Stockport NHS Dialysis Unit

Quality Report

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Date of inspection visit: 22 June and 3 July 2017
Date of publication: 14/09/2017

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

Ratings

Overall rating for this location

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

Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Overall summary

Stockport NHS Dialysis Clinic is operated by Fresenius Medical Care Renal Services. Nephrocare is the service brand of Fresenius Medical Care. Stockport NHS Dialysis Clinic has been operating since July 2013. Patients attending the clinic are referred by their local trust to the specialist renal and dialysis services provided by the

Summary of findings

service's commissioning trust (Central Manchester University Hospitals NHS Foundation Trust). The clinic functions as a satellite clinic for the dialysis services provided by the commissioning trust, and treats patients in the Stockport area.

Stockport NHS Dialysis Clinic is purpose built and is located close to Stockport centre. The clinic is a nurse led clinic, comprising of a manager, deputy manager, a team leader and 9.3 whole time equivalent (wte) registered nurses. The manager, deputy manager and team leader also provided clinical care. The clinic has 18 haemodialysis stations and provides two treatment sessions per station per day (216 appointments per week). 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. Facilities include a patient waiting area with a disabled access toilet, a patient treatment and weighing area, two single rooms that could be used as isolation rooms, a consultation room, office, clean utility, waste utility, staff changing room, kitchen, storeroom, and water treatment plant.

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

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

Services we do not rate

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

We found the following areas of good practice:

- There were reliable systems and processes in place to keep patients safe. These included staff training, incident reporting, infection prevention and control, water quality monitoring and treatment, disinfection and maintenance of equipment, and screening procedures for blood borne viruses.
- The clinic's layout and staff use of equipment, including prompt response to machine alarms, kept people safe. Patient records were managed appropriately. Medicines were stored and managed safely. Staff followed the provider's medicines management policy, and a process was in place for review of patient medicines by the medical team when required.
- Patients were assessed for suitability for treatment to ensure the clinic was able to accommodate their care needs. The multidisciplinary team reviewed individual treatment prescriptions monthly, and patient's vascular access sites were regularly monitored.
- Patients were assessed for risk of deterioration and processes were in place to request urgent medical assessment or resuscitation if needed. Dietitians provided advice monthly to each patient, and there was access to psychological and social work support if needed.
- The clinic had processes in place to ensure higher risk patients, including those with dementia, were referred back to the commissioning trust in accordance with their contract. Staff had received training in and were aware of the principles of the Mental Capacity Act and the Deprivation of Liberty Safeguards.
- Appointment slots were allocated to patients taking into account their individual needs and staff worked to accommodate requests to change appointments as required. Staff supported patients to go on holiday through co-ordinating care at other clinics in the UK, Europe and other countries.
- Care and treatment was evidence based in line with appropriate guidance. Staff were competent to provide the right care and treatment, and competencies were regularly reviewed. New staff were supported through an induction and mentoring programme.
- The clinic had no written complaints in the reporting period; but there was evidence of shared learning from complaints and incidents that occurred in the provider's other clinics.

Summary of findings

- The clinic had a named nurse for each patient, which helped to ensure continuity of care. The annual patient survey indicated that patients felt staff were caring, treated them with dignity, and explained things in a way they could understand.
- Staff supported families who were bereaved.
- The clinic had a clear management and reporting structure. The clinic manager and deputy manager had the appropriate skills, knowledge, and experience to lead and engage effectively with their staff and patients.

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

- In the event of a patient death, notifications were not being routinely notified to CQC in accordance with Regulation 16 of the Care Quality Commission (Registration) Regulations 2009 (part 4).
- Mortality investigations were not being undertaken so lessons learned and reviews of omissions in care and treatment were not taking place.
- The service did 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).
- The clinic did not undertake a Workforce Race Equality Standard evaluation in accordance with the NHS standard contract.

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. Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

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

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Background to Stockport NHS Dialysis Unit

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

Stockport NHS Dialysis Clinic is operated by Fresenius Medical Care Renal Services. The service opened in 2013 and the registered manager has been in post from 16 June 2016. Patients attending the clinic are referred by their local trust to the specialist renal and dialysis services provided by the service's commissioning trust. The clinic functions as a satellite clinic for the dialysis services provided by the commissioning trust, and treats patients in the Stockport area. It also accepts patient referrals from outside this area when capacity permits.

Our inspection team

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

Information about Stockport NHS Dialysis Unit

Stockport Dialysis Clinic is operated by Fresenius Medical Care Renal Service Limited. It is an 18 'station' mixed gender dialysis treatment clinic and is registered to provide the following regulated activity to patients over the age of 18 years:

- Treatment of disease, disorder, or injury.

The service opened in July 2013 and the registered manager has been in post since July 2016. The commissioning trust provides the multi-disciplinary team who support the clinic in providing the dialysis service. The clinic primarily serves communities in and around Stockport.

Stockport Dialysis Clinic is situated in a standalone building in Stockport. Dialysis is provided for patients six days a week from Monday to Saturday. There are no overnight facilities. Two dialysis sessions run each day starting at 7:30am and 12:30pm.

The clinic has 18 treatment stations offering haemodialysis and hemodiafiltration but not peritoneal dialysis. Home dialysis services are not provided by staff at this clinic.

Access to the clinic is via secured doors. Outside there is free car parking for several cars. Entry to the clinic's reception and waiting area is via a secure door bell.

The main referring clinic is the specialist renal centre based at the commissioning trust, which provides an associate specialist (doctor) who visits each week. From time to time patients who are on holiday in the area are treated by the clinic (if there is an available dialysis session).

There are 9.3 registered nurses (two of which held renal dialysis qualifications) employed by the clinic. Two dialysis technicians are directly employed.

Between June 2016 and May the clinic delivered 9724 treatment sessions, an average of 810 treatment sessions per month. All of these treatments were NHS funded. Currently, 72 patients receive dialysis treatment at the clinic, 71 had hemodiafiltration and one had haemodialysis . Services are not provided to children or young people under the age of 18 years.

During the inspection, we spoke with nine staff including; the Regional Business Manager, the area head nurse, the clinic manager, the team leader and two registered

Summary of this inspection

nurses. We spoke with three patients. We also received 29 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed six sets of patient paper and electronic records.

Track record on safety in the previous year:

- The clinic reported no never events in the reporting period from June 2016 to May 2017.
- The clinic reported three clinical incidents in the reporting period from June 2016 to May 2017.
- The clinic reported no serious injuries in the reporting period from June 2016 to May 2017.
- The clinic reported three incidents of hospital acquired methicillin-resistant Staphylococcus aureus(MRSA) and no incidents of hospital acquired methicillin-sensitive Staphylococcus aureus (MSSA) bacteraemia from June 2016 to May 2017.
- The clinic reported no incidents of hospital acquired Clostridium difficile (C. diff). or incidents of hospital acquired E-Coli from June 2016 to May 2017.
- The clinic had received no complaints in the reporting period from June 2016 to May 2017.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. This was the first time the clinic had been inspected.

