Grimsby NHS Dialysis Unit

Quality Report

Diana Princess of Wales Hospital,
Scartho Road,
Grimsby, DN33 2BA
Tel: 01472 279950
Website: www.freseniusmedicalcare.co.uk

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Grimsby NHS dialysis unit is operated by Fresenius Medical Care Limited (FMC), an independent healthcare provider. The unit has 12 stations (comprised of ten stations in the main area and two side rooms which can be used for isolation purposes) providing haemodialysis for stable patients with end stage renal disease/failure. It is contracted by Hull and East Yorkshire Hospitals NHS Trust, to provide renal dialysis to NHS patients. Patients are referred to the unit from Hull and East Yorkshire Hospital Trusts Renal Service.

The service is situated as a 'standalone' dialysis unit on the site of the Diana Princess of Wales NHS hospital. There are plans to increase to 18 stations later this year. The service commenced in 2008 and does not treat children at the unit.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 5 May 2017, along with an unannounced visit to the unit on 22 May 2017.

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

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

Services we do not rate

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

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

- We saw 'missed opportunities' within incident investigation documentation including escalation of the deteriorating patient and lessons learnt were not consistently collated.
- Patient identification policies and processes were not in place in accordance with national guidelines and Nursing and Midwifery Council (NMC) standards in relation to medicines management.
- The unit appeared untidy, with litter and bins reaching full to capacity.
- Initial assessments lacked detail and care plans were not developed to support the care and treatment of patients with specific health needs.
- There was no clear system to ensure staff could consistently identify and manage deteriorating patients, which included sepsis identification.
- One of the water treatment plants had not been serviced according to the manufacturer's instruction and documentation to mitigate against this was not available on the unit.
- The unit was not meeting the 'Accessible Information Standard' (2016) or the Workforce Race Equality Standard (WRES) (2015) at the time of our inspection.
- Staff training compliance was lower than the provider's internal target in several areas and the unit staff had not received training in accordance with the intercollegiate guidance document "Safeguarding Children and Young People" (2014).

However, we found the following areas of good practice:

- Staff were clearly able to describe the incident reporting system and were able to provide examples of incidents and how to report them. Staff understood the classification of incidents as clinical, non-clinical and Treatment Variance Reports (TVR's).

Summary of findings

- We observed staff working with competence and confidence in the unit. Nursing staff were experienced and qualified in renal dialysis. We saw 100% of staff had received induction and appraisal and four staff were completing a renal qualification.
- We observed a caring and compassionate approach taken by the nursing staff and named nurses during inspection.
- We observed that consent processes were in place and documentation was accurate. Easy access to complex patient information in the unit and across the trust supported treatment and care of patients in the unit.
- Performance indicators for 2016/17 showed comparable performance against other Fresenius units nationally.
- The unit was able to provide haemodiafiltration 100% of the time during the last three months reviewed prior to inspection.
- Patients were supported with self-care opportunities and a comprehensive patient education process was in place. Holiday dialysis for patients was arranged to provide continuity of treatment and support the wellbeing of patients.
- Morale at the unit was high and staff spoke positively about the support they received from the clinic manager.

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 three requirement notices that affected dialysis. Details are at the end of the report.

Ellen Armistead
Deputy Chief Inspector of Hospitals (North region)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Dialysis Services		The unit provided only dialysis treatment for adults. We did not rate the service but found that most patients were happy with the care and treatment they received and felt the unit was friendly with competent staff available to provide haemodialysis treatment.

Summary of findings

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Background to Grimsby NHS Dialysis Unit

Grimsby dialysis unit is operated by Fresenius Medical Care Renal Services Limited. The service opened in 2008. It is a private medical dialysis unit, situated in the Diana Princess of Wales hospital in Grimsby. The unit primarily serves the communities of the East Yorkshire and Hull areas. It also accepts patient referrals from outside this area. The hospital has had a registered manager in post since June 2016.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector, one other CQC inspector and a specialist advisor with expertise in renal dialysis. The inspection team was overseen by Amanda Stanford, Head of Hospital Inspections.

Information about Grimsby NHS Dialysis Unit

The dialysis unit has one main ward area, split into three sections and is registered to provide the following regulated activities:

Treatment of disease, disorder, or injury.

There are three treatment sessions for patients who have dialysis on Monday, Wednesday, and Friday, with a maximum 12 patients in the morning, 12 in the afternoon and 10 patients during the evening session. There are two treatment sessions for patients who have dialysis on Tuesday, Thursday, and Saturday mornings when around 12 patients are dialysed.

The usual times for dialysing patients are 6.45am, 12.15pm and 5.30pm. The dialysis unit opens from 6.30am and closes at latest 11.00pm.

Patients were referred to the unit by a local Yorkshire NHS Hospital Trust. The trust provides the renal multidisciplinary team, with two consultant nephrologists visiting the dialysis unit at least four times a month. Multidisciplinary team (MDT) meetings are usually held on the second and third Wednesday of each month where the consultant, dietitian, and clinic manager review patient outcomes, and blood results. The clinic manager also attends the MDT meetings. Medical staff are not on site regularly which includes MDT meetings.

At the time of inspection the service was undergoing an expansion and refurbishment project to increase capacity from a 12 to an 18 station facility. This included the upgrading of the water treatment plant and addition of an extra consultation room for outpatient use. It was anticipated that the works would be completed by the middle of June 2017.

