

Woodgate Dialysis Unit

Quality Report

Unit 54
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May 2017 & Unannounced inspection: 26 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

Ratings

Overall rating for this location

Are services safe?

Are services effective?

Are services caring?

Are services responsive?

Are services well-led?

Overall summary

Woodgate Dialysis Unit is operated by Fresenius Medical Care UK. The clinic opened in 2009. It is contracted by NHS England to provide renal dialysis to patients from University Hospital Birmingham NHS Foundation Trust (UHB). The contract period is for 10 years from 2009 – 2019. The service has 24 dialysis stations, which included four isolation rooms.

Dialysis is used to provide artificial replacement for patients with advanced chronic kidney disease who have lost kidney function.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 17 May 2017 and an unannounced visit to the unit on 26 May 2017.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services:

Summary of findings

are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

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

Services we do not rate

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

We found the following areas of good practice:

- Staff conducted daily water testing and there were no water failures.
- Senior staff shared learning from incidents that had occurred at the clinic and at other Fresenius units with staff.
- The majority of staff treated patients with compassion and dignity and patients reported a friendly environment at the unit.
- Staff monitored patient's pain levels well and ensured patients were as comfortable as possible.
- The clinic had a good relationship with the parent NHS trust who provided all dialysis patients at the clinic with specialist support for their condition.
- New staff were well supported when they started at the unit and were supernumerary to support their learning.
- Clinic staff could access records at the local NHS trust, which nursing staff told us reduced the time it took them to chase blood results and other test results. This also meant it was easier for consultants to give advice to nursing staff regarding patient's treatment as they had access to up-to-date information.
- The majority of staff interacted with patients in a friendly and personal way and welcomed patients when they arrived for their treatment.

- We saw clinic staff worked well together and they felt supported by senior staff.
- Staff at the unit told us the quality of patient care was their priority.
- The area head nurse visited the unit regularly and supported new staff particularly well.
- Senior staff held regular team meetings.

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

- Staff did not always administer medication in line with Nursing and Midwifery Council (NMC) guidelines.
- The centre did not have a sepsis policy or toolkit and staff had not conducted specific sepsis training.
- There was not a robust process in place for oversight of training compliance to ensure staff were up-to-date with their training and competent to carry out their role.
- Staff did not fully understand mental capacity and Deprivation of liberty safeguards (DoLS). We were not confident the unit had effective systems to ensure staff adhered to the Mental Capacity Act and DoLS legal requirements.
- We observed four out of five staff used poor aseptic non-touch technique processes when connecting and disconnecting patients to the dialysis machine.
- During the announced inspection, we observed two occasions where staff did not effectively communicate with patients during treatment. We were also told by two other patients that staff did not keep them up-to-date about their treatment or reassure them.
- One patient told us they experienced a waiting time of approximately four hours to start their dialysis with no updates given by staff.
- During our announced inspection, we noted that one of the three toilets was not available due to maintenance. This was having a negative impact on patients.

Summary of findings

- Staff did not ensure patients with new fistulas commenced dialysis in a timely way. We would expect a risk based rationale for treatment of new fistula patients.
- The clinic manager was new in post and did not yet fully understand the risks to the service.

Following this inspection, we told the provider that it must take some actions to comply with the regulations

and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with one requirement notice. Details are at the end of the report.

Heidi Smoult

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Dialysis Services

Rating

Summary of each main service

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

Summary of findings

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Woodgate Dialysis Unit

Services we looked at

Dialysis Services

Summary of this inspection

Background to Woodgate Dialysis Unit

Fresenius Medical Care UK (FMC) operates Woodgate Dialysis Unit. The service opened in November 2009. It is a private medical dialysis unit in the Woodgate area of the West Midlands region and provides haemodialysis to patients from this local community.

At the time of the inspection, a new clinic manager had been in post for one month and would be applying to become the registered manager once all checks were completed.

The service is registered for the regulated activity of diagnosis and treatment of disease.

The most recent CQC inspection took place in September 2012, which found that the service was meeting all the standards of quality and safety it was inspected against.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, another CQC inspector, and a specialist advisor with expertise in renal dialysis. Tim Cooper, Head of Hospital Inspections oversaw the inspection team.

Information about Woodgate Dialysis Unit

Fresenius Medical Care UK (FMC) is contracted by the local NHS trust, University Hospital Birmingham NHS Foundation Trust (UHB), to provide dialysis for local patients under the care of consultant nephrologists from this trust. All patients at the unit are under the care of a named consultant nephrologist, who has the overall responsibility for the patient.

The unit has a close relationship with the referring trust, in order to provide co-ordinated care to dialysis patients across the two organisations. The unit is supported by the local NHS trust who provide medical consultant cover, satellite haemodialysis unit coordinator support and pharmacy and dietitian cover. These staff regularly visited the unit to assess and support patients when necessary and to attend the quality assurance meetings held each month.

The unit is open between 7am and 6.30pm Monday to Saturday. The service is currently treating 34 patients aged between 18 and 65 and 53 patients over 65 years of age. In the 12 months before our inspection, there were 6093 haemodialysis sessions for 18 to 65 year olds and 7688 sessions for patients over 65 years of age.

The unit employed 12 dialysis nurses (11 full time and one part time) and five health care assistants (four full time and one part time).

The dialysis unit is registered to provide the following regulated activity:

- Treatment of disease, disorder, or injury.

During the inspection, we visited treatment areas where dialysis took place. We also inspected non-clinical areas of the unit, such as the water treatment and storage area, the staff room and record storage room. We spoke with nine staff including; registered nurses, health care assistants, reception staff, medical staff, operating department practitioners, and senior managers. We spoke with nine patients and one carer. We also received 18 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed 10 sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12

Summary of this inspection

months before this inspection. The most recent CQC inspection took place in September 2012, which found that the service was meeting all the standards of quality and safety it was inspected against.

Activity

In the 12 months before our inspection, there were 6093 haemodialysis sessions for 18 to 65 year olds and 7688 sessions for patients over 65 years of age. All patients were NHS funded.

Track record on safety from April 2016 to May 2017:

- No never events
- Four unexpected patient deaths
- No serious incidents
- One fall
- Two incidences of healthcare acquired MRSA
- One incidence of healthcare acquired Methicillin-sensitive staphylococcus aureus (MSSA)
- One incidence of healthcare acquired other bacteraemia

- No incidences of hospital acquired Clostridium difficile (C.diff)

- Two complaints

Services accredited by a national body:

There were no services accredited by a national body, however the clinic had the following accreditations: The ISO 9001 quality management system is a UKAS accredited certification based on numerous quality management principles including customer focus, leadership, and continual improvement.

- The Occupational Health and Safety (OHSAS 18001 H & S) system is a British standard for occupational health and safety management systems.

Services provided at the hospital under service level agreement:

- Dietitian provided by a local trust
- Clinical and domestic waste collection provided by a private company
- Cleaning staff provided by a private company

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 where these services are provided as an independent healthcare single speciality service.

We found the following issues that the service provider needs to improve:

- Some methods of medication administration were in place, which were not in line with policy and best practice guidance. This could increase the risk of patients receiving incorrect medication.
- The clinic did not have a patient identification policy and we saw some staff did not follow NMC guidance for medication administration.
- There was not a sepsis policy or toolkit in place and staff had not conducted specific sepsis training.
- We observed some infection prevention and control practices were not all in line with policy and best practice guidance. This could put patients at risk of developing infections.
- Some staff were not up-to date with the mandatory training appropriate to their role.

However, we also found the following areas of good practice:

- Nursing staffing levels were in line with national guidance and as outlined by the contract with the local NHS trust.
- The unit worked closely with the local NHS trust to provide a coordinated dialysis service to patients.
- The consultant and renal team at the local NHS trust provided medical support to the clinic.
- Staff understood their roles in the event of a major incident to ensure dialysis patients could receive their treatment at other units.
- Staff conducted daily water testing and there were no water failures.
- Senior staff shared learning from incidents regarding their unit and at other Fresenius units with clinic staff.

Are services effective?

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

We found the following areas of good practice:

Summary of this inspection

- Staff monitored patient's pain levels and ensured patients were as comfortable as possible.
- The unit had a good relationship with the NHS trust who provided all dialysis patients at the clinic with specialist support for their condition.
- New staff were well supported when they started at the unit and were supernumerary to support their learning.
- Clinic staff could access records at the local NHS trust. Nursing staff told us this reduced the time it took them to chase blood results and other test results. This also meant it was easier for consultants to give advice to nursing staff regarding patient's treatment as they had access to up-to-date information regarding each patient.

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

- Staff did not fully understand mental capacity and Deprivation of Liberty Safeguards. We were not confident the unit had effective systems to ensure staff adhered to the MCA and DoLS legal requirements.

Are services caring?

