data.
- We were also told by the management that the commissioning trust wanted the unit to adopt their key renal policies and these were being reviewed to ensure that they met the same requirements as the Fresenius policies. This was an on-going action.
- Patients could visit the toilet during dialysis and a protocol was in place to do that. There were male and female toilets and the side rooms were en-suite.
- If a patient needed short term one to one support there was the opportunity for a relative to stay with

them in a side room. The unit did not have the resources to facilitate one to one support by staff. If a patient deteriorated to the extent that they required this, they would be discharged back to the hospital.

- The Oldham dialysis unit was situated next to the local NHS trust and it was convenient for patients from the Oldham, Rochdale and Middleton areas to travel to the satellite unit rather than across Manchester to the NHS trust renal unit that was responsible for their treatment programme.
- The unit was a modern purpose built dialysis unit. There was plentiful free parking outside and space for patient transport vehicles to park close to the unit doors. The unit was located on the ground floor of the building (the first floor was not in use at the time of our inspection). The building was wheelchair accessible. The front door was secured with a remote locking system and patients and visitors had to be buzzed into the unit.
- The unit had the facility to receive holiday patients but had not received any during the past 12 months. On the occasions when they had been asked, they did not have the capacity to accept.
- There was a shared care policy and training package available for patients who wanted to dialyse themselves. There were two patients participating in shared care, who lined their own machines on the unit. No patients were dialysing themselves or self-caring at home.
- Access to a clinical psychologist at the NHS hospital trust was offered to patients who chose not to be registered for a kidney transplant. The psychologist attended the unit if requested and notes were documented on the NHS hospital patient record. This was to try and ensure that patients were making an informed choice.
- There was easy access to the unit for wheelchair users, and a hoist was available on the unit for patients with mobility problems.
- The design and layout of the unit adhered to the recommendations of the Department of Health's Health Building Note 07-01. There was adequate space around each dialysis chair for the equipment so that treatment could be delivered safely. The water

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treatment room met the building note requirements and there was a separate maintenance room where the dialysis machines were service, calibrated and repaired.

- The clinic manager informed us that there were plans to make some adjustments to the internal layout of the unit in order to create an additional clinic room at the back of the waiting area.
- A very small number of patients (less than 10%) used the local ambulance patient transport service as the majority of patients not using their own transport used transport provided by the NHS hospital trust.
- On the rare occasion that there was a problem with the ambulance patient transport service the unit manager would speak with them directly to resolve it. It was not recorded as a clinical incident.
- There were usually no problems with the hospital transport. Drivers were allocated to the service and transport was planned in advance. Extra drivers were scheduled in on the days when Rochdale patients attended the unit. If there was a problem with the transport, patients would mention it to staff and they would escalate it to the trust.
- If any patient using the transport service was suffering from a virus, the unit would arrange a separate pick up for them to ensure that there was no contact with other patients and minimise the risk of infection.
- There was no patient transport user group or transport survey.

Access and flow

- Fresenius Dialysis Unit at Oldham had 22 dialysis stations. There were two treatment sessions scheduled daily, six days per week, usually with 20 patients dialysed in the morning (from 7.15am) and 20 in the afternoon (from 1.00pm). The dialysis unit opened from 7am and closed at 6.30pm. It was closed on Sundays.
- There were four single en-suite side rooms which could be used for patients requiring treatment in isolation, and a self-care area with two dialysis stations. At the time of inspection the self-care area had one dedicated machine specifically for confirmed hepatitis B positive patients.

- There were approximately 910 treatment sessions delivered per month. At the time of inspection there were 77 NHS patients using the service. Of these, 30 were aged between 18 and 65 years, and 47 were older than 65 years. The service did not accept referrals for young people or children under the age of 18.
- All referrals to the unit came from the same NHS trust, Salford Royal. Patients had been seen in the hospital's renal unit, on the renal ward, or by the chronic kidney disease team and were referred by the NHS hospital trust's consultant nephrologists.
- Staff were not aware of a specific policy which defined the admission criteria but said that doctors at the hospital screened potential patients to ensure they were appropriate. Patients with a recent history of a cardiac event, patients on oxygen or patients who were acutely unwell would not be suitable and would not be referred to the unit. Otherwise, provided they were haemodynamically stable a complex medical history would not mean automatic exclusion from referral.
- Patients attended from the Oldham, Rochdale and Middleton areas. Admissions were only authorised by the unit manager or deputy manager.
- Patients were set up promptly on dialysis machines, shortly after arriving at the unit and staff and machines were ready to start the sessions on time.
- There was no waiting list for the unit at the time of our inspection.
- The limited number of treatment chairs, and the high usage capacity in the unit, meant that patients were limited in choice for their initial treatment slots. However, where possible, staff attempted to accommodate changes to appointment slots or swaps with other patients to accommodate patient choice.
- The unit did not have separate treatment beds for patients on holiday. However, the unit was able to accept patients on holiday if there was capacity for the dates required. This was subject to receipt of fully completed documentation, and medical approval and acceptance. This included consideration of any risk

