

Poole Dialysis Unit

Quality Report

Unit M The Fulcrum

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Fresenius Medical Care UK (FMC), an independent healthcare provider, operates Poole dialysis unit. Dorset County Hospital NHS Trust contracts the unit to provide renal dialysis to NHS patients. There are 22 stations (comprised of 12 stations in the general area; two 4-station bays with glass partitions which can be used for cohorting purposes; and two side rooms which can be used for isolation purposes), for providing haemodialysis for stable patients with end stage renal disease/failure. We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 4 May 2017, along with an unannounced visit to the hospital on 15 May 2017. To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate. Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

Services we do not rate

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

We found the following areas of good practice:

- There were processes in place to control and prevent the risk of infection. All areas of the unit appeared clean, tidy and well maintained; they were free from clutter and provided a safe environment for patients, visitors and staff to move around freely.
- We saw evidence that staff monitored water quality for bacteria monthly
- We saw there were appropriate processes in place to support those patients with blood borne viruses (BBV). Staff received a comprehensive induction and had good access to corporate training courses. Nurses were supported to complete external renal nurse training.
- Staff completed a detailed competency assessment when they started work at the unit and were reassessed annually.
- Staff participated in annual appraisals and all staff reported in the last staff survey that they understood their roles and responsibilities.
- Staff were well supported by the clinic manager.
- The Fresenius service had developed a Nephrocare standard for good dialysis care based upon standards of best practice.
- All patients we asked reported the staff were caring and respectful.
- Staff coordinated care safely and effectively with the NHS trust consultants and dietitian.
- The service performed regular staff and patient surveys and responded to feedback.

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

- We did not see consistency of practice for positive identification of the patients attending for their dialysis.
- There were a number of reported patient falls but we did not see dedicated falls risk assessments completed and reviewed for all patients.
- Staff did not always follow the Fresenius corporate policy for infection prevention and control to ensure the clean field was maintained.
- There was no policy in place for staff to follow when a patient shows symptoms of sepsis.
- The service did not have or maintain a Workforce Race Equality Standard (WRES) action plan or publish data with regards to monitoring staff equality.

Summary of findings

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.

Details are at the end of the report.

Professor Edward Baker
Chief Inspector of Hospitals

Summary of findings

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Summary of this inspection

Background to Poole Dialysis Unit

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

Fresenius Medical Care UK operates Poole dialysis unit. The service provides haemodialysis treatment to adults and has been running since September 2007. It is a private medical dialysis unit and primarily serves the communities in Dorset. It also accepts patient referrals from outside this area.

The unit is registered to provide the following regulated activity:

- Treatment of disease, disorder, or injury.

The registered manager, Viraj Chengadu has been in post since April 2016; Fresenius Renal Health Care UK Ltd has a nominated individual for this location.

We previously inspected the service in January 2014 when all standards were met.

We inspected the service on 4 May 2017 with an additional unannounced visit on 15 May 2017

Our inspection team

The team that inspected the service comprised a CQC lead inspector, one other CQC inspector, and a specialist advisor with expertise in dialysis. Lisa Cook, inspection manager, oversaw the inspection team.

Information about Poole Dialysis Unit

Fresenius Medical Care Renal Services Limited (Fresenius) is contracted to provide dialysis for patients under the care of nephrologists at Dorset County Hospital NHS Trust.

All patients attending Poole Dialysis Unit (the unit) received care from a named consultant at the trust, who remained responsible for the patient. The provider had close links with the trust to provide care between the two services. To achieve this, the service had support from the NHS trust to provide medical cover and regular contact with a dietitian. The lead consultant from the trust attended a monthly multi-disciplinary team meeting at the unit to discuss the progress of all the patients attending the unit. The provider was responsible for the staffing, dialysis equipment, consumables and stationary.

There were three treatment sessions for patients who have dialysis on Monday, Wednesday, and Friday, with up to 22 patients in the morning 20 in the afternoon; with an

evening or twilight session for up to 14 patients. There were two treatment sessions for patients on Tuesdays, Thursdays, and Saturdays when up to 22 patients were dialysed per session.

The usual times for dialysing patients were between 8.00am and 12.30pm, then between 13.00pm and 17.00pm with a twilight session from 18.30pm to midnight (Monday, Wednesday, and Friday). On Tuesday, Thursday and Saturdays, the unit provided dialysis from 7.00am and closed at 6.30pm. Both male and female patients were treated in the same areas at the same times.

During the inspection, we visited the clinical areas where dialysis took place, and the other non-clinical areas of the unit, such as the maintenance room, and water storage area. We spoke with a total of 16 staff including the business manager, area head nurse, clinic manager and deputy manager, registered nurses, and dialysis assistants. We also spoke with 22 patients. We received 21

Summary of this inspection

'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed four sets of patient records and five sets of staff records.

There were no special reviews or investigations of the unit ongoing by the CQC at any time during the 12 months before this inspection. The service has been inspected previously, and the most recent inspection took place in January 2014, which found that the service was meeting all standards of quality and safety inspected:

In the reporting period January 2016 to December 2016 there were 14,260 dialysis sessions completed all of which were for NHS patients.

The unit undertook 1,152 treatment sessions per month on average during the reporting period. At the time of our inspection the unit had 96 NHS funded adult patients on treatment; 70 of those were aged over 65.

Track record on safety during the reporting period:

- No never events

- No incidences of healthcare acquired Methicillin-resistant Staphylococcus aureus (MRSA),

In the 12 month reporting period there were four notifications of patient death or serious injury to the CQC including:

- Two deaths not directly related to dialysis.
- One death of a patient while returning home after dialysis treatment.
- One serious incident involving a patient fall while at the unit.
- Nine patient falls during attendance for dialysis.

The service did not receive any written complaints during the reporting period January to December 2016.

Services provided at the unit under service level agreement:

- Physiotherapy, Radiography, Occupational Therapy
- Dietitian
- Social Worker
- Clinical and or non-clinical waste removal
- Maintenance and servicing of medical equipment
- Maintenance of the building
- Pharmacy

The service is accredited by:

ISO 14001 for the environmental management system.

ISO 9001 quality management system

OHSAS18001 Health & Safety system

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 found the following areas of good practice:

- Staff understood the incident reporting process and reported incidents in line with the Fresenius policy. There were systems for sharing learning from incidents including from those that occurred outside the clinic.
- There was an extensive training and educational manual, which outlined the expectations of all staff on mandatory training, additional training, accessing training and the use of the electronic systems.
- Staff were aware of their roles and responsibilities for escalating safeguarding concerns.
- Staff consistently followed the provider's policy for hand hygiene, and wore personal protective equipment.
- Patients with, or at risk of having blood borne viruses were dialysed in one of the units two isolation rooms, on a dedicated dialysis machine to minimise the risk of cross infections.
- All water testing for the unit was carried out in line with the recommendations by the UK Renal Association and European standards for the maintenance of water quality for haemodialysis and haemodiafiltration.
- The service was ISO 14001-2009 accredited for the environmental management system.
- Staff checked medicines daily and all medicines were in date and stored at the correct temperature.
- There was a tailored emergency preparedness plan in place for the unit detailing the plans in place for the prevention and management of potential emergency situations.

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

- Administration of medicines was not in line with Nursing and Midwifery Council (NMC) administration of medicines standards.
- There was not a robust falls risk management process in place.
- The service did not use a distinct early warning scoring system to monitor deterioration in the patient's condition and there was no sepsis policy.
- The safeguarding policies did not make reference to female genital mutilation or to PREVENT.

Summary of this inspection

Are services effective?

