

East Cheshire NHS Dialysis Unit

Quality Report

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unannounced inspection on 15 May 2017
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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

Overall summary

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 5 May 2017, along with an unannounced visit to the unit on 15 May 2017.

East Cheshire Dialysis unit is operated by Fresenius Medical Care Renal Services Ltd.

The unit has 10 dialysis stations in the main ward and two side rooms.

The service provides dialysis services for people over the age of 18, and does not provide treatment for children.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led?

Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate. Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

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

We found the following areas of good practice:

- There were processes in place to control and prevent the risk of infection. We saw that the environment appeared clean and audits of the environment took place to provide assurances. 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 chemical contaminants in water used for the preparation of dialysis fluid was monitored. Chlorine levels in water were tested daily and other contaminants such as nitrates tested monthly.
- We observed equipment stock used for dialysis treatment was CE marked. For example, dialysis needles and accessory kits. This ensured that all dialysis equipment was approved and compliant with relevant safety standards. This was in accordance with the Renal Association guidelines.

Summary of findings

- We saw there were appropriate processes in place to support those patients with blood borne viruses (BBV). There were two side rooms and there was routine blood testing for BBV.
- We observed that patient fistula's (fistula is a connection, made by a vascular surgeon, of an artery to a vein), or central venous catheters (venous catheter is a tube inserted into a vein in the neck, chest, or leg near the groin, usually only for short-term haemodialysis) were assessed pre and post dialysis for infection, with any variances recorded via the electronic system.
- The Fresenius service had developed a Nephrocare standard for good dialysis care based upon standards of best practice. The standards addressed the processes to follow immediately before, at the beginning, during and at the end of haemodialysis treatment and provided a guide for all staff to follow to ensure safe care and treatment for patients receiving treatment at the unit.
- 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.
- All patients we asked reported the staff were caring and respectful.
- Every patient had an individualised treatment prescription to ensure effective dialysis treatment.
- There was no waiting list for treatment. This meant that there were no patients waiting to start treatment.

- We observed that managers were visible and approachable on the unit and provided support to staff as required.

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

- The service does not have a policy or provide training for nursing staff with regards to identification or process for sepsis management. This was not in line with the NICE guideline (NG51) for recognition, diagnosis, or early management of sepsis. (Sepsis is a life-threatening illness caused by the body's response to an infection).
- Conversations and comment card responses were generally good, however, not all patients felt that communication and information from managers had been sufficient.
- The service did not have or maintain a Workforce Race Equality Standard (WRES) action plan or publish data with regards to monitoring staff equality.

Following this inspection, we told the provider that it should make improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals North Region.

Summary of findings

Our judgements about each of the main services

Service

Dialysis Services

Rating

Summary of each main service

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

Summary of findings

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East Cheshire Dialysis Unit.

Services we looked at

Dialysis Services

Summary of this inspection

Background to East Cheshire 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. This inspection was planned to check whether the registered provider was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

The service provides haemodialysis treatment to adults. The East Cheshire dialysis unit opened in 2010 and primarily serves the Macclesfield area population, with occasional access to services for people who are referred for holiday dialysis.

The registered manager (clinic manager) was available on the day of CQC inspection and we met the new clinic manager who was currently undertaking the induction process. Fresenius Renal Health Care UK Ltd has a nominated individual for this location.

The clinic is registered for the following regulated activities - Treatment of disease disorder or injury.

The CQC have inspected the location previously in 2012 and there were no outstanding requirement notices or enforcement associated with this service at the time of our comprehensive inspection in May 2017.

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 Lorraine Bolam, Interim Head of Hospital Inspection.

Information about East Cheshire NHS Dialysis Unit

East Cheshire dialysis unit is operated by Fresenius Medical Care Renal Services Ltd. The service opened in April 2010. The unit primarily serves the communities of the Macclesfield area.

The unit provides treatment and care to adults only and the service runs over six days, Monday to Saturday. There are no overnight facilities. There are two dialysis treatment sessions per day starting at 7am and 12:30pm. The service did not offer any twilight dialysis sessions.

The clinic has 10 stations, or bed spaces, in the main treatment area; two side rooms that were partitioned with glass. Access to the unit and car parking was available directly outside the unit. A security system was in place to access the unit.

Patients were referred to the unit by a local NHS Trust. The trust provided the unit with a consultant nephrologist visiting the dialysis unit twice a week and a dietician.

The unit was situated in the main building of a district general hospital in Macclesfield which was part of a large NHS Trust. Service level agreements were in place with the trust for example fire safety, water supply, and medical emergency response.

The unit on average over the past year provided 2173 treatment sessions to adults aged between 18-65 and 4397 treatment sessions to adults over 65. No services were offered to people under the age of 18. There were 43 people currently using the service.

During the inspection of East Cheshire dialysis unit, we spoke with a range of staff including, registered nurses, dialysis assistants, reception staff, medical staff, and senior managers. We spoke with eight patients. We also received 13 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed six sets of patient records.

Summary of this inspection

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. The most recent inspection took place in 2012. This was the clinic's first comprehensive inspection against the new methodology.

The dialysis unit has one ward and is registered to provide the following regulated activities: Treatment for disease, disorder and injury.

In the reporting period March 2016 to March 2017 there were 6570 day case episodes of care recorded at the unit; of these 100% were NHS-funded.

At the time of inspection 43 people received care and treatment at the unit. 15 people were aged 18 to 65 and 28 were aged over 65. There were five nursing staff including the clinic manager and two dialysis assistants and a team secretary in reception.

A consultant nephrologist from the local trust attended the clinic twice a week, and multi-disciplinary meetings were held monthly alongside the clinic manager.

There were no reported never events.

One in-patient death occurred at the unit in the past 12 months. The death was classed as unexpected and reported to the CQC.

There were two incidents that were classed as moderate or above that triggered a duty of candour process.

There were two inpatient falls reported in the past 12 months.

There were no incidences of healthcare acquired Methicillin-resistant *Staphylococcus aureus* (MRSA).

There were no incidences of healthcare acquired Methicillin-sensitive *Staphylococcus aureus* (MSSA).

There were no incidences of healthcare acquired *Clostridium difficile* (C.Diff) and no incidences of hospital acquired E-Coli.

There was one incidence of other bacteraemia associated at the unit.

There were a total three complaints made by patients at the unit.

The clinic is accredited against ISO 9001 quality management system.

Clinical and or non-clinical waste removal, interpreting services, laundry, pathology, fire safety, water Supply and building maintenance were provided at the hospital under a service level agreement.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

We found the following areas of good practice:

- There were processes in place to control and prevent the risk of infection. We saw that the environment appeared clean and audits of the environment took place to provide assurances. 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 observed equipment stock used for dialysis treatment was CE marked. For example, dialysis needles and accessory kits. This ensured that all dialysis equipment was approved and compliant with relevant safety standards. This was in accordance with the Renal Association guidelines.
- We observed that patient fistula's or central venous catheters were assessed pre and post dialysis for infection, with any variances recorded via the electronic system.
- We saw evidence that chemical contaminants in water used for the preparation of dialysis fluid was monitored. Chlorine levels in water were tested daily and other contaminants such as nitrates tested monthly.

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

- The service does not have a policy or provide training for nursing staff with regards to identification or process for sepsis management. This was not in line with the NICE guideline (NG51) for recognition, diagnosis, or early management of sepsis. (Sepsis is a life-threatening illness caused by the body's response to an infection).

Are services effective?

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

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.
- 100% of patients were receiving Hi Flux dialysis. This is considered to be a better form of dialysis for patients.

Summary of this inspection

- Three out of four of the nursing staff had a renal dialysis qualification, with one member of staff yet to complete the training. This training supports nurses to enhance their knowledge and practice in order to lead and deliver care and treatment to patients with a range of renal conditions.

