Crewe Renal Dialysis Unit

Quality Report

Leighton Hospital
Middlewich Road
Crewe
Cheshire
Tel: 01270 216 970
Website: www.freseniusmedicalcare.co.uk

Date of inspection visit: 7 June 2017
Date of publication: 26/09/2017

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

Ratings

Overall rating for this location

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

Overall summary

Crewe Dialysis Unit is operated by Fresenius Medical Care. The service has 18 stations for dialysis. There are on average 780 treatments sessions delivered a month. The service provides dialysis services for people over the age of 18, and does not provide treatment for children.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 7 June 2017 along with an unannounced visit to the clinic on 13 June 2017.

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

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

We regulate dialysis 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.

Summary of findings

We found the following areas of good practice:

- Staff had been trained in the safeguarding of adults and children and were aware of their responsibilities in this regard.
- The unit was visibly clean and tidy and we observed good infection prevention and control procedures to be followed.
- There were adequate staff to meet the needs of the patients.
- Care and treatment at the unit was evidence based and provided in line with the provider's Nephrocare Standard Good Dialysis Care. The unit's policies and procedures took into account professional guidelines, including the Renal Association Guidelines and research information.
- Data relating to the unit's treatment performance was submitted to the commissioning trust for inclusion in the renal registry, and the unit was benchmarked against the provider's other units across the country.
- A monthly clinic review was completed and actions were taken where the expected targets were not achieved.
- All staff were trained in intermediate life support.
- Staff received an annual appraisal of their work and set objectives for the year ahead.
- There was a thorough induction for new staff.
- There was a good system of multi-disciplinary working through weekly review meetings.
- The annual patient survey indicated that patients felt that staff were caring, treated them with dignity, and explained things in a way they could understand.
- Where issues had been raised by patients these had been addressed by the clinic manager.
- Patients were supported to deliver their own care within the unit, or progress to home dialysis.
- The individual needs of patients were taken into account for example changes to times and length of treatment for social events.
- Individual plans were in place to help patients coming from other units or transitioning from children's' services.
- Family members were supported to be present if a patient wished this to occur.
- Staff addressed any dissatisfaction from patients quickly to prevent it escalating into a formal complaint.
- The unit had effective systems to monitor and action areas of governance and risk.
- The clinic undertook some staff and patient engagement and acted on feedback they received.
- Staff felt their leaders were visible and listened to them.
- Staff felt able to raise any concerns or issues they had.

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

- Incidents which required notification to the Care Quality Commission under the (Registration) Regulations 2009: Regulation 16 had not been reported.
- Not all staff were up to date with mandatory training.
- Medicine storage for one frequently used medicine was not secure and the administration of medicines by dialysis assistants did not meet the provider's policy. This was brought to the attention of the manager during the inspection.
- A process for providing medicines to people other than patients at the unit had been established. The storage and provision of these medicines did not meet with safe medicine management guidance. This process was stopped during the inspection.
- Patient observation records were not consistently completed on both the paper and electronic systems.
- There was no escalation process should a patient's condition deteriorate. There was no sepsis management pathway.
- The records for staff competency assessments had not been fully completed.
- The procedure for obtaining consent from patients with impaired mental capacity was not understood by staff. We found one example of where this had been done incorrectly. This was brought to the attention of the manager during the inspection.
- There was no access to psychological support through the clinic or the commissioning trust. This had to be accessed via the GP. Also there was no advocacy service representative at the clinic.
- There was no audit of the transport arrangements and no patient transport group in the clinic.
- There was no patient changing area or storage facility for outdoor clothing or bags.
- There was no procedure to audit the rate or reasons for patients not attending the clinic.

Summary of findings

- The senior staff were unclear about any admission criteria for the clinic.
- Staff were not able to articulate the organisation vision and values.
- There was limited patient engagement and there was no patient group.

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

Ellen Armistead

Deputy Chief Inspector of Hospitals North West

Summary of findings

Contents

Crewe Renal Dialysis Unit

Services we looked at
Dialysis Services

Summary of this inspection

Background to Crewe Renal 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 Crewe dialysis unit opened in 2013 and primarily serves the Crewe and Leighton 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 regional business manager and the regional lead nurse. 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.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and two other CQC inspectors. The inspection team was overseen by a Head of Hospital Inspection.

Information about Crewe Renal Dialysis Unit

Crewe dialysis unit is operated by Fresenius Medical Care Renal Services Ltd. The service opened in 2013. The unit primarily serves the communities of the Crewe and Leighton area.

The Crewe dialysis unit is located within Leighton district general hospital in Leighton. It 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 unit had a dedicated car park and entrance to the unit. The unit consisted of a reception and waiting area, several rooms used for one to one consultations, meetings and staff training. The ward area had 18 dialysis stations in total. There were eight on the open ward area, four in each of two bays and two individual side rooms. All areas were visible with glass partitions.

The main patient referring unit is the Royal Stoke Hospital, which is part of the University of North Midlands NHS Hospitals Trust. This trust provides the unit with a consultant nephrologist visiting the dialysis unit twice a week and a dietician who visited most days.

Although contracted through University Hospitals of North Staffordshire NHS trust, the unit was situated in the main building of Leighton Hospital which is part of the East Cheshire 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 3574 treatment sessions to adults aged between 18-65 and 5792 treatment sessions to adults over 65. No services were offered to people under the age of 18. There were 61 people using the service.

During the inspection, we spoke with nine staff including; registered nurses, health care assistants, reception staff,

Summary of this inspection

medical staff, operating department practitioners, and senior managers. We spoke with seven patients and one relative. During our inspection, we reviewed twelve sets of patient records.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. This was the services' first inspection since registration with CQC.

In the reporting period February 2016 to January 2017 there were 9366 day case episodes of care recorded at the service; of these 100% were NHS-funded

- Between February 2016 and January 2017 there were no never events or serious incidents which occurred at the unit.
- There had been no patient deaths in the last 12 months; however there had been 12 deaths in the past 24 months. These had been investigated by the referring NHS trust.
- No incidents occurred which triggered the Duty of Candour process.
- One patient fall was reported.
- There were no reports of pressure ulcers, urinary tract infections or venous thrombo-embolism (VTE).
- There were no cases of Methicillin-resistant Staphylococcus aureus (MRSA), surgical site infection, blood borne virus, Clostridium Difficile (C.Diff) or other bacteraemia reported as having occurred in the service.
- No complaints had been received in the unit within this time period.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We do not currently have a legal duty to rate dialysis services. However, we found the following issues that the service provider needs to improve:

- There was no procedure for staff at the clinic to be involved in a mortality review process.
- Incidents which required notification to the Care Quality Commission under the (Registration) Regulations 2009: Regulation 16 had not been reported.
- Not all staff were up to date with mandatory training.
- Medicine storage for one frequently used medicine was not secure and the administration of medicines by dialysis assistants did not meet the provider's policy. This was brought to the attention of the manager during the inspection.
- A process for providing medicines to people other than patients at the unit had been established. The storage and provision of these medicines did not meet with safe medicine management guidance. This process was stopped during the inspection.
- Patient observation records were not consistently completed on both the paper and electronic systems.
- There was no escalation process should a patient's condition deteriorate. There was no sepsis management pathway.