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posed by the incoming patient on the resident patient cohort, for example isolation requirements. Generally, the side room for self-care patients was utilised for these temporary patients.

Meeting people's individual needs

- The unit was located in an area with a diverse population, including a significant proportion of people whose first language was not English. This was reflected in the diversity of patients who attended the unit.
- If patient did not speak English as their first language they could have access to a language line service. There was a cordless phone on the unit so any patient could be given access. Some of the patients who did not speak fluent English brought relatives at the beginning and end of dialysis to relay any minor requests or issues. Some patients would also ring their relatives if there was something to discuss mid-way through treatment.
- We identified one patient who was unable to speak fluent English and saw that a member of the nursing team was able to communicate with the patient. She spoke slowly and gestured to the patient who was able to understand. A member of our team spoke with the patient in their first language and the patient was happy with his care and treatment. They explained that they understood basic English but were not able to speak it. They did not identify any issues around communication.
- There was a poster in the waiting area which provided details of how to access patient information in a wide range of other languages. The patient guide was available in Punjabi, Urdu and Hindi, although the unit did not have copies of this in easy-read or braille format.
- There was a holiday coordinator at the unit who helped patients to organise holiday dialysis. The unit provided patient details to the receiving organisation and we observed some arrangements being made for a patient who was planning a holiday at the time of our inspection.
- There were restrictions in place for patients returning from holiday and there was a policy for dialysis away from the unit. Patients were screened for blood borne

viruses on their return and then every two weeks for three months. Every returning patient used a designated 'holiday' dialysis machine to start with, even if for only one session, until their blood results were back. If the patient had been to a high risk destination (for example Pakistan or India) they followed an isolation policy for three months

- Staff were governed by a corporate code of ethics and business conduct which described the company values in relation to equality and human rights. Specifically, the code of conduct prohibited staff from discriminating people with protected characteristics under the equality Act 2010, such as, race, gender, marital status, age, disability or nationality.
- Patients were seen based on their clinical condition and whether there was space on the unit to accommodate them, irrespective of backgrounds such as race, religion, sexual orientation or marital status.
- Information was published in different languages to help make sure it was accessible to patients from a range of ethnic backgrounds.

Learning from complaints and concerns

- A policy set out the process and staff responsibilities for handling compliments, comments, concerns and complaints. Feedback from patients was received verbally, in writing, through the patient satisfaction survey, or through the unit's 'Tell us what you think' leaflet. The policy and the unit's statement of purpose were displayed within the unit's waiting area.
- The policy set out a 20 working day timescale for complaints and concerns to be responded to, and included a risk assessment to determine the severity of the concern. The assessment level identified which staff needed to be made aware of, investigate, and subsequently approve the response to the complaint. The clinic manager was responsible for ensuring complaints were responded to within the policy's timescales.
- Staff told us they aimed to identify and respond to patient concerns face to face. This meant that concerns were dealt with before they escalated to formal complaints or required formal investigation.

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This was a positive and proactive approach. There was a patient concern log kept on the unit so that low level concerns could be discussed by staff and with the patient and acted upon accordingly.

- The unit had only received two complaints in the 12 months prior to our inspection. Both concerned the televisions above each dialysis station. The unit had since replaced the televisions and no further complaints had been received.
- The unit had received no formal complaints requiring an investigation and action plan, this meant we could not comment on the unit's timeliness for responding to complaints, or the sharing of learning from complaints. However, this positive absence of complaints was reflected in patient comments during our inspection.
- There was a poster on display in the waiting area with details for patients on how to make a complaint.

Are dialysis services well-led?