An average of 680 treatments sessions are delivered each month. Both male and female patients were treated in the same areas at the same times and the expansion was in response to growing demand for the facilities. During the inspection, we visited the three treatment areas where dialysis took place, and the other non-clinical areas of the unit, such as the maintenance room, and water storage area. We spoke with a range of staff including the area head nurse, clinic manager, deputy clinic manager, registered nurses, and dialysis assistants. We also spoke with eight patients. We also received 20 ‘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 unit ongoing by the CQC at any time during the 12 months before this inspection. The service has been inspected

Summary of this inspection

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

Activity

In the reporting period April 2016 to March 2017, there were 3686 dialysis sessions carried out for 18-65 year olds and 5789 sessions for people over 65 years of age.

Currently 23 patients from age 18-65 and 32 patients over 65 years of age are NHS funded and treated at the unit. The unit did not employ any doctors. Doctors were employed by the local NHS trust and provided cover to the unit on an agreed basis. The unit employed eight whole time equivalent (WTE) registered nurses. There were 3.4 WTE healthcare assistants (two full time, two part time).

Summary of this inspection

Track record on safety (April 2016 to March 2017)

- There were no reported never events.
- Four clinical and two non-clinical incidents were reported.
- No incidences of hospital acquired Methicillin-resistant Staphylococcus Aureus (MRSA), were reported.
- No incidences of hospital acquired Methicillin-sensitive Staphylococcus Aureus (MSSA) were reported.
- No complaints were received by the CQC or referred to the Parliamentary Health Services Ombudsman or the Independent Healthcare Sector Complaints Adjudication Service.
- The unit had received seven written compliments from patients.

Services accredited by a national body:

The unit is accredited against ISO 9001 quality management system. The ISO 9001 quality management system is a standard based on a number of quality management principles including a customer focus and continual improvement.

Summary of this inspection

Services provided under service level agreement:

- Renal counsellor
- Clinical and domestic waste
- Laundry and linen services
- Cleaning
- Patient refreshments
- Security services

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.

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

- There was no patient identification policy, which failed to comply with national and Nursing and Midwifery Council (NMC) guidance.
- We were not assured that incidents were reported or investigated thoroughly. We saw 'missed opportunities' which related to communication around the escalation of a deteriorating patient.
- The unit did not collate lessons learnt in a consistent manner and staff were not able to give any examples of lessons learnt as a result of an incident.
- There was no sepsis toolkit or pathway in use at the unit and staff had not received training in this area.
- Initial impression of the unit was poor due to litter on the floor around the dialysis chairs and bins reaching close to capacity.
- A water treatment plant had not been serviced according to its due date and the associated risk assessment was not available on the unit to mitigate for this.
- Initial assessment of patient needs, including medical history was not completed in full and care plans were not developed for patients with a specific medical concern.
- There was a lack of audits to provide assurance regarding medicines management.
- The unit manager had not received any additional safeguard training as the safeguarding lead for the unit.

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

- Staff demonstrated a clear understanding of the clinical incident reporting processes and were able to provide examples of incidents reported under the three categorisations.
- Safety bulletins were shared with staff and we saw high levels of compliance in relation to staff understanding.
- There was an open and transparent culture on the unit and staff were clear when to apply duty of candour when things went wrong.
- All staff were proactively supported with their training and development needs and in the majority mandatory training compliance was high.

Summary of this inspection

- We saw there were some completed care plans in place for specific medical conditions such as anaemia.
- Staff were able to explain what they would do in situations where vulnerable adults needed safeguarding.
- Staff worked flexibly and the rota was planned to ensure safe numbers of staff were available to meet patient need.

Are services effective?

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

We found the following issues of good practice:

- We saw that policies and procedures were developed in line with guidance and standards from the UK Renal Association and had been incorporated into the organisations standard for good dialysis care.
- The average number of patients with an AV fistula was 92%. This was higher and better than the Renal Association guidance of 85%.
- Patients who did not attend appointments were monitored as part of the Treatment Variance Reporting system.
- All staff on the unit were proactively supported with competency and development needs.
- We saw 100% of staff had received an appraisal in the last 12 months.
- In the December 2016 report we saw that the Grimsby unit was in the top 10% when benchmarked against other Fresenius units within the area.

However, we also found areas where the provider needs to improve:

- It was not clear if policies were reviewed and updated regularly as policies only showed the date in which they came into effect.
- We saw within the management reports, in December 2016, 42% of patients did not have the prescribed four hours of treatment.
- The provider did not monitor arrival and pick up times for patients receiving dialysis.
- Pain was not formally or routinely assessed.

Are services caring?

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

We found the following areas of good practice:

- We saw positive interaction between staff and patients. Staff interacted with patients in a respectful and considerate manner.

Summary of this inspection

- Patients received treatment in shared areas; however we saw sufficient space between each patient to maintain privacy and dignity.
- We saw staff speaking with patients about their treatment and blood result in a way they could understand.
- When patients first started treatment they could come to visit the unit first with a family member or friend for a look around.
- There was a variety of information available to patients including dietary information, holiday provision and shared care.
- All of the patients comment cards we received had positive comments about the care patients experienced.
- Patients we spoke with said staff were friendly and had a caring approach.

Are services responsive?