Services accredited by a national body:

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

Services provided at the clinic under service level agreement:

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

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

We found the following areas of good practice:

- The clinic had an incident reporting procedure in place, which staff were aware of and used
- The clinic was well organised and 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 clinic held minimal medicines. These were stored, labelled, and administered appropriately. Staff followed the provider's medicines management policy, and a process was in place for review of patient medicines by the medical team when required.
- Patient electronic and paper records were managed appropriately, and regular record audits were undertaken with actions taken to address issues as required.
- Patients were assessed for risk before, during and after treatment and processes were in place for requesting urgent medical assessment of patients, or resuscitation if needed. The clinic had isolation facilities and staff were aware of processes to follow for screening patients with infection and blood borne viruses.
- Staff were aware of the major incident plan, and undertook regular evacuation exercises to maintain their knowledge.

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

- In the event of a patient death, notifications were not being routinely notified to CQC in accordance with Regulation 16 of the Care Quality Commission (Registration) Regulations 2009 (part 4).
- Mortality investigations were not being undertaken so lessons learned and reviews of omissions in care and treatment were not taking place.
- The service does not have a policy or provide training for nursing staff with regards to identification or process for sepsis management.

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Are services effective?

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

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

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

- The clinic did not undertake a Workforce Race Equality Standard evaluation in accordance with the NHS standard contract.

Are services caring?

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

Are services responsive?

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

- The clinic's service specification was defined and agreed with the commissioning trust to meet the need of local people, and took into account the trust's policies.
- The clinic met the department of health's Health Building Note 07-01: Satellite Dialysis Clinic guideline.
- The clinic was accessible with designated patient parking, access ramps, and secure but automatic doors. Arrangements were in place for patient transport and the clinic had a positive relationship with the local taxi firm contracted by the patient transport service provider.
- Patients were assessed for suitability for treatment at the clinic to ensure it was able to accommodate their care needs in a safe and effective way.
- The clinic opened six days a week and provided 108 individual treatment slots per week, and accommodated requests for holidaying patients where slots were available.
- Appointment slots were allocated to patients taking into account their individual needs and, although flexibility was limited due to the small size of the clinic, staff worked to accommodate requests to change appointments as required.

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 clinic 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 clinic had a clinical governance strategy document, which supports the provider's strategic aims. Effectiveness against the strategy was monitored through monthly benchmarking audits.
- A clinic audit programme was in place.
- The clinic held a risk register, which identified clinical, operational, and technical risks, scoring each appropriately to determine the impact and likelihood with mitigation actions identified.
- The clinic scored highly on both the employee and patient national surveys, and both groups appeared to be engaged with the clinic and the care and treatment provided.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

- The provider had a clinical incident reporting policy, which set out staff responsibilities, definitions of clinical and serious incidents including near misses, and the provider's clinical incident reporting requirements and timescales. The policy detailed the provider's external reporting requirements, including to the CQC, coroner, police, local safeguarding boards, and Public Health England. It also set out specific reporting requirements for a range of incident types such as, but not limited to cardiac arrest, medical device incidents, medicines errors, safeguarding, and seroconversion. However, at the time of our inspection the clinical incident policy did not outline a process which met the requirements of the Health and Social Care Act in terms of death notifications to CQC.
- At Stockport Dialysis Clinic three patients had died within close proximity to their dialysis treatments. The clinic had followed the correct internal procedure in two of the three cases, but CQC notification was delayed in the first case and not submitted in the other two cases. We escalated the issues regarding the policy and death notification reporting to the provider at the time of our inspection and are working with them at corporate level to address this issue.
- Staff we spoke with were aware of the policy requirements, how to report incidents, and the escalation process.
- 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, the clinical incident team would decide if this needed to be referred to the clinical Governance committee, currently led by the Clinics Services Director, in the absence of the Medical Director which was being recruited for. Clinical incidents were monitored centrally with clinic updates and learning bulletins distributed by the chief nurse to support lessons learned across the organisation. We saw examples of these at the time of our inspection. The clinic's section of these forms was appropriately completed. However, the sections that required completion at provider level were not comprehensively completed. We escalated this directly to the provider at the time of our inspection.
- Learning bulletins were disseminated across the organisation when there were lessons to be learnt from clinical incident reports. These were discussed at daily handover, and a copy was recorded in the clinic awareness file with a read and sign sheet for any staff that were not present. These sheets were monitored by the nurse in charge and the manager checked that they were completed.
- There had been no incidences of pressure ulcers, urinary tract infections of hospital-acquired VTE.
- The service had different systems in place for monitoring incidents. As well as the clinical incident reporting system they had 'treatment variation 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. In the reporting period the clinic reported there were 1208 treatment variation reports which related to patients who did not attend appointments, shortened dialysis times and variations in treatment prescribed. These reports were all reviewed by the unit manager and Area Head Nurse and, where required actions to address the variation were listed.
- There were also 'non-clinical' incidents, which included falls, and 'clinic variation reports' which related to environmental incidents.

- 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.
- There were three clinical incidents recorded between 1 June 2016 and 31 May 2017. We reviewed the reports and found they related to the three deaths, discussed above.
- The clinic had no serious incidents or never events between June 2016 and May 2017.
- Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- 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.
- Staff told us they were aware that they needed to be open and honest with patients if things went wrong.
- The clinic reported no incidents of moderate or severe harm or death between June 2016 and May 2017 that triggered the duty of candour. The duty of candour was referred to in the clinic's clinical incident reporting policy and in the being open and duty of candour policy.

Mandatory training

- All dialysis staff had a contemporaneous training record on following standard operating procedures relevant to their roles. This included minimising the risk of infection, electrolyte imbalance and symptomatic dialysis-related hypertension.
- Mandatory training was delivered through a mix of classroom and online training. A training matrix was held which identified which groups of staff required training for each module. The training matrix was updated every three months, and was overseen by the area head nurse. The clinic manager had the flexibility to train additional staff in a subject area not identified as applicable to their group.
- Mandatory training for staff included a range of subjects mandated by legislation and by the provider. These included information governance, the mental capacity act, equality, diversity and human rights, conflict resolution and dialysis specific training. All staff had completed their mandatory training with the exception of a new starter who had a mandatory training programme in place. The clinic manager monitored this.
- Bank staff were supplied from the provider's in-house flexibank directorate. Mandatory training for bank staff was monitored by the flexibank administrators who held the training records centrally. Where training had lapsed, bank staff were suspended from shift allocation until proof of mandatory training completion was provided. This meant senior managers at the clinic were assured that bank staff had completed all relevant mandatory training before arriving on site.