However, we found the following areas of good practice:

- Staff had been trained in the safeguarding of adults and children and were aware of their responsibilities in this regard.
- The unit was visibly clean and tidy and we observed good infection prevention and control procedures to be followed.
- Isolation facilities were provided.
- The environment was accessible for those patients with mobility problems, spacious and patients could be observed in all areas.
- Equipment was well maintained.
- There were adequate staff to meet the needs of the patients.
- Staff were aware of their role in a major incident.

Are services effective?

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

Summary of this inspection

- Care and treatment at the unit was evidence based and provided in line with the provider's Nephrocare Standard Good Dialysis Care. The unit's policies and procedures took into account professional guidelines, including the Renal Association Guidelines and research information.
- Data relating to the unit's treatment performance was submitted to the commissioning trust for inclusion in the renal registry, and the unit was benchmarked against the provider's other units across the country.
- Patients' had individualised treatment prescriptions that were reviewed monthly by the multidisciplinary team.
- A monthly clinic review was completed and actions were taken where the expected targets were not achieved.
- Staff made sure patients were free from pain during their treatment.
- Dietician advice was provided as part of the monthly review process and between if required.
- All staff were trained in intermediate life support.
- Staff received an annual appraisal of their work and set objectives for the year ahead.
- There was a thorough induction for new staff.
- There was a good system of multi-disciplinary working through weekly review meetings.
- The unit was not meeting the Workforce Race Equality Standard (WRES) (2015) at the time of our inspection.

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

- The records for staff competency assessments had not been fully completed.
- The procedure for obtaining consent from patients with impaired mental capacity was not understood by staff. We found one example of where this had been done incorrectly. This was brought to the attention of the manager during the inspection.

Are services caring?

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

- The unit had a named nurse for each patient, which helped to ensure continuity of care.
- We observed staff interacting with patients in a compassionate and caring manner. This was reflected in comments made to us by patients during the inspection.

Summary of this inspection

- The annual patient survey indicated that patients felt that staff were caring, treated them with dignity, and explained things in a way they could understand.
- Where issues had been raised by patients these had been addressed by the clinic manager.
- Patient's specific wishes and needs were taken into account and catered for by the staff.
- A patient guide was given to each patient, which included a range of helpful information about dialysis care and external sources of information.
- Staff supported patients to go on holiday through co-ordinating care at other clinics

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

- There was no access to psychological support through the clinic or the commissioning trust. This had to be accessed via the GP. Also there was no advocacy service representative at the clinic.

Are services responsive?

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

- Patients were supported to deliver their own care within the unit, or progress to home dialysis.
- The individual needs of patients were taken into account for example changes to times and length of treatment for social events.
- Individual plans were in place to help patients coming from other units or transitioning from children's' services.
- Family members were supported to be present if a patient wished this to occur.
- Staff addressed any dissatisfaction from patients quickly to prevent it escalating into a formal complaint.

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

- There was no audit of the transport arrangements and no patient transport group in the clinic.
- There was no patient changing area or storage facility for outdoor clothing or bags.
- There was no procedure to audit the rate or reasons for patients not attending the clinic.
- The senior staff were unclear about any admission criteria for the clinic.

Summary of this inspection

Are services well-led?

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

- The corporate vision and values were available for patients and staff and kept patients at the heart of the business.
- The unit had effective systems to monitor and action areas of governance and risk.
- The clinic undertook some staff and patient engagement and acted on feedback they received.
- Staff felt their leaders were visible and listened to them.
- Staff felt able to raise any concerns or issues they had.

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

- Staff were not able to articulate the organisation vision and values.
- There was limited patient engagement and there was no patient group.
- There were no areas of innovation.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

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

Incidents

- The clinic followed an up to date Fresenius wide clinical incident reporting policy that detailed the responsibility of staff and clinic managers on the various types and categories of reportable incidents, incident investigations, duty of candour, staff involvement and support. The policy guided staff on the reporting requirements and escalation process.
- There was electronic system process in place for reporting incidents. Staff told us there were different processes for reporting incidents. Staff reported minor incidents to the corporate incident team electronically via email. While they completed an incident form for major incidents. Some staff we spoke with said they reported incidents to the manager who completed the incident report form.
- The clinic manager informed the organisation and area head nurse via email of reported incidents with additional information. The area head nurse sometimes sent back the incident form if there were issues or it was not completed correctly before notifying the corporate clinical incident team. The organisation had a corporate log and a process in place for their clinical incidents team to remind staff if an incidents review was outstanding.
- Although the process for completing the clinical and non-clinical incidents was set out in the clinical incident reporting policy. Staff were unclear about how to report incidents. Some staff told us that they would not report any incidents personally but rather inform the clinic manager. We found an example where an incident had not been reported. This related to the management of medicines for patients not using the clinics dialysis services. Staff told us that they were concerned about this practice; however they had not reported this through the incident reporting channels set out in the clinical incident policy.
- Staff told us that they did not receive feedback from issues which they raised.
- Fresenius Medical Care were in the process of procuring an electronic reporting system and advised that this would be in place by the end of 2017.
- Reported serious incidents were investigated by the clinical services manager and the chief nurse and a root cause analysis was completed including an action plan to prevent future occurrence.
- The clinic had not reported any serious incidents in the 12 months prior to the inspection.
- There had been no never events reported for this service in the same period. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- Staff had a good understanding of when they would report incidents, and gave examples such as patient's falls, patient's deterioration and needle stick injuries. However staff told us they did not fully understand their incident reporting process but felt happy to raise concerns and incidents with their clinic manager. This did not follow best practice guidance.
- Staff told us that they were provided with learning from incidents in other clinics. They gave an example regarding the caps on dialysis lines and how an alert had been generated to advise staff to exercise caution in relation to the removal of these caps. Staff had to sign to confirm they had read and understood any such alert or learning bulletin.