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

We found the following areas of good practice:

- The building met most of the core elements of provision for dialysis patients. This included level access and dedicated parking facilities.
- The unit was accessible by people who used wheelchairs. There was a hoist available, which staff used if patients were unable to transfer on to the dialysis chair.
- The unit operated at around 90% capacity and so had spaces to accommodate for holiday treatment sessions for people staying in the local area, provided this had been medically approved and there was session availability and all relevant information was available.
- Work was in place to extend the number of dialysis chairs in response to the growing number of referrals to the unit.
- There was no waiting list for referrals.
- Appointment sessions were offered to patients in accordance with their personal needs and circumstances.
- Staff told us adjustments could be made for someone with learning disabilities or who were living with dementia; for example they could have someone with them during treatment.

However, we also found areas where the provider needs to improve:

- There was no evidence the unit monitored against The National Institute for Health and Care Excellence (NICE) quality standards in relation to the arrival of patients within 30 minutes of the allotted time and collected to return home within 30 minutes of finishing dialysis.

Summary of this inspection

- Senior staff told us any concerns would be discussed at the weekly team meeting so that staff could learn from these and improvements could be made; however they were not able to provide evidence of this.
- There was no patient involvement group where patients could make suggestions about the service or care of patents on the unit, or where staff could share information about the service with patients.

Are services well-led?

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

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

- There was evidence that incidents investigated by senior managers had not captured 'missed opportunities' in relation to escalation processes.
- There was a lack of systems and processes to ensure the effective and consistent recording, investigation, and learning from incidents.
- Systems were not in place to follow national guidance around the observation of and management of deteriorating patients.
- There were failures to develop and follow policy and procedures in relation to confirming patient identity in relation to medicines management.
- We saw none of the corporate policies had review dates on them. This meant up to date guidance and legislation may not be incorporated into the organisations policies. For example the FMC medicines management policy referred to NMC guidance which had been updated eight years previously.
- The unit had not produced workforce data which was part of the NHS contract to ensure staff equality and fair treatment in the workplace. We acknowledged the local area had low numbers of black and minority ethnic population (BME).
- There was no process to ensure that people who have a disability, impairment, or sensory loss were provided with information that they can easily read or understand and with support so they could communicate effectively with staff. From August 2016 onwards, all organisations were legally required to follow the Accessible Information Standard.

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

- Morale in the unit was good and staff felt supported by local managers.
- There was a friendly culture, and the manager was visible and approachable.

Summary of this inspection

- The unit manager carried out patient rounds on all shifts to ensure all patients had the opportunity to speak to them regarding any concerns or questions they had.
- All staff placed patients at the forefront of everything they did and were aware of the vision of the company.
- The unit manager had developed a strategy to develop services and improve patient outcomes.
- The unit staff worked together and seemed to have supportive relationships.
- We saw views and experiences of patients had been sought through the national patient survey 2016 and 91% of patients said they had complete confidence in the nursing staff.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

- During the reporting period February 2016 to January 2017 there had been no never events. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- The provider did not report any serious incidents in the last 12 months.
- There had been two notifications of patient death to CQC in the 12 month reporting period 2016 to 2017. We reviewed the investigation of both deaths and saw that escalation processes were followed on these occasions and documentation was thorough. These were not classified as serious incidents and did not occur on the unit.
- We reviewed the clinical incident register, and saw that there were four clinical incidents in the 12 month reporting period 2016 to 2017. One incident related to the death of a patient following dialysis treatment. The second related to a cardiac arrest on the unit in which the patient was transferred to the local NHS hospital. The third related to a positive swab culture and the fourth was later re-categorised as a non-clinical incident and related to a central line site infection, which was in line with FMC Clinical Incident Reporting.
- We saw the provider had a policy for the reporting of incidents including near misses. Nurses were able to input the details of incidents into the electronic database and these would be reviewed by the clinic manager. These would then be submitted to the area head nurse and then the chief nurse to be reviewed and we saw documents, which corroborated this.
- Incidents were categorised as clinical or non-clinical and there was in addition to this a system of reporting any variance from the care pathways. These were known as treatment variance reports or TVR's. Staff were able to describe examples of events, which were reported under these headings.
- The chief nurse and the health and safety officer were responsible for the analysis and investigation of all incidents in the Fresenius group. They reported into a clinical governance framework and then to the clinic manager and local clinic review process.
- We were not assured that incidents were reported or investigated thoroughly and consistently. We reviewed the clinical incident report form relating to a patient death and we saw that nurses did not escalate patient health concerns immediately. This was noted on two separate occasions within the first incident we reviewed. We saw notes made by the area head nurse as part of the review process. No escalation concerns were noted as part of her review. We reviewed the Root Cause Analysis (RCA), completed by the clinic manager following the incident, which did state that nursing assessment and documentation was not to the standard the provider expected. It was also noted that there was a lack of escalation processes in place. There was no date on this RCA and we were not able to see evidence of a timely investigation process. We saw an action plan but this did not show completion dates.
- We saw within the same RCA that the clinic manager advised that all staff on the unit were to receive further assessment and documentation training. Only 50% of staff had received this training since the incident in January 2017. We were told by the clinic manager that there were plans to complete the remaining 50% later in the year.
- We also reviewed a clinical incident relating to the omission of medicines. This incident was not submitted to us prior to our inspection as requested. We saw

several areas of concern related to this incident including a lack of medicine stock, a nurse who forgot to ask for the prescription from the visiting consultant and subsequent delays in escalating the lack of availability of medicine on the unit.