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

- The service did not have or maintain a Workforce Race Equality Standard (WRES) action plan or publish data with regards to monitoring staff equality.

Are services caring?

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

We found the following areas of good practice:

- We observed that nurses had close working relationships with their patients. Interactions were positive, friendly and professional.
- All patients we asked reported the staff were caring and respectful.

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

- Conversations and comment card responses were generally good, however, not all patients felt that communication and information from managers had been sufficient. For example, a toilet was out of order and no updates were given as to when this would be repaired.

Are services responsive?

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

We found the following areas of good practice:

- Every patient had an individualised treatment prescription to ensure effective dialysis treatment.
- Parking facilities were available for patients, and we saw there were dedicated spaces outside the unit and transport was arranged for those who needed it.
- Patients were offered hot and cold drinks and sandwiches whilst receiving treatment.
- Patient information was provided in English, however could be obtained in other formats if required.
- There was no waiting list for treatment. This meant that there were no patients waiting to start treatment.

Summary of this inspection

Are services well-led?

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

We found the following areas of good practice:

- There was a clear leadership structure from unit level to senior management level.
- All staff we spoke with reported they had a good relationship with their managers.
- We observed that managers were visible and approachable on the unit and provided support to staff as required.
- The service followed a clinic environmental plan to monitor and reduce its environmental impact. The unit monitored elements such as air, water, and waste to ensure resources were not wasted.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

- The unit had an up to date clinical incident reporting policy for staff to follow, which was available to them through their intranet. The policy set out the accountability, responsibility and reporting arrangements for all staff in relation to incidents.
- We saw there was an electronic incident reporting system that captured details regarding clinical, non-clinical and treatment variance incidents that occurred on the unit.
- Treatment variances were recorded using an electronic patient record system. An example of treatment variance included when a patient decided they did not want to receive the full dialysis session as per their prescription. We saw that patients were required to sign a document to consent to not receiving the full treatment, and this was also documented on the electronic patient record.
- We saw that the service had a clinical and non-clinical reporting log to record incidents on the unit. This included the times when the emergency services had been called. The record log was used for monitoring purposes to ensure that any actions required were completed.
- All staff we spoke with had a good understanding of the reporting system and could access the system.
- The service had reported no 'never events' from February 2016 to February 2017. 'Never events' are serious, largely preventable patient safety incidents, which should not occur if the available preventable measures have been implemented by healthcare providers.
- Between January 2016 to December 2017, the unit reported a combined total of 800 incidents and treatment variances. This included two falls and one patient death. Of these 800 incidents, only two incidents were categorised as moderate or above and triggered a full investigation.
- We saw that incidents were reviewed and investigated by the appropriate manager to look for improvements to the service. Moderate and severe incidents were investigated through a process of root cause analysis (RCA), with outcomes and lessons learned shared with staff.
- We saw that the service followed their duty of candour policy following an incident where moderate harm and above had resulted. We saw from the electronic patient record that meetings had occurred with the patient and their family, and an apology letter from the clinic services director had been sent. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person.
- Staff we spoke with were aware of their duty of candour regulatory duty and reported that duty of candour training was available through on line learning as part of the fundamental nursing skills training. The training matrix from the provider showed that only the clinic manager had completed this training.
- The clinic manager, area head nurse and regional business manager had oversight of any incidents that occurred within the unit. Once the incident form had been completed, the clinical incident forms were sent to the clinical incident team for triage. This team screened

Dialysis Services

the incident to ensure that the detail and quality of the incident report was sufficient. If required a safety bulletin could be produced to share across the organisation to aid learning.

- Non clinical incidents were reported to the health and safety team. We were informed that they could also produce a safety bulletin to aid shared learning.
- We saw evidence from team meeting minutes and unit bulletins that incidents were discussed to share learning following the occurrence of an incident. For example, we saw that a safety bulletin had recently been produced to ensure that all staff verbally confirmed the identity of the patient and compare with the patient documentation in order to ensure patients received the right treatment. We saw the bulletin was shared with staff and they had signed to say it had been read.
- We saw that following an incident where a dialysis line had become disconnected, staff double checked to ensure lines were securely fastened and patient vascular access was not covered. This ensured staff could visibly see the dialysis line connection. We observed that a poster had been placed on the notice board to remind patients that they should refrain from covering their vascular access site with clothing or blankets. Patients we asked confirmed that staff checked that dialysis lines were connected properly.
- Clinical, non-clinical and treatment variance incidents were reported into the clinical governance framework to monitor numbers and themes of incidents. We saw that these were reported to the trust and the corporate Fresenius senior managers had oversight.

Mandatory Training

- 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. Staff we spoke with told us that it had been difficult to complete training due to past staffing shortage levels but this had now improved.
- Mandatory training included fire training, moving and handling, adults and children's safeguarding, and evacuation training

- We saw evidence of training records on a database that indicated whether staff had completed their mandatory training modules. The system used a colour coding system that highlighted in red if a staff members training had expired.
- The training records database showed that all staff had completed their mandatory and their training record was up to date.
- Staff training was co-ordinated and monitored by the unit manager to ensure staff training was completed.

Safeguarding

- The clinic manager was the safeguarding lead for the unit. However, the unit linked into the safeguarding team at the unit's hosting trust for safeguarding advice and support.
- All staff we spoke with were aware of their safeguarding adults and children responsibilities and who to contact if guidance was required.
- Staff were trained to recognise adults at risk and were supported with a safeguarding policy which they could access via the intranet.
- Data provided by the service showed that all staff had completed safeguarding adults and children level 2 training.
- There were no services delivered for persons under the age of 18 years. However, staff received this training as children may visit the unit.

Cleanliness and Infection control

- All staff we spoke with were aware of their safeguarding adults and children responsibilities and who to contact if guidance was required.
- Staff were trained to recognise adults at risk and were supported with a safeguarding policy which they could access via the intranet.
- Data provided by the service showed that all staff had completed safeguarding adults and children level 2 training.
- There were no services delivered for persons under the age of 18 years. However, staff received this training as children may visit the unit.

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- We saw that there was an Infection Prevention and Control (IPC) policy in place to maintain a safe environment for patients, visitors and staff.
- Between March 2016 and March 2017, the service reported no cases of Methicillin-Resistant Staphylococcus Aureus (MRSA) and 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.
- In June 2016, the service reported one healthcare acquired bacteraemia. We saw evidence that this had been incident reported and actions taken. Action included removal of the central venous catheter and the access site moved to a fistula.
- 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 observed that staff cleaned and disinfected each dialysis machine, 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 service had a contract with an external cleaning partner to provide cleaning services outside of the unit working hours. We saw evidence that standard operating procedures were used for each activity that included how to mop the flooring. Standards were maintained by auditing by the cleaning supervisor.
- We saw Personal Protective Equipment (PPE), and hand sanitising gel was available across the unit. We observed staff were compliant with 'bare arms below the elbow' guidance and that PPE was used on a regular basis in line with their policy.
- The service had an IPC lead from the local trust to provide staff with advice and support with infection control issues and to support infection prevention audits.
- The service completed hygiene and infection control audits on a monthly basis. Results from January to March 2017 showed 100% compliance with the audit. In April 2017, results showed 95% compliance. Findings included clutter on the nursing station and the spare dialysis machine room was untidy. Action were taken immediately to rectify any problems found and signed once completed. We found all areas of the dialysis unit to be free from clutter.
- Observational hand hygiene audits were completed on a monthly basis. Audit results for January and February 2017 showed 100% compliance against the audit. In March 2017, the compliance rate was 95%. Actions included reminders given to staff to ensure future compliance. We saw that audit findings were discussed in team meetings and results posted in the staff areas. We saw from our observations that staff adhered to good hand hygiene principals.
- In the patient satisfaction survey, 96% of patients thought the unit was clean, and from our observations, the unit appeared clean.
- Procedures were in place to screen patients monthly for blood born viruses (BBV) such as Hepatitis B, C and HIV.
- Those patients identified as carriers of Hepatitis C or with HIV were dialysed in a side room using their own dedicated dialysis machine.
- 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.
- We saw evidence that all staff had completed training in infection control and prevention and all staff were conversant with infection control principles.
- We saw evidence that chemical contaminants in water used for the preparation of dialysis fluid was monitored. Chlorine levels in water were tested daily and other contaminants such as nitrates tested monthly to ensure the quality of the water used. This testing was in-line with the Renal Association guideline 3.3 – HD: Chemical contaminants in water

Dialysis Services

used for the preparation of dialysis fluid. 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.