Safeguarding

- The clinic 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. As patients in the clinic rarely had visitors or carers in attendance during treatment, training on safeguarding vulnerable children was offered to level one.
- At the time of the inspection, all but one staff member had completed safeguarding adults level two training and safeguarding children level one training. The staff member who had not completed the training was new. The unit manager had completed level three safeguarding training. All staff could seek further guidance from the provider's head office.
- The clinic 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. [AP1]
- 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 clinic's offices.
- The clinic had not reported any issues of a safeguarding nature in the 12 months prior to the inspection.

Cleanliness, infection control and hygiene

- 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 paper clothing, which could be easily removed if contaminated. This reduced the risk of cross contamination between patients.
- We observed staff following hand hygiene protocols, including 'arms bare below the elbows', in line with the organisation's Nephrocare Standard Hygiene and Infection Control policy. One patient comment card, received during the inspection said, "Each time they see a patient, they wash their hands and gel." Posters explaining the World Health Organisation's 5 Moments of Hand Hygiene were also displayed which helped make patients, staff and visitors aware of effective hand washing techniques.
- Between January 2016 and December 2016, the clinic achieved an average of 99% compliance with hand hygiene procedures. The results were displayed on the staff room wall so all staff were aware of them.
- Antibacterial gel dispensers were located in the waiting room, throughout the treatment area, and at each patient chair. Hand washing facilities were also located in the waiting and treatment areas with clear instructions displayed on the correct hand washing techniques.
- We observed that patients were given gloves to wear during the process of removing the needles, which reduced the risk of infection at the exit site.
- A disposable curtain was available around each chair to be used to provide privacy for patients if required. All the curtains had been replaced within the previous two months, which reduced infection risk.
- A full infection prevention and control audit was carried out each month. This looked at a range of risks in all areas of the clinic, including the treatment area, staff areas, toilets, staff practice, and cleaning staff duties. Between January 2016 and December 2016, the clinic achieved an average of 96.6% compliance.
- Dialysis needles and lines were single use only and were appropriately disposed of as clinical waste after use.
- Each machine underwent a heat disinfection cycle at the end of each treatment session, which was confirmed by a machine self-test at the end of the cycle. We observed staff cleaning the treatment chairs and associated equipment, and decontaminating each dialysis machine between patient treatments. 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."
- There were procedures in place to assess and treat carriers of blood borne viruses such as hepatitis B and C. Staff were knowledgeable about and understood the procedures and policies which managed and reduced the risks related to the infections.
- Stockport Dialysis Clinic had 6 Carbapenemase-producing Enterobacteriaceae (CPE) patients. These patients were already CPE infected when being admitted to Stockport Dialysis Clinic. The clinic cohorted patients with communicable infections into a segregated bay. They were dialysed on the afternoon session then cleaners and staff could ensure the room was deep-cleaned. There were also other segregated bay areas/ individual stations which could also be used to ensure patients who may present with conditions such as flu could be dialysed.
- There was clear guidance available to staff to guide them in deciding when patients required isolation and how this should be carried out.
- The clinic reported three cases of methicillin resistant staphylococcus aureus (MRSA) in the 12 months prior to the inspection. These incidents were investigated and lessons learned were shared across the clinic. There were no reported cases of methicillin sensitive staphylococcus aureus (MSSA) and Clostridium difficile (C.Difficile).
- The clinic followed best practice guidelines in relation to the water treatment systems, dialysis water and fluid quality. The Fresenius Medical Care team also had an internal water team who could provide guidance and advice on any issues relating to water treatment and quality.
- We also found that regular quality checks were performed in relation to water and dialysis fluid. These checks were processed by Fresenius microbiology services and checked for infections such as legionella.
- The clinic had an infection control and prevention link nurse. This nurse had undertaken additional training and other staff were aware of who this nurse was.

Environment and equipment

- The clinic was visibly clean and well organised.

- The maintenance of dialysis machines and chairs was scheduled and monitored using the Dialysis Machine Maintenance and Calibration Plan, which detailed the dialysis machines by model type and serial number along with the scheduled date of maintenance.
- The clinic also had a similar plan for dialysis chairs, beds and other clinical equipment including patient thermometers, blood pressure monitors and patient scales.
- The dialysis machines, chairs, beds and water treatment plant were all maintained by Fresenius Medical Care technicians.
- The majority of additional dialysis related equipment was calibrated and maintained under contract by the manufacturers of the equipment or by specialist maintenance and calibration service providers. This was arranged by the corporate and clinic management staff.
- We found that records relating to the maintenance of equipment were comprehensive, clear and up to date.
- The water treatment room was secure and procedures were in place to ensure the safety of patients should any failure occur. There had been no incidents in the last 12 months involving the water treatment.
- In January 2017 Fresenius Medical Care brought Facilities Management in-house. This now involves a dedicated facilities management team, a designated manager and helpdesk coordinators. The rationale for this was to provide the clinics with both reactive and planned preventative maintenance work. Staff told us that this system was helpful and they did not encounter any issues relating to the maintenance of the equipment they used.
- There had been no reported incidents relating to equipment in the 12 months prior to the inspection.
- We found that equipment such as the resuscitation trolley were checked on a regular basis. We reviewed three months of checks for these trolleys and ground that they were all completed and up to date.
- Annual electrical safety testing is part of the clinics Planned and Preventative Maintenance schedule which was managed by the facilities management team.
- The unit had a spare set of weighing scales and three spare dialysis machines in the event of equipment breakdown.
- We saw evidence that staff has been trained on the use of specific medical devices.
- We saw that each dialysis station had a call bell facility and nurses were highly visible at all times.
- There was sufficient space around each dialysis station to permit rapid access in the event of an emergency.
- Haemodialysis machines were replaced after seven years or after 40,000 hours usage, whichever was the sooner which allowed for sustainability of the service.

Medicine Management

- The clinic had a medicines management policy, which was supported by staff training in the prevention of medicines errors. The clinic manager was responsible for the safe and secure handling of medicines within the clinic.
- There were no medicine errors reported at the clinic in the period June 2016 to May 2017.
- The clinic did not administer or store any controlled drugs. Medicines used in the clinic that were not required to be refrigerated, were stored in a locked medicines cabinet. The cabinet was located within the temperature controlled store room, which reduced the risk of extremes in temperature affecting the medicines. The range of the room temperature was checked and recorded daily. We reviewed the logs, which confirmed that daily temperature checks had been carried out.
- Medicines that required refrigeration were held in a locked fridge. The fridge's temperature range was appropriately recorded and logged daily on the records that we checked. The medicines held were within the manufacturers' recommended expiry dates, and were stored to ensure that the oldest medicines was used first. The nurses used pre-filled syringes so they did not have to draw up any medication.
- Keys for the cabinet were held by a suitably trained and responsible person at all times.
- Medicines were organised to ensure the oldest medicine was used first. We checked different medicines stored in the cupboard, all of which were within their manufacturers' recommended expiry dates. The clinic did not hold oral liquid medicines. An oxygen cylinder was appropriately stored in the room was also within the recommended expiry date.
- Staff collected relevant medication for each patient from the medicines room.
- A lockable fridge for the storage of patient blood samples awaiting collection was located within the dirty utility room. The fridge maximum and minimum temperatures were recorded. We reviewed the log and there were no instances when these temperatures were exceeded.