- Staff received training on the duty of candour and understood its meaning and implication for practice. There was also a policy in place which guided staff on how to exercise this duty and gave examples of when it should be exercised. The clinic had not made any duty of candour notifications in the 12 months prior to the inspection.
- 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) ofcertain 'notifiable safety incidents'andprovide reasonable support to that person.
- The clinic told us that 12 patients in receipt of dialysis treatment had died in the 24 months prior to the inspection. These patients had all died either at home or in another care setting. Two of these deaths had occurred unexpectedly and ten had been expected. The registered manager was unable to tell us how they had reached the conclusion as to whether the deaths had been expected or unexpected. They also told us that no after death analysis had taken place within the organisation to determine whether their dialysis treatment had any impact on their deaths.
- In one of these cases a patient had died unexpectedly within 24 hours of receiving dialysis. The registered manager was unable to tell us the cause or circumstances of this patient's death. They also confirmed that the clinic had not undertaken any after death analysis or contributed to any mortality review process with the acute trust in relation to this death.
- We spoke with the trust who commissioned the dialysis services of the clinic. They told us that they review the deaths of all patients in receipt of dialysis from the clinic. However they did not routinely involve the staff at the clinic or feedback any findings to Fresenius Medical Care. During the inspection we were informed that the clinic would be involved and invited to all future mortality reviews with the trust.
- The clinic's clinical incident reporting policy set out how notifications of deaths should be submitted to the CQC under the Care Quality Commission (Registration) Regulations 2009: Regulation 16. However the clinic had not reported any of the deaths of service users which had occurred in the 24 months prior to the inspection, including the two unexpected deaths which had occurred. This regulation states that the registered person must notify CQC of any deaths which occurred while services were being provided in the carrying on of a regulated activity or have, or may have, resulted from the carrying on of a regulated activity.

Mandatory training

- The clinic followed the Fresenius Medical Care mandatory training program. This program was a rolling program of comprehensive training in numerous different subjects. Training was delivered at one and three year intervals dependent on the subject. These subjects included health and safety, fire safety, infection prevention and control, basic and immediate life support, hand hygiene, information governance and medicines management.
- Compliance and uptake levels of mandatory training were monitored by the clinic manager using a training monitoring tool. The levels of training for each staff member were determined by using a training matrix.
- We reviewed the training completion levels for all mandatory training subjects and found that in some subjects uptake levels were high. These included basic life support and immediate life support where the uptake level were 100% for both subjects. We also found that 92% of staff had undertaken up to date training in the management of anaphylaxis and 100% of staff had undertaken training in the prevention and management of falls.
- However some subjects had a very low uptake level including prevention of medication errors. In this subject records provided by the clinic showed that 30.7% of staff had undertaken this training. The training uptake level for duty of candour training was 50%. We found that only 64% of staff had up to date training in moving and handling patients.
- The clinic manager did not have an action plan in place to address the areas of low training uptake.
- Staff we spoke with told us they were encouraged to undertake training and that the clinic manager reminded them when their training was due.

Safeguarding

- Staff were provided with safeguarding children and adults training.
- The uptake levels for safeguarding adults training was 92% and for safeguarding children 93%.
- The provider expected staff to undertake level 1 safeguarding children training which is in line with the

intercollegiate document titled, 'Safeguarding children and young people: roles and competencies' (2014). This document sets out the levels of competencies and training for staff working with children and young people. This document states that all staff should undertake level 1 training if they are not directly involved with providing and planning care for children.
- The clinic had clear systems and processes in place to keep patients safe from potential and avoidable harm.
- Staff were aware of their roles and responsibilities for escalating safeguarding concerns. Staff were knowledgeable about how to deal with and raise safeguarding issues and were able to give us examples of when it would be appropriate to do so.
- There was a Fresenius Medical Care policy on safeguarding adults and children. This policy was easily accessible and there were also quick reference guides for key safeguarding contacts displayed prominently in the clinics offices.
- The clinic had not reported any issues of a safeguarding nature in the 12 months prior to the inspection.

Cleanliness, infection control and hygiene

- The clinic used the Fresenius Medical Care policy on hygiene, infection prevention and control (IPC) which guided staff on processes and practices such as hand hygiene, personal protective equipment (PPE), dialysis machine disinfection, cleaning and isolation.
- The clinic undertook audits in relation to these infection prevention and control standards on a monthly basis. The results of these had improved to 90% in May 2017 following the implementation of an action plan when the result had been 77% in April 2017.
- Staff received mandatory training regarding infection prevention and records showed that 84% of staff had undertaken their annual update on infection control and prevention.
- The clinic did not report any cases of infection for the 12 months prior to the inspection including, methicillin resistant staphylococcus aureus (MRSA), methicillin sensitive staphylococcus aureus (MSSA) and Clostridium difficile (C.Difficile).
- There were procedures in place to assess and treat carriers of blood borne viruses such as hepatitis B and C. Staff were knowledgeable about and understood the procedures and policies which managed and reduced the risks related to the infections.
- The unit had two side rooms which could be used to treat patients with communicable infections. There were also two segregated bay areas which could also be used to cohort patients who may present with conditions such as flu.
- There was clear guidance available to staff to guide them in deciding when patients required isolation and how this should be carried out.
- There were adequate hand washing and sanitising facilities in the clinic for staff and visitors. We observed that staff adhered to hand hygiene guidance and were compliant with bare below the elbows initiative and personnel protective equipment practices.
- We observed staff completed a thorough cleaning procedure of the treatment chair and all equipment between patient treatments. This procedure included disposing of the clinical waste, cleaning pillows and checking the floor area for spillages.
- Staff were knowledgeable about handling of clinical waste and spillage. We observed that clinical waste was segregated and managed appropriately.
- We observed staff discarding sharps appropriately and found that sharps bins were correctly assembled, labelled and not over-filled. However we did note occasions when the lids of sharps bins were left open which could potentially pose a risk of injury to patients and staff.
- We observed staff undertaking appropriate cleaning of equipment after patient use. There were also cleaning schedules in place and these were all up to date and completed fully.
- The clinic was visibly clean and tidy.
- The clinic followed best practice guidelines in relation to the water treatment systems, dialysis water and fluid quality. The Fresenius Medical Care team also had an internal water team who could provide guidance and advice on any issues relating to water treatment and quality.
- We also found that regular quality checks were performed in relation to water and dialysis fluid. These checks were processed by Fresenius microbiology services and checked for infections such as legionella.
- The clinic had an infection control and prevention lead nurse. This nurse had undertaken additional training and other staff were aware of who this nurse was.

Environment and equipment

- The clinic was located adjacent to an acute NHS Hospital on the ground floor. There was designated free parking for patients using the clinic.
- Access was through a main entrance into a spacious waiting area where a reception desk was located. This area was fully accessible and push button access for patients living with a disability was available.
- The main clinic area was through secure doors which could only be opened by staff from the clinic. This area was spacious and highly visible from the nursing station.
- There were 18 dialysis stations split into four separate areas. These areas were the main clinical area where there were eight stations, a further two bay areas which contained four stations each and also two isolation side rooms.
- We saw that each station had a call bell facility and nurses were highly visible at all times.
- The maintenance of dialysis machines and chairs was scheduled and monitored using the Dialysis Machine Maintenance and Calibration Plan, which detailed the dialysis machines by model type and serial number along with the scheduled date of maintenance.
- The clinic also had a similar plan for dialysis chairs, beds and other clinical equipment including patient thermometers, blood pressure monitors and patient scales.
- The dialysis machines, chairs, beds and water treatment plant were all maintained by Fresenius Medical Care technicians.
- The additional dialysis related equipment was calibrated and maintained under contract by the manufacturers of the equipment or by specialist maintenance and calibration service providers. This was arranged by the corporate and clinic management staff.
- We found that records relating to the maintenance of equipment were comprehensive, clear and up to date.
- The water treatment room was secure and procedures were in place to ensure the safety of patients should any failure occur. There had been no incidents in the last 12 months involving the water treatment.
- In January 2017 Fresenius Medical Care brought Facilities Management in-house. This now involves a dedicated facilities management team, a designated manager and helpdesk coordinators. The rationale for this was to provide the clinics with both reactive and planned preventative maintenance work. Staff told us that this system was helpful and they did encounter any issues relating to the maintenance of the equipment they used.
- We observed staff followed the organisations guidance for example wearing personal protective equipment, including a visor, prior to starting a patient's treatment.
- There had been no reported incidents relating to equipment in the 12 months prior to the inspection.
- We found that equipment such as the resuscitation trolley were checked on a regular basis. We reviewed three months of checks for these trolleys and ground that they were all completed and up to date.
- Electrical safety testing was part of the clinics Planned and Preventative Maintenance schedule which was managed by the facilities management team. However a register was kept on-site confirming testing has taken place and was easily accessible to staff and the clinic manager.