- We saw that dialysis fluid was produced by the mixing of treated water, acid (dialysate) and bicarbonate concentrates to provide ultrapure dialysis fluid, free from microbiological contaminants. This was in-line with the Renal Association haemodialysis guideline 3.5. We saw evidence that an audit programme was in place and contaminants were monitored. We saw that the chemical contaminants within the water had been tested in February 2017 and met the relevant international standards organization (ISO) 13959 standard.
- The unit had two side rooms per 12 dialysis stations for patients who carried infection or were at risk of infection. This was in line with the health building note 04-01 supplement A – isolation facilities in acute settings.
- We observed that all dialysis lines were pre-packed and were for single use only. Once dialysis treatment was completed, we saw that all used lines were disposed of in clinical waste bags and any needles placed in sharps bins.

Environment and equipment

- 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 to stand with mobility difficulties.
- All corridors were wide to provide ample access to the main ward treatment area and were suitable for wheelchair use.
- All areas of the unit flooring were easy clean surfaces in case of spillages and appeared free of dirt and staining.

- We observed that the clinic manager carried out spot checks of the environment to ensure the all areas of the unit were kept clean.
- Access to the unit was controlled. Patients and visitors were required to press a call bell to gain access.
- There was a receptionist to welcome patients and visitors to the unit, and visitors were required to sign in. We observed that the receptionist was professional and friendly.
- All storage areas, including the dirty sluice room were well organised and tidy. Stock was placed on shelving and we observed that stock was rotated.
- 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 guidelines. Guideline 2.2 - HD: Haemodialysis equipment and disposables.
- We saw that all dialysate was CE marked in accordance with the Renal Association guidelines. Guideline 3.1 - HD: Concentrates for haemodialysis. This ensured that the dialysates used met the required standards for safe patient treatment.
- We saw that the water treatment plant was organised and appeared clean and tidy.
- We observed that spare dialysis machines were kept on site. The unit had four spare dialysis machines in case a fault developed on any of the machines on the main ward. We saw that these machines appeared clean and ready for use.
- There was adequate space between dialysis chairs to allow for privacy, but also space for staff to be able to attend to patients.
- Side rooms had internal floor to ceiling windows so that staff were able to safely maintain visual contact with patients receiving treatment.
- The nurses' station was located centrally to the ward area, so that staff were able to maintain visual contact with patients.

Dialysis Services

- We observed that a nurse call bell system was in use. We saw that staff attended to patients needs quickly following the call bell being used.
- All staff and managers reported that new dialysis machines had been ordered and were due for delivery in July 2017. Managers reported that there was a system of replacement of dialysis machines after seven to ten years. This was in line with the renal association guidelines. Guideline 2.3 - HD: Haemodialysis equipment and disposables.
- We observed that a program of maintenance for the equipment was place to ensure continuity of service. Technicians that visited the unit carried out maintenance. Staff we spoke with reported that technicians provided a good service and attended quickly if a fault developed.
- We saw from staff files that competencies were in place for all medical devices. This included the use of the dialysis machines and safety equipment. For example the defibrillator.
- We saw evidence that electrical safety testing was being completed across the service. We reviewed five items of electrical equipment including printers and scales and saw that they had been tested and safe for use in September 2016.
- Emergency equipment was checked consistently, with items appropriately packaged, stored and ready for use.
- The clinic manager was the lead responsible for the safe and secure handling and control of medicines, and was available on the unit to provide support and guidance. There was also a deputy clinic manager to provide guidance if required.
- The nurse in charge held the keys for the medicine cabinet. We observed that medicines cabinet was kept locked.
- We saw that all medicines in the medicines cabinet were in date and records kept of expiry dates.
- The unit did not store or administer any controlled drugs.
- The service did not use any patient group directions (PGD's) and none of the nurses were trained in non-medical prescribing.
- Fridge and room temperatures were all within normal ranges which meant that medicines were stored at the correct temperature. Records indicated that staff completed daily fridge and room temperature checks in line with their corporate policy.
- Staff had access to pharmacy support from the local NHS trust pharmacy for additional advice relating to dialysis drugs and the service head office had pharmacy support for staff to access.
- The NHS consultant completed all medication prescriptions. We saw that the medicines prescriptions were kept on the electronic system and were printed out into the paper patient records.
- We observed that nursing staff administered medication following the NMC standards for medicines management. We observed that staff checked identity of the patient against the prescription and signed the prescription form immediately. We saw no medication was left unattended.

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.
- We saw that every patient had an individualised treatment prescription. Any changes to these prescriptions are made by the nephrologist who visited the unit twice weekly. 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.

Records

- The dialysis unit used a combination of electronic and paper records. Data was uploaded daily from the electronic record to the referring trust database in order for data sharing. This ensured that Consultant Nephrologists had access to the patient records at all times.

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- Staff were competent in its use and all had received training in order to effectively use the system.
- We observed six patient records and saw that the staff updated the electronic record throughout the patient's treatment in order that the record was complete and contemporaneous.
- The records contained all patient demographics including height, weight along with the patient prescription and blood results.
- Any variances to treatment required staff to complete a treatment variance record. This included if the patient wished to terminate dialysis prior to the required treatment time. We saw that the patient also signed an early termination report. This was also 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 prior to commencement of a new session. This ensured that staff were aware of any specific issues relating to care and treatment.
- As the electronic system was used across the organisation, this enabled other dialysis units to share information if a patient moved area to access treatment.
- We saw that a referral form was completed by the trust for all new patients requiring treatment. The referral form included patient demographics, treatment required and a quality of data check to ensure that all fields of the referral were completed prior to the commencement of treatment. This ensured the unit had the necessary information regarding the patient to ensure their needs could be met.
- Staff completed a patient concerns record that was shared electronically with the nephrologist. The record highlighted any problems encountered in treatment and further advice and support required. We saw that patient concerns were discussed within the monthly clinical governance meeting.
- We saw evidence that a records audit had been completed in March and April 2017. The April audit

highlighted two forms missing from the paper record. These included a consent form and a patient training record. Actions were included to rectify the missing forms.

- Records were also checked as part of the area head nurse internal unannounced inspection. We saw evidence that records checks were completed as part of the June 2016 unannounced inspection.

Assessing and responding to patient risk

- Prior to commencement to treatment, patients were assessed for their suitability for treatment at the unit. Only once the patient was deemed stable for treatment 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.
- Patients were clinically assessed on each visit and any issues highlighted to the clinic manager and to the nephrologist. We were informed urgent issues were discussed immediately with the nephrologist or registrar. All other issues were documented using a patient concerns register for review when the nephrologist visited the unit. Any patients whose needs deteriorated were referred back to the local NHS trust to receive their treatment until clinically stable.
- Patient records contained completed assessment 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 to minimise the occurrence of falls.
- Routine monthly blood samples were taken to screen blood for blood borne viruses, and further blood samples could be taken if necessary between the monthly routine blood samples. A service level agreement was in place for blood samples to be examined by the dialysis unit host trust in Macclesfield.
- We saw that prior to dialysis needle insertion, needles were primed using a syringe with saline. This is considered best practice and we observed that this

Dialysis Services

process was outlined in the Nephrocare standard for good dialysis care procedures for the staff to follow. We also saw that this had been raised in a safety bulletin to ensure that staff followed this process.