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

We found the following areas of good practice:

- The majority of staff treated patients with compassion. Staff provided care in a way that protected patients' privacy. Patients could request to use the quiet room for confidential discussions about their care, if required.
- Staff kept patients updated with their care and treatment and explained monthly blood results with patients.
- The majority of staff interacted with patients in a friendly and personal way and welcomed patients when they arrived for their treatment.
- We received 18 comments cards where 15 out of 18 comments cards patients had completed reported positive experiences at the unit.

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

Summary of this inspection

- During our announced inspection, we observed two occasions where staff did not effectively communicate with patients during treatment. We were also told by two other patients that staff did not keep them up-to-date about their treatment or reassure them.
- We saw a nurse did not reassure a patient when they were feeling anxious about some aspects of their dialysis treatment.

Are services responsive?

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

We found the following areas of good practice:

- The building complied with the relevant standards, which included designated patients' car parking spaces close to the unit.
- At the time of our inspection, the unit did not have a waiting list of patients needing to have treatment.
- The unit was accessible for wheelchair users.
- Staff made adjustments for patients with learning disabilities and those living with the early stages of dementia.
- The unit offered patients suitable treatment days and times to suit their lifestyles.
- Translation services were easily accessible for patients via the parent NHS trust.

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

- One patient told us they experienced a waiting time of approximately four hours to start their dialysis with no updates given by staff.
- Two patients told us there were currently insufficient toilet facilities for the number of patients at the unit as one of the toilets had been out of order for one week.
- We saw staff treated a patient with a new fistula after all other patients during a dialysis session. We would expect a risk based rationale for treatment of new fistula patients.

Are services well-led?

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

We found the following areas of good practice:

Summary of this inspection

- Results from the patient satisfaction survey in 2016 showed 97% of patients felt the atmosphere in this dialysis unit was friendly and happy.
- We saw clinic staff worked well together and they felt supported by senior staff.
- Staff at the unit told us the quality of patient care was their priority.
- The area head nurse visited the unit regularly and supported new staff particularly well.
- Senior staff held regular team meetings.

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

- We had concerns the unit's systems did not support the management of risk and safety at the clinic.
- The clinic manager was new in post and did not yet have a detailed knowledge of the risks to the service.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Information about the service

Fresenius Medical Care UK (FMC) operates Woodgate Dialysis Unit. The service opened in November 2009. It is a private medical dialysis unit in the Woodgate Valley area of the West Midlands region and provides haemodialysis to patients from this local community.

At the time of the inspection, a new clinic manager had been in post for one month and would be applying to become the registered manager once all checks were completed.

The service is registered for the regulated activity of diagnosis and treatment of disease.

The most recent CQC inspection took place in September 2012, which found that the service was meeting all the standards of quality and safety it was inspected against.

Are dialysis services safe?

Incidents

- Information we received from the unit showed there had been no never events or serious incidents in the 12 months before our inspection. Never events are wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers.
- The clinic manager told us and we saw the unit recorded incidents as either: clinical incident reports (CIR), treatment variance reports (TVR) and non-clinical incidents (NCI). Senior staff told us CIRs included incidents such as medication errors and needle dislodgements, TVRs covered access issues and non-clinical incidents included falls.

- Staff told us and the clinic manager confirmed staff would report incidents to either the clinic manager or nurse in charge. The clinic manager would record the incident on behalf of staff on an electronic system. We saw the unit had a system to record, investigate, and monitor incidents. The clinic reported one non-clinical incident between May 2016 and May 2017, which was a patient fall. The unit had not had any other serious Incidents in the 12 months before our inspection.
- During the inspection, we learned of a medication error, where nursing staff incorrectly gave iron to a patient as part of an external study the clinic was participating in. Once staff had identified this incident, senior staff reported this as a clinical incident. Senior staff investigated the incident in full and the nursing staff involved conducted some reflective learning and competency assessments.
- We saw from team meetings learning from this incident was shared across the team. The clinic manager told us the parent trust gave refresher training for the external study and would conduct sessions for new staff at the unit. However, we asked staff to show us the current policy for the study or supporting guidelines and they were unable to do so. We were not assured staff were following the latest version of the guidance for this study. This had not been identified as an issue as part of the incident investigation. When requested, the clinic manager was quickly able to locate an up-to-date hard copy of the policy and confirmed the policy was available on the shared drive for staff to access.
- Staff discussed incidents at team meetings and at each handover. Minutes of team meetings we reviewed confirmed senior staff shared learning from incidents with clinic staff.

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- We saw a Fresenius bulletin from 10 May 2017 highlighted a change of practice in response to a CQC visit at another clinic where an issue relating to staff needing to clamp the circuit before and after when connecting the patients to the dialysis machine had been raised.
- Data received from the provider showed there had been four unexpected patient deaths in the 24 months before our inspection. We saw from root cause analyses conducted following these deaths that learning points had been identified by senior staff. We saw from the associated action plans, learning had been shared with staff
- We saw Fresenius Medical Care's clinical incident policy referred to duty of candour. Providers need to comply with the duty of candour regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations, 2014 by being open and transparent with patients about their care and treatment when things go wrong. Providers must inform people about the incident, provide reasonable support, truthful information, and apologise.
- The clinic manager told us the unit had an open and honest reporting culture in line with the duty of candour regulation. Incident reporting fed into their clinical governance framework and local clinic review process. We saw that Fresenius head office distributed patient safety alerts and the clinic manager reviewed them for relevance for patients at their clinic. The chief nurse distributed clinic updates and learning bulletins to support lessons learned across the organisation.
- Staff we spoke with had some understanding of the duty of candour. One staff member told us they would 'inform patients if they had made a mistake and would apologise.' A nurse told us about an incident where they had used scissors to cut some gauze resulting in an injury to the patient who was then admitted to the trust for treatment. We saw the unit sent an apology letter to the patient and the staff member apologised to the patient directly. Lessons were learned from this incident, and we saw staff were updated about this incident via a staff memo the clinic manager circulated to staff at the unit.
- All staff were required to undertake mandatory training, dependent on their role. The training monitoring tool showed training was split into different categories such as fundamental haemodialysis nursing skills and reassessment of competence. Staff completed the training in classroom sessions or online. Each member of staff had a training record to manage their ongoing training and monitor competencies in dialysis related tasks.
- The training for new staff included safeguarding, prevention of healthcare associated infections, sharps management, waste management, medicines management, records management, risk assessment, planned preventative maintenance, reporting of incidents, accidents and near misses, root cause analysis and management of emergencies and disaster management.
- We reviewed the unit's training monitoring tool. The clinic manager explained it was colour coded: red for when training was overdue, yellow for when training was due soon, and green when staff had completed the training. We saw there were numerous gaps in the mandatory training staff had completed. For example, the clinic's training monitoring tool for 2017 showed annual training for basic life support and automated external defibrillator had expired for six staff required to conduct this training. The clinic manager's training was also overdue by one day on the day of our announced inspection, one staff member was overdue by around two weeks, another was overdue by two months, and the remainder of overdue staff did not have a date specified on the matrix as to when their training was due. The clinic manager did not appear to be aware this training was overdue and could not give a date of when staff would be completing this training.

Safeguarding

- Staff told us they would raise any safeguarding concerns with the clinic manager or nurse in charge. We saw staff could easily locate the clinics safeguarding adults and children policy for guidance.
- The safeguarding link for children's and adults safeguarding at the unit was the clinic manager, who was trained to level one for safeguarding vulnerable adults. The provider had a company safeguarding lead

Mandatory training

Dialysis Services

in place who was trained to level three for safeguarding vulnerable adults and children and an additional member of the training team was trained to level three for safeguarding vulnerable adults.

- Staff were required to complete level one for children and adult safeguarding training at the unit. The unit's training and education matrix and monitoring tool we saw during the inspection was not up-to-date and showed not all staff had completed this training. However, following our inspection, senior staff provided us with an updated matrix which confirmed all staff had been up-to-date with safeguarding training at the time of our inspection.