Medicine Management

- There was a Fresenius wide medicines management policy which guided staff on the handling, storage, administration and reporting of errors in relation to medicines management.
- There were no patient group directives in use at the time of the inspection and any as required medicines were administered through prescriptions.
- The clinic did not use or store controlled drugs at the time of inspection.
- The service used anticoagulant drugs during the dialysis treatment. Staff able to describe the anticoagulant process.
- Medicines were stored securely in a clinical room in locked cupboards and a medicines fridge. We observed that the anticoagulant injections used routinely were left at patients bedsides unsecured. However this area was only accessible to staff, patients and a low number of relatives. We raised this with the clinic manager who advised that she would undertake a risk assessment in relation to this issue. This had not been completed at the unannounced inspection and was raised again.
- Staff told us although they prepared these medicines in advance there would be two staff members who did this as a checking mechanism. We saw that not all records for medicines which were part of this procedure had two signatures, which meant the policy was not being followed.

- We observed one dialysis assistant administer Tinzaparin without registered nurse supervision. Although this staff member's competence had been assessed the lack of supervision was not in line with the medicine management policy.
- Medicines that required refrigeration were stored appropriately and we found that daily checks of the temperature of this fridge were undertaken. We reviewed the drug fridge records for a three month period and found that these checks were recorded fully and appropriately during this time.
- We reviewed the medicines prescription and administration records of 12 patients and found that these were completed fully and legibly. These prescriptions were reviewed on a regular basis at the monthly multi-disciplinary meeting.
- Emergency medicines used in the resuscitation of patients were available, accessible and in date.
- There was a dialysis specific pharmacist who was able to advise and guide staff on any dialysis related issues.
- Staff were required to undertake mandatory prevention of medicine errors training. At the time of the inspection 30.7% of staff had completed this.
- We inspected the medicine storage cupboards and found that all medicines were in date.
- However we found three bags of medicines which did not belong to patients receiving treatment at the clinic. The clinic manager told us that the consultants from the acute NHS trust brought over medicines from the NHS hospital and left them on the dialysis clinic for patients to collect. These medicines were transported by the doctors and handed to a receptionist in the clinic who would then give them to the nurses to lock in the cupboard.
- Staff told us that patients would attend to collect these medicines on an ad hoc basis. There was no feedback mechanism to alert the acute trust if the patients didn't collect their medicines since the patients were not attending the clinic for dialysis treatment.
- Staff also told us that they could not undertake ID checks prior to giving the medicines as the labels did not contain any details apart from a name. These patients were unknown to staff so told us that they could not be sure that they were providing the medicine to the correct individual. Staff also told us that they routinely would provide these medicines to the patient's relatives and friends.
- These medicines also did not arrive with a prescription or list of what should be in the bag. For this reason nursing staff were not able to check patient allergy status or advise on any contraindications and administration cautions.
- There was also no checking in or receipt process for these medicines and we found that two of the medicines had been dispensed a number of months prior to the inspection in April and February 2017.
- The practice was not covered in the contract between the NHS trust and the clinic and the NHS business manager was not aware the practice was happening.
- Staff told us that they had raised concerns with managers about this practice as they felt it was not safe and no actions had been taken.
- We highlighted this immediately and senior managers assured us that the practice had ceased and would not restart.

Records

- There was a Fresenius wide clinical record keeping policy that guided staff on record keeping ensuring a consistent approach in documentation, management and the quality of patients' clinical records.
- We found that patient records were stored securely and completed contemporaneously, comprehensively and legibly.
- The staff at the clinic used the Fresenius patient treatment electronic record for documenting patients' records and this automatically transferred patient data into the local NHS hospital clinical database system. This helped ensure that all relevant staff had the most up to date information about the patients receiving treatment.
- Records of patient's blood pressure, temperature and pulse during dialysis were recorded on both paper and the electronic system. We saw that for two patients with clinical signs which gave cause for concern the paper record had not been fully completed which meant this record was inaccurate.
- Do not resuscitate records were present on the files for patients who wished to have these in place. We reviewed two of these records and they were recorded that they had been discussed with the patient who had the mental capacity to understand their decision and was signed by the consultant nephrologist.
- There was a record that the resuscitation wishes of patients had been reviewed at the clinic appointments.

- There was a question to indicate if a living will was in place. This was completed on the files we saw.
- Fresenius required that each clinic carried out monthly nursing records audits and aimed to audit between 10 and 15% of all patient records.
- Audits for March, April and May showed varied results with eight omissions or actions being required in April and two in May. No themes were identified on the audit forms although in all three months there was at least one of the ten Waterlow scores (pressure ulcer risk assessment tool) out of date.
- The 2016 patient satisfaction result showed 100% of patients felt the service held their information securely.