We found the following areas of good practice:

- Information about the outcomes of patients' care and treatment was collected and monitored by the service to ensure good quality care outcomes were achieved for each patient.
- Policies and procedures were developed in line with national guidance.
- We saw evidence that the service had an audit schedule to ensure compliance with the corporate policies.
- The service captured results and treatment data in the electronic system for inclusion to the UK Renal Registry.
- There were systems and processes in place to ensure that staff were competent to deliver safe care and treatment.
- All staff completed competencies, which were reviewed annually by the clinic manager as part of the appraisal process.
- There was an effective multidisciplinary team meeting with healthcare professionals from the local NHS trust.
- Staff were aware of their roles and responsibilities in relation to the requirements of consent

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

- The Nephrocare standard good dialysis care policy and procedures (September 2016) did not refer to recent NICE guidance on Renal replacement therapy services for adults.
- The service did not have or maintain a Workforce Race Equality Standard (WRES) action plan or publish data with regards to monitoring staff equality.
- The service was not compliant with the NHS England Accessible Information Standard.

Are services caring?

We found the following areas of good practice:

- Staff treated patients in a kind, calm, caring and friendly manner. This was reflected in the positive patient feedback we received during the inspection.
- We observed that nurses had close working relationships with their patients. Interactions were positive, friendly and professional.
- Nursing staff gave patients time to ask questions during treatment.
- Staff could refer patients to support services, such as a social worker or psychologist if required.

Summary of this inspection

- The clinic had established a named nurse approach to foster patient- centred relationships with regular reviews.

Are services responsive?

We found the following areas of good practice:

- There was free parking at the clinic, which patients appreciated.
- The clinic was suitably designed for the delivery of dialysis services.
- New patients could visit the clinic before they were admitted, to familiarise themselves with the environment and procedures.
- There was a range of useful patient information in the waiting room, relating both to the haemodialysis process and to the clinic's performance.
- Patients had access to television with separate headphones in each bed space.
- The unit provided assistance to patients wishing to go on holiday.
- There was no waiting list for the unit and patients experienced flexibility in rearranging timeslots.
- The unit had received no written complaints within the past twelve months.

Are services well-led?

We found the following areas of good practice:

- There was a clear leadership structure in the Fresenius Medical Care organisation which was applied to the Poole Dialysis Clinic, with visible accessible managers.
- Corporate objectives were developed each year that focused on the patient, the employee, the community and the shareholder. These objectives were centred on improving patient outcomes and clinical effectiveness.
- The Fresenius quality management system produced a monthly clinical dashboard, which was discussed with the area head nurse. Each of the indicators had an explanation and an action plan for improvements where necessary.
- Staff understood their roles and responsibilities and made patient care their priority.
- Staff had effective, close working relationships with staff from the NHS trust; monthly quality meetings included senior staff from both the NHS trust and the unit.
- The clinic manager had developed an electronic risk register to provide an oversight of the clinic risks.
- The unit captured patient feedback through the annual patient satisfaction survey in October each year, in order to improve the service they provided.

Summary of this inspection

- The unit also sought feedback from staff with an annual satisfaction survey. Staff we spoke with told us that they returned the completed survey and appreciated actions taken.

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

- Not all policies included reference to the most up to date guidance.

Dialysis Services

Safe

Effective

Caring

Responsive

Well-led

Are dialysis services safe?

Safe means the services protect you from abuse and avoidable harm.

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

Incidents

- The service had reported no 'never events' from February 2016 to February 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 Fresenius clinical incident reporting policy, June 2016, outlined responsibilities and actions to take when incidents, accidents or near misses occurred. The policy described the process, how to protect people from further risks, who needed to be told about the incident and how to investigate incidents.
- All staff we spoke with had a good understanding of the reporting system and could access the system.
- We saw that the electronic incident reporting system captured details regarding clinical, non-clinical and treatment variance incidents that occurred on the unit. The clinic manager, area head nurse and business manager had oversight of any incidents that occurred within the unit. Staff reported non-clinical incidents to the health and safety team. For the year January to December 2016 staff reported 15 incidents, six were graded as causing severe harm, three moderate harm, and six were graded as causing low levels of harm.
- We saw that incidents were reviewed and investigated by the clinic manager who was trained to do so.

- Reports contained timelines and actions; the clinic manager investigated moderate and severe incidents through a process of root cause analysis (RCA), with outcomes and lessons learned shared with staff. E.g. a patient not attending for treatment was recorded as a treatment variation report (TVR) and needle dislodgement was recorded as a clinical incident (CIR). The outcomes were shared with staff via the regular bulletins issued by senior company nurses for staff learning and discussion.
- A unit variance report (UVR) was also available to staff; this would be completed for example, if an abnormality was found in the water supply during the monthly checks.
- 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 we spoke with were aware of their duty of candour regulatory duty. They told us training was available to them and we saw there was a policy in place and staff had signed to say they had read and understood it. None of the staff we spoke with had been involved in, or reported an incident where duty of candour had been required.
- In early 2017 an endotoxin organism was found to be present in the water supply which meant that the haemodiafiltration (HDF) treatment had to be suspended. The patients received haemodialysis (HD) until the HDF resumed two weeks later. This was clearly reported and documented. Patients told us that they had received a full explanation of this incident of water contamination which caused delays for their dialysis.

Mandatory training

Dialysis Services

- Fresenius Medical Care (FMC) had an extensive training and educational manual. This outlined the expectations of all staff on mandatory training, additional training, accessing training and the use of the electronic systems.
- Mandatory training was made available to all staff to enable them to provide safe care and treatment to patients. Some of the training was completed through e-learning which staff could access at a time to best suit their needs.
- We saw evidence of the monitoring of the completion of training using an electronic system. The clinic manager maintained the information and used a colour coding system which highlighted if a staff member's mandatory training had expired.
- Records demonstrated that most clinical staff were up to date with essential mandatory training. A number of staff were newly recruited during the previous 12 months and for the period January to March 2017 the staff group as a whole had completed 79% of training.
- The mandatory training for all staff at the clinic included the following:

Basic Life Support & Automated External Defibrillator

Anaphylaxis

Evacuation Chair Training

Fire Marshal Training

Infection control

Practical Moving & Handling

Safeguarding Children

Safeguarding Adults

- There were e-learning modules that were also completed including legionella, control of substances hazardous to health regulations (COSHH) and disability discrimination.
- The area nurse manager facilitated unannounced simulated life support training for staff on site and we noted that the last one took place in the autumn of 2016. We do not know if the trainer was certified by the resuscitation council to facilitate this training.

Safeguarding

- There were systems, processes and practices in place to keep patients safe from avoidable harm. There was a corporate policy to guide staff regarding their

responsibilities for safeguarding. This contained flowcharts to advise what actions to be taken. Staff were aware of their roles and responsibilities for escalating safeguarding concerns.

- The clinic manager was safeguarding lead for the unit, and received training in safeguarding for managers from the local authority. The training covers the stages of practice in investigating abuse, good preventative practice, Dorset's procedures in relation to investigating the abuse of adults at risk, and the law in relation to adult abuse.
- Nursing staff told us they had not had to report or escalate any safeguarding concerns but were able to talk through scenarios and were clear about their responsibilities.
- Staff received training updates in safeguarding adults and children every three years; we saw they were up to date with the training requirements in both safeguarding adults and safeguarding children. The training was equivalent to safeguarding children level 2.
- The corporate policy and guidance for staff in safeguarding and protecting vulnerable did not refer to female genital mutilation, or to PREVENT (anti-terrorism) training programmes, which includes the recognition and protection of vulnerable individuals from risk of grooming and involvement in terrorist activities or supporting terrorism. We saw however a training session entitled radicalisation was available.