Cleanliness, infection control, and hygiene

- The unit was visibly clean and tidy on both our announced and unannounced inspections. The unit used an external cleaning company to clean non-clinical areas. A patient we spoke with told us they liked coming to the unit because it was clean. We saw cleaning records were up-to-date and showed cleaning had taken place each day the unit was open, Monday to Saturday. However, the reception toilets did not have cleaning schedules in place and the floor felt sticky underfoot. The clinic manager told us the external cleaning company did not use daily cleaning checklists but they were looking into implementing them. During the unannounced inspection, we saw the unit had addressed this issue, as the floor was clean.
- There were sufficient handwashing facilities with disposable paper towels and soap dispensers.
- Staff disposed of clinical waste appropriately into sharps bins and separated clinical and domestic waste correctly. However, during our announced inspection we saw blood spillages outside some sharps bins. When we highlighted this to staff, they quickly cleaned them.
- There were clear infection prevention and control policies for staff to follow. The clinic manager was the infection prevention and control link nurse.
- We reviewed training compliance figures from the clinics training monitoring tool for 2017 for the infection prevention and control annual assessment received before our inspection. This showed only three staff were up-to-date with this training and the remainder of staff had not yet completed their annual training. Following our inspection, the provider informed us that staff training compliance had improved, but did not provide additional evidence to allow us to say by how much.
- Between April 2016 and May 2017 there were two incidences of MRSA swab positive results, one incidence of healthcare acquired Methicillin-sensitive staphylococcus aureus (MSSA), one incidence of healthcare acquired other bacteraemia and no incidences of hospital acquired Clostridium difficile (C.diff). The centre fully investigated these and found one patient was MRSA positive before starting treatment at Woodgate Dialysis unit and the other MRSA positive patient had been admitted to the parent trust and discharged with a wound which was MRSA positive. The MSSA incident was from a non-healing wound where Fresenius staff took a swab and blood culture. The other bacteraemia was also a MSSA infection which the patient had acquired from a newly created dialysis access arterio-venous graft.
- Records we reviewed showed the clinic manager carried out infection control audits at the end of each month. For January 2017, compliance was 100% and 99.02% for February 2017 to April 2017, which was above the compliance target of 95% for the clinic.
- The clinic completed hand hygiene audits each month based. Hand hygiene audit results for January 2016 to December 2016 showed an average of 90% compliance against the target compliance of 92%. We saw the clinic manager had completed feedback and follow up actions in response to the audit results. For example, in October 2016 when the unit achieved 77%, the feedback stated 'this was mostly due to not completing the required time for hand hygiene.' To address this issue, the clinic manager discussed this with staff in handovers and at team meetings. Monthly compliance rates for January 2017 to May 2017 ranged from the lowest compliance at 91% in April to 100% compliance in February 2017.
- We saw staff were bare below the elbow and wore the correct uniform and footwear, which was clean and tidy.

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- We observed nurses disconnecting patients from the dialysis machine. They washed their hands before attending to patients and followed 'five steps of hand hygiene'.
- However, four out of five staff we observed did not always follow good infection prevention and control practices and aseptic non-touch technique. Aseptic non-touch technique is a method designed to prevent contamination from microorganisms when undertaking certain procedures. It involves actions to minimise infection risks. For example, we observed some poor aseptic non-touch technique processes when staff were connecting and disconnecting patients to the dialysis machine.
- Staff wore suitable personal protective equipment (PPE) such as aprons, sterile gloves and an anti-blood splash face visor when attending to patients. Staff also used sanitising hand gel before putting on their gloves.
- The unit had four isolation rooms for patients the service had identified as being an infection risk. This complied with Department of Health building requirements (Satellite dialysis units: planning and design HBN 07-01) guidance which stated there should be an allocation of one to two isolation rooms per 12 dialysis stations. All isolation rooms were accessible from the main dialysis area and had a viewing window so the patient was visible to staff. However, the four side rooms were not visible from the nurse's station.
- Some patients who had returned from holiday from high-risk areas such as parts of Africa and India would use the side rooms on their return to the unit. The unit had a strict policy on the segregation of these patients and staff monitored them for three months. This followed national guidance.
- At risk patients used the same dialysis equipment and rooms for each treatment session to prevent cross infection to other patients.
- We saw dialysis machines automatically started a heat disinfectant treatment at the end of each session. We observed staff wiped down the dialysis machines and chairs between each patient and at the end of the day. Staff followed the infection prevention control policy and manufacturer guidance for the disinfection of the dialysis machines.
- To prevent risks to dialysis patients, the service used specially treated water for treatment. This followed the UK Renal clinical practice guidelines. We saw staff conducted water testing each morning before dialysis treatment started. Health care assistants monitored the water treatment room each day. We saw the results of the water testing checks for April 2017 and May 2017 (up to and including 17 May 2017) were all within safe ranges.
- Healthcare assistants also carried out monthly water testing checks. We reviewed the monthly water microbiology results summary for January 2017 to April 2017 and no contamination was present. We saw there was a contingency plan for failed water sample tests. This included retesting the water, escalating the results to the Fresenius' quality assurance manager and plant managers when results were outside of the recommended parameters.
- We saw staff used fabric tourniquets and blood pressure cuffs. Staff cleaned them with antiseptic wipes between patients in accordance with the provider's infection control policy.
- We checked five curtains at dialysis stations at the unit and found all to be in date.

Environment and equipment

- The unit's environment and equipment met the needs of dialysis patients receiving treatment with the exception of the toilet facilities. During our announced inspection, we noted that one of the three toilets was not available due to maintenance. This was having a negative impact on patients.
- There were 24 dialysis stations, 20 in the main clinic area and four isolation rooms with one station in each.
- Patients could access the unit via the main entrance, which led into the patient waiting area. The receptionist was located at the entrance in a separate office. All doors into the clinic area were secured with an electronic keypad access.

Dialysis Services

- The unit had three consulting rooms with computer access, sink, and handwashing facilities in each. There were staff and patient toilets, a staff room and a kitchen area to prepare hot drinks for dialysis patients.
- The unit had a dedicated smoking area outside the main front doors. During the announced inspection we smelt a strong tobacco odour in one of the patient toilets and saw no smoking signs were on the toilet wall. We raised our concerns regarding smoking taking place with the clinic manager and deputy chief nurse. They explained they were aware some patients had been smoking in the toilets in the past and they had displayed no smoking signs in an attempt to address the problem. We saw this was not on the clinic's risk register.
- The clean utility room was not locked on the day of our unannounced inspection, although it was lockable. The room was at risk of unauthorised people accessing medications. When we returned for the unannounced inspection, the clinic had rectified this as staff had locked it. It was free from clutter, had good lighting and the floor was in a good state of repair. There was also a hand-washing sink with soap and hand towels.
- The dirty utility was locked. This room was used to prepare cleaning solution and to prepare and store blood samples. We saw there was a separate sink for handwashing and another for cleaning product preparation.
- The clinical waste room contained correctly labelled clinical waste bags, which were. This room was also locked. Staff told us an external company collected the clinical waste twice a week. We saw they used a separate entrance for the collection of waste and supply deliveries, so they would not have to walk directly through the clinic area to minimise the possibility of infection and contamination.
- We saw the storeroom was well organised, spacious, vented and had oxygen cylinders correctly stored. All stock was stored off the floor on metal shelving or on pallets, so staff could clean them easily. We randomly checked eight products and all were within expiry date and had packaging intact.
- The main clinic was a large room with windows and good lighting. The reception, waiting area and clinic areas appeared clean and tidy and clutter free.
- All dialysis stations had a dedicated reclining chair, dialysis machine, table and ceiling mounted television with remote control. Each treatment chair had a nurse call button and staff would be able to access patients quickly in an emergency. We saw the nurse call system was working on the day of our announced and unannounced inspections and we did not observe staff overriding the alarms.
- We saw each dialysis station had enough space around the dialysis chairs in accordance with 'Health Building Note 07-01 – Satellite dialysis unit'. Each treatment chair had a nurse call system in place. We also noted there was sufficient space around each dialysis chair to maintain patient's privacy in addition to a disposable curtain.
- Staff could not easily see the patients in the four isolation rooms from the nurse's station and visibility of patients in the main clinic area was poor from the nurse's station. Staff only had a good view of patient's directly in front of the nurse's station.
- The unit had both male and female staff changing rooms. Staff told us they changed into their uniforms on arrival, which is good infection prevention control practice.
- Staff had completed the resuscitation equipment checklist every day the clinic was open for April 2017 and May 2017 (up to and including 17 May). All equipment was in working order and supplies in date. The trolley was clean and dust free.
- We saw the maintenance systems in place at the clinic and use of equipment, kept patients safe. The unit had 28 dialysis machines with five spares. Two of these machines were dedicated for holiday patients (both returning patients and patients going on holiday). One machine was an isolation machine and staff used it for one patient. We checked five dialysis machines and dialysis chairs and found all were in service date from November 2016 to December 2017. The machines had been used for between 21,574 hours and 26,979 hours. This was in accordance with Renal Association Guideline 2 which recommends dialysis machines

Dialysis Services

should be replaced between seven and ten years' service or after completing between 25,000 and 40,000 hours of use for haemodialysis depending on assessment of machine condition.