- We observed that each dialysis machine had an alarm guard so that significant risks such as detection of a dislodged needle could be identified to prevent significant blood loss. We saw nursing staff attended promptly when the alarm sounded to ensure the safety of patients.
- Patients used nominated dialysis machines to aid tracking and traceability.
- We observed that patient fistula's or central venous catheters were assessed pre and post dialysis for infection, with any variances recorded via the electronic system.
- We observed that for patients with a central venous catheter (CVC), a multi-racial visual inspection catheter tool (Mr Victor) was used. This guide provided nursing staff with a consistent and recognised description of the condition of the CVC using a score of 0-4. The assessment tool provided nurses with pictures and guidance on the assessment and monitoring of CVC's to quickly highlight signs of infection.
- From the records, we observed that the electronic system recorded information with regards to vascular access (VASACC). The records we reviewed showed that nurses assessed the vascular access site prior to any treatment and recorded their findings.
- Patients on the shared care pathway used their electronic card which was picked up on arrival to the main ward to record their weight. Prior to commencement of the treatment staff checked patient identity and prescription. Prior to commencement, the dialysis machine also prompted staff to confirm the patient identity. This process ensured that patients received the correct treatment, as the machine would not progress until the identity had been confirmed and a button pressed on the dialysis machine. Patients we spoke with confirmed that their identity was confirmed prior to treatment.
- Patients were monitored throughout their dialysis treatment. Mid-point assessments were completed and documented by the nursing staff. We saw evidence of this in patient records and observed practice.
- Although there was not a formal early warning score system in place. We observed in one patient record that observations were increased to every 15 minutes as the patient's condition had deteriorated. All staff we spoke with confirmed that they checked to ensure patients remained stable and explained the process to follow if a patient deteriorated.
- As the dialysis unit was situated in a district general hospital, a process was in place with the trust if a patient required immediate escalation. The service had access to the trust cardiac intensivists should a patient suffer a cardiac arrest. Staff we spoke with were aware of the process to follow.
- The unit did not have a policy or training for staff with regards to identification or process for sepsis management. This was not in line with the NICE guideline (NG51) for recognition, diagnosis, or early management of sepsis. Sepsis is a life-threatening illness caused by the body's response to an infection. However, staff had a good understanding of sepsis and patients could be transferred to the hosting trust accident and emergency department should sepsis be identified. Senior managers we spoke with were looking at a process to support staff with sepsis management that included adopting the referring trust sepsis process. We saw this was on the newly developed risk register, however we did not see that a formal risk assessment at the dialysis unit had been completed.
- Data provided by the service showed between February 2016 to February 2017 three patients were transferred to accident and emergency with suspected sepsis. This confirmed that staff had a recognition of sepsis and the need for transfer to an acute hospital setting.
- We observed that patient temperature, blood pressure, pulse was taken and recorded throughout patient treatment to monitor patient's physical condition. Staff also asked patients how they were

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feeling in order to establish if a patient was deteriorating. We observed this during the inspection and patients reported that they were monitored throughout their treatment.

- From February 2016 to February 2017 a total of 48 patients were transferred to another health care provider. This included those patients that attended the accident and emergency department whilst receiving treatment on the unit due to their health deteriorating. Data provided by the service showed the service had transferred patients back to hospital due to various medical conditions. This included patients with reduced mobility, pneumonia, bacterial infections and sepsis.
- We saw that Heparin (anticoagulants) were used for patients who were not at risk of bleeding to reduce the risk of clotting. This was in line with Renal Association guidelines. Guideline 7.1 - HD: Anticoagulation without added risk of bleeding. Anticoagulants were prescribed by the nephrologist and only given as part of the patient prescription.

Staffing

- 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 staff ratio with a skill mix of 67% nurse staff and 33% dialysis assistants. The service provided 70% nurse staff to 30% dialysis assistants. The ratio was established to ensure there were always two trained nurses on shift during dialysis sessions.
- We observed that staffing rotas were based upon the numbers of patients requiring treatment to ensure there were adequate staff to the numbers of patients. We were informed that the clinic would not start unless there were two trained staff on shift to maintain patient safety. Staff confirmed this process and staffing rotas we looked at confirmed there were always two trained nurses on shift.
- The service employed eight staff that included a clinic manager, a deputy clinic manager, team leader, two further dialysis nurses, two dialysis assistants and a secretary on the main reception.
- Information provided by the unit showed that there was one team vacancy for a registered nurse. The vacant post was for 23 hours.
- From March 2016 to March 2017, the service reported there had been 25 shifts covered by bank staff and 32 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.
- All staff we spoke with highlighted that their only concerns was due to the need for more staff on the department to provide safe care and treatment.
- Patients we spoke with and comment cards we received from patients highlighted that they had been concerned over the staffing levels. However, staff and patients acknowledged that staffing levels over the past month had improved.
- We saw evidence that duty rotas were completed four weeks in advance and managers were working towards moving to rotas eight weeks in advance. The regional business manager was responsible for authorising bank and agency staff.
- We saw evidence that staff levels were improving. Bank and agency staff use in the four weeks from 3 April 2017 was 52 hours. This had improved to 34 hours in the four weeks from 1 May 2017. The forward planned rota from 29 May 2017 only required 11.5 hours.
- Managers reported that rotas were completed on time, however filling last minute sickness was an issue.
- We observed that the rotas were completed using an electronic system that highlighted how many staff were required per day dependent on the number of patients attending for treatment.
- Bank and agency staff were arranged by a renal flexi bank team to support co-ordinating staff across the organisation.
- A new clinic manager had commenced employment within the last month. The existing clinic manager was also in post to provide the necessary training and mentorship. We saw there was an induction pack that

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included visiting other areas of the corporate business to understand how the business operated. The new clinic manager reported that the induction was thorough and enjoyable.

- The dialysis unit was a nurse led service, with a nephrologist visiting twice weekly to review patients. Staff and managers reported they were able to access the nephrologist or registrars through the trust if they needed advice and support and were contactable via phone, email or pager. For advice and support out of hours there was a bleep system available.
- There was an associate specialist available to support when the nephrologist for the unit was not available, covering annual leave and absence.
- The unit did not employ any service technicians. Technicians employed by the organisation, completed routine maintenance, and provided both telephone support and on-site support as necessary. Staff we spoke with told us that any queries were quickly dealt with.

Major incident awareness and training

- The service had an Emergency Preparedness Plan. This highlighted the actions taken in event of an emergency. This included actions to take in the event of a fire, water loss or loss of electricity.
- A service level agreement existed with the unit's hosting trust for fire alarms, water and emergency response to a critically ill patient.
- Staff understood their responsibilities in relation to major incidents and received training in evacuation.
- We saw that the emergency plan contained relevant emergency telephone numbers to contact in the event of an emergency.
- 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.
- We saw the unit had fire extinguishers that were secured to the wall and within their service date, and were ready for use in the event of a fire.

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 all patients receiving treatment had their vascular access site monitored and maintained prior to dialysis. We observed nurses to visual monitor the access site and record any variances using the electronic system. 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 service had developed a Nephrocare standard for good dialysis care based upon standards of best practice. The standards addressed the processes to follow immediately before, at the beginning, during and at the end of haemodialysis treatment, and provided a guide for all staff to follow to ensure safe care and treatment for patients receiving treatment at the unit. The standard provided staff with a standard working instruction to ensure best practice was followed and all staff completed treatment the same way to the same standard. Staff were aware of the guidance and we observed staff to follow the guidance.
- Policy and procedures were linked to the Nephrocare standard for good dialysis care. The Nephrocare standard set out procedures 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. This was linked to a local hygiene policy (UK-CI-09-04) with the rationale to prevent contamination risks. We observed that staff followed this practice.
- We were informed that new dialysis machines had been ordered to enhance the delivery of dialysis care to patients. We were informed that the new machines would offer greater opportunity for patients to self-care and opportunities for home care dialysis. At

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present the dialysis unit did not offer any home care dialysis opportunities. This did not meet NICE guidance QS72 Statement 5: Adults who need long term dialysis are offered home based dialysis.