Cleanliness, infection control and hygiene

- There was a Nephrocare Standard Hygiene Infection Prevention and Control (IPC) policy in place. This was a comprehensive document put in place in July 2016, to promote a safe environment for patients, visitors and staff.
- Between January 2016 and April 2017, the service reported no cases of Methicillin-Resistant Staphylococcus Aureus (MRSA) but the service reported one case of Methicillin-Sensitive Staphylococcus Aureus (MSSA). MRSA and MSSA are infections that have the capability of causing harm to patients. MRSA is a type of bacterial infection and is resistant to many antibiotics. MSSA is a type of bacteria in the same family as MRSA but is more easily treated. The provider had not reported any cases of clostridium difficile within the same reporting period.

Dialysis Services

- All staff were trained and used an Aseptic Non Touch Technique (ANTT). This minimised the occurrence of infection transmission between patients. We observed that staff used appropriate personal protection and drapes were used to minimise cross infection.
- We saw Personal Protective Equipment (PPE) such as disposable aprons and gloves, and hand sanitising gel was available across the unit. We observed staff were compliant with 'bare below the elbow' guidance and they wore PPE including visors on a regular basis in line with their policy.
- We observed that staff cleaned and disinfected each dialysis machine and the chair/bed area between uses to ensure good standards of hygiene. This included all medical devices that were used.
- We saw competencies in staff files to show that staff were trained in cleaning procedures for the dialysis machines.
- The clinic manager, supported by the company head nurse, completed a comprehensive hygiene and infection control audit on a monthly basis. Results from January to April 2017 showed a compliance range between 92% and 97% for the clinical practice sections of the audit.
- We saw that audit findings were discussed in team meetings and reminders given to staff to ensure future compliance such as making sure aseptic techniques are followed according to Fresenius policy.
- We did note that fabric cuffs used for blood pressure monitoring and shared between patients were only cleaned if there was a spillage on them. This did not apply to tourniquets which were personal to each patient.
- The cleanliness audits also included a general cleaning and premises section completed by the clinic manager supported by the cleaning staff manager. This included the waiting area, staff areas and store cupboards and the compliance range for this section ranged between 88% and 90% for the same reporting period.
- Procedures were in place to assess patients as carriers of blood borne viruses (BBV) such as Hepatitis B and C. This included routine testing of susceptible patients in line with best practice guidelines. Policies gave staff clear guidelines in regard to appropriate infection practice, for example MRSA and MSSA screening, BBV, no-touch aseptic technique and the use of isolation rooms.
- In the event of a patient testing positive for a BBV such as Hepatitis B or C, staff were able to dialyse them in one of the two isolation rooms. The unit had appropriate colour-coded protective equipment for staff.
- All water testing for the unit was carried out in line with the recommendations by the UK Renal Association and European standards for the maintenance of water quality for haemodialysis and haemodiafiltration. We saw evidence that the staff monitored the water for chemical contaminants; chlorine levels in the water were tested daily and other contaminants such as nitrates tested monthly to ensure the quality of the water used. We saw that records of compliance and a standard operating procedure was in place for staff to follow to ensure the procedure was completed accurately.
- Procedures were in place for those patients who had recently returned from holiday. This included being dialysed in a side room until three clear blood results were obtained to ensure the patient did not have a BBV.

Environment and equipment

- We saw that the service was ISO 14001-2009 accredited for the environmental management system.
- The layout of the dialysis unit was compatible with health and building notification (HBN07-01) guidance. Access was good for both able bodied and disabled patients, with a secure single entry point. There was a call buzzer for access when the receptionist was not available. The reception desk was manned daily between 10am and 2pm.
- All areas of the unit were tidy and well maintained; they were free from clutter and provided a safe environment for patients, visitors and staff to move around freely. All doors were unobstructed and fire escapes were clear.
- In the reception area, we saw that there were easy clean chairs for patients to use whilst waiting for treatment. Chairs had arms to aid patients with mobility difficulties to stand.
- The weighing scales, located in waiting area, were serviced in April 2017. The registered manager told us that they do not keep spare weighing scales on site but have a contract which will ensure the company come out that day or the next to repair them.
- The Department of Health provides best practice guidance for the design and planning of new healthcare buildings (Department of Health Renal care Health

Dialysis Services

Building Note 07-01: Satellite dialysis units 2013); a preferred minimum of 900 mm between stations is recommended in this guidance. We saw that the unit was compliant with this requirement, the space between dialysis chairs allowed for privacy, and space for staff to be able to attend to patients.

- In the clinical area a nurse's station allowed visibility of all patients during dialysis although curtains were available when required.
- The layout of the multi-station dialysis area should enable patients to talk to one another, and nurses to call for assistance from one station to another, but care must be taken to allow sufficient space between dialysis stations to prevent the risk of cross-infection and for a degree of privacy ('). –
- The water treatment plant was at the back of the unit; we found it visibly clean and tidy with drainage in the floor to prevent flooding. No floods were reported in the 12 months prior to our visit. There were two reverse osmosis water plants which were serviced in July 2016 and were next due for service in July 2017. There was a salt tank present which was functioning at optimum level.
- There was a locked utility room with a hand basin, liquid soap and a supply of towels. We saw that it was visibly clean and clutter free. This room contained a locked cupboard for flammables clearly marked with 'hazardous' signs
- The store cupboard was visibly clean and well maintained; all the equipment and supplies in storage were in date and shelved above floor level. We observed equipment stock in the storage areas was CE marked. For example, dialysis needles and accessory kits. This ensured that all dialysis equipment was approved and compliant with relevant safety standards and met the Renal Association Guideline 2.2 - HD: Haemodialysis equipment and disposables.
- The dialysis machines had been in use since 2008, we noted that one of the machines had been operational for 31,535 hours. The Renal Association standard states that machines 'should be replaced after between seven and ten years' service or after completing between 25,000 and 40,000 hours of use for haemodialysis, depending upon an assessment of machine condition.'
- There was not a current replacement program in place, and we did not see a risk assessment relating to the age of the equipment.

- We saw records were maintained relating to the maintenance and calibration of all equipment used at Poole dialysis unit. Maintenance of the dialysis machines and chairs were scheduled and monitored using the dialysis machine maintenance/calibration plan, which detailed the dialysis machines by model type and serial number along with the scheduled date of maintenance. There was also a maintenance plan for other clinical equipment, for example patient thermometers, blood pressure monitors, patient weighing scales etc.
- The maintenance technicians were employed by the local NHS trust and were available and responsive to assist for any technical problems that may arise. There were four spare machines and a spare chair on the unit, and there were bed spaces free on the main clinic floor, should they be required due to faults or breakdowns.
- There was resuscitation equipment available for use in case of emergency which was checked daily and was ordered and dust free. We saw the completed check lists for the previous month were in place and the anaphylaxis box and first line drugs were in date. The unit had an automated defibrillator, working suction and a full oxygen cylinder with a new mask attached next to the resuscitation trolley for use in an emergency.
- During our inspection we discussed some of the equipment on the trolley which staff were not trained to use; they explained that the trolleys were supplied fully equipped. We expressed our concerns that it was not ideal for staff to have access to equipment they were not fully trained to use.

Medicine Management

- The service had a corporate medicines management policy that was available to all staff through the service intranet. Staff were aware of where to find it should they need guidance.
- All staff completed training in preventing medication errors.
- The clinic manager was the lead responsible for the safe and secure handling and control of medicines, and was able to provide support and guidance. There was also a deputy clinic manager to provide guidance if required.
- The nurse in charge for each session held the keys for the medicine cabinet. We observed the medicines cabinet was kept locked.