- We saw the clinic manager advised as part of the incident review that stock management of medicines (to ensure there was always sufficient available) was a problem. They outlined plans to implement weekly stock checks following the incident. We asked to see these checks but the clinic manager did not know where they were.
- Prior to our inspection the provider sent us information which showed two safety incidents, had occurred in the last 12 months, both of which were patient falls. These were categorised by the provider as non – clinical incidents in line with Fresenius clinical incident reporting. We reviewed the incident forms and saw that the patients sustained no injuries following the falls. We did not see completed risk assessments to prevent any further falls.
- We asked the clinic manager for details of the near miss events. We were told by the clinic manager that these would be logged within the TVR data and the chief nurse could access this.
- Senior nursing staff told us team meetings were held each week and incidents were discussed. Staff told us that the clinic manager shared details of all incidents that had occurred on the unit. We reviewed minutes taken from a staff meeting in May 2017, which corroborated this.
- Nursing staff were able to identify clinical incident reporting procedures but were not able to give examples of learning following the incidents.
- We saw that patient safety alerts were held within a file in the manager's office for all staff to read. For each alert there was a staff signature page to confirm that they have seen the alert and read it. We saw staff regularly read these alerts and had signed to say they understood them.
- The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- Duty of candour was described in the clinical incident policy and staff could describe to us about the need to be open and transparent if something went wrong. It was not clear when duty of candour should be applied. Following the medicine error, which occurred the week before our inspection, it was not clear from the documentation, which had been subsequently completed whether the patient had been informed; however staff told us that an apology was given.
- Information was displayed in the patient waiting area regarding health and safety incidents. The information displayed was from January 2017 to April 2017 and showed one needle stick injury in March 2017 and two falls in April 2017.

Mandatory training

- All staff were required to complete a programme of induction, which included mandatory training modules appropriate to their role.
- Training was divided into several stages, which included induction, fundamental skills, advancing skills and management skills. Management skills training was specific to nurses and not the dialysis or dialysis assistants.
- We were provided with the annual spreadsheet which showed training for the staff working on the unit and when training was due. The sheet was colour coded, for example showing red where training was due, amber if the training was due soon, and green if the training was within date.
- Mandatory training was up to date in most of the areas we reviewed. There were some gaps in the training register, for example:
  - Annual training for basic life support training had expired for three of the 12 staff on the unit.
  - Five of the 12 (42%) staff required anaphylaxis training.
  - Four of the 12 (33%) staff required fire and deprivation of liberty (three yearly) training.
  - Annual hand hygiene assessments were out of date for six of the 12 (50%) of staff on the unit.
  - Four of the twelve (33%) staff required basic life support training.
- Mandatory training records for agency nursing staff were monitored by the Flexi bank administrators to ensure training was always up to date. If training lapsed the member of staff was suspended from shift allocation until evidence of completion was received. Flexi bank training records were retained centrally.

Safeguarding

- There was a corporate safeguarding and protecting vulnerable people policy and procedure, which included guidance on safeguarding adults and children. Training requirements and examples of when to raise a safeguarding concern were included. This document did not refer to female genital mutilation or PREVENT (anti-terrorism) training programmes. PREVENT training the recognition and protection of vulnerable individuals from risk of grooming and involvement in terrorist activities or supporting terrorism. However, we saw a training session entitled 'radicalisation' was available.
- All staff we spoke with were clear who their safeguarding lead was and which local authorities they would contact.
- The service lead for safeguarding vulnerable adults and children was the clinic manager. We asked the manager what level training they had completed, but they were unsure and this level of training requirement was not included in the policy. The policy directed staff to report any safeguarding issues to the chief nurse and also into the NHS trust safeguarding team. There had been no concerns raised in the 12 months leading up to inspection. Staff we spoke with could not give us examples of escalation of any safeguarding concerns.
- We saw 93% of staff had completed online Safeguarding Adults Awareness training. (One member of staff had not completed due to long term sick).
- Data showed 86% of staff had completed Safeguarding children level one.
- Local safeguarding phone numbers were displayed on the walls within the unit so staff knew who to contact if necessary.
- Staff underwent disclosure and barring checks just prior to appointment but there was no policy or process in place to revisit these.

Cleanliness, infection control, and hygiene

- There were clear infection prevention, control policies and hygiene plans for staff to follow. All staff we spoke with told us they were aware of the procedures in place. The chief nurse was the lead for infection prevention control. There were two single rooms on the unit, which could be used for isolation purposes if patients had or were suspected to have an infectious condition.
- There was evidence of litter on the floor throughout the patient areas from needle packages and a rubber glove on the floor upon entering. The unit was visibly clean.
- Bins were full. They were not overflowing but were reaching full capacity at the start of our inspection, which was early morning. We were told by the clinic manager that cleaning including rubbish removal was completed at the end of each day by the cleaners or during the day as required by the nurses.
- Protocols were in place to screen patients returning from holiday to high risk of infection regions for blood borne viruses, methicillin resistant staphylococcus aureus (MRSA) and methicillin sensitive staphylococcus aureus (MSSA). The unit had reported zero cases of hospital acquired MRSA, MSSA, Clostridium difficile (c.diff) or Escherichia-Coli infections in the reporting period April 2016 to March 2017. There were two cases of 'other bacteraemia' which reported within the incident reporting process.
- Monthly hygiene audits were carried out based on the World Health Organisation (WHO) 'Five moments for hand hygiene' guidelines. The unit displayed monthly hand hygiene audit information in the patient waiting area, results for the dialysis unit showed monthly improvements in compliance from 83% in January 2017 to 100% in April 2017.
- We saw staff complied with bare below the elbow policy and they washed their hands at appropriate points of care. We observed good aseptic technique when attaching and removing lines.
- Infection prevention and control audit results for January to April 2017 were provided to us after our inspection. Results ranged from 84% to 90%; the average for the four months was 86%. This was an improvement on the overall results from 2016.
- Patients we spoke with said that the environment was always 'clean and hygienic'.
- Chairs were covered by sheets and pillows with disposable pillowcases, which were changed between patients.
- We inspected seven pieces of equipment including dialysis stations and suction pumps. We found all to be visibly clean.
- Staff we spoke with told us dialysis machines were cleaned between each patient and at the end of each

day. These followed manufacturer and IPC guidance for routine disinfection. Single use consumables such as blood lines were used and disposed of after each treatment. We saw staff followed the guidance.