- Patients receiving care at the unit were carefully accepted to ensure their needs could be met. As the unit was a nurse led unit with a nephrologist visiting twice weekly, the referring trust renal unit treated patients with complicated medical histories and problematic dialysis access sites. This ensured that patient care needs were planned and delivered safely.
- Staff received training in equality, diversity and human rights. Staff we spoke with informed us that patients were 'like family'; they knew them well and respected religious and cultural beliefs.
- 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.
- Data uploaded to the local NHS trust with regards to efficacy of the service provided at the dialysis unit was used for inclusion for the renal registry. The inclusion of this data supported benchmarking for the NHS trust.

Patient Outcomes

- Information about the outcomes of patients' care and treatment was collected and monitored by the service to ensure good quality care outcomes were achieved for each patient. This data was monitored via a clinic review report and shared with the area head nurse to be able to support the unit to achieve expected results and outcomes for patients.
- Results and treatment data were captured by the service electronic system which fed into the trust database for inclusion to the UK Renal Registry.
- Submission of data to the UK Renal Registry was undertaken by the parent NHS Trust. The unit data was combined with the parent NHS Trust data and submitted as one data set. This data set only included patients under the direct care and supervision of the trust.

- As the UK Renal Registry data is representative of all parent NHS trust patients this does not permit the review of patients and outcome trends specifically treated within East Cheshire dialysis Unit. Therefore, data specific to the unit and available via the electronic database was used to benchmark patient outcomes at clinic level and nationally against all Fresenius Medical Care UK clinics.
- We saw that the electronic system provided reports, trend analysis to monitor patient outcomes and in turn quality of life. Data could be viewed 'live' by the clinic manager and consultant to monitor individual dialysis performance.
- Data provided by the service showed that 100% of patients were being dialysed using Hi Flux haemodialysis. This provides higher rates of removal of small and middle molecules and may lower the risk of developing complications due to dialysis related amyloidosis (a group of diseases in which abnormal protein, known as amyloid fibrils, builds up in tissue). In patients with established renal failure if it was shown in randomised controlled trials to provide better patient outcomes. This was in-line with Renal Association Guideline 4.3 - HD: High flux HD and haemodiafiltration.
- Dialysis treatment times (frequency of haemodialysis) were monitored by the service. Data supplied by the service showing the quality standard 90 days after admission to the unit showed from January to April 2017, 97% of patients received haemodialysis (HD) three times per week. This was in-line with the Renal Association guidelines. Guideline 5.1 - HD: Minimum frequency of haemodialysis, recommends that HD should take place at least three times per week in nearly all patients with established renal failure.
- The service used standard methods of measuring dialysis dose. Urea Reduction Ratio (URR) is the most widely used index of dialysis dose used in the UK. URR is the percentage fall in blood urea achieved by a dialysis session and studies have shown the URR should be at least 65%. Data provided by the service showed from January and February 2017, 100% of patients achieved at least 65% reduction and from March to April 2017, 97% of patients achieved at least 65% reduction. This was in-line with Renal Association guidelines. Guideline 5.3 - HD: Minimum dose of thrice

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weekly haemodialysis - recommends that every patient with established renal failure receiving thrice weekly HD should have consistently either urea reduction ratio (URR) > 65% or equilibrated Kt/V of >1.2 calculated from pre- and post-dialysis urea values.

- Patient blood was tested for potassium, phosphate, calcium aluminium concentrations in-line with the renal association guidelines. Guidelines 6.4 to 6.7. We saw that blood results were contained in the electronic records so they could be reviewed by the nephrologist. The renal association sets out guidelines for dialysis units to follow based on evidence and research. The guideline promotes the adoption of a range of standardised audit measures in haemodialysis; promote a progressive increase in achievement of audit measures in parallel with improvements in clinical practice, to achieve better outcomes for patients.
- We saw patients' blood results were monitored each month as per a defined schedule provided by the NHS Trust Consultant. These bloods were individually reviewed monthly to audit the effectiveness of treatment and define/action improvements and changes to care provision to improve outcomes.
- Pre dialysis serum potassium in patients' blood was monitored on a monthly basis. The Renal Guidance suggests that pre-dialysis serum potassium should be between 4.0 and 6.0 mmol/l in HD patients. Audit data from the quality standard 90 days after admission, showed that from January 2017 to April 2017 the percentage range of patients whose pre dialysis serum potassium within these parameters was 68% to 79%. Guideline 6.4 - HD: Pre-dialysis serum potassium concentration.
- Patient haemoglobin (HB) levels were measured to ensure that they remained within 10.5-12.5g/dl target range. Data provided by the service showed from January to April 2017, the percentage range of patients with a HB within this range was 59% to 76%. We saw as part of the action plan that the service had acted to ensure timely changes to prescription charts for Erythropoietin injections (stimulates the production of red blood cells) in response to consultant review of monthly blood results.

- The service did not participate in audits of travel time or waiting time pre and post dialysis.
- From May 2016 to May 2017, there were 156 patients who did not attend for dialysis. We were informed that any patient that did not attend (DNA), they would contact the patient or family member if they were not able to make contact. This was reported as a treatment variance and highlighted to the nephrologist. We saw that DNA's were recorded using the electronic system and reports of who did not attend, and how often, could be produced for discussion with the consultant nephrologist.

Pain relief

- Local anaesthetics prior to dialysis needle insertion were available if required by the patient as part of their prescription written by the nephrologist. We did not see any patients that required this during the inspection.
- Staff we spoke with informed us that pain relief medication such as paracetamol was written on the patient prescription by the consultant as PRN medication (as required). Once pain relief was given we saw that this was recorded appropriately on the drug administration record.

Nutrition and hydration

- A dietician visited the dialysis unit on a twice-monthly basis. We saw evidence that patients were seen with regards to their nutritional and hydration needs, with summaries of their plans recorded in the patient paper records.
- We saw that dietetic advice booklets were provided to patients explaining fluid allowances and why diet was important. The booklets contained sample menus and there were separate booklets for those patients with diabetes.
- Patients were provided with hot drinks, biscuits and sandwiches whilst receiving treatment.
- We saw that sandwiches were stored in fridges and offered to patients as directed by the dietetic service.
- One Patient informed us that as they were on the unit early in the morning they would have preferred to have snacks earlier than they were currently being given.

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- In reception, there was a fresh water cooler for patients and visitors.