Leadership and culture of service

- Nationally, the Fresenius clinics were organised into three geographical regions, each led by a regional business manager. In turn, each region was divided into three further areas, each served by an area head nurse. There was a head nurse responsible for seven clinics in total, of which Oldham was one.
- Staff said they felt well supported at a local level, and that the unit manager and area head nurse were available and approachable. The unit manager felt well supported by the area nurse.
- The clinic manager had a visible presence on the unit, and the area head nurse visited regularly. The Clinic Manager undertook regular clinical shifts on the unit and there appeared to be a comfortable working relationship with lower grade staff.
- However, at a wider, organisational level staff felt there was little recognition of qualified or unqualified nursing staff and they did not feel appreciated or valued.

- Other corporate teams supported the staff in the unit including a clinical incident team and regional training centres.
- The clinic manager had received training in leadership and management within the last three years. Having had this training and regular clinical duties incorporated into the role, the manager had the capacity, capability and experience to lead staff effectively.
- The manager also had an understanding of the challenges to providing good quality care and was able to tell us how these were being addressed.

Vision and strategy for this core service

- The provider's strategy was "to provide safe, effective quality care for adults with end stage renal disease." This was supported by a mission statement, which was set out in the employee handbook and corporate code of ethics detailed its "commitment to providing high quality products and services and bringing the optimal sustainable medical and professional practices to patient care. We are committed to honesty, integrity, respect and dignity in our working and business relations with our employees and business partners."
- The provider had three core values of quality, honesty, and integrity; innovation and improvement; and, respect and dignity. The provider's had four objectives focused on patients, employees, shareholders and the community: to improve life expectancy and quality of life for patients; to promote staff professional development; to ensure continuous development of the company; and to reflect social responsibilities, legal and safety standards and contribute to maintaining the environment.
- The provider's strategy and vision was clearly displayed within the unit's waiting area. Staff understood the vision and strategy and staff appraisals and objectives were based around it.

Governance, risk management and quality measurement

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- A local risk register had just been introduced by the unit. This was in its infancy, but we saw evidence that managers were working pro-actively to develop this. They acknowledged that prior to inspection this had not been in place.
- The clinical incident team, led by the chief nurse, decided whether or not an investigation was required.
- The whole team were invited to staff meetings, held every two months at the end of a working day. Ad hoc meetings were called as and when they were deemed necessary. The meetings were chaired by the unit manager and minutes were circulated via the unit diary, with a 'read and sign' sheet so indicate that they were correct.
- Staff did not have access to emails so the agenda was displayed on the notice board in the staff waiting room. Matters for discussion typically included any health and safety issues and clinical incident reports.
- Meetings were held in each region for all the local clinic managers. These were held approximately every three months in this region which included seven clinics.
- Similarly, the area head nurse was supported by the regional business manager and met with her approximately twice a month, but spoke on the telephone daily. There were communication systems in place which promoted regular, easy contact with senior managers and the area nurse regularly used these to speak with the chief nurse. Area nurses met with each other approximately every three months and if they were unable to attend they could dial in using teleconference facilities.
- The chief executive retained overall responsibility and accountability for clinical governance. Individual clinic managers had responsibility to ensure their unit established and implemented the clinical governance plan to improve the quality of care provided; facilitate the delivery of the clinical governance plan, and to submit monthly clinical governance reports.
- The clinic manager was the lead for governance in the unit, and was responsible for collating and submitting governance data, reviewing updates in policies and ensuring these were disseminated to staff.
- The clinic managers from the satellite dialysis units at Oldham and Rochdale attended regular joint commissioning meetings with Salford Royal NHS Foundation Trust.
- The provider had achieved ISO 9001 accreditation for its Integrated Management Systems (IMS). There were systems, processes and practices in place within the unit which were embedded within the accredited ISO 9001 quality management system (QMS) and the occupational health and safety assessment series (OHSAS) 18001 system, and were therefore subject to regular audit and review. The most recent OHSAS 18001 report commissioned by QMS International, dated 8 September 2016 was not available for us to review as it was held centrally by the organisation, however there was an accreditation certificate in place indicating compliance with this standard had been achieved.
- The IMS system, which all staff had access to, held current and previous versions of all the organisation's policies and procedures. This meant staff were able to access the most up to date policies. The system also included a document version control facility, which tracked the review of documents including previous versions. Staff had the ability with the system to highlight any errors or issues with documents to the relevant document owner. The review date on some of the hard copy policy documents provided to us was not clear and seemingly out of date; however, we saw evidence on the system that these documents had been recently reviewed and ratified.
- The Workforce Race Equality Standard (WRES) is a requirement for organisations which provide care to NHS patients. This is to ensure employees from black and minority ethnic (BME) backgrounds have equal access to career opportunities and receive fair treatment in the workplace.
- WRES has been part of the NHS standard contract, since 2015. NHS England indicates independent healthcare locations whose annual income for the year is at least £200,000 should produce and publish WRES report.