- A technician told us he attended the unit around three times a year to service the dialysis machines.
- The clinic manager told us maintenance of dialysis machines and chairs was scheduled and monitored using the dialysis machine maintenance and calibration plan. We saw this included the model type and serial number of all dialysis machines with their scheduled date of maintenance. All of the equipment we checked was up-to-date with maintenance checks. We saw there was a similar plan for dialysis chairs and beds and other clinical equipment, for example: patient thermometers, blood pressure monitors and the patient scales. Fresenius Medical Care technicians maintained the dialysis machines, chairs, beds, and water treatment plant.
- The additional dialysis related equipment was calibrated and maintained under contract by the manufacturers of the equipment, or by specialist maintenance or calibration service providers. The service maintained records relating to the maintenance and calibration of all equipment used at Woodgate Dialysis Unit.
- In January 2017, Fresenius brought Facilities Management (FM) in-house. The dedicated FM team consisted of an experienced FM Manager and two helpdesk coordinators. The team provided the clinic with both planned and unplanned preventative maintenance work. The unit could log a call with the help desk regarding any facilities issue, such as a blocked toilet or emergency lights not working. A job number and priority level (priority one being most urgent to priority four, least urgent) was allocated and the FM helpdesk ensured a contractor was requested to attend the unit to resolve the issue, according to the priority level.
- All staff we spoke with told us they had enough equipment to meet the needs of the patients. Staff confirmed the maintenance technicians supported them well.
- The weighing scales were up-to-date with calibration checks. During the unannounced inspection, the

deputy manager told us the unit had a spare set of scales that patients could use if the main scales failed; however, staff could not locate them. After the inspection, the clinic manager informed us the unit had digital weighing scales, which patients could be use temporarily. The clinic manager told us these scales would be risk assessed and used alongside a robust pre and post treatment nursing assessment of the patient. At Woodgate Dialysis Unit, the weighing scales had not broken since opening in 2009.

- Annual safety testing was part of the units planned and preventative maintenance schedule managed by the Fresenius maintenance team. The clinic kept a safety testing register on-site documenting testing dates and this was checked during the annual health and safety audit.
- Staff knew how to report faulty equipment. There were five spare dialysis machines stored in the maintenance technician's room. Staff disinfected these machines every 72 hours so they were available for use when needed.
- We saw staff used some single use equipment to minimise infection risk to patients and staff appropriately disposed of this in the clinical waste bins.

Medicine Management

- Controlled drugs were not stored at the clinic or administered as part of the services provided at the unit. The clinic manager had lead responsibility for the safe and secure handling and control of medicines. Staff told us and we saw, the key holder for the medicines cabinet was a senior member of staff. Responsibility varied by shift pattern. On the day of our inspection, we saw it was the nurse in charge.
- We saw dialysis medication was correctly stored in a locked cupboard in the clean utility room. All medication we checked was in date.
- Fridge temperature checks were in place for April 2017 and May 2017 (up to and including 17 May) for each working day (Monday to Saturdays). All temperatures were within safe temperature ranges and the fridge was clean and tidy. There was also guidance in the folder explaining what to check and what to do if the fridge temperature was not in range.

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- Staff monitored the clean utility room temperature each week. We saw staff had completed all checks between March 2017 and May 2017 and all temperatures were within range.
- Nursing staff liaised with the local NHS pharmacy for additional advice relating to dialysis drugs. In addition, staff had access to a pharmacist at Fresenius' head office if needed.
- Staff told us the clinic did not use non-medical prescribers in the delivery of dialysis services.
- We reviewed five medication and dialysis prescription records for an anti-coagulant drug and staff had documented them all appropriately. Anticoagulants are medicines that reduce the ability of the blood to clot.
- During dialysis treatment, we observed two nurses checked intravenous medication against the drug chart and asked the patient's name and date of birth to confirm identity. Intravenous medication is administered into a vein or veins.
- We saw that both nursing staff checked patients' name and date of birth on medicine charts when collecting medication, but did not follow the 'six rights' of medication administration as per the Nursing and Midwifery Council standards and the medicines management policy (right patient, right drug, right dose, right time, right route and write down i.e. document the administration or refusal of the drug).
- Patients brought their own personal medication to their dialysis session if needed.

Records

- Of the nine records we reviewed, staff had completed all accurately and legibly. When patients were receiving their dialysis treatment, we saw staff kept their records next to the dialysis machine or the nurse caring for the patient had the file with them at their desk.
- We saw when patient files were not in use they were stored in a cabinet behind the nurse's station. During our announced inspection, we found the cabinet was unlocked and there was the potential for unauthorised people to access the files. We fed this back to the clinic manager at the end of the

announced inspection. When we returned on our unannounced inspection staff had addressed this as the cabinet was locked. The service stored archived notes in a locked room.

- We saw the unit used both paper and electronic patient records. The unit shared data from their Fresenius Medical Care patient treatment database and the referring trust's clinical database system. This meant the consultant would have access to up-to-date patient records at all times, and staff would be able to ask for advice and guidance.
- We saw clinic letters from the consultant were stored in the patient files and were copied to the patient's GP, the patient and the dialysis unit, by the consultant's secretary.
- If other medical professionals, such as the dietitian, had changed any medications, staff would document this in the patient records.
- Information governance training was part of the staff induction and staff were required to complete this annually. Data received from the clinic showed 16 of the 18 staff who should have completed this training, were not up-to-date with this training.

Assessing and responding to patient risk

- The unit had 25 patients who were transferred from the service to another health care provider between May 2016 and May 2017.
- Patients had to be stable to dialyse at the unit. If a patient had acute renal problems, they would be treated at the renal unit at the parent NHS hospital. This is because they would have increased support to meet their additional needs at the trust.
- On entry to the clinic, patients took their electronic patient cards from the nurse's station. The cards had the patient's initials, the days the patient dialysed, either morning or afternoon session and the patient's usual bay number.
- Patients weighed themselves before their dialysis treatment began. We saw healthcare assistants were available to help weigh patients with restricted mobility and wheelchair users. Staff or patients inserted the electronic patient card into the electronic weighing scales to record the patient's weight. If

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patients were in a wheelchair they could be weighed on the scales in the chair as the chair weights had been pre-recorded and were written on the side of the chairs. Staff could then calculate the patient weight accurately. This is a vital part of the dialysis process, as staff need to know how much excess fluid patients have before starting dialysis.

- Before starting dialysis, staff recorded patient's observations such as blood pressure and pulse to ensure patients were well enough to start their dialysis treatment. Staff asked patients how they had felt since their last dialysis treatment.
- Some staff confirmed patient's identity before starting dialysis treatment, by asking their name and date of birth. However, we observed some staff checked the patient card with the patient file rather than asking the patients directly to confirm identity, and patients told us staff did not always ask them to confirm their identity. This meant staff could not be certain they were giving patients the correct treatment.
- Staff told us and we saw they had access to the portal at the parent trust to access discharge summaries. The trust's satellite coordinator told us the trust had put this in place following a medication error, where nursing staff at UHB had given the clinic staff incorrect information about one of their patient's medication. UHB now give clinic staff a handover, over the phone, in addition to an email.
- One patient told us: "staff are fantastic; I would trust them with my life." He had seen staff respond quickly to other patients in an emergency.
- We saw each dialysis station had a call bell. Patients told us nursing staff responded quickly to call bells to check what assistance the patient needed.
- Dialysis machine alarms sounded for a number of reasons, such as patient movement, filter leaks, or patient blood flow changes. We saw and patients confirmed staff usually responded quickly to these alarms. However, we saw a number of occasions where it took staff a couple of minutes for staff to respond. Staff informed patients not to silence their own alarms when activated. Only self-care patients who were trained to do so and could silence their own alarms.
- All patients had an individualised personal emergency evacuation plan (PEEP) to document how they would safely leave the building in an emergency. We observed that the individualised needs of a patient with learning disabilities were documented in their care plan and PEEP. Staff used the waterlow score to assess patient's risk of getting pressure ulcers. We saw staff provided patients with pressure relieving mattresses if patients were at risk. Falls assessments had been completed where appropriate. Each patient had a detailed care plan outlining the care and treatment they required.
- Staff told us if a patient did not attend (DNA) a treatment session they would contact the patient and, if necessary, they would request the police carry out a safe and well check.
- We saw if patients wished to finish treatment without completing their fully prescribed dialysis time, they would have to sign a form to state they understood the risks of doing so.
- A national early warning score (NEWS) was not used by staff in the assessment of patients who had abnormal vital signs. If during patient monitoring patients exhibited abnormal vital signs staff told us they would raise this with the clinic manager or nurse in charge and contact the consultant at the trust for support if necessary.
- Fresenius Medical Care did not have a sepsis pathway or use a sepsis toolkit. Staff would use the policy from the parent NHS trust as guidance. Sepsis is a life-threatening illness caused by the body's response to an infection. Dialysis patients have a higher risk of developing sepsis due to a lowered immune system and as during dialysis treatment devices have direct access to patient's blood stream.
- Staff told us if a patient's condition deteriorated during dialysis, they would seek advice from the clinic manager or nurse in charge and contact the patient's consultant for advice and transfer to the local NHS trust if urgent treatment was required. Staff had not completed specific training to recognise or manage sepsis. This does not comply with the National

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Institute for Health and Care Excellence guideline (NG51) for recognition, diagnosis, and early management of sepsis as there was no formal process for staff to identify the deteriorating patient.