Dialysis Services

- The medicines fridge was locked and was visibly clean; the temperature readings were logged daily and within acceptable range.
- The nurses had access to the local NHS pharmacy for additional advice relating to medicines used during dialysis. In addition, they were able to contact a pharmacist at Fresenius head office should this be required.
- We saw that all medicines in the medicines cabinet were in date and records kept of expiry dates.
- No controlled drugs were stored or administered as part of the services at Poole dialysis unit.
- The service did not use any patient group directions (PGDs) and none of the nurses were trained in non-medical prescribing.
- We saw that every patient had an individualised treatment prescription. Any changes to these prescriptions were made by the consultant nephrologist who visited the unit twice weekly.
- A review of five patient prescription charts showed that the prescriptions dated back to 2016 with no evidence of review. However, we learned that the patient prescription charts were checked at monthly quality assurance meetings, and reviewed against the monthly blood results. The outcome from the meetings was available to staff in the 'QA folder'. The folder contained updated decisions on patient care which included the medication prescription.
- Staff followed a set routine for medicines administration. The routine practise was for two registered nurses to prepare, check against the prescription, and leave the medication ready at the station for administration to the patient. Another staff member then administered the medication to the patient. This practice did not meet the Nursing and Midwifery Council (NMC) standards for medicines management or the Fresenius policy which states that "Two registrants must check medication to be administered intravenously, one of whom should also be the registrant who then administers the IV medication."

Records

- Fresenius had a clinical record keeping policy that gave staff guidance on record keeping, ensuring a consistent approach in document management and the quality of patients' clinical records. This policy also included

principles of record keeping and completing clinical records, NMC code professional responsibility, patient file and storage of records. Patients' records were kept in a secured cabinet behind the nursing station.

- Access to the electronic system was password protected; we saw that staff protected logged in and out of the system appropriately.
- The service used the Fresenius patient treatment database for documenting patients' records and this database automatically transferred patient data into the local NHS hospital clinical database system. The consultant nephrologist was able to access the patients' clinical information at all times.
- All patients had a named personal data cards electronically linked to the dialysis equipment. These were collected by patients when they arrived and cross checked by staff when the patient was at the treatment station.
- The records contained all patient demographics including height, weight along with the patient prescription and blood results.
- The records we reviewed included among other details, care plans, consent, monthly blood results, routine observations, intravenous line checks, a named nurse, named nurse checklist, evidence of multidisciplinary review, prescription and screening results. The staff updated the electronic record throughout the patient's treatment in order that the record was complete and contemporaneous.
- Staff completed a comprehensive patient referral/admission document for all new patients. This included information from the referring unit and the dialysing unit. A data quality confirmation check was also included on the form to ensure the data provided by the referring trust reflected accurate patient information. Any discrepancies were documented on the records.
- We reviewed four patient paper records and found that all contained an observation chart, dialysis prescription, patient consent form, admission assessment form, manual handling assessment and a personal emergency evacuation plan. These were completed by the nurse on referral to the unit and updated at regular intervals. Those seen were completed legibly and accurately.

Assessing and responding to patient risk

Dialysis Services

- Prior to starting treatment, patients were assessed for their suitability for treatment at the unit. Only once the patient was assessed as stable on dialysis was a referral made to the unit for their treatment. We saw that referrals also contained relevant past medical history, medical conditions, and infection status to support staff with care and treatment. In the event of a change in condition staff liaised with the NHS consultant to discuss a plan of care.
- As this was a nurse led unit there was a strict selection criterion for patients to receive their treatment at the unit which was monitored by the consultant nephrologist from the local referring trust. The consultant was available on site twice weekly for the patients who required medical review or consultation
- Patients were required to verbally confirm their date of birth prior to treatment and medicines. Patient's details were held on an electronic system and each patient had their own electronic card. On arrival to the unit, patients would be weighed, and the weight collected on the card. Patients would then be called into the dialysis unit, where the cards were inserted into the dialysis machines.
- Patient records contained completed assessments with regards to manual handling and pressure areas. The manual handling assessment recorded any patient mobility problems so staff could make the necessary adjustments in care. This record did not fully consider all the elements of a falls risk assessment and we did not see evidence that this record was reviewed on a regular basis.
- Staff performed observations on all patients before and during dialysis. The electronic monitoring system alerted staff to a deterioration in a patient's blood pressure or heart rate. If a patient appeared unwell or showed signs of deterioration staff monitored them more closely and would either continue monitoring, or return the circulating fluid and discontinue the dialysis as per guidelines. They would assess whether the patient required transfer to an acute hospital via emergency services.
- The service did not use a distinct early warning scoring system to monitor deterioration in the patient's condition. Staff explained their observations and alarms meant that continuous monitoring was in place.
- The unit staff recorded variances in treatment; this included areas such as problems with cannulation, clotting concerns, episodes of poor blood flow and equipment malfunction. Variances recorded included if the patient wished to terminate dialysis prior to the prescribed treatment time. We saw that the patient also signed an early termination report. This was recorded in the electronic record to inform the nephrologist.
- Prior to treatment, any variances from the previous treatment session needed to be acknowledged by staff. This ensured that staff were aware of any specific issues relating to care and treatment.
- Guidelines were not in place on the process to follow in the event of a patient showing signs of sepsis at the time of our visit, but the manager told us that Fresenius was in the process of developing procedures for staff to follow in the event of a potential case of sepsis. The patient assessment prior to dialysis included monitoring the intravenous catheter for signs of infection using a venous catheter surveillance tool recognised description of the condition of the fistula using a score of 0-4.
- During inspection, we saw that dialysis machine alarms were responded to within a few seconds. Alarms would sound for a variety of reasons, including sensitivity to a patient's movement, blood flow changes or leaks in the filters.
- We observed experienced trained nursing staff used a technique called 'dry needling' to cannulate a fistula without a primed needle. The unit's policy 'Nephrocare standard good dialysis care' (22 September 2016) stated that wet needling (primed needle) was the recommended cannulation technique. We raised this during our inspection with the unit manager, the area manager and Fresenius senior nurse. When we returned for our second visit Fresenius had instructed all staff to flush needles with saline prior to cannulation. The chief nurse for the provider issued a bulletin to all Fresenius dialysis clinics, which clarified the requirement for the wet needling technique for cannulation.
- We observed consistent wet needling technique employed by the staff on our second site visit.
- Patients did not receive blood transfusions at this unit. Where a blood transfusion was required this would be carried out at the referring trust.
- Fresenius had a patient transfer policy in place. Emergency transfers of care were undertaken via local emergency ambulance services using a 999 call. Any non-urgent transfers were performed in consultation with the nephrology consultants. Between January 2016 and December 2016, 39 transfers of care occurred.

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Staffing

- At the time of our visit the unit had a full complement of registered dialysis nurses, 12; they were supported by four healthcare assistants. There were two vacancies for healthcare assistants.
- Staffing levels and skill mix were planned and reviewed so that patients could receive safe care and treatment at all times. The unit was contracted to provide a staff to patient ratio of 1:4 with a skill mix of 70%/30% registered nurses /dialysis assistants, plus one healthcare assistant per shift.
- The business manager reviewed rotas weekly against the contract and the clinic manager managed sickness and worked regular clinical shifts to maintain the agreed ratios.
- During January to March 2017 the service reported there were 76 shifts covered by bank staff and 57 shifts covered by agency workers to ensure the skill mix and numbers of staff were appropriate to provide safe care and treatment for patients. Managers reported that sickness was monitored monthly and during the same reporting period staff sickness rate was averaging 0.3%. We were told that recruitment could be difficult in the area and many staff moved on after two years. The high use of bank and agency usage allowed for new staff to receive a full induction and supernumery period.
- The clinic manager completed exit interviews with all leavers. Most staff had left for personal location reasons or promotion.
- Bank and agency staff were arranged by a Fresenius renal flexi bank team to support co-ordinating staff across the organisation.
- Renal flexi bank staff underwent an induction programme with a training shift and competency assessment in the same standards and procedures as full-time staff.
- We saw the handover between the morning and afternoon staff. This was a well-structured handover where staff discussed every patient who attended the unit. Nursing staff were fully aware of all the patients, their history and any changes to treatment. The written nursing handover form contained a small amount of information with the detail being added verbally during the handover.