Competent staff

- 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, although this had been problematic due to low staffing levels in the past.
- 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 and patient holiday co-ordinator.
- Three out of five of the nursing staff had a renal dialysis qualification, with one member of staff yet to complete the training. This training supports nurses to enhance their knowledge and practice in order to lead and deliver care and treatment to patients with a range of renal conditions.
- New members of the team were provided with a mentor to support them through their learning. We saw in staff records that mentorship competencies were completed to ensure they were appropriately trained to provide mentorship to new starters.
- New staff completed a training and education progression plan. This included a wide range of essential training such as vascular access techniques, management of intravenous cannulas and dialysis machine use and decontamination. Following the supernumerary period staff commenced a probationary and supervised period that has individually tailored to them.
- We reviewed four staff competency files and saw that courses certificates were included, and an integrated competency document with dates and signatures of competencies completed. Competencies included medical devices, infection control and medicines management.
- Evidence provided by the service showed that all staff had received an appraisal within the last 12 months. We reviewed that appraisals included a review of current objectives and set future objectives to aid development. For example, available courses and training. However, although the appraisals were kept in the manager's office they were not kept in a locked cabinet at all times. The documents contained personal private information and should be stored with personnel records which was kept locked at all times. We raised this with the clinic manager and they were moved to a secure locked cabinet.
- We were informed that all staff had undergone a disclosure and barring service (DBS) check. We were informed by managers that this was completed on commencement of employment but was not routinely done thereafter by human resources. However, the employee handbook did state the any new convictions should be disclosed to the employer.
- We saw evidence that the service had a nurse revalidation log. This supported the clinic manager to ensure that all staff had gone through the revalidation process. This meant the service conducted annual checks to make sure all the nurses are registered with the Nursing and Midwifery Council (NMC) and is considered good practice.
- We observed that an electronic training database provided information as to training completed by the staff. The database included dates that training needed to be completed and any out of date training was highlighted red.
- All registered nursing staff had completed immediate life support training (ILS) and all dialysis assistants had completed basic life support training (BLS). This training provided staff with the knowledge and skills to be able to respond to patients requiring resuscitation.
- We saw from the internal unannounced inspection completed by the area head nurse in June 2016 that simulation resuscitation training was completed in order for staff to practice their skills.
- Fire safety training was provided by the host trust for the dialysis unit. This ensured that all staff were aware of the trust guidance on evacuation and fire drill procedures.
- Staff at the unit had not received training on the recognition and management of sepsis. However all staff we spoke with reported that any signs of patient deterioration was immediately recorded, observations

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increased, and escalated for a senior to review. This included phoning for emergency assistance or escorting the patient to the accident and emergency department situated on the same floor in the hospital close to the dialysis unit. We saw one record that showed that observations were increased following a patient deteriorating whilst receiving dialysis.

- Managers informed us that poor or variable performance was monitored. This included sickness absence. Where staff underperformed, then improvement plans were implemented and further training supported.
- Staff at the dialysis unit did not carry out blood transfusions. We were informed that if a patient required a transfusion this would be done at the local NHS trust.

Multidisciplinary working

- The nephrologist had overall responsibility for the care and treatment of the patients on the unit and visited twice a week to review their care. We saw evidence of patient reviews and changes in prescriptions within the patient records.
- The nephrologist provided the GP with the necessary information as to the patient's current treatment. Any letters were kept on file within the patient record.
- The clinic manager held monthly meetings with the nephrologist to discuss patient's treatment plans and any treatment variances.
- We saw evidence that dieticians routinely provided input into the patient treatment plans and when available attended the multidisciplinary meetings.
- Patients could access psychological, counselling or therapy services through a referral process to the referring trust.

Access to information

- Staff told us they had access to policies and procedures through the electronic database.
- Patient records were easily accessible via the computer terminals. All staff had secure, personal log

in details and had access to e-mail and all hospital systems. We observed that no computer terminals were left unattended displaying confidential information.

- 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 the instructions ensured that staff maintained the safety of patients at all times.
- Staff had access to all blood results which were shared with the referring trust
- The nephrologist was able to access both the trust database along with the dialysis unit database to ensure they were informed of the treatment outcomes for each patient.
- The nephrologist provided the necessary information for the staff on the unit to be able to provide the correct treatment for each patient through their individual prescription. We saw prescriptions were printed out and kept as a paper record.
- We saw that all relevant care plans were available and took into account the mobility of the patient and pressure areas.
- Patients were able to access their blood results in order to remain informed about their condition.
- Patients were actively encouraged to take part in shared care. We saw that patients weighed themselves upon arrival to the ward. This information was captured on the patient identification card and used to start the dialysis process.
- The dialysis unit database uploaded to the trust database daily to ensure the trust had the latest information to support data collection and ensure the nephrologist received the latest dialysis information for every patient.

Equality and Human Rights

- From 1st August 2016 onwards, all organisations that provide NHS care were legally required to follow the Accessible Information Standard. The standard aims to make sure that people who have a disability,

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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 saw that the service was aware that they currently did not fully meet this standard and was listed on the risk register.
- The risk register highlighted the actions Fresenius planned to take which included a full assessment of accessible information criteria, so Fresenius can understand their NHS partner approach, policy, procedures and 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.
- 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.

Consent, Mental Capacity Act and Deprivation of Liberty

- The unit had a current policy for consent to examination or treatment. This was available for staff on the intranet.

- Staff were able to demonstrate their knowledge of consent and mental capacity and staff told us if there were concerns over a patient's capacity to consent, they would seek further advice and assistance.
- Patient records contained a consent to treatment record. We reviewed four patient records and found they had been fully completed including date and signature. Consent forms were required in order to start treatment at the dialysis unit.
- Prior to commencement on dialysis, we saw that staff informed patients of their prescription to discuss the fluid removal level and their current weight.
- At the time of inspection, all patients receiving treatment had capacity to consent to treatment.
- Patients who lack the capacity to consent to treatment would be referred to the referring NHS trust. Any new patient attending the clinic who lacked the capacity to consent to treatment would need to have been assessed and best interests decisions made prior to treatment. This ensured that the service was able to best meet the needs of the patient.
- All patients had a care plan and risk assessments in order to provide staff with the necessary information to provide safe care and treatment. We saw that initial referrals to the unit also contained patient specific information to support safe care and treatment.

Are dialysis services caring?

Compassionate care

- We spoke with eight patients and we received 13 CQC comment cards. From our conversations and the comments received, patients informed us that nurses treated them with dignity and respect.
- Comments included 'all the nurses are great' and a 'wonderful service'. All comments regarding the care and treatment from nursing staff were positive.
- We observed that nurses had close working relationships with their patients. 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.

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- We observed that curtains were pulled round if a patient required some privacy.
- Facilities were provided to provide comfort and support for patients. We saw that the dialysis chairs were electrically operated with pressure relieving mattresses to maximise comfort during treatment.
- From the comment cards, and our conversations with patients they all reported that the staff were caring and respectful.
- All patients we asked reported they felt safe having dialysis at the unit.
- 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.
- Private conversations were difficult to have on the ward due to the close proximity of the dialysis chairs. However, following dialysis we were informed private conversations could be had in the clinic room or the manager's office.
- The service completed a patient satisfaction survey in 2016. Results from the survey showed that 64% would recommend the service to family and friends and 77% thought the unit was well organised. From our conversations with patients, the main reasons for their scores were due to the past staffing vacancies and they did not always receive information. We saw that the service had devised an action plan. This was posted on the wall in the waiting area. Actions included offering explanations when the unit was running late. Patients we asked reported their satisfaction scores improved since more staff had started on the unit.
- 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. We did not see specific results or actions from recent feedback.
- We saw whilst on inspection that a patient had brought a beautiful large cake into the unit following

their birthday. The cake was highly decorated that included the words 'to all the nurses at the Macclesfield unit'. The cake was a token of appreciation to all the nurses at the unit.

Understanding and involvement of patients and those close to them

- We observed that staff spoke to the patients to explain the treatment they were going to receive. We observed that discussions regarding the patient's weight and fluid removal was discussed.
- We saw that patients were involved in their care, and weighed themselves in readiness for their treatment.
- Two patients we spoke with did not feel the information they received met their needs, and felt that there was not enough communication and information. They told us, 'Information should be written down rather than being verbally handed over'. For example, staffing shortages and toilet repairs.
- Patients had a named nurse to provide their care and treatment. The named nurse approach fosters good relationships and communication between patients and staff. One patient reported that this had been well received.
- For those patients with a learning disability, carers were able to stay during treatment in order to provide support with any additional needs.
- Monthly blood results were discussed with patients to help them to understand their on going treatment. We were also informed that their results were available to them online.