- We had concerns that lack of staff sepsis awareness in conjunction with some poor infection prevention and control practices and aseptic non-touch technique we observed during the inspection, dialysis patients at this unit were at risk of developing an infection.
- We saw an up-to-date Fresenius document named 'complications, reactions and other clinical event pathways' which provided details of what to do in the event of a patient medical emergency, or unexpected event. This also covered technical failures and other incidents such as slips, trips, and falls.
- Staff told us they conducted basic life support simulations to ensure staff were prepared for medical emergencies. Three simulations had been conducted at the unit in the last six months.
- The clinic manager gave us an example from November 2016, where a patient stopped breathing whilst on dialysis, and was transferred to the local NHS hospital by an emergency ambulance. The patient was treated and recovered fully. We saw a letter from a relative of a patient who had been at the unit when this incident occurred, who stated: "the staff were so quick and very efficient".

Staffing

- The clinic manager had been in post for one month at the time of our inspection. There was a vacancy for a deputy clinic manager, as the clinic manager had previously covered this role. Deputy clinic managers from other clinics were covering this role at the time of our inspection. The clinic manager told us he spent 30% of his time covering the clinic and 70% conducting managerial duties.
- The unit employed 12 dialysis nurses (11 full time and one part time) and five health care assistants (four full time and one part time). The clinic manager and one of the team leaders held the dialysis qualification. During our inspections, we saw the unit's staffing

levels met patients' needs. The nurse to patient staffing ratio was four patients to one nurse, and two healthcare assistants per shift as defined by the contract the unit had with the referring NHS trust.

- The clinic manager told us they planned staffing rotas eight weeks in advance using the provider's e-rostering system. The clinic manager forwarded the rotas to the regional business manager for their approval. This advanced planning ensured staff covered all shifts for that particular timeline.
- Annual leave was included in the overall staffing levels and statistics. The clinic manager told us they assessed staffing levels each day based on the actual number of patients attending for dialysis. This also took into account unexpected staff shortages caused by sickness and unavoidable personal issues for example.
- When the unit had staff shortages, the clinic manager would rearrange shifts with the cooperation of clinic staff. Where permanent staff employed at Woodgate Dialysis Unit could not cover extra shifts, the clinic manager contacted FMC Renal Flexibank, who arranged cover. When Flexibank could not cover shifts, the unit used an external nursing agency (approved by FMC).
- Nursing staff we spoke with felt they had enough staff, which gave them time to give quality care to patients. This was despite the unit having a vacancy for one full time equivalent dialysis nurse at the time of our inspection.
- In the three months before our inspection, the unit had used bank staff to cover seven shifts and agency staff to cover three shifts. The clinic manager told us if they used agency nurses to cover shifts, they specified they needed to have renal experience and where possible, hold a renal qualification. The clinic manager worked closely with an external nursing agency to try to rebook nurses to cover shifts who had previously worked at the clinic and were already familiar with Fresenius systems, processes, and patients at the clinic.
- The unit did not employ any doctors as a dedicated consultant from the parent trust visited the clinic every two to three weeks. We saw patients received regular

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reviews from the trust's consultant. If patients were identified as requiring additional reviews, the consultants could accommodate these during their usual visits to the clinic.

- The clinic manager told us nursing staff could contact the consultant nephrologist responsible for each patient for telephone advice, during working hours. Out-of-hours or if the consultant was not able to answer their mobile, unit staff e-mailed the consultant with their query or concerns. All staff knew who and how to contact the trust's medical staff when they needed advice.
- Out of clinic hours, patients contacted their GP for advice about their care and treatment. Staff told us if patients had a dialysis related emergency, they would be transferred to the local NHS trust.

Major incident awareness and training

- We saw the unit had an Emergency Preparedness Plan (EPP) in place. This gave details of the plans the unit had for the prevention and management of possible emergencies such as fire, electricity loss, or loss of computer data. We saw the plan included defined roles and responsibilities, emergency services contact details and key personnel. The EPP also covered facilities and business recovery plans. The clinic manager was the emergency officer. This document was easily accessible in the event of an emergency as it was positioned at each fire exit.
- The plan outlined dialysis machines had a 15-minute battery back-up, so in the event of a power cut, the patient's blood could be recirculated and returned to the patient.
- Staff we spoke to told us there was a contact number if there was an IT failure. In cases of adverse weather, patients would receive treatment at the nearest dialysis unit.

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

Evidence-based care and treatment

- We saw that staff could easily access the unit's policies and procedures regarding treatment on their intranet. Policies and procedures referenced National Institute

for Health and Care Excellence (NICE) guidelines. For example, staff checked the vascular access for all patients receiving treatment in line with the National Institute for Health and Care Excellence (NICE), QS72 statement 8.

- Consultants from the parent NHS trust led clinical care with the aim to achieve the UK Renal Association Standards in relation to dialysis quality outcomes.
- We saw individualised patient treatment prescriptions to ensure best patient care outcomes with needs further assessed and planned in line with the prescription requirements, care pathways and care plans.
- Senior staff told us the unit audited achievement of quality standards (Renal Association guidelines, patient observations, dialysis access specific data, treatment variances, and infection control interventions.) The Fresenius data manager and medical director produced a monthly report summarising each dialysis unit, which they shared with the area head nurse, who worked with the clinic manager to address improvement areas. The clinic manager told us a new 'clinic review' process further captured overall month on month clinical effectiveness and improvement areas. As part of the Fresenius Clinical Governance Review and reporting, the unit sent the respective NHS trust clinicians a report defining the clinic achievement against Renal Association standards.
- The unit could measure individual clinical outcomes for all renal patients on dialysis at the unit by their blood test results, before and after dialysis treatment, as recommended by the Renal Association Standards.
- The trust consultant reviewed patients' blood results each month to monitor the effectiveness of treatment, and to determine if any improvements and changes to care provision would improve outcomes.
- The clinic's electronic database fed into the trust's electronic records. The unit's data management system provided customised reports and trend analysis, to monitor and audit patient outcomes and treatment parameters. This highlighted the opportunity to improve outcomes and patients' quality of life. Live data was available for the clinic

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manager and consultant to monitor and audit individual patient performance month on month, to identify where the unit could make improvements in the achievement of national standards.

- The parent NHS trust was responsible for the creation of patient's fistulas. Staff at the unit were responsible for monitoring the condition of patient's fistulas. Before patients can start haemodialysis, they usually need to have a special blood vessel created in their arm, called an arteriovenous fistula (AV fistula). This blood vessel is created by connecting an artery to a vein. AV fistulas are considered to be the best type of vascular access for adult haemodialysis patients. They last longer and have a reduced risk of complications compared to other vascular access types.
- The unit monitored patient's AV fistulas. Between January 2017 and March 2017, 64% of patients (56 out of 88) had AV fistulas. This was lower than the Renal Association recommendation of 85%. Senior staff advised nursing staff to refer patients without fistula access for fistula formation.

Pain relief

- The unit stocked and administered paracetamol tablet or local anaesthetic if this was prescribed for patients. We saw if some patients needed pain relief they brought in their own which was prescribed by their GP. For example, we saw a patient had numbing cream to lessen the pain from the injection when being connected to the dialysis machine.
- Staff checked patient pain levels when connecting them to dialysis machines. We saw nursing staff attempted to make patients as comfortable as possible, for example for a patient whose arm was aching, staff provided a cushion for them to rest it on.
- If nursing staff identified any patients in pain, they told us they would escalate this to the consultant or the trust's satellite unit coordinator.

Nutrition and hydration

- Renal failure patients need to keep to a strict diet and have to restrict their fluid intake to have a healthy lifestyle.
- We observed patients were weighed on arrival at the unit before they were connected to the dialysis

machine. This was so staff could calculate the fluid weight required to be removed during the dialysis treatment. Some patients were able to weigh themselves and health care assistants assisted patients who required additional help.

- We saw patient's nutrition and hydration needs were assessed and met at the unit. A dietitian from the parent trust attended the unit three times a week and visited patients at their bedside to provide dietary advice and support. Patients told us they received ongoing dietary information from the dietitian, who explained if certain levels were high from blood results and gave patients nutritional advice to address this.
- Patients told us staff offered them one hot drink and biscuits during their dialysis treatment. We observed the refreshment round and saw staff also offered tea to visitors at the unit. Some patients told us they would like to have more refreshments whilst on dialysis. For example, one patient told us they had asked for another drink and staff had refused. Another patient told us they would prefer to have their drink later on in the morning, but staff had told them this was not possible.
- We saw a noticeboard in the reception area, which displayed information on dietary salt intake to help renal patients with their fluid management.

Patient outcomes

- The unit did not submit data directly to the UK Renal Registry. The clinic's data was combined with the parent NHS trust data and the trust submits it as one data set. Senior staff told us this data only included patients under the direct care and supervision of the parent trust and would not include patients undergoing dialysis away from base, for example. 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 Woodgate Dialysis Unit. Therefore, data specific to the unit and available via the unit's database, was used to benchmark patient outcomes both as an individual clinic and nationally against all Fresenius Medical Care UK clinics.
- The clinical outcomes of dialysis patients can be measured by the results of patient's blood tests. The unit monitored patient's blood test results each

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month in accordance with the referring NHS trust. These results showed how the unit performed compared to UK Renal Association guidelines. The unit conducted monthly reviews of patient outcomes with the patient's consultant. This was also discussed at the monthly contract reviews with the trust.