- Staff carried out daily water tests to monitor the presence of chlorine in the water in line with the UK Renal Association clinical practice guidelines. The daily checks carried out in the first three months of 2017 were all within safe ranges apart from two days in January 2017.
- Staff were able to describe the management of the water systems for the presence of bacteria.
- As part of the renovation work at the unit, one of the water treatment plants was due to be de-commissioned. There was an additional new plant in place, as well as the older system and the unit used both systems consecutively. The plant technician told us that the old water treatment plant had not been serviced according to its due date, but a risk assessment was in place to cover this.
- The clinic manager, regional business manager and area head nurse were not able to provide us with this risk assessment at the time of inspection but this was sent following our inspection. This clearly showed an interim maintenance agreement in place and decommissioning date.
- The unit provided haemodiafiltration 100% of the time during the last three months that we reviewed.
- Records we reviewed showed that staff carried out the correct procedures in regards to flushing of water outlets to prevent contamination of the water supply.
- Training compliance figures for infection prevention and control indicated 10 of the 12 staff had completed the annual reassessment of this competence.

Environment and equipment

- The unit had 12 dialysis chairs / stations across two different areas. The first area patients entered was part of the original unit with the new section in place towards the end of the room. In addition there were two individual isolation rooms. There was plenty of space around each station to allow for patients, staff, and equipment.
- Maintenance of the dialysis machines and chairs was scheduled and monitored using the Dialysis Machine Maintenance/Calibration Plan; this detailed the dialysis machines by model type and serial number along with the scheduled date of maintenance by technicians. We reviewed the maintenance records, which were up to date.
- A similar plan was present for dialysis chairs and other clinical equipment for example; patient thermometers, blood pressure monitors and patient weighing scales. There were two back up dialysis machines stored and ready for use in the clinic.
- One patient told us he was unable to lay straight on his chair due to a damaged mattress. This resulted in regular neck and back pain. We saw the mattress was completely compressed in the right hand corner and provided no support to the patient. We were told by the patient that the mattress had been like this for some time and a new mattress was on order. We brought this to the attention of the clinic manager who chased the order up immediately.
- Alarms on the machines would sound for a variety of reasons, including, sensitivity to patient's movement, blood flow changes, or leaks in the filters. We saw the alarms were used appropriately and not overridden; when alarms went off we saw nursing staff check the patients and the lines before cancelling the alarms.
- In January 2017, Fresenius brought Facilities Management (FM) in-house as it was previously with an external contractor. A dedicated FM team was developed, which included an experienced FM Manager and two helpdesk coordinators provided the unit with both reactive and planned preventative maintenance work.
- The additional dialysis related equipment was calibrated and maintained under contract by the manufactures of the equipment or by specialist maintenance/ or calibration service providers.
- Annual electrical testing was part of the unit's planned and preventative maintenance scheduled by the FM team and we saw completed documentation checks.
- We checked the resuscitation trolley and found the equipment was correct and in date. Access to oxygen was available. Equipment checklists were available which showed the previous four weeks checks were up to date. We also checked the stock held on two general dressings' trolleys and found all equipment to be in date and in good order. All staff we spoke with told us that there were adequate supplies of equipment and received good support from the maintenance technicians.

- We asked for evidence of the replacement programme for dialysis machines, which should be replaced every seven to ten years or between 25,000 to 40,000 hours of use according to Renal Association guidelines. We reviewed the machine maintenance plan but it was not clear when the machines were due to be replaced.
- There were no additional pressure relieving equipment on the unit but the manager told us if a patient needed a specific item, staff could order what was needed.

Medicine Management

- There was a detailed medicines management policy. There was no guidance to support audit of practice to provide assurance that standards of practice were monitored and reviewed by pharmacy or senior staff. We spoke with senior staff who confirmed that currently no medicines audits were performed.
- The unit did not use or store any controlled drugs. The clinic manager had lead responsibility for the safe and secure handling and control of medicines.
- The nurse in charge varied depending on shift patterns but was always an experienced nurse. Staff told us they were the key holder for the medicines cabinet on a day to day basis.
- There were a small number of medicines routinely used for dialysis, such as anti-coagulation and intravenous fluids. The unit also had a small stock of regular medicines such as EPO (erythropoietin – a subcutaneous injection required by renal patients to help with red blood cell production). Some stock medicine was ordered from Fresenius, with the majority provided by Hull Royal Infirmary and was stored in a locked cupboard.
- Medicines requiring refrigeration were stored in a fridge, which was locked and the temperatures were checked daily. Staff were aware of the action to take if the temperature recorded was not within the appropriate range.
- Records we reviewed showed that fridge temperatures were consistently recorded.
- Staff told us they could access pharmacy support from the local NHS trust pharmacy for advice relating to dialysis drugs. Staff also had access to the company pharmacist at head office.
- Managers told us GPs were sent letters after the monthly MDT meeting, which would include notification of any medicine changes.
- Staff told us that any prescription changes were done by one of the doctors during their weekly visits to the unit. If any medicines needed to be prescribed at other times then nurses told us they called the renal registrar on call or signposted the patient to their GP or A&E if the patient's condition required urgent treatment.
- Patients we spoke with said they took their regular medicines at home prior to coming to the unit or when they went home.
- We observed staff administering IV medicines to patients. We saw the use of two person checks, prior to administering medicines but did not see any guidance or policies specific to patient identification checks, to ensure practice was consistent. We informed managers of this at the time. We were told the company did not have a policy for this but had been considering implementing a process. Managers were unable to clarify when a process would be implemented and what it would be.
- Dialysis assistants could administer saline and anti-coagulants under the supervision of a registered nurse; they must have completed the appropriate competency document and have been deemed competent in all aspects of medication administration. We reviewed the training files for these staff and saw that a new training competency specific to the administration of these medicines had been developed following feedback from another local inspection.
- We looked at the prescription and medicine administration records for four patients on the unit. These records were fully completed and were clear and legible.