Emotional support

- Staff we spoke with were able to tell us that extra support was available to patients via the referring trust at Manchester. This included access to social services and psychological services.
- A patient informed us that following the death of a patient on the unit, there was no recognition of the effects this may have had on others, and no communication or additional support had been offered following the event.
- We observed that staff monitored patients throughout their treatment, and informed us that if a patient was

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not well they offered more support to alleviate any anxieties. For example, we saw that following the dialysis machine alarm alert, staff provided reassurances to patients as to the reason why the alarm had sounded.

- Patients told us that if they had any concerns and worries they felt they could speak to the nursing staff who would support them.
- Patients we spoke with informed us that staff along with the team secretary supported them to be able to go on holiday and receive the necessary dialysis they required whilst away. One patient reported that everything was arranged by the unit for them to go away and the service was excellent.

Are dialysis services responsive to people's needs?

(for example, to feedback?)

Service planning and delivery to meet the needs of individual people

- The dialysis unit followed their corporate patient referral and acceptance to treatment policy. The policy outlined the criteria for acceptance to the unit. This included, established functioning access for dialysis, haemodynamically stable, and BBV status. Approval to the unit was completed by the clinic manager to ensure care and treatment could be safely managed.
- Staff recognised when patients needed additional support to help them understand and be involved in their care and treatment. This was highlighted in the care plan so reasonable adjustments could be made. For example, patients with mobility difficulties.
- Patients were referred for haemodialysis treatment from the local NHS trust renal unit. The referral was based upon the patient being medically suitable for treatment in a satellite renal unit, and living within 30 minutes travel time from the unit. Renal association 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 with 25 miles of the patients' home.

- Transport of patients was arranged as part of the NHS contract. Transport for the unit was organised with two separate transport services, and offered ambulance and taxi services to enable patients to access their care and treatment.
- Parking facilities were available for patients, and we saw there were dedicated spaces outside the unit.
- Access to the unit was safe and convenient, as the dialysis unit was close to the main entrance and was located on the ground floor.
- A full range of dialysis sessions were available for patients, taking into consideration working, cultural needs and family responsibilities. We saw that the unit offered two dialysis sessions per day over a six day period. Staff informed us that they were flexible to change appointment times to meet the needs of the patients.
- The service used an appointment system to plan patient appointments and track available capacity to allow flexibility for patient choice.

Meeting the needs of local people

- There was good access to facilities in the unit. The unit was spacious and offered good provision for people with individual needs. For example, corridors and doorways were wide to offer wheelchair access.
- There were two separate toilets off the main corridor which had wheelchair access and supported patients with mobility issues. One of the toilets was out of order. Patients informed us that this toilet had been out of order for several weeks and they received little information as to what was being done. Managers informed us that they were in communication with the host trust facilities management to rectify the situation.
- We were informed that treatment could be suspended should a patient require the toilet during treatment.
- We observed that patients were encouraged to participate in their care. We saw that patients weighed themselves prior to treatment and we were told that two patients were able to set up their own dialysis lines. We did not see any evidence to support this, including any evidence of shared care training sessions for these patients.

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- Patients had access to television with separate headphones in each bed space, and were able to bring in their own reading material if required.
- We saw that patients were offered hot and cold drinks and sandwiches whilst receiving treatment.
- Family members were able to stay with patients who required extra support. For example, a patient with learning disabilities received extra support from a relevant carer whilst receiving treatment.
- Patient information was provided in English, however could be obtained in other formats if required. We saw for example the dietician booklets contained information on how to receive the information in other formats.
- Access to interpreter services were available to those patients whose first language was not English.
- There were no patient representative groups that visited the unit on a regular basis. However, there was literature for patients in the waiting area for if they wished to contact them.
- Dieticians provided information leaflets to explain why diet was so important. We saw that the leaflets included those patients who had diabetes and contained sample menus.
- Signage's around the unit including exit and toilet signs were bold and contained braille to aid those patients with sight impairment.
- Patients were allocated a dialysis machine prior to receiving treatment. Patients used the same dialysis machine on each visit to the unit. Patients we spoke with confirmed that they used the same dialysis machine on each visit to the unit.
- We observed a hoist was available for those patients with mobility problems, and all dialysis specific chairs and beds had pressure relieving mattresses.
- The service measured the utilisation of capacity. For the reporting period from December to February 2017, the utilisation capacity ranged from 78% to 84%. This meant that there were usually vacant appointments available for patients.
- From March 2016 to March 2017, the service reported there were three cancelled appointments by the unit. We were informed this was due to a staff member calling in sick. We were told that bloods were taken and the consultant informed to authorise the patients to miss a dialysis session.
- For the same reporting period the service reported there had been 23 delayed appointments. We were informed that this was due to machine breakdown. Staff reported that following a machine breakdown setting up of the spare dialysis machines took time to prepare.
- Dialysis sessions were based upon availability either in the morning or afternoon. Staff informed us that every effort was made to accommodate patients expressed wishes.
- We saw that once patients arrived they were seen quickly to start their dialysis session.
- The nephrologist visited the unit twice weekly to review prescriptions and see patients. Visits were co-ordinated to ensure both cohorts of patients were seen and negated the need for patients to attend clinics on days they did not receive treatment. We were informed that each patient would receive a full review within a six month period.
- The service operated on a six days service providing two sessions per day. Patients usually dialysed every other day for four hours, three times per week. This was in accordance with the renal guidance. Guideline 5.1 - HD: Minimum frequency of haemodialysis per week and Guideline 5.4 - HD: Minimum duration of thrice weekly haemodialysis. We saw from the clinical review report for February 2017 that the number of patients receiving their effective weekly treatment time was 76% which showed an increase over the past month of 72%. The target set for all Fresenius units was 70%.

Access and flow

- The dialysis unit reported there was no waiting list for treatment. This meant that there were no patients waiting to start treatment.

Learning from complaints and concerns

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- The dialysis unit followed their corporate feedback policy that covered compliments, comments, concerns and complaints. The policy was available to all staff via the intranet and was known as the 4C's.
- The service received three complaints in the 12 month reporting period March 2016 to March 2017.
- We received 13 completed comments cards from patients receiving treatment at the unit. Five patients raised they did not feel there were enough staff, two patients felt the ward was too cold, one patient reported they only saw a doctor every six months and was asked to see the GP although the problem was renal related.
- We saw that complaints were kept on file in the manager's office and was an agenda item at team meetings.
- Complaints could be raised to the management team either verbally, written, satisfaction surveys or through 'tell us what you think' leaflets. Patients informed us that they could raise any issues with the staff at any time.
- We saw that 'tell us what you think' cards were left in the waiting areas for patients to complete on arrival or leaving the unit.
- We saw an action plan had been developed following the patient satisfaction survey. This included conducting an introductory session to dialysis with the patient when they first start dialysis and allocating a named nurse before commencement of dialysis.
- The service feedback policy and statement of purpose were visibly displayed in the patient waiting area in order for patients to know what to expect from the service in regards to their care and treatment.
- The clinic manager was responsible in ensuring all complaints were dealt with within 20 working days. We did not see any evidence on inspection of any current open complaints.

quality monitoring in the dialysis unit. We saw that the clinic manager was well supported by a knowledgeable wider management team that included a regional business manager and area head nurse.

- A new clinic manager had recently been appointed and was undergoing an extensive induction process supported by another clinic manager. The newly appointed manager reported that the induction process was thorough and included all areas of the corporate business.
- We saw that the service had a current registered manager. We were informed that the process had been started for the new clinic manager to become the registered manager. A registered manager is the person appointed by the provider to manage the regulated activity on their behalf. This is a requirement under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 7.
- There was a clear leadership structure from unit level to senior management level. Within the unit, there was a team leader, and a deputy clinic manager to support the clinic manager with the daily operation of the unit.
- We observed that relationships throughout the unit were positive, professional and friendly. This included the relationships between the unit staff and those at a senior management level.
- All staff we spoke with reported they had a good relationship with their managers. However, not all staff reported they received consistent answers from managers, although this had greatly improved since the present, and the newly appointed manager had been on site.
- The present clinic manager managed two dialysis units. This meant that management responsibilities were split between the two sites. The newly appointed manager once completing induction would be based at the unit full time, and would not need to manage more than one dialysis unit to provide the continuity required to effectively manage the unit.
- The regional business manager and area head nurse provided the overarching management to the unit. Roles were distinct in that the area head nurse was responsible for the clinical areas of the business, with

Are dialysis services well-led?