- We reviewed patient's blood test results for three months from January 2017 to March 2017. This included the patient's outcomes for the following standards:
- During this time period, 71% of patients had safe levels of haemoglobin (hb). Patients with renal failure are at risk of anaemia, which can increase mortality risks and cardiac problems. This meant 29% of patients had lower than recommended haemoglobin levels. In December 2016, 67.6% of patients at the unit had safe haemoglobin ranges. The unit was 22nd out of 43 when compared to other Fresenius units where the best performing unit had 91.7% of patients with safe haemoglobin levels. This was also compared to the lowest performing unit which had 18.9% of patients with safe haemoglobin levels.
- The service monitored potassium levels in the blood in accordance with the Renal Association guidelines. Between January 2017 to March 2017, 77% of patients had acceptable levels of potassium. This meant 23% of patients (21 out of 88 patients) had potassium levels above the normal range. Higher levels of potassium in patient's blood can cause acute cardiac complications. As a result of these results, senior staff had encouraged named nurses to encourage their patients to take their phosphate binders.
- Results for January 2017 to March 2017, showed 34% of patients had albumin within the specified range compared to a target of 50%. Albumin provides the body with the protein needed to both maintain growth and repair tissues. It can also help with fluid removal during the dialysis treatment. If patient's albumin level is good, fluid will move more easily from swollen tissues into the blood, where the dialyzer can then remove it. These results showed 29 patients had albumin levels at less than 35g/l. The referring trust set their target at greater than 30g/l.
- During the same time period, 99% of patients (87 out of 88 patients), received haemodiafiltration (HDF) treatment. This is a more effective treatment for kidney failure. One patient was on HD as they could not tolerate HDF.
- We reviewed the dashboard, which demonstrated the clinic's performance compared to other Fresenius Medical Care (FMC) dialysis units for numerous patient outcome measures. For December 2016, 70% of patients at Woodgate Dialysis Unit achieved their weekly treatment time target. The unit was in the middle of the range compared to other Fresenius Units. The best performing Fresenius unit for this outcome in December 2016 achieved 92% and the lowest result was 43%.
- Waste reduction from dialysis is measured by the urea reduction ratio. In December 2016, Woodgate Dialysis Unit was in the top three best performing FMC clinics for this outcome (result was 85%). The average result for patients at the unit between January 2017 to March 2017 was 77%. The Renal Association guidelines indicate a target of 65%. Patients with high levels of waste reduction through dialysis have better outcomes and improved survival rates.
- Between January 2017 to March 2017, 71% of patients who attended the clinic three times a week were dialysed equal to or longer than the prescribed four-hour treatment duration. This is above the recommended target of 70%. However, this also showed 29% of patients did not have the prescribed four hours of treatment.
- The clinic manager coordinated all changes to patient treatment parameters or referrals to other services and reported them to the clinical staff for further action. The named nurses and dietitian discussed outcomes and changes with all patients. The clinic provided written information to patients to ensure they had an ongoing record of their treatment outcomes.

Competent staff

- The clinic manager and one registered nurse held a renal qualification (BSc Renal Nursing). The deputy

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clinic manager had been approved for enrolment on this course starting in April 2018. We were told the provider encouraged all registered nurses to take this renal course.

- In the last 12 months, all staff had received an appraisal and staff we spoke with told us it was a good opportunity to discuss any training required and raise any issues. We saw the appraisal plan for 2017 was up-to-date to ensure all staff had an appraisal booked in.
- We checked the Nursing and Midwifery Council (NMC) registration of ten staff at random; all were in date. We saw staff were responsible for checking their own registrations each month and data provided by the trust before the inspection stated all staff had their professional registration checked by the clinic manager.
- However, in the unit's January 2017 contract review meeting minutes we reviewed, the minutes stated a nurse's NMC registration had expired on 31 December 2016 and this nurse had worked on 2 January 2017. This was the second time the nurse's registration had expired. They were suspended without pay until their NMC registration was in place and a disciplinary meeting was held. However, following the inspection we were informed this instance related to another Fresenius unit and not to Woodgate Dialysis Unit. Therefore, the unit did not have a robust system in place to ensure contract meeting minutes accurately reflected what was discussed. In addition, a process was in place to identify when NMC registration lapsed, however this did not remind staff beforehand.
- We saw the unit had a thorough induction process for new staff. This included topics such as emergency procedures, training, and supervision of their clinical practice, preceptorship and mentoring and health and safety induction training.
- New staff at the unit had a six-month probationary period when they began working at the unit. Staff had a supernumerary period during their first year of employment, where senior staff closely supervised their clinical practice. Staff told us they started to connect and disconnect patients to dialysis machines under supervision once they had worked at the unit for six weeks. Staff had full competency assessments during their probationary period.
- Senior staff told us the unit offered existing staff continual professional development opportunities for ongoing assessment and maintenance of competencies, to support NMC registration. We saw the unit also held dialysis specific study days, e-learning sessions and virtual classroom training for existing staff.
- The clinic manager told us there was a procedure about how to report suspension or unfitness to practice on clinical or professional grounds to the Nursing and Midwifery Council and the General Medical Council. In addition, the clinic had internal performance management systems to manage staff who were not performing to the expected standards. The clinic manager explained the disciplinary investigation process in detail.
- We saw two nurses had been responsible for a medication error in April 2017. This had been identified by another staff member on 10 May 2017 when they were checking the patient's prescription. The staff involved had to complete a re-assessment of competency for administration of medication, assessed by the clinic manager. The clinic manager also ensured they re-read the Fresenius medication management policy and completed a 1500 word reflection to review and learn from the error. The clinic manager reassessed the competency of the staff members responsible for the medication error. We reviewed their training files and saw evidence that confirmed this had taken place.
- The clinic manager, deputy clinic manager and team leaders were competent to sign off staff competencies in certain dialysis practices.
- The clinic manager planned the staff rota to ensure an experienced staff member was always on duty at the clinic. As the unit was not attached to the parent NHS trust, staff were trained to manage emergencies and we saw staff had dealt with emergencies well, when they had occurred.

Multidisciplinary working

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- Staff told us the unit had a good relationship with the parent NHS trust who provided all dialysis patients at the unit with specialist support for their condition.
- The trust's satellite coordinator was at the unit on the day of our announced inspection to supported staff at the unit. The unit held monthly contract meetings with the trust, which the unit's head nurse would attend. Senior staff discussed any variances at this meeting.
- The unit held monthly multidisciplinary meetings. The consultant, dietitian, and satellite haemodialysis unit coordinator from the referring trust attended these meetings along with the clinic manager. Staff told us the agenda usually included patients' current condition, patient's care plans, blood results, and medication. Staff recorded these discussions in the electronic patient record.
- We saw the consultant's review letters were also sent to the patient's GP to update them regarding their patient's condition.
- Staff told us the renal consultant from the referring trust had overall responsibility for patient care. Staff told us and patients confirmed, the consultant visited the unit two or three times each month to conduct patient's clinical reviews.
- Patients had access to the trust's dietitian who reviewed patients before the monthly multidisciplinary meetings.
- A social worker was also available to patients to give financial advice and discuss entitlement to benefits. Staff told us one of their patients was receiving housing support from the trust's social worker, to assist the patient to be rehoused nearby. We spoke with this patient who told us they wanted to live nearby so they could still receive treatment at this unit.

Access to information

- The unit held a daily handover each morning to discuss patients receiving dialysis at the unit that day. This included any updates to patients' medical care and any concerns staff needed to be aware of.
- Staff had access to all necessary information to be able to deliver effective care and treatment to patients. The trust's satellite coordinator told us and

we saw, the unit had recently had access to the NHS portal so the parent NHS trust could share information with the unit. Nursing staff told us this reduced the time it took them to chase blood results and other test results. This also meant it was easier for consultants to give advice to nursing staff regarding patient's treatment as they had access to up-to-date information.

- Patient data was automatically uploaded to the trust's electronic database after each session. This meant consultants at the trust had access to up-to-date information regarding their patients.
- Staff told us, and patients confirmed they had access to their own blood results.
- When the trust's consultant was on holiday, they would provide a contact number for the covering consultant.

Consent, Mental Capacity Act and Deprivation of Liberty

- Patients must consent to and receive information about their treatment before they receive it. Patients consent forms were present in the 10 patient files we checked.
- We saw a patient had been enrolled onto a study run by a research and teaching university. There was no evidence in the patient file they had consented to this and some staff at the clinic were not aware the patient was part of the study. Following the inspection, we were told the parent trust held the consent for their patient's on this study and was available to staff at the unit via the on-line portal.
- Continuing professional development was provided to staff to enhance the nursing team's awareness of dementia care, the Mental Capacity Act 2005, consent and deprivation of liberty standards. Senior staff told us this helped to promote the specialist care needed by some patients referred to the unit.
- The Deprivation of Liberty Safeguards (DoLS) are part of the Mental Capacity Act (MCA) 2005. These safety measures are in place to ensure people are cared for without inappropriately restricting their freedom. Staff did not fully understand the processes in place to assess mental capacity and DoLS of patients and told

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us the consultant would ensure this was completed if necessary. We were not confident the unit had effective systems to ensure staff adhered to the MCA and DoLS legal requirements.