- Nursing staff liaised with the NHS pharmacy at the host trust for any general medicines enquiries. Staff were also able to contact the Renal Pharmacist at the commissioning trust for more advice on specific dialysis medicine. Additional pharmacy support was available from the head of regulatory and pharmacy services at the provider's head office.
- Any medicines needed were prescribed by the patient's associate specialist nephrologist. The clinic did not use non-medical prescribers. A process was in place to fax urgent prescriptions to the clinic with the signed hard copy of the prescription forwarded to the clinic within 24 hours (or a maximum of 72 hours for bank holidays and weekends. This was in line with the provider's medicines management policy.
- We reviewed medicine prescription and administration cards held in six patient files. These were clearly written out, legible, and including relevant information such as the dose, frequency of administration, prescriber's signature, and checked by signature, and initials of the staff member administering the medicine. We could see that medicines were administered in line with the prescription instructions, and staff carried out appropriate identification of patients prior to administration of medicines.
- The clinic held a log for medical safety alerts, which included alerts for medicines. The clinic manager reviewed each alert to determine if it applied to the clinic. We saw evidence that relevant alerts were forwarded to staff, who signed to confirm they had received and read the information.
- Staff told us the clinic did not hold any medicines that could be administered under a patient group directions. A patient group direction, signed by a doctor and agreed by a pharmacist, enables an authorised nurse to supply or administer prescription-only medicines to patients using their own assessment of patient need, without referring back to a doctor for an individual prescription.

Records

- All staff were trained in the provider's record keeping policy, which included nursing documentation. The area head nurse told us that a new classroom training programme had recently been launched by the provider for new staff on patient assessment and documentation.
- The clinic used a mixture of electronic and paper records. Paper records were stored in a locked cupboard located in the main clinic area, and only moved from the cupboard when treatment was being provided.
- Patient's clinical measurements, vital observations and treatment variations before, during and after treatment were recorded and held within the clinic's electronic system. This automatically transferred treatment data to the patient's main electronic hospital record at the commissioning trust. Pre dialysis, post connection, mid dialysis and post dialysis observations were also recorded within the patient's paper records. We reviewed six sets of patient paper and electronic records. All six included records of the observation readings for each patient treatment session. Patient files were in line with the expectations of what should be in a patient file, set out in the Fresenius Clinical Record Keeping Policy.
- Patient blood results were held within the commissioning trust's electronic system which nursing and medical staff at the clinic had access to. This meant that the renal associate specialist were able to access the patient's blood results when required. Staff in the clinic highlighted any abnormal results for review by the associated specialist to review weekly.
- All the paper files we viewed were structured and labelled on each page with the patient's identification details. Handwriting was clear and legible and there were no loose sheets.
- The clinic manager, deputy clinic manager and team leader could access NHS clinic letters.

Assessing and responding to patient risk

- Staff undertook a detailed assessment of patients prior to commencement of their treatment at the clinic. This reviewed each patient's admission form which included their clinical details, primary and renal diagnoses and vascular access type, past medical history, their existing medicines and current prescription and medicine administration chart, special needs or mobility requirements, information relating to activities in daily life, and the patient's emotional and religious needs.
- Patients were already established on dialysis before attending the clinic. However, new patients were given an appointment to see the associate specialist in renal medicine at the next scheduled outpatients' clinic usually within two weeks of starting treatment at the clinic.

- Nurses we spoke to told us they did not use early warning score systems to help them identify when patient conditions are worsening. Instead nurses used clinical observations to determine how well patients were. We saw that these were entered into patient records we reviewed. Additionally, each dialysis machine allowed staff to pre-programme the frequency of observations to ensure they were completed as regularly as required. Patients also used call bells to alert staff if they were feeling unwell and we saw this process working during our inspection.
- Patients self-administered oral antibiotics if these had been prescribed by their GP. Intravenous antibiotics could be administered if, following a blood culture, these were prescribed by the on call registrar in the commissioning trust. The clinic accepted faxed prescriptions; however, these were followed by a hard-copy written prescription within 24 hours, or a maximum of 72 hours over a weekend or bank holiday. This was in line with the provider's medicines management policy.
- Each patient had an individual identification card for use with the clinic'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, there was a small risk that patient's names could be read from the card itself.
- Prior to commencement of dialysis treatment, staff inserted the patient's identification card into the dialysis machine. The machine automatically required the staff member to confirm the name of the patient by pressing the relevant on-screen button. Staff then cross referenced the electronic information record on the machine with the patient's paper session treatment record. In many cases, staff had known their patients for a long time; however, the process followed meant the risk of mis-identifying patients was reduced.
- There was no formal policy in place to guide the practice of patient identification. However, we observed that patients were asked for identification when they were being set up on the dialysis machine and again before any dialysis drug was administered. This is in line with NMC guidance.
- We saw evidence that patients were appropriately assessed at the start, during and after dialysis to ensure they were fit to commence treatment and following treatment. Vital observations were automatically recorded on the clinic's electronic patient record. Staff assured themselves that patients were fit to leave before they left the clinic.
- We saw clinical risk assessments were completed in the patient files. These included the risk of developing a pressure ulcer and a moving and handling risk assessment.
- The clinic had a formalised admission and exclusion criteria to screen patients before they were accepted to the clinic. This criteria helped ensure only patients who were clinically stable attended the clinic. Individual patients risk was assessed minimally on a monthly basis through multi-disciplinary team meetings.
- We also saw that all staff did a ward round on each dialysis session. This meant that staff were aware of all patients' current conditions. The ward round also facilitated learning for staff.
- We found that patients had up to date, comprehensive risk assessments completed for areas such as pressure damage and falls.
- Blood tests were carried out minimally on a monthly basis. This allowed staff to make informed decisions about the risks associated with dialysing patients.
- Dialysis machines flagged up possible causes for the alarm going off and suggestions as to what needed to be checked. Staff were responsive to alarms. We did not observe any patient switching off their machine's alarm.
- The clinic 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, this issue had been raised with the provider following inspection of another location and a policy was about to be released. The clinic manager and staff were aware of sepsis indicators.
- If a patient did not attend an appointment, staff followed this up with the patient, their relatives and notified the associate specialist. If the patient could not be contacted the service also informed the referring trust.