Records

- The unit used a combination of paper and electronic records. Data was shared between the electronic database of the unit and the NHS hospital. This meant the consultant had access to the patient records at all times.
- The paper records included the dialysis prescription, patient, and next of kin contact information, and GP details. There were also nursing assessments, medicine charts, and patient consent forms. Records also contained standardised pathways for Haemodiafiltration (HDF) and management of Arteriovenous (AV) fistulas and grafts. A fistula is a special blood vessel created in a patients arm.

- We looked at five sets of records and found that all patients had regular observations recorded pre, during and post treatment with few gaps noted. Records contained a new patient admission assessment, which included a short review of 'activities of daily living'. Two of the five records had gaps in the new patient assessment.
- We saw that five patients entered the service between 2009 and 2015 but had no documented reassessment of their needs since their first admission. We saw risk assessment documentation for manual handling, pressure ulcer risk, nutrition but not every patient had all of the assessments. We saw one patient was diabetic but there was no corresponding assessment of needs and care plan relating to this issue. We did however, see care plans for patients with anaemia, at risk of anaemia and fistula management.
- Four out of five (80%) patients had been assessed as high risk using a recognised assessment tool to determine risk of developing pressure ulcers, however, there were no individualised care plans and we did not see any record of visual skin checks made. Nursing staff and managers told us it was not usual practice to visually check pressure areas, however, they told us they asked patients if they had any sore areas. One of the patients told us they had a healed pressure ulcer but did not want the dialysis staff looking at it. They preferred to care for this in their own way with the help of their community nurse if needed. We did not see any individualised preventive processes or equipment in place.
- Three out of the four (75%) patients requiring monthly pressure area assessment each had one or two had gaps from January 2017 and April 2017. These standards were not in line with the NMC Code of Professional Conduct in relation to record keeping.
- Documentation audits were carried out on a monthly basis. Three different sets of records were selected each month. Twenty seven aspects of documentation were looked at each time; (for example legibility, signature, clear prescription, care plan in place).
- We looked at documentation audit results for the six months during our inspection. We saw regular documentation reviews but none of the comments related to a lack of care plans or initial assessments. Comments largely related to missing signatures. Results of blood tests carried out at the local NHS trust were sent to the unit electronically.
- Each registered nurse held a caseload of approximately eight patients. Staff were expected to update patient records and care plans for patients on their caseload but we did not see any guidance for staff in relation to this.

Assessing and responding to patient risk

- Only clinically stable patients were dialysed on the unit; if someone was acutely ill with renal problems they were treated at a main NHS hospital. This was to ensure that patients who required additional support received their treatment at the local NHS trust where a nursing ratio was increased to ensure patient safety.
- Patients weighed themselves before treatment began. They inserted an electronic card, which identified them, into the electronic walk- on weighing scales. This was to establish any excessive fluid, which had built up in between treatments and to determine the correct dialysis.
- Observations of vital signs such as blood pressure and pulse were recorded before, during and after dialysis treatment.
- Patients we spoke with felt their treatment was carried out safely, efficiently and effectively and referrals to consultants were made promptly when needed.
- Managers told us there was referral and escalation criteria in use for staff to follow should a patient's condition or results deteriorate. They told us that poorly patients were escalated to the renal consultant on-call and an email was sent to the patient's own consultant to ensure they were aware of any changes in condition.
- There was a guidance document, 'complications, reactions, and other clinical event pathway' but no specific system such as an early warning score (national 'NEWS' or modified) was in place to identify deteriorating patients. We saw that this was on the unit risk register with action to be undertaken by the Fresenius chief nurse to look at potentially developing a modified tool for use in dialysis settings.
- The unit did not use an early warning score system to identify the deteriorating patient. Nursing staff we spoke with were experienced and able to articulate the clinical condition of a deteriorating patient, however they had not received any specific training about national early warning scores (NEWS) and could therefore not describe the recognition of the patient deteriorating in the same context. Staff could describe how they would support and escalate concerns in the absence of a NEWS system.