- A patient with learning disabilities attended the unit with their carer for every dialysis session. We saw the carer had signed the consent form for the patient's dialysis treatment at the start of the patient's treatment, in January 2017. However, staff told us and we saw there was not a best interest decision in place for this patient. We saw in their patient records, an individualised care plan had been in place since February 2017.

Are dialysis services caring?

Compassionate care

- We reviewed 18 'Tell us about your care' comments cards patients had anonymously completed before our inspection. Out of the 18 cards, 15 were positive, two cards contained both positive, and negative feedback and one card had negative comments.
- The positive comments were very complimentary about the caring, professional, and responsive manner of staff, and the cleanliness of the unit. Positive comments included 'the staff are so caring and if you have a problem they will sort it out for you,' 'staff treat me with dignity and respect at all times,' and 'all areas were spotlessly clean and tidy.' Negative comments related to a shortage of toilet facilities and lack of integrated care for other complex needs.
- We saw the majority of nurses spoke to patients in a friendly and caring way and took time to listen and talk to them. We saw staff greeted patients on arrival to the unit and said goodbye to patients when they left the unit after their treatment.
- One patient told us staff were friendly, considerate, and caring. Another patient told us staff were "excellent".
- However, during our announced inspection, we also saw two occasions where nursing staff did not communicate effectively with patients during treatment and two patients also told us sometimes staff did not keep them up-to-date about their treatment or reassure them. For example, one patient told us they were concerned about their fistula and their arm was painful and looked bruised. Nursing staff had advised this was how it would look for a while but did not offer any further reassurance or information. We observed the nurse did not communicate with this patient during the whole connection process.
- We saw another patient who told us they had recently had a new fistula as the previous one had ruptured. The patient told us they were anxious, as the nurse who was caring for the patient today had ruptured the previous one. The nurse did not give any reassurance to the patient.
- We saw another patient coughed for a few minutes without staff asking how they were, or offering them a drink.
- One patient told us they had requested some personal hygiene products from staff and nursing staff told the patient the unit did not stock them. Staff were not able to offer an alternative.
- The clinic manager was popular with patients who told us they were friendly and deserved their promotion to clinic manager.
- Staff provided care to patients in shared areas however, if required, staff could use the curtains for additional privacy. Patients felt there was enough privacy and could request to use the quiet room for confidential discussions about their care, if required.
- Two patients and one carer told us staff took time to communicate with them. However, a patient in the isolation room felt staff did not always take time to interact with them. Staff would wave from outside but did not regularly come inside to check on them or say hello.
- Patients told us there was enough entertainment during a dialysis session as each station had its own ceiling mounted TV with remote control. Patients could also bring in their own entertainment from home.

Understanding and involvement of patients and those close to them

- Patients we spoke with felt they were involved in decisions about their treatment. Each patient had a

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named nurse, which staff wrote on the front of the patient notes. Patients we spoke with knew who their named nurse was and told us they would discuss their dialysis treatment with them.

- Patients told us when they first started dialysis treatment they were invited to have a tour of the unit with family or friends to familiarise themselves with the facilities, staff and routine.
- One patient told us the consultant assessed them on the unit rather than in a separate clinic appointment, as they preferred this.
- Staff told us they could access translators from the parent trust for patients whose first language was not English if required.

Emotional support

- Staff told us they knew patients well as they cared for them regularly, often for a number of years.
- Senior staff told us the unit worked in partnership with a social worker and renal psychologist based at the renal unit of the parent trust. They could arrange for additional support for patients if they needed it.
- A patient told us they did not realise how little movement they would have in their arm from having a fistula fitted. They told us how they enjoyed beading to pass the time when on dialysis and this prevented them from doing it. The patient told us nursing staff had not discussed any of these concerns. We also saw nursing staff did not give the patient a pillow to ease discomfort.
- We saw the unit provided patients with details of support networks for patients and relatives such as the Kidney Patient Association.

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

Meeting the needs of local people

- The parent NHS trust renal unit referred patients to the unit for their haemodialysis treatment. The unit's priority was to ensure patients were physically well enough for satellite treatment and they lived in the local area.
- The unit was contracted by NHS England to provide renal dialysis to patients from University Hospital Birmingham NHS Foundation Trust (UHB). The contract period was for 10 years from 2009 – 2019. The parent NHS trust referred patients to the unit for their haemodialysis treatment.
- The building complied with the standards outlined in the Department of Health Renal Care Health Building Note 07-01: Satellite dialysis unit. The unit had drop-off points for ambulances and designated patients' car parking spaces close to the unit. Patients who drove themselves to the clinic told us there was plenty of parking for patients.
- The entrance had automatic doors that led to a door with a camera and intercom system. The receptionist or staff on the unit permitted entry. However, the entrance was not covered so did not protect patients and visitors from inclement weather.
- We saw a 'you said, we did' poster in the waiting area displaying actions of a recent survey. Because of patient feedback, there was now a dedicated area to store wheelchairs.
- Data provided from the unit confirmed there was no transport user group for those patients who used patient transport services. Both staff and patients told us there had been problems with the patient transport services and patients were sometimes delayed following treatment. The clinic manager told us of liaison between the clinic, patient transport services, and the trust to identify solutions to better manage this issue.
- Another provider had the contract to provide the patient transport service. This was implemented on 1 May 2017 as part of a new contract and was still in the transition process. The patient transport service was contracted to another provider and therefore the unit did not monitor patient travel times in accordance with National Institute for Health and Care Excellence (NICE) quality standards (QS72 – standard 6). Under the previous patient transport contract, staff at the

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unit arranged and booked transport for patients. As part of this new contract, staff and patients told us patients would have to book transport themselves. Patients and staff told us they were normally collected on time.

- Staff told us and we saw, staff made suitable adjustments for patients with learning disabilities and early stages of dementia. They could have a family member or carer with them during their treatment.

Access and flow

- Referrals for admission were controlled by the parent trust who informed the unit they had new patients they wanted to receive dialysis treatment at Woodgate Dialysis Unit.
- Staff would allocate new patients dedicated dialysis appointment times in accordance with social care and work commitments, day slot availability for the elderly, vulnerable or those with more complex care needs, length of journey to the unit and number of hours or days of dialysis. One patient told us they were able to change their morning slot to the afternoon to fit in with their personal circumstances.
- A twilight shift was not available at this unit and this was not part of the contract with the trust. Staff told us if patients needed this service, the trust would allocate them to another unit.
- The parent NHS trust referred new patients for dialysis treatment at the unit. For patients to be accepted they needed to meet the clinic's acceptance criteria. The unit accepted patients over 18 years, who had functioning haemodialysis vascular access, were clinically stable for satellite treatment, and had medical approval. Staff requested comprehensive details regarding the patient requirements pre-transfer to ensure all of the patient's care needs.
- Senior staff told us they did not have any patients on their waiting list for dialysis treatment and there were no dialysis sessions cancelled for a non-clinical reason in the 12 months before our inspection.
- Data received from the unit before our inspection showed the unit utilised 85.9% of treatment slots in November 2016, 84.2% in December 2016, and 84.6% in January 2017.

- One patient told us waiting times varied and a family member had complained in the past about long waiting times. On the day of our inspection, one patient told us they had been waiting for approximately four hours to start their dialysis treatment as the morning patient had started their dialysis treatment late, but stated this was not a common occurrence. Staff had not apologised for the delay or given any updates. We raised this issue with senior staff during our inspection. The unit did not collect data on patient delays to treatment.

- During our announced inspection, we saw a patient with a new fistula was an hour late to start treatment as staff were treating this patient at the end as they had a new fistula. Staff had not kept the patient up-to-date with the delay. We would expect a risk based rationale for treatment of new fistula patients. A new fistula where there is no history to review would make these patients higher risk than those who were known to the service.

Service planning and delivery to meet the needs of individual people

- The unit was easily accessible for disabled patients and had equipment to support treatment of those with additional care needs such as a bariatric wheelchair.
- There were two unisex disabled toilets in the reception area. During our announced inspection, one toilet had been out of order for one week awaiting repair. There was no other hand basin or handwashing facilities in the reception. However, there was sanitising hand gel at the entrance to the clinic.
- We saw there was sufficient seating in the reception. Chairs were wipe clean and staff could therefore clean them effectively. There were also four bariatric chairs.
- The unit had wheelchair access and plenty of space in the waiting area for wheelchairs.
- Staff at the unit provided pressure-relieving mattresses for patients at risk of pressure ulcers. A trust viability nurse from the trust supported staff with this.
- We saw information leaflets including the patient guide, were available in a number of different languages to help patients understand their condition,

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and treatment provided at the unit. These reflected the cultural diversity of the local population. We saw the patient guide was available in a number of language options. The local NHS trust arranged access to translation services. Staff could translate for patients who did not have English as their first language. Staff at the unit spoke over 10 different languages, which included Romanian, Indian, and Filipino. Staff told us they would contact the next of kin where patient consent was needed, or the parent trust could arrange a face-to-face translator.