Assessing and responding to patient risk

- The clinic did not use an early warning score system to identify patients at risk of deterioration. Staff told us that they were aware of a policy which guided them on how to escalate patients with deterioration but could not tell us how they would find this policy.
- We could not find any evidence of an escalation protocol or process which would help staff identify and recognise deterioration in patient's conditions.
- Staff told us that their decisions about when to escalate patients to a higher level of care were largely based on their clinical judgement.
- There was a Fresenius wide clinical incident reporting policy, which contained guidance for staff to follow to escalate patients including if a patient suffered a cardiac arrest or death in the unit or had an adverse drug reaction.
- Fresenius had a clinical risk management policy that advised staff on the management of clinical risk. The clinic manager was aware of this policy but staff working in the clinic were not aware of this policy.
- We saw clinical risk assessments were completed in the patient files. These included the risk of developing a pressure ulcer and a moving and handling risk assessment. For one patient who's moving and handling requirements had changed significantly, increasing their risk, their evacuation plan had not been updated.
- The clinic had a formalised admission and exclusion criteria to screen patients before they were accepted to the clinic. These criteria helped ensure only patients who were clinically stable attended the clinic. Individual patients risk was assessed minimally on a monthly basis through multi-disciplinary team meetings.
- We also saw that staff had a safety briefing handover in the mornings which included discussion of key patient risk factors. This was not recorded although discussions had taken place about doing so.
- The clinic did not have a sepsis policy or pathway. Staff told us that they would use their clinical knowledge to identify sepsis and act on this. However staff were unable to tell us the keys signs of sepsis such as hypotension, tachycardia and increased respiratory rate.
- We found that patients had up to date, comprehensive risk assessments completed for areas such as pressure damage and falls.
- Blood tests were carried out minimally on a monthly basis. This allowed staff to make informed decisions about the risks associated with dialysing patients.
- Patients who became unwell during their dialysis treatment were assessed by staff and transferred to the nearest emergency hospital. There were 29 patient transfers to another healthcare provider in the 12 months prior to the inspection.
- We observed that two patients who had high early warning scores had not been escalated to the medical team. In one of these cases the patient had significantly deranged clinical observations showing a low blood pressure and high temperature. Despite this the patient was not notified to medical staff or the nurse in charge, We highlighted this to unit manager who advised that she would action this with the member of staff involved immediately.
- There was no locally agreed protocol for transferring patients to accident and emergency. Staff told us that they would not always use an ambulance to transfer patients to the acute hospital. They advised that they would sometimes take them in wheelchairs, with a porter and an emergency radio, as it was a short distance. There was no risk assessment in place to assess and mitigate the risks involved with this practice.
- There was no formal policy in place to guide the practice of patient identification. However we observed that this was undertaken by asking patients for their name and date of birth which was checked against electronic and paper records.
- We observed that staff undertook these checks prior to connecting a patient to the dialysis machine.

Staffing

- The clinic was nurse led and employed 13 clinical staff and one administrative staff member. These

compromised of one clinic manager, one deputy clinic manager, two registered nurse team leaders, five registered nurses, four dialysis assistants and a clinic secretary.
- There was one nurse vacancy post during inspection. The data submitted showed two nurses and one dialysis assistant were employed in the unit and one staff member left the service within the last 12 months.
- The sickness rate for the last three months of 2016 amongst dialysis nurses was 1%, but amongst health care assistants it was 7%.
- The clinic worked to a ratio of one nurse to four patients and 70% registered nurses to 30% dialysis assistants.
- Staff told us that they felt well-staffed and that they had enough time to care for patients.
- The clinic manager reviewed the staff rota daily to ensure adequate staffing based on the number of patients attending dialysis and this was further overseen by the regional business manager.
- The clinic used low numbers of bank and agency staff. If there was short term staffing deficits these would be filled by the Fresenius bank staff. The service had a flexi bank which was able to provide Fresenius trained staff to fill any short term or long term staffing deficits.
- Staff were supported by the clinical manager who was expected to have 90% supernumerary management time. The deputy clinic manager was also available to support staff and worked 40% supernumerary management time.
- There were three team leaders who had responsibility for supervising less experienced staff. They had additional responsibilities such as the lead for health and safety.
- The clinic was supported by two renal physician consultants from the NHS Trust. One of them was on site at the clinic at least two days per week and they attended the monthly review meetings for their patients. However they were always available by phone and pager. Staff told us that they did not encounter any issues with accessing medical advice when required.

Major incident awareness and training

- The clinic had an "Emergency preparedness plan" which was accessible on the unit. This contained telephone numbers for emergency officers in the organisation as well as for the utilities such as water and electricity. Emergency drills took place twice a year six months apart and the clinic manager ensured all staff were present at either of these.
- Staff were aware of what to do in a fire and knew how to raise the fire alarm.
- There was an emergency grab box accessible for staff to use in the event of an emergency which required patients to be unexpectedly disconnected from dialysis. This bow contained equipment which would enable staff to safely close of lines and catheters.
- There were individual personal emergency evacuation plans in patients records. Of those we reviewed one had not been updated with a significant decrease in the patients mobility and changes to the way they were assisted.

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

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

Evidence-based care and treatment

- 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 nurses visually examined a patients' vascular access site prior to dialysis.
- The provider developed a Nephrocare Standard Good Dialysis Care that took into account professional standards, best practice and research literature from a range of sources. The procedure for staff to follow throughout dialysis treatment was documented and provided a guide for all staff to follow to ensure safe care and treatment for patients receiving treatment at the unit. The standard provided a framework against which the provider's other policies and procedures were linked.
- Staff used the prescriptions for an individual patient to provide their specific treatment regime. These prescriptions were then reviewed at the monthly disciplinary meeting and in line with the patient's latest blood results.

- Assessment of patients' vascular access was carried out before and during treatment. Continuous monitoring by the dialysis machine meant that nurses were alerted by a machine alarm to any potential issues that could relate to poorly functioning fistula.
- We observed a doplar assessment of a fistula site was carried out when observation of the site caused concern.
- Staff at the unit were unable to meet NICE guidance QS72 Statement 5: Adults who need long term dialysis are offered home based dialysis. This was because patients would use a different dialysis machine, provided by the NHS trust, if they had home based dialysis. Therefore staff were unable to assist patients to use the correct equipment.
- Patients had their weight, blood pressure and pulse monitored during their treatment. There was an automatic system for patients to be weighed using an identity card which then automatically sent the results to the patient's records. This was done at the beginning and end of treatment.
- We observed blood pressures to be checked before and after treatment and during the treatment if the patient gave consent. Nurses told us some patients did not like to be disturbed; however they would always try to take a blood pressure reading halfway through the treatment. This was in line with the clinic's policy and best practice guidance.
- There was an annual clinic audit schedule which listed 23 compulsory audits. 11 of these were completed monthly and the results provided information for the clinic scorecard. The remainder consisted of clinical, non-clinical and corporate audits.

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 who monitored this information to assess performance.
- This clinic review included performance against targets such as the time for infusion, vascular access and hydration status. The report for April 2017 had actions documented for improvement where the provider's targets had not been achieved or performance had decreased from the previous month.
- The effective weekly times were monitored (patients completing their dialysis treatment over a period of four hours). The data for April 2017 showed 75% of patients achieved the clinic target which was 70%. This was an increase from 70% the previous month.
- There were 12 patients who did not have a fistula which represented 77% of the total patients. This met the clinic target of 76%. There were plans for four of these to have a fistula with two refusing this and two had long term lines.
- Findings also showed that 79% of patients had phosphate levels within an appropriate range. This was an improvement on the previous month and met the clinic's target of 75%.
- Data from this clinic was submitted to the UK Renal Registry by the parent NHS Trust. This unit's 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 this renal dialysis unit. Therefore, data specific to the unit and available through the internal database was used to benchmark patient outcomes both as an individual clinic and nationally against all Fresenius Medical Care UK clinics.
- Patients' blood results were monitored each month as per a defined schedule dictated by the NHS Trust Consultant. These bloods were individually reviewed monthly to audit the effectiveness of treatment and define any actions for improvements and changes to care provision that will improve outcome. The results and treatment data were captured by the clinic's database and fed into the trust's database.
- Patient blood was tested for potassium, phosphate, calcium aluminium concentrations in-line with the renal association guidelines. The renal association sets outs 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.