- There was no sepsis toolkit or pathway in use at the unit. This was not in line with the National Institute for Health and Care Excellence (NICE) guideline (NG51) for recognition, diagnosis, or early management of sepsis. (Sepsis is a life-threatening illness caused by the body's response to an infection).
- We spoke with staff about the lack of a sepsis pathway. Following our inspection we were provided with information that the company did not have a sepsis policy; they would normally follow the policy from the local NHS hospital. The lack of a sepsis policy was placed on the risk register.
- Staff told us the service held emergency resuscitation simulations every six months. We saw that the last simulation was January 2017.
- Managers told us of a patient safety initiative called 'be safe be seen'. This ensured vascular access lines were clearly visible and uncovered as there was less risk of these becoming dislodged.
- At our unannounced visit we saw that the unit received safety bulletins and practice updates regarding safety issues. A very recent bulletin had been received regarding 'dry needling'. This is not considered to be best practice as it carried the risk of introducing air into the patient's bloodstream. The bulletin advised staff to stop using this technique with immediate effect. All staff in the unit had seen the bulletin and signed to say they had read and understood the information. We saw that staff were compliant with best practice.
- We looked at five sets of patient records and saw that all patients had personal emergency evacuation plans in place and these had been updated within the last three months.
- Patients were prescribed up to a maximum of one litre of normal saline as required for administration in larger doses for hypotension. This was part of the pathway for the treatment of hypotension within the 'Complications, Reaction and Other Clinical Pathways' document. It was not clear from the drug card or the pathway how big a bolus should be administered. Nurses told us that the first additional dose would be 150ml and a second could be 300ml if hypotension had not resolved. Dialysis would be stopped if a patient became hypotensive. If the patient remained hypotensive the pathway stipulated the escalation process for the deteriorating patient was to be followed.
- Staff recorded variances during the period of dialysis in the patient records for example, falls risks, mobility post dialysis, weight recording and changes in vital signs measurements. Staff used this information to help plan the next dialysis session and to identify any themes or risks occurring during dialysis.
- The renal consultant visited the unit once a month to review patients who were there that day. Treatment was reviewed and changes could be made.
- There was an agreement with the local NHS trust that patients who became ill would be transferred to the hospital. In the year before our inspection, 20 patients had been transferred to the acute trust. We were not able to establish if this was a high number for the size of the unit.
- We were told by a senior manager that a new 'draft risk register' had been developed following inspection feedback from another local provider dialysis unit.

Staffing

- The unit was generally staffed to a 1:4 staff to patient ratio, trained dialysis assistants were counted in addition to the registered nurses. Managers told us there was always a minimum of two Registered Nurses on duty with the manager working approximately 40% of their time clinically.
- The unit employed eight whole time equivalent (WTE) registered nurses (all full time). There were 3.6 WTE dialysis assistants (Two full time, and two part time).
- At the time of inspection the unit had one WTE dialysis RN vacancy. The turnover in the 12 months prior to inspection was reported as six staff having left the service and six staff recruited. Three of the six staff recruited, were returning to work at the unit, after having left.
- We reviewed the exit interviews for these staff and saw that these three staff had left the service to try a new role but had decided to return. Other members of staff had been promoted rather than left the service. The service routinely asked leavers for exit information by a postal questionnaire.
- The average sickness during the three months prior to inspection was 6.6% for registered nurses. This is higher than average but could be accounted for by the low numbers of registered nurses in the unit. The average sickness rates for dialysis assistants in the three months before our inspection had been 32%, which was significantly higher than the national average, which is around 3- 4%.

- Managers acknowledged there had been staffing problems and told us they reviewed rotas on a daily basis to assess staffing levels based on the actual number of patients attending for dialysis and for unexpected staff shortages caused by sickness or absence and as all vacancies had now been filled there was very little agency use.
- Staff worked longer hours on a Monday, Wednesday and Friday when the unit had three treatment sessions. Staff worked from 6.30am to 6.00p.m Tuesday, Thursday, and Saturday. If patients were delayed commencing treatment due to transport problems, the staff were flexible and worked over.
- If staffing levels could not be maintained by permanent staff, requests were made to FMC Renal Flexi bank, who arranged for cover. When Flexi bank could not cover shifts, external nursing agencies (approved by FMC) were used.
- The unit senior nursing team ensured compliance with staffing ratios through the application of an electronic system. This is completed eight weeks in advance by the clinic manager, and we reviewed the live rota and found this to be in place. We noted two shifts, which required cover on the paper rotas we reviewed.
  The clinic manager advised there were two rotas, paper and an electronic version, which was up to date. We saw they had been covered by the Flexi bank.
- The unit did not employ any doctors. Two renal consultants provided cover to the unit. Managers told us consultant staff visited the unit weekly and formally reviewed patients at monthly multi-disciplinary meetings.
- Nurses told us consultants could be contacted at any time for advice or support regarding individual patients and that they would undertake individual reviews as necessary if a patient's condition or results changed.

Major incident awareness and training

- The emergency officer was the clinic manager. An Emergency Preparedness Plan (EPP) was in place. This detailed the plans for the prevention and management of potential emergency situations, such as fire, loss of electricity or water leaks. The plan included defined roles and responsibilities; contact details for emergency services, public services and utilities and key headquarter personnel.
- Personnel emergency evacuation plans we reviewed and found to be appropriate to the patient's needs.
- Evacuation simulations were conducted biannually.
- Information sent to us before the inspection indicated all staff were aware of this plan, and there was a requirement for it to be included in training.
- Staff told us the dialysis machines had a 15 minute battery back-up so in the event of a power cut, the patient's own blood could be recirculated and returned to them.