- There were no medical staff employed at the unit. Twice a week a dedicated renal consultant employed by the commissioning NHS trust attended the clinic for renal outpatient appointments.

Major incident awareness and training

- Prior to our visit we saw that there was a tailored emergency preparedness plan (EPP) in place for Poole dialysis unit detailing the plans in place for the prevention and management of potential emergency situations.
- We saw that the plan addressed a number of situations that could arise including; prevention plan for fire, loss of electricity, loss of computer systems and data. The plan included a site evacuation plan for situations which included; gas leak, minor and major water leak and storm damage.
- The EPP also addressed facilities and business recovery plans to ensure business continuity.
- Staff we spoke with were aware of this plan, and there was a requirement for training and site evacuation drills for which evidence of completion was maintained within the unit. The plan included defined roles and responsibilities; emergency contact details for emergency services, public services and key headquarter personnel.
- We observed appropriate emergency equipment including carbon dioxide and water fire extinguishers.
- We saw in patient records that a personal emergency evacuation plan (PEEP) was recorded. The plan included any patient mobility issues in order to evaluate the level of help required in the event of an emergency evacuation.

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

Effective means that your care, treatment and support achieves good outcomes, helps you to maintain quality of life and is based on the best available evidence.

Evidence-based care and treatment

- Fresenius had produced their own 'Good Dialysis Care' policy and procedure document for all their clinics, which was compliant with European Renal Best Practice (ERBP) and the Kidney Disease Outcome Quality Initiative (KDOQI) guidelines. It contained instructions

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for staff in how to use the specific dialysis equipment and there was clear referencing to other policies and best practices. The Good Dialysis Care policy excluded medicine management guidelines for units in the UK, as Fresenius had created a separate UK medicines policy in accordance with the UK Nursing and Midwifery Council Standards.

- We observed care and treatment was delivered to patients in line with these guidelines. For example, we saw that all patients receiving treatment had their vascular access site monitored and maintained prior to dialysis. We observed nurses visually monitor the access sites and record any variances using the electronic system.
- The procedures linked to the Nephrocare standard for good dialysis care. This described the processes for staff to follow with a rationale for the process in place. For example, the standard provided information to perform hand hygiene, put on a plastic apron and wear a visor. We observed that staff followed this practice.
- However the Nephrocare standard good dialysis care policy and procedures (September 2016) did not refer to recent NICE guidance such as the NICE Quality Standard 72, 'Renal replacement therapy services for adults', November 2014, updated January.
- We saw evidence that the service had an audit schedule to ensure compliance with the corporate policies. For example, audits were undertaken with regards to infection control, records and hand hygiene.

Pain relief

- Staff assessed and managed patients' pain relief needs appropriately. Patients did not routinely receive oral analgesia during their dialysis sessions: however, local analgesia was available for cannulating the patients' arteriovenous fistula or graft (AVF/G). This included local anaesthetic creams and paracetamol.
- We saw that patients were offered pain relief, prior to dialysis. Patients we spoke with said they were offered pain relief if required and staff checked that pain relief administered had been effective.

Nutrition and hydration

- Patients who have renal failure require a strict diet and fluid restriction to maintain a healthy lifestyle. The dietitian attended the unit for a monthly multidisciplinary team (MDT) meeting and was available to speak with patients and advise them on their diet.

- The waiting area displayed educational information for patients to support the understanding of their condition
- There was tea and biscuits available to patients during their dialysis session and a water cooler available in the reception area.
- We saw that some patients brought their own refreshments to consume while having their treatment.

Patient outcomes

- Patients were weighed on arrival to the centre at each visit. This was to identify the additional fluid weight that needed to be removed during the dialysis session. This varied from patient to patient and formed part of their dialysis treatment plan, which staff adjusted as required.
- 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. The data system provided customised reports and trend analysis to monitor and audit patient outcomes and treatment parameters.
- Clinical outcomes for renal patients on dialysis can be measured by the results of their blood tests. The blood results were monitored on a monthly basis before and after dialysis treatment in accordance with the Renal Association Standards. Results were collated on the electronic database used at the unit.
- The results show how the unit performed in the achievement of quality standards based on UK Renal Association guidelines. We reviewed results of blood tests for three months from February to April 2017. These comprised of a number of outcomes, for example:
- Two standards we looked at show how much waste products were removed from the patient and how effective the dialysis was;
 - the rate blood passes through the dialyzer over time, related to the volume of water in the patient's body (expressed as ' $Kt/V \geq 1.2$,h') and
 - the Urea Reduction Ratio (URR)•
- On average just over 92% of patients had effective dialysis based on the first standard.
- For the URR, Renal Association guidelines indicate a target of 65%. The average URR for the patients at the Poole Dialysis Unit from February 2017 to April 2017 was 98%. Patients with these levels of waste reduction through dialysis had better outcomes and improved survival rates.
- We also looked at the standards indicating that patients' haemoglobin (Hb) was at safe levels. Anaemia can be a

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complication of renal failure and dialysis associated with increased risks of mortality and cardiac complications. From February to April 2017, the average number of patients with the NICE recommended target of Hb (100-120 g/l) was 67%. This meant the other 33% of patients had lower Hb levels. When a patient had low levels they were given injections of a stimulating agent to help their body produce more blood cells.

- Potassium levels in the blood are monitored as part of the Renal Association standard. From February to April 2017, an average of just 3.5% of patients in Poole had high levels of potassium (greater than 6.0 mmol/l). If potassium levels are higher than 6mmols, it can cause acute cardiac problems. This means around 96.5% of patients had potassium levels within acceptable ranges.
- During the same period, outcome standards for the unit showed 98% of patients received haemodiafiltration (HDF) treatment. This is the most effective treatment for kidney failure.
- In the 12 months leading up to our inspection, 100% of patients received high flux dialysis. High flux dialysis is a form of more effective clearance of the waste products and fluid. High flux dialysis delay long-term complications of haemodialysis therapy.
- From February to April 2017, we saw 100% of patients who attended three times a week were dialysed for the prescribed four hours treatment time. This was more than the minimum standard of 70%.
- The consultant reviewed patient blood results to ensure effective dialysis treatments for each patient and adjusted their prescriptions to ensure effective outcomes. We saw treatment prescriptions were individual to each patient based upon their specific needs.
- Data specific to the unit and available via the electronic database was used to benchmark patient outcomes at clinic level and nationally against all Fresenius Medical Care UK clinics.

Competent staff

- We saw that there were systems and processes in place to ensure that staff were competent to deliver safe care and treatment.
- A central human resources' team managed the pre-employment checks for staff and the business

manager monitored progress. This included disclosure and barring service (DBS) checks. A start date would not be provided for a new member of staff until all checks were fully completed.