Staffing

- The clinic was nurse led and employed 11 clinical staff and one administrative staff member. These comprised of one clinic manager, one deputy clinic manager, one registered nurse team leaders, five registered nurses, three dialysis technicians and a clinic secretary. There were two nurse vacancies at the time of our inspection, one of which had been recruited to.
- The clinic worked to a ratio of one nurse to four patients and 70% registered nurses to 30% dialysis technicians.
- Staff told us that the clinic felt well-staffed and that they had enough time to care for patients. Rotas we reviewed, for the three months prior to inspection, all confirmed that the clinic had been appropriately staffed.
- The clinic manager used a bespoke e-rostering system to schedule staff shift attendance, taking account of annual leave, six to eight weeks in advance. The schedule was approved by the regional business manager. This ensured that all shifts complied with the clinic's contracted staffing levels and skill mix.
- Two staff within the clinic had completed the qualification in renal nursing and a further two were due to complete this later in 2017.
- The clinic manager reviewed the staff rota daily to ensure adequate staffing based on the number of patients attending dialysis and this was further overseen by the regional business manager.
- The clinic used low numbers of bank and agency staff who were familiar with the unit. If there was short term staffing deficits these would be filled by the Fresenius bank staff. The service had a flexi bank which was able to provide Fresenius trained staff to fill any short term or long term staffing deficits.
- Staff were supported by the clinical manager who was expected to have 90% supernumerary management time. The deputy clinic manager was also available to support staff and worked 40% supernumerary management time.
- There was one team leader who had responsibility for supervising less experienced staff.
- The clinic was supported by a renal associate specialist from the NHS Trust. The associate specialist was on site at the clinic at least three days per week and they attended the monthly review meetings for their patients. However they were always available by phone and pager. Staff told us that they did not encounter any issues with accessing medical advice when required.
- The clinic did not have any on-site technical staff; however, staff were able to request urgent unscheduled visits from the provider's technicians to carry out work on the equipment if needed. The clinic manager told us they had no concerns about the responsiveness of the provider's technicians.

Major incident awareness and training

- The clinic had an emergency preparedness plan for the prevention and management of emergency situations. The plan included defined roles and contact details for the emergency, public, and utility services. It also set out detailed instructions for staff to follow in various scenarios including fire, power failure, minor and major water leaks, storm damage, and release of toxic fumes or gases.
- Emergency plans were located at each exit.
- Staff told us that in the event of a major incident which affected the operation of the clinic, patients would be referred back to the renal clinic at the commissioning trust or to other satellite clinics within the region to continue with their treatments.

Staff were aware of their roles in an emergency, and this was tested through evacuation exercises every six months. Patients were included in the exercises so that they knew what to expect and this helped to keep patients calm. As part of this staff checked that patients were aware of the assembly point. PEEPS (Patient emergency evacuation plan) were also available for each patient.

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

Evidence-based care and treatment

- Care and treatment was delivered to patients' in line with the National Institute for Health and Care Excellence (NICE) guidelines. For example, we saw that staff monitored and maintained vascular access for all patients receiving treatment. A patient concerns record was also used to raise any issues with the nephrologist. This was in line with the National Institute for Health and Care Excellence (NICE) QS72 statement 8.

- The unit met certain national recommendations outlined in the Renal Association 'Haemodialysis Guidelines' (2011). For example, Guideline 6.2: 'Monthly monitoring of biochemical and haematological parameter (blood tests)'.
- 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 clinic. The standard provided a framework against which the provider's other policies and procedures were linked.
- The service had an established ISO accredited Integrated Management System (9001) that ensured all policies and procedures supported best practice evidence, with an annual review requirement that provided assurance that the evidence base was current.
- Treatment to patients was provided by staff in line with their individual treatment prescriptions. Prescriptions were reviewed and amended by the multidisciplinary team following monthly monitoring of patient's individual blood results. This enabled the medical team to review the effectiveness of treatment and to make improvements or changes to a patients care plan.
- Patient's weight, temperature, pulse, and blood pressure were checked before dialysis commenced, after the patient had been connected to the dialysis machine, and after dialysis ended. Additional readings were taken during dialysis if clinically required and if the patient requested this. The readings were automatically transferred to the patient's electronic record. We observed patients and staff undertaking these observations.
- We observed staff followed the organisation's guidance for example hand hygiene procedures and wearing of personal protective equipment, including a visor prior to starting a patient's treatment.
- We observed blood pressures to be checked before and after treatment and during the treatment if the patient gave consent.
- There was an annual clinic audit schedule which listed 23 compulsory audits. 11 of these were completed monthly and the results provided information for the clinic scorecard. The remainder consisted of clinical, non-clinical and corporate audits.
- 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 balanced 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 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 49%. For January to April 2017 this figure was 49%. The clinic had 32/72 patients that did not have a fistula (a vein and artery that have been joined together to optimise dialysis treatment). This impacted against their scorecard results. The unit had an action plan in place to help improve measures within their control.

Pain relief

- Patients were not prescribed any pain relief in the clinic. This meant if a patient required simple pain relief for example for a headache, this would have to be prescribed by a doctor.
- Staff said where possible the patient would be encouraged to self-administer their pain relief.
- Patients told us the nursing staff did ask them if they had any pain or discomfort during the procedure and would act to relieve this if required.
- 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 patient's GP.

Nutrition and hydration

- Patients were given sandwiches and drinks during their treatment. These were provided by an external company and patients' individual likes and dislikes were catered for. We saw these were appropriately stored in the clinic.
- A dietician was present in the clinic for most days of the week and was available on an on call basis in addition to this. Between this they could be contacted by telephone and pager. They attended the weekly quality assurance meetings and discussed any concerns raised about a patient's nutritional management.
- A dietician reviewed each patient once a month to discuss patient's diets and to provide advice. Staff were able to contact the dietician separately if further advice was needed. The clinic had a communications file to enhance communication between the dietician and staff

Patient outcomes

- The UK Renal Registry data is representative of all parent NHS trust patients, so this does not permit the review of patients and outcome trends specifically treated within this renal dialysis clinic. Therefore, data specific to the clinic and available through the internal database was used to benchmark patient outcomes both as an individual clinic and nationally against all Fresenius Medical Care UK clinics.
- 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 who monitored this information to assess performance.
- Quality Assurance meetings on a monthly basis reviewed all patients' blood results, progress and general condition with the Associate Specialist in Renal Medicine, Dietician and Clinic manager or Deputy Clinic manager. All changes to treatment parameters or referrals to other services were coordinated by the Clinic manager and reported to the clinical staff for further action. Outcomes and changes were discussed with all patients by the named nurses and dietician. Written information was also provided as standard to ensure the patient had an ongoing record of their treatment outcomes.
- Patients' blood results were monitored each month as per a defined schedule dictated by the NHS Associate Specialist in Renal Medicine. These bloods were individually reviewed monthly to audit the effectiveness of treatment and define/action improvements and changes to care provision that will improve outcome. Results and treatment data were captured by the computer system.
- The data management system provided customised reports and trend analysis to monitor and audit patient outcomes and treatment parameters. This highlighted the opportunity to improve outcomes and in turn quality of life. The information was available to the Clinic manager and Associate specialist to monitor and audit individual patient performance month on month to identify where improvements and maintenance in achievement of national standards could be made.
- The clinic was included in the provider's monthly benchmarking audit of performance against other clinics. This looked at effective weekly treatment time, infusion blood volume, single pool Kt/V, vascular access, albumin levels, haemoglobin and phosphate levels by each clinic in the group. It also calculated each clinic's percentage change over a six month period.
- At the unit the Kt/V was reported via the balance scorecard at 59.3% against a target of 70%. This figure was affected because 32 out of 72 patients did not have a fistula and a further seven patients had shortened dialysis sessions at their request. The unit nurses and associate specialist were working with these patients to improve their patient outcomes.
- The new unit managed had influenced improved patient outcome data. This showed an improvement over the last twelve months. However, the clinic was somewhat limited in how they could improve patient outcomes in view of the higher number of patients who did not have fistulas. The clinic had worked with 16 of the 32 patients and had placed them on the fistula pathway. However, the remaining 16 of the 32 patients were reluctant to move to fistulas. The clinic were taking reasonable steps with them whilst ensuring they retained patient choice.
- The clinic audited: achievement of quality standards (Renal Association Guidelines); patient observations; dialysis access specific data; treatment variances and infection control interventions.
- In addition each month a report summarising each dialysis clinic was produced for all clinics by the Fresenius Data Manager and Medical Director. Within Fresenius, the dataset was shared monthly with the Area Head Nurse who worked with the Clinic manager to