Pain relief

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

Nutrition and hydration

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

Competent staff

- All staff completed basic life support and immediate life support training as part of their mandatory training. This contained information on signs of potential deterioration in patient's conditions.
- The clinic was also subject to basic life supporting simulation training. This was facilitated by area lead nurses. Staff last had a simulation exercise in May 2017.This training helped staff improve the practical competency on basic life support.
- There was a very comprehensive competence assessment document which should be completed during induction by each staff member. We reviewed seven of these records and four had not been fully completed. In one other it was documented "previous experience at trust – competent" and for another "transferred from trust competent in renal since (and a date 30 years previously)". This meant the up to date competence of those staff to carry out their tasks safely had not been assessed. This was brought to the attention of the manager during the inspection. In another record the competencies were not fully signed off and additional tasks were added to the printed version in pen with no signature.
- This competence assessment included vascular access assessment, water treatment competency and portal disinfection.
- There was an annual re-assessment of competence. Of the staff members for whom this was applicable 37% were overdue this assessment at the time of the inspection.
- We reviewed five records of this annual competence and saw they were not fully completed. Examples included general comments such as "discussed" and it was not clear if observation of the tasks involved had taken place.
- Ongoing competence with the skills and knowledge required was provided by a variety of classroom sessions, online learning and practical supervision. Training certificates were present in the files we reviewed.
- Externally provided renal nursing course training modules were available. These were optional and undertaken by staff if agreed as part of their personal development plan. One of the eight nurses eligible for this course had completed it at the time of the inspection.
- In the 12 months to May 2017 90% of dialysis nurses and 100% of health care assistants had received an appraisal.
- We reviewed appraisal documentation and saw staff and their manager reviewed their performance over the last 12 months and set objectives for the next 12 months.
- Checks of the Nursing and Midwifery Council nursing validation registration PIN numbers had been carried out for all relevant staff at the unit in May 2017.
- Bank staff were provided by the provider's in-house agency: Renal Flexibank. All bank staff underwent an induction programme, which included competency assessment to the same standards as permanent staff. Bank staff were provided with key clinical policies and work instructions as part of their induction training.

Multidisciplinary working

- A weekly multi-disciplinary meeting took place for each of the two consultants to discuss the patients having treatment. This was attended by the clinic manager, the consultant present that day, the dietician and another senior nurse. Notes from these meetings showed that any change to the patient's treatment, additional tests required or concerns were noted with actions for follow up.
- All changes to treatments or referrals to other services were coordinated by the clinic manager. Outcomes of these referrals were discussed with the patient by the named nurse and the dietician.
- Any communication with GPs was done via a letter following the review of the patient in clinic.
- A pharmacist attended one of the two monthly quality assurance meetings; however they did not attend the other one at the request of that consultant.
- The consultant at the referring NHS trust remained the clinician with overall responsibility for the patient.

Access to information

- We saw that patient information was provided to nursing and medical staff in both paper and electronic formats. The patient's care plans, risk and health assessments, medical history and test results were readily accessible.
- There was no formalised system whereby if a patient had a blood test in another healthcare setting the results would be automatically available to the clinic. This included those taken by a GP practice. They relied on the patient to give the nursing staff this information.
- Patient's blood test results were held on the commissioning trust's electronic computer system, which was accessible by all staff including the renal consultant. This meant multi-disciplinary medical and nursing teams had the latest information available for patients undertaking dialysis.
- Letters generated following clinic appointments were copied to the unit and the patient's GP.
- Should a patient visiting the area and requiring dialysis away from their usual base then the "Incoming Holiday Patient Forms" were used to ensure all relevant information was gathered relating to the incoming patient. This included assessments to ensure they did not pose a risk to the resident patient cohort, such as infections requiring isolation, and treatment prescriptions could be met.

Equality and human rights

- The corporate code of ethics and business conduct gave staff the expected framework for treating patients, relatives and other medical professionals with equality, dignity and respect.
- In this document it was stated employees were not permitted to discriminate based on gender, age, disability, nationality, religion or any other protected characteristics.
- We observed that reasonable adjustments had been made to accommodate a staff member to be able to carry out their duties.
- An e-learning module on equality, diversity and human rights was available for staff to complete once during their employment. At the time of the inspection 50% of staff had completed this training.
- The unit was not meeting the Workforce Race Equality Standard (WRES) (2015) at the time of our inspection. This is a requirement for organisations (providing care to NHS patients with an income of more than £200,000) to publish data to show they monitor and assure staff equality and have an action plan to address any data gaps in the future. The risk register indicated that although Fresenius had not produced a WRES report, race equality formed part of their wider approach to ensure equality for all employees.

Consent, Mental Capacity Act and Deprivation of Liberty

- We reviewed consent documentation for six patients. We found that for one patient this had been completed by a person other than the patient. There was no documentation to clarify that this person had the legal right to do so.
- Training on the mental capacity act and deprivation of liberty safeguards was provided via e-learning. This should be completed every three years. Of the 14 staff who needed to complete this training 13 were up to date
- Staff we spoke with did not understand how consent should be obtained for patients who did not have the mental capacity to do this themselves. There had been no best interest meeting or documentation of a best interest decision for a patient whom staff told us had impaired mental capacity.

- The most up to date organisational policy for obtaining consent had not been used in this unit. Instead an out of date version was in use which had not been reviewed when the latest policy was issued.
- Staff completed an e-learning course on caring for a patient with dementia. They told us most patients with dementia did not receive their treatment in this unit due to the exclusion criteria meaning they would be cared for in the trust.
- Staff told us they had raised concerns previously regarding patients whose mental capacity to consent to treatment had been impaired. There had been a lack of consistent approach to managing this patient between the medical and nursing staff. Nursing staff showed a good understanding of the need to accept verbal refusal or behaviour which could indicate refusal of treatment and cease the dialysis. There were no patients who refused treatment at the clinic at the time of the inspection.

Are dialysis services caring?

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

Compassionate care

- Staff delivered care in line with the '6 Cs' of nursing. These are a set of values focused on placing the patient at the heart of their care and include care, compassion, competence, communication, courage and commitment.
- We observed staff to treat patients with kindness and respect. They spoke to them in a friendly and informal but professional manner.
- Privacy curtains were available around each patient treatment chair and we saw these used to protect patient's dignity.
- A chaperone policy was available on the unit.
- The last patient satisfaction survey in the unit showed that 83% of patients would likely to recommend their unit to friends and family in need of dialysis and had confidence in the nursing staff.
- However 47% of patients said the unit was not comfortable. This was mainly about the temperature of the areas where they received treatment. Actions taken to improve this were discussions with patients about which treatment stations to use to ensure they were not directly under an air conditioning vent and altering the temperature level. We saw patient comfort was monitored during their treatment.
- The unit also collected feedback through a 'Tell us what you think' anonymous leaflet system which allowed patients to comment on the service using Freepost direct to the Head Office. This feedback was shared with the Regional Business Managers who shared any actions required to improve patient care.