- Staff were able to access training internally and externally. There was an online learning system across the organisation where staff could access additional training opportunities. All staff we spoke with reported that they were encouraged and able to access training to improve their knowledge and skills.
- Staff files including training records were held for each member of staff. These were up to date and monitored by the clinic manager using a colour coded electronic spreadsheet. The files included details of up to date Nursing and Midwifery Council registration and revalidation.
- The service had a number of link nurses to provide advice and guidance to others, this included health and safety, training and education, electronic records.
- The training and education progression plan included a comprehensive induction and preceptorship programme for all new staff. This included a wide range of essential training. Following induction there was a supernumerary period, and then staff commenced a probationary and supervised period. During this time staff were supported by the clinic manager, and deputy clinic manager.
- Staff received medical device training as part of the supernumerary period of training. This was managed locally and we saw documentation confirming that all staff had received medical device training.
- Staff did not perform dialysis alone until they had achieved all relevant competencies, such as supervision in catheter dressing, vascular accessing techniques, and safe injection practices, management of intravenous cannula, tunnelled and temporary central lines, AV fistulas and grafts. We reviewed five staff records during our inspection, and these included course certificates and an integrated competency document with dates and signatures for competencies completed.
- Training was made up of face to face, online electronic learning or virtual classroom sessions. Staff also received simulation training within the clinic environment.

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- Bank staff received the same training and regular assessment as permanent staff. Agency staff received a local orientation to the unit and a record of the orientation was kept and signed by the agency nurse and the clinic manager.
- The dialysis assistants (DAs) worked with the qualified nurses to manage patients care and treatment. The DAs were assessed in clinical skills to assist with the completion of dialysis. This included the needling of patients arteriovenous fistulas (AVFs), programming of dialysis machines and administration of some medicines. The DAs were assessed using competencies to perform these skills, and worked alongside a qualified nurse for each clinical duty.
- Three of the 13 registered nurses in the Poole dialysis unit had completed external renal courses.
- Annual appraisals identified any areas for development and an agreed timescale for completion. All staff completed competencies, and these were reviewed annually by the clinic manager as part of the staff member's appraisal. All of the staff had completed their annual appraisal at the time of our inspection. The clinic manager receives annual assessment and appraisal from the area head nurse.
- At Poole there was a peer assessment to demonstrate that staff could act as patient advocates through the named nurse approach and foster and maintain patient engagement. This assessment identified whether staff could escalate information appropriately, and if they understood the clinic review process. There was some psychological training available to staff and Fresenius had a confidential line available for staff to access for support.
- The clinic manager monitored staff practice closely; this included annual observation of their key skills such as cannulation of fistulas, and maintained a spreadsheet to keep track of staff competencies.
- Whilst on the unit we observed good communication and support between members of the team, nursing staff and patients we spoke with described good working relationships amongst all staff involved in care and treatment, including clinical and ancillary staff and transport services.
- There was a multidisciplinary team meeting held at the unit which included the trust consultant and the renal dietitian, as well as the registered manager or a designated deputy. We saw that patients' current condition, most recent blood results and medicines were discussed and recorded in the electronic patient record.
- The meeting included decisions relating to patients on the 'gold' list. This was a list of patients who were on an end of life care plan.
- All patients received a full medical review once a quarter, with more frequent reviews as results indicated. Patients on the gold list were able to attend with family members.
- Patients could access psychological, counselling or therapy services through a referral process to the referring trust.

Access to information

- The information needed to deliver effective care and treatment was available to staff through either electronic or paper records. Paper records consisted of patient risk assessments, consent forms and dialysis and medicine prescriptions. Electronic records, including those from the NHS trust and blood test results, were accessible to staff at the unit.
 - Staff told us they had access to policies and procedures through the electronic database.
 - We saw that there were standard operating procedures (work instructions) for staff to follow. The instructions provided systematic instructions in areas such as water testing, and good dialysis care. These instructions aimed to ensure that staff maintained the safety of patients at all times.
 - Dialysis away from base (holiday dialysis) was available at the unit when capacity allowed. There were systems in place to ensure that the clinic received the relevant information required to ensure that holiday stays could be managed safely. The clinic manager checked medical acceptance was also sought
 - The service offered dialysis to patients from out of area who may be on holiday. We saw that arrangements for
- One consultant nephrologist from the local NHS trust took overall responsibility for the patients' medical care at the unit. Other consultants support for on-call or absence and a vascular surgeon formed part of the team.
 - We saw staff had effective working relationships with the consultants and other healthcare professionals from the local trust.

Multidisciplinary working

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referrals were through Fresenius head office or through the patient's own hospital to the dialysis clinic. Staff provisionally allocated dialysis space availability that was subject to receiving completed documentation and medical approval and acceptance. The unit treated the patient as high risk and ensured all relevant information were gathered that related to the holiday patient, to reduce risks to other patients.

- The clinic staff were also able to support their patients with holiday dialysis arrangements. Staff coordinated this effectively, by liaising with the holiday dialysis site and sharing the necessary clinical and non-clinical details about the patient.

Equality and human rights

- From 1st August 2016 onwards, all organisations that provide NHS care were legally required to follow the NHS England Accessible Information Standard. The standard aims to make sure that people who have a disability, impairment, or sensory loss are provided with information that they can easily read, understand or with support can communicate effectively with health and social care services.
- We were informed that prior to attending the unit for treatment, all patients would be assessed to ensure their needs could be met and language interpreters could be accessed via the referring trust if required. Throughout the inspection we did not see any patients who required materials in other formats to support their understanding of care and treatment, but staff assured us that they could access appropriate support and materials when required.

Consent, Mental Capacity Act and Deprivation of Liberty

- Staff were aware of their roles and responsibilities in relation to the requirements of consent. We saw that patients were asked for verbal consent at the start of each dialysis session and for any treatments or care during their attendance at the centre.
- The Fresenius Medical Care policy for consent to examination or treatment detailed the process for staff to follow if there was any doubt about a patient's mental capacity. Patients who were unable to consent for their dialysis would be referred back to the NHS trust.

- All the unit staff had completed training regarding consent, Mental Capacity Act 2005, and deprivation of liberty safeguards. Nursing staff told us that currently they did not have any patients who lacked mental capacity.
- We saw that each patient completed consent forms for the completion of treatment and for dialysis. This consent form was filed in the patient's paper records. The forms included a section to document if patients had an advance directive and if they had (or did not have) a 'do not attempt cardiopulmonary resuscitation' (DNACPR) agreement in place.
- During our inspection, all the patients we saw receiving treatment had capacity to consent.
- The staff demonstrated a clear understanding of the right of a patient to decline treatment or request a shorter dialysis time. They recognised that for different reasons, patients sometimes wanted to leave the clinic earlier and they supported patients to make reasonable adjustments to the dialysis schedules.
- There were no patients on treatment living with dementia at the time of our inspection but some staff had experience of working with a patient with a learning difficulty who did not always understand. Arrangements were in place for a carer to remain with the patient during dialysis, and the consultant was available by telephone if any further support was required.

Are dialysis services caring?

Caring means that staff involve and treat you with compassion, kindness, dignity and respect.

Compassionate care

- Staff understood and respected patients' personal, cultural, social and religious needs. Where possible, they altered dialysis sessions to accommodate these. We saw staff chatting to patients and putting them at ease during dialysis.
- Staff were aware of the vulnerability of their patients and described supporting them during difficult family times.
- During our visit a number of patients had altered their session times in order to attend the funeral of another patient, and staff had helped them with these arrangements.