Leadership and culture of service

- The clinic manager was responsible for monitoring and leading on delivering effective governance and

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the regional business manager having overall responsibility with regards to the dialysis unit performance. Throughout the inspection, the management team showed they were knowledgeable and well cited to the performance of the unit.

- We observed that managers were visible and approachable on the unit and provided support to staff as required.

Vision and Strategy

- 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.
- We saw that the mission and values were posted on the wall of the unit to remind all staff of the core values. These included quality, honesty and integrity, innovation and improvement and respect and dignity. 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. For, example corporate recycling contracts that included the recycling of sharps bins.
- In reception, we saw there was a clear corporate statement of purpose that set out the core values and what patients could expect during a visit to the hospital. These included the aims and objectives for the patients, staff, shareholders and the community.
- Staff we spoke with understood their roles and responsibilities in meeting the core values of the service.

Governance, risk management and quality measurement

- There was a committee structure to support governance and risk management. Clinical governance meetings were held monthly that included the nephrologist from the local NHS trust. This governance meeting fed into the wider governance team to ensure oversight by the Fresenius senior management team and the referring trust.
- We saw there was a clear clinical governance strategy policy that set out the strategic aims of the service.

The aims included continuous improvement in patient care and promote evidence based clinically effective care. We saw from evidence supplied by the service that this was a priority for the service and monthly monitoring of patient dialysis outcomes were assessed and shared with the trust and the wider governance team.

- 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.
- The service used a clinic communication matrix which showed where information from the unit was to be reported to and by when. The matrix included where incident reports, audits and managerial paperwork were to be sent. From the matrix it was clear that all information relating to the unit was filtered up through the Fresenius corporate management structure and to the referring trust. The matrix provided clear guidance on when, frequency and who was to report the information. We saw that senior managers were cited on information from the unit that confirmed they received this information from the unit.
- We saw that key performance indicators (KPIs) were set for patient outcomes. Patient KPIs were based upon the renal association guidelines for improving dialysis process and outcomes. For example, weekly dialysis time and urea reduction rates. We saw that KPIs were monitored and reported through a quarterly clinic review report. Managers were aware of the report content and a balance score card containing patient outcomes performance was posted in the staff area. Where the service had not met the required performance we saw that action plans were developed to improve performance. We were informed that managers were supported by the area head nurse to improve the clinical performance of the unit. The area head nurse informed us that they met with the clinic managers on a three monthly basis to discuss actions taken to improve performance and help set new action plans.
- We saw that from the monitoring of the key performance indicators contained within the clinic review report, each service could be benchmarked against all of the other Fresenius dialysis units. We saw that the document provided bar graphs showing all

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Fresenius dialysis units against a number of patient outcome measures such as effective weekly treatment time scores and infusion/blood volume scores. The benchmarking document also contained graphs of improvement or deterioration so that senior managers could act quickly to rectify poor performance.

- We saw evidence that the service had risk assessments in place. Risk assessments included use of clinical equipment and environment areas. These were kept on file in the manager's office. We reviewed that these assessments contained the hazard or risk with the current controls and additional controls required to minimise or mitigate the risk with a review date.
- A risk register had been newly developed to provide an oversight of risks associated in renal dialysis practice and the dialysis environment. The register was split to contain operational risks, clinical risks and technical risks. We saw that risks were rated red to green with current controls in place to support the rating.
- Senior managers recognised the need to develop a sepsis pathway, and included it on the risk register. They told us they would develop this with the local referring NHS trust. A sepsis pathway provides staff with the necessary steps to take to detect a patient with sepsis.
- We saw evidence that performance reports were produced and sent to the local trust to support evidence of patient outcomes, including incidents and complaints. The trust reported they had meetings with the unit every two months and also received feedback from the nephrologist.
- We saw evidence that the area head nurse completed unannounced inspection visits quarterly to ensure service quality standards. We reviewed the inspection report from June 2016. The report covered patient records review, staff observations, resuscitation simulation, training compliance and a service records review. We saw that following the inspection an action plan had been developed to address the findings with dates for completion.
- The local NHS trust advised that they had just awarded a new contract to the service which was effective from April 2017 and reported the service to be proactive, receptive and accommodating.

- We saw evidence that an audit plan was in place that included patient outcomes, water testing, and infection control. The auditing was systematic and followed renal association guidelines to ensure patients received safe care and treatment.
- We saw evidence that the service had developed clinical work instructions to ensure that staff carried out their duties in-line with corporate policy and legislation. For example, we saw there were comprehensive work instructions for the management of blood borne viruses, complications, reactions and other clinical event pathways such as needle dislodgement. The work instructions provided staff with flow diagrams to follow. A folder with the work instructions was kept in the manager's office for staff to review. We saw that staff had signed to say they had read and understood the work instructions.

Public and staff engagement

- The service performed annual patient surveys. We reviewed the two surveys from 2015 and 2016 and saw there were differences. In the 2015, patient survey the response rate was 71% against a Fresenius average of 53%. In the 2016, patient survey the response was low at 30%. We saw that the action plan was posted on the wall in reception to share with the patients. However, the action plan did not include any actions to increase the response rate.
- The service performed annual staff surveys. In the 2016, staff survey the response rate was 75% (6 responses). The survey showed that only 33% of staff would recommend the unit to family and friends and only 20% would recommend the unit as a place to work. We saw an action plan had been developed to address the issues raised in the survey that included the appointment of a new clinic manager, regular staff meetings and staff to be given allocated time for training. Staff we spoke with told us that the reason the staff survey results were low was due to the low staffing having an impact on the unit, and this had now improved.
- Staff we spoke with reported that they felt supported by the current and newly appointed clinic manager. One member of the nursing team reported that the unit has improved since January 2017 and now feels valued.

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- We saw that 'Tell us what you think' cards were available in the main reception for patients to raise issues or compliments if they did not want to raise them directly with the staff.

Innovation, improvement and sustainability

- The service had plans to replace all the dialysis machines and move to a newer model. Managers and staff were all able to confirm that these were due in July 2017. Managers informed us that this would provide improved shared care opportunities for patients and improved patient safety measures. For example, the new dialysis machines would have integrated blood pressure monitors, body temperature monitors and blood volume monitors.
- The service followed its clinic environmental plan set out in the corporate environmental policy statement. The policy statement set out what the company will do to reduce their environmental impact and improve

environmental performance. For example, general waste was separated from cardboard so could be recycled other than going to landfill. We saw evidence that the service monitored its environmental impact using an environmental impact evaluation sheet. The evaluation sheet covered impacts elements from air, water, people and waste, with current control measure and future improvement planning actions. We saw evidence that environmental factors were included on the clinical review reports for review by the senior management team and actions to improve environmental performance.

- The service aimed to move 75% of patients onto dialysate that was stored in a large central delivery system (CDS). This large tank held dialysate rather than using small plastic drums. This would reduce costs to the service, and reduce the amount of plastic used in the dialysis process.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **SHOULD** take to improve

- The provider should take action to provide staff with procedures and training with regards to the identification, process, and management of patients with sepsis.
- The provider should take action to ensure that all patients are communicated with and receive information that best meets their individual needs.
- The provider should take action to monitor and publish data with regards to the Workforce Race Equality Standard (WRES).