address improvement areas. At the time of our inspection a new 'Clinic Review' process had been developed to capture overall month on month clinical effectiveness and improvement areas. As part of the Fresenius Clinical Governance Review and reporting, a report defining the clinic achievement of the Renal Association standards was sent to the respective NHS Trust clinicians.

Competent staff

- Staff underwent annual competency checks, which were signed off by the clinic manager. A number of the checks were undertaken through self-assessment. Self-assessments were signed off by a staff member of at least one grade higher. We reviewed five staff training files which included fully completed competency records and annual staff reassessment record, infection prevention and control annual assessment, individual training and education plan, and employee notification of risks.
- All staff were expected to have an up to date disclosure and barring service certificate. These were held centrally by the provider's human resources department.
- Existing staff were supported in maintaining their professional development and in revalidation with their professional body. All staff were up to date with their NMC registration.
- New staff members underwent a training and education progression plan. As part of this supervised practice, staff were supernumerary for at least six weeks under the guidance of a mentor while undertaking their induction and competency checks. Each mentor was supernumerary for two weeks during this period. During the period new staff were able to consolidate their skills and clinical practice.
- The clinic was notified of any updated policies and procedures by the corporate training team. The clinic manager reviewed each new policy and, using the training matrix, identified which staff members were required to read the updated document. Staff signed to confirm when they had done so.
- Bank and agency staff were informed of any updates through a different system where the corporate training team notified the relevant organisations. The clinic manager told us it was expected that bank and agency staff had received all updates before arriving at the clinic.
- Bank staff were provided by the provider's in-house agency: Renal Flexibank. All bank staff underwent an induction programme, which included competency assessment to the same standards as permanent staff. Bank staff were provided with key clinical policies and work instructions as part of their induction training. This reduced the time taken to orientate bank staff to the clinic and minimised any disruption to patients.
- New bank and agency staff were required to undertake a health and safety temporary worker induction checklist, which included orientation to the clinic and the use of emergency equipment. We saw documentary evidence that this has been completed.
- The provider's specification for agency staff required staff to have renal experience and, where possible, a renal qualification. The provider worked closely with the agency to use nurses who had previously covered shifts at the clinic. Staff told us that any concerns about the competency of new bank or agency staff were fed back to, or checked with, the relevant organisations.
- Staff records showed that all staff were up to date with their appraisals. Staff we spoke with confirmed they had received an appraisal in the past 12 months.
- All staff had access to the provider's online learning centre, and staff told us the clinic supported further development through this.
- All staff had completed immediate life support training.
- Staff in the clinic undertook other roles such as the link nurses for bacteraemia, anaemia, dialysis access, and infection prevention and control; education and training co-ordinator; stock control; and, hepatitis B records administrator.

Multidisciplinary working

- The multidisciplinary team was made up of associate specialist nephrologists, a dietician, psychologist, specialist vascular access nurses, transplant co-ordinator and the clinic manager.
- The associate specialist 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 clinic. They visited the clinic 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 MDT reviewed the patient's treatment records and care plan. Any changes to patient's care and prescriptions were recorded and subsequently entered into a diary for each named nurse to initiate the agreed actions. Outcomes and changes were discussed with all patients by the named nurses and dietitian, and we saw evidence that written information relating to blood results were provided to each patient to help them understand their care.
- A multidisciplinary meeting (MDT) was held monthly to review each patient's blood results, progress and general condition. This meeting included the associate renal specialist, a dietitian and the clinic manager. Additional psychological and social work support could be accessed by the team MDT if needed, although these individuals did not routinely attend MDT meetings. We saw evidence that there was good communication between the team and with the commissioning trust.
- Reports from the MDT meetings were sent to the commissioning trust each month. These included the details of any treatment variances and reasons for the variance.
- A communication book was used to enhance communication between the renal specialist and the named nurses for the patients.
- Clinic letters were copied to patients' GPs and a copy of letters was kept within each patient's paper records. Staff were able to contact patients' GPs separately as and when necessary, for example to enquire if a patient had been admitted to hospital if they failed to attend their dialysis session.
- Transplant meetings were held monthly with a designated transplant co-ordinator. The transplant link nurse at the dialysis clinic 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.

Access to information

- Staff had access to standard operating procedures, policies and protocols. Staff we spoke with told us they had access to all the relevant information they needed to provide effective care to patients. This included previous treatment records and current observation records, up to date prescriptions, and patient's clinic letters from the renal team to their GPs.
- Patient's blood results were held on the commissioning trust's electronic computer system, which was accessible by staff including the renal associate specialist and the associate specialist in renal medicine. This meant the medical and nursing teams had the latest information available for patients undertaking dialysis.
- Clinic letters from the medical team were copied to the clinic and the patient's GP.

Equality and human rights

- Staff were governed by a corporate code of ethics and business conduct which described the company values in relation to equality and human rights. Specifically, the code of conduct prohibited staff from discriminating people 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 clinic 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.

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" ([AP1]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 clinic 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 clinic. A best interest meeting, involving the patient's relatives, the patient, clinic manager and associate specialist would generally be held to determine whether it was safe an appropriate to treat the patient at the satellite clinic. The manager told us that they had attended such a meeting to decide what was the best way to treat the patient.

- Patients in the clinic 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 clinic. We were told that, if a patient started to display any problems around their mental capacity then the clinic would phone the associate specialist immediately for advice and a decision would be made on whether it was safe to continue treatment at the clinic.
- In order to ensure patients gave valid consent, the clinic were able to access language line or use the staff within the clinic to assist with interpretation if a person's first language wasn't English.

Are dialysis services caring?