Understanding and involvement of patients and those close to them

- We saw staff checking with patients if they were comfortable and had everything they needed before they started the dialysis treatment.
- The specific requests of patients were sought and respected by staff. These included which treatment chair to use and how often they wanted to be disturbed for their observations to be monitored during the treatment.
- A named nurse system was used which meant patient's had a point of contact to discuss any issues or concerns they may have. It was the responsibility of this nurse to ensure patients were kept up to date with information about their care and treatment.
- The five patients we spoke with told us they were kept up to date with information about their treatment, including any proposed changes.
- We observed nurses discussing with the patients the results of their blood tests and what this meant for their treatment regime.
- We saw nurses altered the times or days of treatment for patients, were it was safe to do so, to accommodate their social arrangements.
- The unit provided new patients with a patient guide. This comprehensive guide included information on how to use the electronic patient record card, health and safety information, safeguarding information, hygiene and infection control advice, understanding dialysis including the various types of venous access and other sources of information.
- Staff encouraged 'self-care' with all patients in the unit, and took opportunities to discuss this with patients and their families. They supported a patient who carried out part of their treatment themselves within the unit and another who had chosen to move to home dialysis.

Emotional support

- Staff showed an understanding of the need to support patients with the emotional difficulties of receiving long term treatment.
- Due to the nature of the treatment and the fact that some patients had been attending the unit for many years staff told us they were able to recognise if a patient was upset or in need of additional support.
- Strategies were in place to support new patients to the unit and those moving from other units or to an adult unit for the first time. This included a staged introduction to the unit and being accompanied by a family member.
- Patients understood the potential need for additional support for those patients awaiting a transplant or having the disappointment of this option not being available.
- A quiet room was available in the unit where patients could have confidential discussions about their care with any members of the multidisciplinary team should they so wish.
- There was no direct access to counselling services. Patients would be referred back to their GP if staff thought this was necessary.

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

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

Meeting the needs of local people

- Due to the main referring renal unit being the Royal Stoke Hospital, which is part of the University of North Midlands NHS Hospitals Trust patients could have to travel longer distances to get to the unit. Their travel time to the clinic was taken into account when referrals were received.
- There was dedicated parking for the use of patients receiving dialysis treatment. This was immediately outside the clinic. Patients told us they could always park when they attended the clinic.
- There was no transport user group at the clinic and no audit or survey of the transport provided had been completed. This was discussed with the manager as issues with transport for individual patients were recorded as a reason for delays in treatment.
- Patients we spoke with said there could be delays with the transport both to and from the clinic. Some said they waited a long time after their treatment whilst others spent "too long" on the transport due to dropping off other patients on the way home.
- The design and layout of the unit adhered to the recommendations of the Department of Health's Health Building Note 07-01: Satellite dialysis unit. The entrance was separate to the rest of the hospital and had secure entry system. There was additional secure access within the unit to prevent uncontrolled access from the main hospital which was linked by a secure door within the unit.
- The waiting area was spacious and had a reception which was staffed Monday to Friday. The treatment area was light and airy with glass partitioning into the bays for ease of observation of patients having treatment. The nursing administration area was central to the treatment area and provided easy observation of all areas.
- Two isolation rooms were available for patients with infections.
- There were adequate facilities for staff including meeting and training areas and rest areas.
- However, there was no separate changing area for patients or lockers for patients to store outside clothing; coats and bags were stored with the patients at the treatment chairs.

Access and flow

- The unit provided treatment to 23 patients between the ages of 18 and 65, and 38 patients aged over 65.
- Two dialysis sessions per day took place at each treatment chair which meant 216 sessions took place every week if the clinic ran at full capacity.
- The utilisation of the capacity of the service had been 95% in December, 92% in January and 93% in February 2017. This meant there was some capacity for flexibility within the service for patients already receiving treatment there.
- The clinic did not have a waiting list.

- No treatment sessions had been cancelled for non-clinical reasons in the past 12 months.
- Two treatment sessions had been delayed due to equipment failure in the past 12 months.
- The treatment times available allowed for flexibility for patients to have an early morning start or a weekend dialysis session. The usual times for dialysing patients would be 7am and 12.30pm Monday to Saturday. The dialysis unit opens from 6.30am and closes at its latest at 6pm.
- Staff made sure each treatment area was prepared with all the equipment they would need prior to the session starting. This meant when patients arrived their waiting time was kept to a minimum.
- The unit did not have separate treatment beds for patients on holiday. However, the unit was able to accept patients on holiday if there was capacity for the dates required. This was subject to receipt of fully completed documentation, and medical approval and acceptance. This included consideration of any risk posed by the incoming patient on the resident patient cohort, for example isolation requirements.
- Staff would assist patients to identify dialysis treatment in another area should this be required for them to have a holiday. This included sharing appropriate information.
- We discussed the eligibility criteria for treatment at the unit with senior staff. They told us there were no specific criteria but they would not take patients who were on oxygen. The consultant deemed a patient to be medically stable enough to receive their dialysis at the clinic rather than the acute trust renal centre.
- From June 2016 and May 2017 between 13 (October 2016) and 34 (July 2016) patients failed to attend each month. The do not attend rate was not audited therefore themes and trends were not identified.
- We reviewed the records for two patients who had failed to attend for appointments. There was no documentation of the reason for non-attendance or how this was followed up in the patient's electronic records. There was a note in the diary as to why they had not attended, but no follow up.
- One patient who had failed to attend four times in six weeks had subsequently been admitted into hospital as an emergency. This had been discussed at the monthly quality assurance meetings; however we were told it "wouldn't necessarily be documented".

Service planning and delivery to meet the needs of individual people

- The option for patients to manage their own dialysis within the unit was offered. This was not taken up by most patients. However one patient had been supported so they could carry out some procedures, within the unit, at the start and finish of their treatment.
- Patients measured their own weight both before and after treatment. This was automatically transferred to their computer record.
- Patients and staff told us how treatment days and times would be changed to meet individual preferences. This included social events, other health appointments
- There was equipment available to accommodate patients with complex needs such as a hoist for those who were not mobile and pressure mattresses on the dialysis chairs.
- Toilets, including wheelchair accessible facilities, were available on the unit to allow patients to use them prior to treatment commencing.
- The allocation of treatment times was completed taking account of a patient's individual wishes and needs. This included work and social commitments as well as one off events.
- Patient information leaflets on display were in English only; however staff could obtain these in other languages if needed. Currently all patients spoke English as their first language.
- Should a patient require a translator to be present this service could be obtained from the referring NHS trust.
- Staff discussed how they had supported patients with dementia to understand their treatment through additional time spent with them and involving family members.
- Patients who attended from the age of 18 years following treatment at a centre for children were assisted to transition to the adult unit. This included visits to the unit, staff from the unit visiting them at their children's unit, shorter sessions to being with and a family member remaining with them.
- We saw patients had family members present throughout their treatment if they requested this.
- The service was running to almost full capacity and there were no identified concerns about sustainability.