- A non-English speaking patient told us she understood her medical condition because of information she had received from the parent NHS trust rather than at the unit. Holiday dialysis treatment was available and encouraged for stable patients visiting the local area when the unit had capacity.
- We saw the clinic provided dialysis treatment for a learning disability patient, who attended the unit on the day of our announced inspection with their carer.
- We saw the unit had support from the Kidney Patients Association to support patients and those close to them.
- Patients told us the written information they received was sufficient. We saw information leaflets in the waiting area to aid patient understanding about their renal issues such as albumin levels.
- Staff told us a learning disability nurse was not available at the unit to provide support however, they could be accessed via the parent trust if necessary.
- The unit did not treat patients with severe dementia or learning disabilities as the local trust would treat them, as they had a higher patient to nurse ratio to provide additional support for their needs.

Learning from complaints and concerns

- We saw the unit had a formal process in place to manage complaints in accordance with their complaints policy. The clinic manager had the responsibility for ensuring complaints were dealt with within a maximum of 20 working days.
- Senior staff told us they were committed to dealing with the '4 C's' (compliments, comments, concerns and complaints) in a sympathetic and understanding

way. They told us they recognised that lessons for continuous quality improvement for patients might develop as a direct result of a concern or complaint. The unit had a feedback policy, which Fresenius had developed in line with the approach taken by the NHS.

- The unit had two complaints in the year before our inspection. Senior staff told us they could receive complaints either verbally, written, or via their patient satisfaction survey. We saw 'Tell us what you think' leaflets in the patient waiting area to encourage patients to share comments, concerns, or compliments. The clinic shared feedback with the regional business who outlined what follow up actions the unit required. Senior staff told us they always took complaints seriously and the unit manager handled them sensitively. We saw Fresenius' feedback policy and statement of purpose displayed in the patient waiting area.
- One patient we spoke with told us she did not know how to complain. Another patient said they would raise concerns directly with the clinic manager. We saw a poster in the waiting explaining how to complain.

Are dialysis services well-led?

Leadership and culture of service

- At the time of our inspection, the clinic manager had been in post for one month and the area head nurse was supporting them closely throughout the inspection. The clinic manager was previously the deputy manager at the clinic and as they had been promoted from the deputy manager position, the deputy clinic manager post was vacant at the time of our inspection.
- The clinic manager reported to the area head nurse, who attended the clinic on our announced inspection. We saw and staff told us, the area head nurse regularly visited the unit and was supportive to staff and spoke with patients at the unit.
- As the unit was part of a large organisation, the dialysis unit had a defined management structure from a local, regional, and national perspective. The area head nurse supported staff locally and monitored the performance of the unit.

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- We saw staff and patients confirmed there was a friendly atmosphere at the clinic. Staff and patients told us the clinic manager was approachable, visible, and supportive.
- We saw staff worked well together as a team. Staff told us they enjoyed working at the unit because of the good teamwork.
- The Workforce Race and Equality Standard (WRES) is a requirement for organisations providing care to NHS patients. This ensures employees from black and minority ethnic (BME) backgrounds have equal access to career opportunities and receive fair treatment in the workplace. Woodgate Dialysis Unit was situated in a culturally diverse area and the clinic employed staff to reflect their local population.

Vision and strategy for this core service

- In the reception area there were posters displaying Fresenius' commitment to patients, employees, shareholders and the community.
- Nursing staff could not define the vision and strategy of the clinic but stated their priority was to deliver good quality care to patients. We were told senior staff discussed Fresenius Medical Care's vision and values at staff team meetings.

Governance, risk management, and quality measurement

- The clinic manager was the lead for governance and quality monitoring at the unit. Senior staff told us Fresenius had recently appointed a quality and risk manager, which was a new role in the organisation.
- We saw the performance matrix for January 2017 to April 2017 which included the unit's data for patients who had completed their full dialysis time and do not attend rates for example. Woodgate Dialysis Unit was within the top five Fresenius clinics for their performance when compared to all 55 Fresenius clinics in the UK.
- The clinic manager and area head nurse met with the trust each month for quality assurance meetings to review the unit's performance against the contract requirements with the trust.
- We saw the unit had its own local risk register last reviewed in May 2017. The chief nurse and clinic

manager reviewed the unit's local risk register each month. This was split into operational, clinical, and technical risks. Fresenius had implemented this risk register in January 2017. Senior staff told us operational risks included loss of water, clinical risks included medication errors and problems with IT would be classed as technical risks.

- We had concerns the clinic's systems did not support the management of risk and safety at the clinic. The clinic manager told us they reviewed the clinic's risk register each month. However, during the inspection, they could not explain it in detail and the area head nurse explained on their behalf. The clinic manager was new in post at the time of our inspection and did not yet know the risk monitoring in place in detail.
- Sufficient action had been taken since the three clinical medication errors, and measures had been put in place to prevent re-occurrence.
- We saw senior staff discussed risks at the monthly clinical governance meetings.
- The clinic manager conducted monthly patient record audits to ensure all relevant documentation was in place and up-to-date. We saw the clinic manager also audited appraisal and mandatory training rates and staff needle stick injuries each month.
- From 1 August 2016 onwards, all organisations that provide NHS care were legally required to follow the 'Accessible Information Standard'. This aimed to ensure people who have a disability, impairment, or sensory loss has information in a form they can easily read or understand and support to communicate effectively with health care. Following the inspection, senior staff told us this was highlighted as a gap Fresenius-wide early on in the CQC Inspection programme. We saw the provider had added this to their corporate risk register and had a plan in place with the aim to be compliant by 27 July 2017.

Public and staff engagement

- The unit conducted annual patient and employee satisfaction surveys and actively encouraged patients to provide feedback about their experiences at the unit.
- We saw the results of the patient satisfaction survey, 2016 which had 40 respondents:

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97% of patients were likely to recommend the unit to friends and family in need of dialysis, 92% patients were satisfied with the unit, 86% of patients said they had complete confidence in the nurses here, 85% of patients thought the treatment rooms were well maintained and clean, 79% of patients thought this clinic was well organised, 97% of patients felt the atmosphere in this dialysis unit was friendly and happy.

- We saw action plans from the 2016 patient satisfactory survey detailed actions for improvement such as staff needing to explain to patients how dialysis works.
- The unit also collects feedback through a 'Tell us what you think' anonymous leaflet system, which allowed patients to comment on the service using freepost direct to the Fresenius head office. This feedback was shared with the regional business managers and they determined follow up actions with the unit where necessary.
- Areas for review from the October 2016 employee satisfaction survey were being planned at time of our

inspection. There were 14 respondents (88% of staff). 100% of staff said they would recommend the dialysis unit to friends and family, 85% said they would recommend the unit as a place to work compared to 59% of staff would recommend their organisation in the NHS.

- The clinic manager did regular walk arounds of the unit and spoke directly with patients to obtain feedback about their care and treatment.

Innovation, improvement and sustainability

- The unit took part in a clinical research programme led by a teaching hospital.
- The unit shared good practice with other Fresenius units. We saw senior staff shared learning from other Fresenius units with staff.
- Staff told us they were happy with the unit as it was and did not describe any areas they would like to improve.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- Ensure nursing staff check patient identity before starting dialysis treatment and before administering medication, in line with NMC guidance.
- Ensure staff have a sepsis policy to access about the management of suspected sepsis and complete specific sepsis training.

Action the provider **SHOULD** take to improve

- Ensure staff follow infection, prevention, and control practices and specifically aseptic non-touch technique.
- Ensure staff are up-to-date with mandatory training.
- Ensure nursing staff communicate effectively with patients during treatment and keep patients up-to-date.
- Ensure staff fully understand the Mental Capacity Act and Deprivation of Liberty Safeguards.

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>Regulations 2014 Safe care and treatment</p> <p>12 (1) Care and treatment must be provided in a safe way for service users.</p> <p>(2) (a) assessing the risks to the health and safety of service users of receiving the care or treatment;</p> <p>(g) the proper and safe management of medicines;</p> <p>How the regulation was not being met:</p> <ul style="list-style-type: none">• Nursing staff were not always checking the patient identity before starting dialysis treatment and before administering medication, in line with NMC guidance.• There was no sepsis policy or toolkit for staff to access about the management of suspected sepsis. Staff did not complete specific training to recognise or manage sepsis. There was no formal process for staff to identify the deteriorating patient.