Compassionate care

- During the inspection, we received 29 'tell us about your care feedback cards.' 28 cards were positive and included comments outlining that staff were 'very caring and helpful,' that staff 'have bent over backwards to help,' that a patient had 'received excellent service from staff' and that treatment was 'first class in every respect.' However, one comment card outlined concerns regarding some staff members approach. We escalated this to the clinic manager at the time of our inspection.
- Staff delivered care in line with the '6 Cs' of nursing. These are a set of values focused on placing the patient at the heart of their care and include care, compassion, competence, communication, courage and commitment.
- We observed staff interacting with patients in a compassionate and caring manner.
- Staff treated patients with kindness and respect. They spoke to them in a friendly and informal but professional manner.
- Privacy curtains were available around each patient treatment chair and we saw these used to protect patient's dignity.
- A chaperone policy was available on the clinic.
- In the 2016 patient survey the clinic received responses from 64% (46) patients. Of these, 89% said they would recommend the service to friends or family in need of dialysis, 78% said they had complete confidence in the nurses and 91% thought the treatment rooms were well maintained and clean. 74% of patients thought the clinic was well organised and 93% of patients felt the atmosphere in the clinic was happy and friendly. Results of the survey were shared with the NHS hospital trust and displayed in the patient waiting area, with the actions taken. The clinic had an action plan in place to address the surveys findings.

Understanding and involvement of patients and those close to them

- The clinic provided new patients with a patient guide. The guide included information on how to use the electronic patient record card, health and safety information, safeguarding information, hygiene and infection control advice, understanding dialysis including the various types of venous access, diet information, holiday information, how to complain, and other sources of information.
- Staff encouraged 'self-care' with all patients in the clinic, and took opportunities to discuss this with patients and their families. However, most patients chose not to self-care. The clinic had two self-care patients and two partial self-care patients. It did not have any patients who provided self-care at home. Staff explained blood results to patients. Each patient was also provided with a 'your monthly bloods' information leaflet. This helped patients to understand what each blood test result meant.

Emotional support

- The clinic 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 clinic for many years. Staff were aware of the impact of chronic kidney disease on their patients and how long-term dialysis affected their individual needs.
- The staff were able to access advice from the renal social worker and a renal psychologist at the trust should this be required.

- Staff would provide access to a private room if a patient wanted to discuss things in privacy.
- Staff told us that patients in the clinic supported each other, for example, in the event of a patient death, and often contacted each other outside of the clinic.
- There was no formal framework in place within the clinic 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 dialysis clinic was situated in close proximity to Stockport centre. The clinic was a modern purpose built dialysis clinic. There was free parking outside and space for patient transport vehicles to park close to the clinic doors. The clinic was located on the ground floor of the building, which was wheelchair accessible. The front door was secured with a remote locking system and patients and visitors had to be buzzed into the clinic.
- The design and layout of the clinic 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 treatment room met the building note requirements and there was a separate maintenance room where the dialysis machines were service, calibrated and repaired.
- Some patients accessed the service using ambulance transport. If there was a problem with the transport, patients would mention it to staff and they would escalate it to the commissioning trust, who had responsibility for transport.
- If any patient using the transport service was suffering from a virus, the clinic 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.
- The clinic offered two treatment sessions per day and tries to accommodate patient's requests to move session where possible.
- Televisions and headphones were available for all patients to use.

Access and flow

- Stockport NHS Dialysis clinic has 18 haemodialysis stations and provides two treatment sessions per station per day (216 sessions per week). The service is open from 07:30 – 18:30 from Monday to Saturday.
- The service provides dialysis services for 31 adults from 18 to 65 and 39 adults who are over 65 years of age.
- All referrals to the clinic came from the same local NHS hospital trust. Patients had been seen in the hospital's renal clinic, on the renal ward, or by the chronic kidney disease team and were referred by the NHS hospital trust's associate specialist nephrologists.
- The service did not provide regulated activities related to dialysis services at any other place (for example, a satellite clinic or in the homes of patients) outside of the dialysis clinic.
- The service offered a staggered appointment system to improve timeliness and minimise delays. Staff made sure each treatment area was prepared with all the equipment they would need prior to the session starting. This meant when patients arrived their waiting time was kept to a minimum.
- The clinic did not have separate treatment beds for patients on holiday. However, the clinic 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 posed by the incoming patient on the resident patient cohort, for example isolation requirements.
- Staff would assist patients to identify dialysis treatment in another area should this be required for them to have a holiday. This included sharing appropriate information.
- Between 1 June 2016 and 31 May 2017 478 appointments were not attended. Of these appointments, 152 appointments were not attended because the patient was hospitalised, had been transplanted or for another similar reason. The do not attend rate was not audited therefore themes and trends were not identified.
- If patients did not attend appointments, the clinic would try to contact them. They would also contact the patient's next of kin if they could not contact the patient. If the clinic could not obtain a response, the staff would contact the associate specialist to inform them.

- In the twelve months prior to the inspection no dialysis sessions were cancelled or delayed for non-clinical reasons.
- We observed that staff at the clinic tried to facilitate a flexible approach to patient's dialysis session by changing days and times when possible.
- The utilisation of the capacity of the service had been 97% in December, 93% in January and 93% in February 2017. This meant there was some capacity for flexibility within the service for patients already receiving treatment there.

Meeting people's individual needs

- Provision was in place for patients attending for haemodialysis to visit the toilet before their treatment commenced. Staff would also ensure patients could access the toilet during treatment if needed. Toilets, including wheelchair accessible facilities, were available on the clinic to allow patients to use them prior to treatment commencing.
- The service was planned to encourage patients to participate in their own care. Patients measured their own weight both before and after treatment. This was automatically transferred to their computer record.
- Patients and staff told us how treatment days and times would be changed to meet individual references. This included social events and other health appointments.
- The allocation of treatment times was completed taking account of a patient's individual wishes and needs. This included work and social commitments as well as one off events.
- There was equipment available to accommodate patients with complex needs such as a hoist for those who were not mobile and pressure mattresses on the dialysis chairs.
- Patient information leaflets on display were in English only; however staff could obtain these in other languages if needed.
- Staff within the clinic had access to language line (a telephone translation service). Some staff were also bi-lingual so could assist with translation for patients and those close to them.
- 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 clinic did not have copies of this in easy-read or braille format.