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- One patient told us 'all the staff here are outstanding' another wrote on one of our 'tell us about your care cards' - 'I have been coming here for over seven years and can honestly say that the care and kindness has been first class; in my eyes the staff are absolute angels; they go that extra mile- more like friends than nurses'.
- We saw that staff greeted patients as they arrived for treatment, and it was clear that they knew the patients. We observed that staff asked about them and their families and discussed any appointments or events they had attended. Interactions were positive, friendly and professional. Staff informed us that due to seeing patients every other day they had the opportunity to get to know them well and it was like a family.
- The unit undertakes an annual patient satisfaction survey; the most recent one was refined with support from the Fresenius patient group. The last survey in Poole showed that 80% of patients were likely to recommend their unit to friends and family in need of dialysis. However those we spoke with were more than satisfied with their treatment in the unit.
- Of the patients surveyed 95% were generally satisfied with the dialysis unit; 87% of patients also said they were treated with dignity and respect.

Understanding and involvement of patients and those close to them

- All the patients at the unit were allocated named nurses. This key role was to provide a specific person for the patient to discuss any issue with and access support. Patients we spoke with during the inspection, knew who their named nurse was.
- Patients said they understood the treatment they were receiving and felt they had enough information from the outset. They said they were prepared for dialysis before they attended this clinic, whilst in hospital. The patients we spoke with all preferred coming to this unit rather than the hospital as the atmosphere was more relaxed and friendly.
- We saw that staff spoke openly about the treatments provided, the blood results and dialysis treatment plans. Many of the patients were observed speaking with staff about their latest blood results and what these meant and staff responded appropriately.
- Staff told us that patients were very much encouraged to be involved in decisions about their care and participate in self-care.

- The patients spoke positively about the staff and treatment at the unit.

Emotional support

- Staff recognised the emotional impact that dialysis and their illness had on individual patients.
- Staff we spoke with were able to tell us that extra support was available to patients via the referring NHS trust. This included access to social services and psychological services; support was also available from Fresenius
- Patients told us that if they had any concerns and worries they felt they could speak to the nursing staff, who would support them. During the inspection we witnessed support being given to a patient who was still coming to terms with making changes to their lifestyle.
- We saw that the staff in the unit had provided details of support networks that were available in information posters in the reception area, for patients and their relatives.
- Nursing staff were observed giving patients time to talk about any concerns. The manager was well known to patients and talked to them often throughout the day.

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

Responsive services are organised so that they meet your needs.

Service planning and delivery to meet the needs of local people

- Poole Dialysis Unit was contracted by a Dorset NHS trust to complete dialysis treatment. The local trust renal unit and consultant nephrologist team for haemodialysis referred the patients.
- Referral to the unit was based upon the patient being medically suitable for treatment in a satellite renal unit, and the responsibility for patients' care remained with the local NHS referring trust.
- The local clinical commissioning group was represented at contract meetings held with the Fresenius business manager for the Poole unit and the referring NHS trust
- The dialysis unit followed their corporate patient referral and acceptance to treatment policy. The policy outlined the criteria for acceptance to the unit. Renal association

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guidelines indicate that except in remote geographical areas the travel time to a haemodialysis facility should be less than 30 minutes; or a haemodialysis facility should be located within 25 miles of the patients' home.

- A full range of dialysis sessions were available for patients, taking into consideration working, cultural needs and family responsibilities. Staff told us of times when an extra session would be added to accommodate a patient in exceptional circumstances. We saw evidence of this, and patients told us they could change their dialysis session in order to accommodate family events and trips away.
- Some patients accessed the clinic using patient transport. There was no transport user group, but the clinic manager commented that patient feedback consistently highlighted transport as an area of concern. Patients told us delays in patient transport was their only complaint. The service monitored and reported on transport delays to the NHS trust, which commissioned the patient transport services.
- Parking facilities at the unit were plentiful and free for patients who were able to drive themselves for dialysis.

Access and flow

- Poole dialysis unit used an appointment system designed to minimise delays for patients as far as possible. We saw that staff had a flexible approach to the patients' dialysis sessions changing appointment days and or times as far as possible to accommodate external commitments/appointments or social events the patients may have. Patients told us they didn't have any choice about attending this unit but some choice with regard to appointment times.
- The appointments were staggered with a ten minute gap between each to minimise waiting times for the patients.
- The unit did not have a waiting list and for the first three months of 2017 was running at a capacity of between 71% and 73%.
- There were three dialysis treatment sessions provided daily on Mondays, Wednesdays and Fridays, and two sessions on Tuesdays, Thursdays and Saturdays. There were usually up to 22 patients for the morning 20 for the afternoon sessions and up to 14 patients for the evening sessions.
- We were told that the unit would employ more staff if there was a need to increase the current number of patients attending for dialysis.

- Information received prior to the inspection told us that there were no dialysis sessions cancelled or delayed for non-clinical reasons in the reporting period between January and December 2016.
- The consultant nephrologist visited the unit twice weekly to review prescriptions and see patients. We saw from records that each patient received a full review every three months.

Meeting people's individual needs

- The unit was accessible to patients who used wheelchairs. There was a hoist, as well as other moving and handling equipment for those patients needing manual handling assistance to access the dialysis chairs. The policy for patient referral and acceptance for treatment outlined the requirements for new referrals, to help the unit plan for new patients, such as making provision for patients with bariatric needs.
- There was a range of useful patient information in the waiting room, relating both to the haemodialysis process and to the clinic's performance. There were photos of the staff and information on who was on duty that day, so patients and visitors knew what to expect. Two wheel chair accessible toilets were available in the waiting area for patients to use prior to dialysis, and patients weighed themselves on the walk-on scales.
- The waiting area had a number of well-maintained notice boards with useful information for the patients, for example on nutrition; raising concerns; shared care; and a regular newsletter. 'You said we did / tell us what you think' comments, with the annual patient satisfaction results and analysis also displayed
- The unit provided information in formats which supported and reflected cultural diversity with the patient guide available in a number of language options. Access to translation services was arranged via the NHS hospital.
- We were informed that prior to attending the unit for treatment, all patients would be assessed to ensure their needs could be met. Throughout the inspection we did not see any patients who required materials in other formats to support their understanding of care and treatment.
- The NHS hospital rarely referred patients to the service who they assessed as needing additional support, for example because they lived with dementia or a learning disability. Staff told us they could accept patients with a learning disability and would arrange for such patients

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to be supported by a carer and social worker as required. This arrangement enabled the dialysis team to ensure that the patient understood the necessity for treatment and the practicalities of the routine.

- Patients had named nurses to take overall responsibility for their individual care. The named nurses had monthly discussions with patients and built relationships through regular reviews of their care and wellbeing. Due to shift changes, the named nurse did not have day-to-day responsibility for a patient's care, but the aim of offering named nurses was to develop a more holistic approach to care.
- Prior to commencement on dialysis, we saw that staff informed patients of their prescription to discuss the fluid removal level and their current weight.
- Patients were able to reduce the time they dialysed if they had appointments or family activities. We saw that patients completed early termination forms, consenting to the reduction in dialysis time. We were told that patients were informed that any time taken off a dialysis session was added at the next attendance.
- On-going monitoring of the treatment ensured that the needs of the patient at the unit could be met. Once a patient became medically unstable, they were referred back to the NHS trust for treatment.
- Patients had access to television with separate headphones in each bed space, and were able to bring in their own reading material or mobile devices if they preferred.
- During our inspection we observed one patient who was entirely self-caring. The unit also encouraged shared care which aimed to reduce the reliance of dialysis patients on nursing staff by enabling individuals to take control of their dialysis and equip dialysis nurses with skills to educate and support patients to take on greater responsibility for their own care. There were no patients on the program at the time of our visit.
- The unit had a nurse who took responsibility for supporting patients to arrange dialysis away from home. The liaising nurse shared paperwork, arranged a blood test one month in advance and ensured medicines were available at the receiving unit.