Learning from complaints and concerns

- The unit received no formal complaints in the period February 2016 to January2017. This meant we could not comment on the unit's timeliness for responding to complaints, or the sharing of learning from complaints.
- One complaint about the unit had been received by the referring NHS trust. The issues had been shared with the clinic and the investigation was ongoing by the trust.
- The service had received two written compliments in the same period.
- In the patient satisfaction survey in November 2015 some patients had said they did not know how to raise a complaint. This had been resolved and information for patients about how to make a complaint was displayed in the unit. This was also included in the patient information each patient received when they started their treatment.
- Staff discussed how they would talk to patients about any issues they raised to resolve them quickly and prevent the need for them to escalate to a written complaint. They gave examples of where this had been done which included additional equipment being purchased and changes to monitoring during treatment.

Are dialysis services well-led?

Leadership and culture of service

- There was a clear leadership structure for the clinic and also within the corporate team. The service had a registered manager, who acted as the clinic manager and who had been working at the unit for four years. There was also a deputy clinic manager who assisted in the day to day leadership of the clinic.
- The clinic was overseen by a regional head nurse and business manager both of whom fed information to the chief nurse and clinical services manager.
- Staff spoke positively about the local and corporate leadership team. They told us that the clinic manager and deputy manager were visible and supportive.
- Staff also spoke positively of the support they received from the corporate Fresenius team and told us that they felt part of the Fresenius 'family'.
- Team leaders were supported by the clinic management team and dealt with any issues of performance management comprehensively and promptly.
- Fresenius had an employee handbook which was provided to all staff and easily accessible online. This set out what was expected from staff on areas like whistleblowing, equality and dignity.

Vision and strategy for this core service

- There was an overall vision for Fresenius Medical Care and this was to create a future worth living for dialysis patients worldwide every day. This vision was not displayed within the clinic and staff were not aware of this vision. There was no local vision or mission statement for the clinic itself.
- Fresenius Medical Care had a set of corporate values which were expected to be exercised in local clinics. These values were quality, honesty and integrity, innovation and improvement, and respect and dignity. Staff were not aware of these values. However we observed staff exercising practice that embodied these values during our visit.
- Staff were also all provided with a company handbook which contained the company values and vision.

Governance, risk management and quality measurement (medical care level only)

- A contract review meeting took place every three months with the referring NHS trust.
- Monthly Fresenius wide governance meetings took place which were attended by the clinic manager.
- An infection control governance meeting was carried out every three months.
- The clinic managers met every six months to discuss changes to policies and procedures and any shared learning.
- CQC had not been notified of incidents in line with the legal requirements of a registered provider. This was discussed with the manager and the system was for them to raise it with the chief nurse and for them to make the ultimate decision. The responsibility to complete these notifications was discussed with the managers.
- The risk register was reviewed monthly by the clinic manager. A revised risk register procedure and documentation had been implemented in January 2017.
- A "patient concerns register" had been implemented in April 2017. Any patient where staff had highlighted

medical, social or emotional concerns was entered on this register. This was then reviewed monthly and any ongoing concerns, themes or trends were discussed as part of the governance processes.
- The clinic manager discussed the workforce management with the regional business manager every Monday. This allowed for any risks associated with staffing levels to be resolved.
- Staff at the clinic had meetings every three months.

Public and staff engagement

- The provider performed an annual staff survey. This was performed across all clinics and specific information for each clinic was shared with the staff on that site. The 2016 survey showed 86% of staff responded to the survey. Staff highlighted appraisals as an area for improvement and as a result the clinic put an action plan in place and was available for staff to review progress in the staff room of the dialysis unit.
- Staff told us they have seen some changes from the concerns raised with the management for example the internet and Wi-Fi issues have been resolved.
- Staff had regular staff meetings; we found that these were not structured and the time elapsed between each meeting was different.
- Staff told us the managers discussed any issues or updates with them on ad hoc basis and also during the daily briefing.
- Staff told us that they felt listened to and felt they could raise any issue they had with the unit manager or her deputy.
- There was limited formal patient feedback and there was not a patient group or patient representative in clinic meetings. However patients told us that they would raise any issues and provide feedback informally to staff working in the clinic. The clinic also took part in the Fresenius patient feedback survey.
- The patient satisfaction survey for 2016 showed 58% response rate. The results that 47% of patients thought the unit was not comfortable (17 patients out of 38). Some patients felt they did not know what to do in case of fire or other emergency. Some patients felt they did not know how to raise a complaint or grievance. Some patients did not know if they were receiving enough dialysis. A number of TV's do not work especially in the morning.
- We found that the clinic had an action plan in place to address these issues and this was available for patients to review progress in the patient waiting area of the dialysis unit.
- There was no patient user group at this clinic. We were told this used to be in place; however when the patient who had led this was no longer able to continue there was no other patient who wanted to be involved.
- The last patient satisfaction survey had been completed in October and November 2015. The actions required as a result of this had been completed within three months, apart from issues with the televisions. This had been addressed by February 2017 due to delays by the external organisation involved.
- There were "Tell us what you think" comment cards available in the waiting area. These were collated monthly.

Innovation, improvement and sustainability

- Fresenius Medical Care were in the process of procuring an electronic reporting system and advised that this would be in place by the end of 2017.
- Some areas for improvement had been highlighted from the staff and patient survey. Action plans had been implemented and were monitored.

Outstanding practice and areas for improvement

Outstanding practice

Start here...

Areas for improvement

Action the provider MUST take to improve

- There must be safe systems in place for the management of medicines.
- Consent for treatment must be obtained in line with the Mental Capacity Regulations
- The CQC must be notified of all incidents as per the requirements of the regulations.

Action the provider SHOULD take to improve

- There should be a process in place for staff at the clinic to participate in mortality reviews in the commissioning NHS trust.
- Staff should be up to date with mandatory training
- Patient observations should be consistently recorded.
- An escalation pathway including for sepsis recognition and management should be developed.
- Records of staff competency assessments should be completed for all staff.
- The provider should consider how they provide psychological support for patients who require this.
- A patient and transport support group should be in place.
- The provider should consider how they identify any themes in patients who do not attend.
- Staff should be aware of any admission criteria for the unit.
- The provider should consider how they inform all staff of the vision and values of the organisation.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment There must be processes and procedures in place for the safe storage and administered of medicines. Staff must follow these procedures. There must be robust procedures for staff to understand what constitutes an incident and how this should be reported. Patient deaths must be investigated to determine if there were any actions or omissions attributable to the service.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 11 HSCA (RA) Regulations 2014 Need for consent The requirements of the mental Capacity Act must be followed when consent for treatment is obtained.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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