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 clinic's 'Tell us what you think' leaflet. The policy and the clinic's statement of purpose were displayed within the clinic's waiting area.
- The clinic had received five complaints in the 12 months prior to our inspection. Three complaints were about the televisions above each dialysis station. The clinic had since replaced the televisions and no further complaints had been received. The other two complaints were appropriately responded to.
- The clinic had received no formal complaints requiring an investigation and action plan, this meant we could not comment on the clinic's timeliness for responding to complaints, or the sharing of learning from complaints.
- The policy set out a 20 working day timescale for complaints and concerns to be responded to, and included a risk assessment to determine the severity of the concern. The assessment level identified which staff needed to be made aware of, investigate, and subsequently approve the response to the complaint. The clinic manager was responsible for ensuring complaints were responded to within the policy's timescales.
- Staff told us they aimed to identify and respond to patient concerns face to face. This meant that concerns were dealt with before they escalated to formal complaints or required formal investigation. This was a positive and proactive approach. There was a patient concern log kept on the clinic so that low level concerns could be discussed by staff and with the patient and acted upon accordingly.
- 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. The area Stockport belonged to was led by a head nurse responsible for seven clinics in total.

- Staff said they felt well supported at a local level, and that the clinic manager and area head nurse were available and approachable. The clinic manager supported by a deputy clinic manager and a team leader led the clinic. The clinic manager also undertook clinical duties. The clinic manager felt well supported by the area nurse.
- Staff we spoke with said they felt well supported at a local level and managers were available and approachable. The clinic manager had a visible presence on the clinic, and the area head nurse visited regularly.
- Other corporate teams supported the staff in the clinic including a clinical incident team and regional training centres.
- The clinic manager had significant experience in dialysis treatment in a range of settings. As a result 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 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 clinic's waiting area.
- Staff we spoke with were aware the provider had a strategy and values. Staff were unable to discuss these in detail; however, they were able to describe the objective of improvement in life expectancy and quality of life for their patients. Staff were aware of how their roles contributed to achieving this objective.

Governance, risk management and quality measurement

- The clinic had a clear staffing structure which supported them at work. This included the clinic manager, deputy manager, team leader and nursing staff. Other corporate teams supported the clinic such as a clinical incident team.
- The clinic had a clinical governance strategy document, which supported the organisation's strategic aims and a statement of purpose which was displayed for patients attending the clinic.
- The strategy document set out the roles and responsibilities of the Clinical Governance Committee; its membership including the medical director, director of clinical services, and regional manager; its five objectives; and the clinical governance reporting structure from the NHS nephrologists through to the board.
- The statement of purpose listed aims and objectives for a range of stakeholders including patents. Employees, shareholders and the local community. These included aims to increase life expectancy, professionally develop staff, provide good financial returns for stakeholders and adhere to legal and safety standards which could affect the community.
- The chief executive retained overall responsibility and accountability for clinical governance. Individual clinic managers had responsibility to ensure their clinic 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 clinic, and was responsible for collating and submitting governance data, reviewing updates in policies and ensuring these were disseminated to staff.

- The clinic had recently introduced a risk register. This reflected some of the risks within the service. The clinic told us it was in development and had recently been introduced by the provider.
- Staff we spoke with were clear about their roles in providing care and treatment for patients, and in supporting the clinic in their additional lead roles, for example the holiday co-ordinator.
- There was a close working relationship between the clinic and its NHS stakeholders. The clinic functioned as a satellite clinic for, and under contract to, the commissioning trust. Monitoring meetings were in place with the trusts to review performance against the clinic's contract.
- The clinic was included in the provider's monthly benchmarking audit of performance against other clinics. This looked at effective weekly treatment time, infusion blood volume, single pool Kt/V, vascular access, albumin levels, haemoglobin and phosphate levels by each clinic in the group. It also calculated each clinic's percentage change over a six month period.
- The provider had achieved ISO 9001 accreditation for its Integrated Management Systems (IMS). The IMS system, which all staff had access to, held current and previous versions of all the organisation's policies and procedures. This meant staff were able to access the most up to date policies. The system also included a document version control facility, which tracked the review of documents including previous versions. Staff had the ability with the system to highlight any errors or issues with documents to the relevant document owner.
- Data reviewed showed that since the new clinic manager was in place, patient outcomes had improved.
- The clinic had a book in place, which contained all updates for staff. Staff had to sign to say they had read the updates.
- The clinic had achieved OHSAS 18001 accreditation for its health and safety management systems.
- Whilst effective systems and processes were in place across most areas, CQC had not been notified of patients' deaths in line with the legal requirements of a registered provider. This was discussed with the provider and it was noted that the corporate policy did not mirror the provider's legal requirements. This issue was escalated with the provider at the time of the inspection and we are working with them to address this issue.
- The Workforce Race Equality Standard (WRES) is a requirement for organisations which provide care to NHS patients. This is to ensure employees from black and minority ethnic (BME) backgrounds have equal access to career opportunities and receive fair treatment in the workplace.
- WRES has been part of the NHS standard contract, since 2015. NHS England indicates independent healthcare locations whose annual income for the year is at least £200,000 should produce and publish WRES report.
- Fresenius did not have or maintain a WRES report or action plan to monitor staff equality. We saw that this was on the risk register and reported that it was part of their wider approach to ensure equality for all employees.

Public and staff engagement

- The clinic carried out an annual patient satisfaction survey. The latest survey data available was for 2016, which had been published in January 2017. The survey had a response rate of 64% with most patients indicating the atmosphere in the clinic was friendly and happy. Results of the survey, and the action plan, were displayed in the clinic's waiting area. The provider had put in place an action plan to address the survey's findings and was in the process of completing the actions at the time of the inspection.
- 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.
- The clinic did not have any patient user groups; however, this did not appear to have any negative impact on the patients attending the clinic.
- Staff we spoke with appeared to be engaged with the clinic and the service as a whole. They had the opportunity to meet with staff from the provider's other clinics at staff meetings and conferences. One staff member felt the employee handbook was helpful and another staff member told us they felt the training was the best they had ever had.
- The staff survey in 2016 indicated that 90% staff would recommend the clinic to family and friends (compared to 69% in the NHS); while 60% said they would recommend the organisation as a place to work (59% in NHS). The survey action plan outlined steps the clinic were taking to address the survey feedback.

- The clinic also collected feedback through a 'Tell us what you think' anonymous leaflet system which allowed patients to comment on the service using Freepost direct to the Head Office. This feedback was shared with the Regional Business Managers who shared any actions required to improve patient care.

Innovation, improvement and sustainability

- Improvements were implemented when issues were highlighted. For example, the clinic manager was aware of recommendations following an audit of similar clinics by Public Health England. As a result, documentation was updated to provide assurance and evidence that patients had weighed themselves as part of the pre and post dialysis assessment.
- There were plans to make incident reporting more efficient by introducing the an incident management 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.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must implement a system that ensures in the event of a patient death, notifications are routinely notified to CQC in accordance with Regulation 16 of the Care Quality Commission (Registration) Regulations 2009 (part 4).
- 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.

Action the provider SHOULD take to improve

- The provider should undertake reviewing its compliance with the Workforce Race Equality Standard evaluation in accordance with the NHS standard contract.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **Care and treatment must be provided in a safe way for service users.** 1. 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:** **Mortality investigations were not being undertaken so lessons learned and reviews of omissions in care and treatment were not taking place.** This is a breach of regulation 12 (2) (a) (b)