Learning from complaints and concerns

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

- We saw information displayed in reception providing patients and relatives on how to raise concerns and make a complaint. There were also feedback boxes available, to enable patients to make comments or suggestions anonymously.
- We were told that there were no written complaints made to the unit during the reporting period between January and December 2016. None of the patients we spoke with during the inspection had any complaints about the service, they were positive about the unit and the staff. They told us they knew how to make a complaint if they wished.

Are dialysis services well-led?

Well-led means that the leadership, management and governance of the organisation make sure it provides high-quality care based on your individual needs, that it encourages learning and innovation, and that it promotes an open and fair culture.

Leadership and culture of service

- The management team within Fresenius was organised into regions. An overall clinical service director supported the clinical staff. The regional head nurse had close contact with the unit and attended regularly for unit meetings, supporting new staff, providing simulation training and working closely with the clinic manager.
- The clinic manager was responsible for monitoring and leading on delivering effective governance and quality monitoring in the dialysis unit. We saw that the clinic manager was well supported by the knowledgeable wider management team which also included an area business manager.
- We were told by the medical consultant "the unit has visible and identifiable leadership. There is a very high level of cooperation between the management and medical staff."
- Within the unit, there was a deputy clinic manager to support the manager with the daily operation of the unit as well as team leaders for each shift.
- We observed relationships throughout the unit were positive, professional and friendly.

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- The clinic manager held team leader meetings monthly, and whole team meetings every quarter. We saw minutes of these meetings, which included feedback to staff regarding incidents and audit performance.
- We were told that the manager had an open door policy and saw staff and patients asked for advice, assistance or information when necessary.

Vision and strategy for this core service

- The vision of the service was set out in the corporate code of ethics and conduct document and within the employee handbook. The vision set out the business commitments and core values of the business.
- The mission and values included quality, honesty and integrity, innovation and improvement and respect and dignity. Senior managers were able to describe clearly that they were focused on providing high quality care for all patients and strived for continual improvement through auditing of patient outcomes, investment in new equipment, infection prevention, and environmental savings.
- Staff also had the company handbook, which provided an overview of Fresenius Medical Care and its values, aims and objectives. Staff said their focus was patient care and ensuring a good patient experience. They told us they liked working at the unit because they enjoyed supporting the patients.

Governance, risk management and quality measurement

- Fresenius's clinical governance policy described the clinical governance framework. The medical director chaired the clinical governance committee (CGC), which was a subcommittee of the Fresenius board. The CGC was responsible for establishing effective quality improvement practices, such as audit, updating practices and policies in line with best practice guidelines and developing the workforce. The strategy required clinics to report to the CGC each month, with their clinical governance meeting minutes, clinical variance reports, audit outcomes and reports on serious incidents, accidents and near misses.
- Corporate objectives were developed each year that focused on the patient, the employee, the community and the shareholder. These objectives were centred on improving patient outcomes and clinical effectiveness. All units received these and described actions taken to

improve compliance with clinic objectives. We saw evidence of the Poole clinic objectives, how they fitted with the corporate objectives and the progress of achievement.

- The Fresenius quality management system produced a monthly clinical dashboard, which was discussed with the area head nurse. This was a colour rated (red, amber, green) detailed analysis of the unit's performance against the key performance indicators (KPIs). We saw that each of the indicators had an explanation and an action plan for improvements where necessary. The area head nurse monitored and reviewed key performance indicators at a clinic review.
- The Poole Dialysis Unit worked closely with the local NHS trust. Monthly quality meetings included senior staff from both the NHS trust and the unit. We reviewed clinical governance reports and saw that patient concerns, access problems list, clinical variances, quality standards (dialysis outcomes for patients), and water testing reports were discussed.
- Fresenius had a clinical risk management policy dated 2009. This policy described the risk management principles and process for assessing risk.
- Senior Fresenius staff acknowledged that individual clinics had not set up systems for identifying and managing their key risks. This was an area that was being addressed corporately at the time of the inspection, with the appointment of a new quality and risk manager and the piloting of local risk registers at some clinics.
- The clinic manager in Poole had started to develop a local risk register to provide an oversight of risks associated in renal dialysis practice and the dialysis environment. The register was maintained electronically and we saw this at the time of inspection. The register reflected issues of concern relating to the environment for example some areas of the floor requiring repair; or non-conformities identified in OHSAS18001 Health & Safety accreditation surveillance report. The manager told us that this was now reviewed as part of the governance process and would be developed further in line with corporate developments.
- The unit had a contract for service provision in place with the local NHS trust. This contract had recently been extended and was due for renewal in 2018. This impacted on the decisions around an equipment replacement program.

Dialysis Services

- The Workforce Race Equality Standard (WRES) is a requirement for organisations which provide care to NHS patients. WRES has been part of the NHS standard contract since 2015, and is designed to ensure employees from black and minority ethnic (BME) backgrounds have equal access to career opportunities and receive fair treatment in the workplace. 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 currently have or maintain a WRES report or action plan to monitor staff equality.

Public and staff engagement

- The unit sought patient feedback in order to improve the service they provided. This was formally captured through the annual patient satisfaction survey in October each year. As a result of the feedback the clinic had introduced an introductory session to dialysis for patients when they first attended the unit for dialysis.
- We saw that newsletters and 'tell us what you think' cards were available in the waiting area so that patients could inform the team of any concerns or compliments. This feedback was shared with the regional business managers and they determined follow up actions with the unit where necessary.

- The unit also had a 'you said we did' initiative in place; information on the process was displayed for patients, but no outcomes or actions the staff had taken were displayed at the time of our visit.
- Patients on an end of life care plan were able to bring family members to quarterly clinical review meetings with the consultant to support them in decision-making.
- Patients were aware of a national forum but there was no local representative and none of the patients we spoke with were engaged with the national group.
- The unit also sought feedback from staff with an annual satisfaction survey. Staff we spoke with told us that they returned the completed survey and appreciated actions taken. The 2016 survey showed that 88% of staff thought their training helped them to do their job more effectively, and 100% would recommend their unit as a place to work.
- All Fresenius staff were given a handbook when they joined the company, which included advice on raising concerns, and the company's whistleblowing policy and process.

Innovation, improvement and sustainability

- Monthly Quality Assurance meetings which took place between the NHS medical staff, dietician, social worker and the unit manager or a deputy worked effectively.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

The provider must:

- Ensure that staff follow the organisation policy for administration of medicines which states that “Two registrants must check medication to be administered intravenously, one of whom should also be the registrant who then administers the IV medication.”
- Develop a policy and procedures for management of patients with sepsis to ensure staff are equipped to recognise symptoms and deal with them appropriately.

Action the provider **SHOULD** take to improve

The provider should:

- Take action to provide staff with procedures and training with regards to a positive identification process.

- Develop a dedicated falls risk assessment which is completed and reviewed for all patients; ensure that falls risks for patients are identified, assessed and monitored consistently.
- Refer to female genital mutilation and to PREVENT (anti-terrorism) within the corporate policy and guidance for staff in safeguarding and protecting vulnerable adults.
- Develop a replacement programme for the dialysis machines.
- Take action to monitor and publish data with regards to the Workforce Race Equality Standard (WRES).
- Take action to become compliant with the NHS England Accessible Information Standard.

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	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>How the regulation was not being met</p> <ul style="list-style-type: none">• Staff did not follow the corporate policy for safe administration of medicines prior to dialysis. The practice was not in line with Nursing and Midwifery Council (NMC) administration of medicines standards. <p>Regulation 12 (2)(g)</p>

Regulated activity	Regulation
Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>How the regulation was not being met:</p> <p>There were no systems or processes in place to support staff in the identification and management of potential sepsis in a deteriorating patient</p> <p>Regulation 12(1)(2)(a)</p>