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- Fresenius did not have or maintain a WRES report or action plan to monitor staff equality. We saw that this was on the risk register and reported that it was part of their wider approach to ensure equality for all employees.

Public and staff engagement

- Results from the November 2016 staff survey showed that all 14 staff (100%) completed the annual staff survey. Of these, 85% said they would recommend the unit to friends and family. 82% knew what their work responsibilities were and felt trusted to do their job. 100% said their training and development helped them to do their job more effectively and stay up to date with professional requirements.
- However, only 38% would recommend their dialysis unit as a place to work.
- Staff we spoke with said that while the training offered to them was good, there was little time available in which to complete it. The unit was usually too busy for e-learning to be completed during a routine shift as they had “constant duties”.
- Patients participated in a patient satisfaction survey on an annual basis.
- Patients were able to provide anonymous feedback through the provider’s free-post ‘Tell us what you think’ leaflet system. Completed forms were sent directly to the clinic services director for review.
- Before the unit opened there was an open day for incoming patients to show them the facilities and answer any questions.
- The unit did not have any patient user groups; however, this did not appear to have any negative impact on the patients attending the unit.

- Twice yearly there was a nephrocare conference held over two days. All head nurses, clinic managers, and senior staff were invited to attend.
- Nurses were invited to apply to the European Dialysis Transplant Nurses Association annual conference. Places were available to those nurses selected who had submitted a piece of work or poster, even if the conference was held abroad.

Innovation, improvement and sustainability

- Managers told us there was an annual conference held by the European Dialysis Transplant Nurses Association and any nurse could apply to submit a presentation or a poster for this. The area nurse said she had done this when she was a clinic manager.
- There were plans to make incident reporting more efficient by introducing an incident reporting system so that incidents could be reported electronically to a company-wide system. This would enable better analysis of incidents and subsequently learning from incidents and widespread issues could be more easily identified.
- Fresenius followed a “green nephrology” ethos with the aim of minimising waste produced by dialysis treatment. The company had targets for contaminated waste per treatment; electricity consumption per treatment and water consumption per treatment. The unit was achieving targets for clinical waste and electricity consumption but water consumption per treatment was well above the target of 394 litres per treatment at 632.86 litres per treatment (61% above the target). This had been reported to technical services for the water treatment unit to examine why the figure was so high. There were on-going targets to reduce current green nephrology targets by a further 10% in 2017.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must take action to ensure mortality reviews are undertaken to review whether there are any lessons to be learned or any omissions in the care and treatment of that patient.
- The provider should take action to provide staff with procedures and training with regards to the identification, process, and management of patients with sepsis.
- The provider must take steps to ensure that staff receive Level 2 Childrens' Safeguarding Training

Action the provider **SHOULD** take to improve

- The provider should take continue to fully embed the new risk register.
- The provider should carry out a Workforce race Equality Standard (WRES) to ensure employees from black and minority ethnic (BME) backgrounds have equal access to career opportunities and receive fair treatment in the workplace and to be compliant with the NHS standard contract.
- The provider should take actions to reduce the risks associated with language diversity and other protected characteristics.

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment 12.— 1. Care and treatment must be provided in a safe way for service users. 2. Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include— A. assessing the risks to the health and safety of service users of receiving the care or treatment; B. doing all that is reasonably practicable to mitigate any such risks; This is because: • The service does not have a policy or provide training for nursing staff with regards to identification or process for sepsis management. This was not in line with the NICE guideline (NG51) for recognition, diagnosis, or early management of sepsis. (Sepsis is a life-threatening illness caused by the body's response to an infection).
Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment 13. – 1. Service users must be protected from abuse and improper treatment in accordance with this regulation. 2. Systems and processes must be established and operated effectively to prevent abuse of service users.

This section is primarily information for the provider

Requirement notices

This is because:

- The service does not train staff to Level 2 Childrens as recommended by the intercollegiate guidance document published by the Royal College of Paediatrics and Child Health.