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

Evidence-based care and treatment

- The provider developed policies and procedures, which were developed in line with guidance and standards from the UK Renal Association and National Institute for Health and Care Excellence (NICE) and had been incorporated into the organisations 'NephroCare standard for good dialysis care'.
- We looked at nine policies, these all had included a date they became effective and a revision date, but did not have a date to indicate when the policy expired. It was not clear whether the revised and effective date refers to the date of the original policy or date of the last review.
- Treatment was led by an NHS Consultant; staff told us that treatment was prescribed to ensure best patient care outcomes.
- Haemodiafiltration (HDF) was offered to all patients attending the unit. If water purity levels fell below the level that this could be offered, then patients were given traditional haemodialysis treatment (HD). Staff we spoke with spoke told us this had happened only on very rare occasions and we saw that haemodiafiltration was available on hundred percent of the time in the three months leading up to inspection.
- We found that the service analysed clinical outcome data on a monthly basis and staff told us this was used at MDT meetings to inform discussions regarding patients' treatment and medicine.
- We saw the unit followed some generic care pathways which were appropriate to the individual's needs. Individual prescriptions were in each patient documentation file and all were reviewed within the last month.

- The senior team described an established International Standards Organisation (ISO) accredited integrated management system (9001) which ensured all policies and procedures support best practice evidence. This worked alongside an annual review requirement which was stated as providing assurance that the evidence used was current.
- The local NHS trust was responsible for the creation of fistulas; staff at the unit were responsible for monitoring them. A fistula is a special blood vessel created in a patients arm, called an arteriovenous fistula (AV fistula). The blood vessel is created in an operation by connecting an artery to a vein, which makes the blood vessel larger and stronger. This makes it easier to transfer the patients' blood into the dialysis machine and back again. AV fistulas are regarded as the best form of vascular access for adults receiving haemodialysis. This is because they last longer, and have less risk of complications than other types of vascular access.
- The unit monitored the AV fistulas, which forms part of the NICE quality standard. We were told that more experienced staff were responsible for cannulating patients with less established fistulas.
- In the 12 months before our inspection, the average number of patients with an AV fistula was 92%. This was higher and better than the Renal Association guidance of 85%.
- We found that some of the patients were involved in pivotal trials. Pivotal is a clinical trial or study intended to provide evidence for drug marketing approval.
- We saw the unit had an audit schedule, which included hand hygiene, documentation, patient experience and infection control. Staff could not recall the most recent results but were able to show where audit results were located. We saw several audit results displayed on the walls of the unit.
- One holiday placement was available for patients per week, should they require it.

Pain relief

- The unit prescribed and administered paracetamol for patients who had pain. If patients needed pain alternative pain relief, they brought their own medicine. If any in-patients from the local NHS hospital were receiving dialysis treatment, ward staff provided their medicine.
- Staff told us that local anaesthetic was prescribed for patients who found the commencement of treatment particularly uncomfortable. We did not see this prescribed in any of the charts we reviewed.
- Pain levels were not formally assessed. Several nurse told us they would offer paracetamol should patients require it.
- Two patients told us they had been provided with paracetamol when they needed it.

Nutrition and hydration

- Staff told us there was a contract in place with a local food supplier to provide sandwiches for patients receiving treatment in the unit.
- Patients were offered hot and cold drinks and pre prepared sandwiches or biscuits while they were having their treatment and there was a cold water dispenser in the reception area.
- The renal dietitian visited the unit on a monthly basis to give support and advice; staff told us the dietitian was also available at the NHS hospital.
- Several magazines and leaflets were displayed in the reception area, which provided nutritional advice for patients.

Patient outcomes

- The unit did not directly submit data to the UK Renal Registry; this was undertaken by the 'parent' NHS Trust. The data from Grimsby unit was combined with the NHS Trust data and submitted as one data set.
- Data obtained through treatment, such as blood results were collated and held within the electronic recording database. Clinical outcomes for renal patients can be measured by the results of their blood tests. The data was available for the clinic manager and consultant to review so they could see individual patient outcomes and results were fed into the trust system.
- The clinic data management system provided customised reports and trend analysis to monitor and audit patient outcomes and treatment parameters. The multidisciplinary team used this to improve outcomes and in turn quality of life. The report provided specific unit scores in areas such as infusion / volume, albumin, weekly treatment, vascular access, and haemoglobin. This was referred to as the 'balanced scorecard'.
- Patient outcome reports were produced every six months by the central quality team and shared with the clinic manager. The results showed how the unit

performed in the achievement of quality standards based on UK Renal Association guidelines. It was used to internally benchmark Fresenius units against each other. We reviewed the December 2016 report and saw that the Grimsby unit had scored highly overall in most areas and was in the top 10% of the units.

- We looked at several scores from these reports. The first indicated patients' haemoglobin (Hb) against the recommended safe levels. Anaemia can be a complication of renal failure and dialysis associated with increased risks of mortality and cardiac complications. In the December 2016 report we saw that the average number of patients with the NICE recommended target of Hb (100-120 g/l) was 62%. This meant that 38% of patients had lower Hb levels. Where patients had low levels they were given injections of a stimulating agent to help their body produce more red blood cells.
- In the same timeline, outcome standards for the unit showed 100% of patients received haemodiafiltration (HDF) treatment.
- We also saw in the same reporting period that 58% of patients who attended three times a week were dialysed for the prescribed four hours treatment time. This is lower than the minimum standard of 70%. It also meant 42% of patients did not have the prescribed four hours of treatment. We did not see an action plan to improve this. The clinic manager told us that the results reflected the frailty and complexities of the patients, which were being cared for on the unit at that time.
- The unit monitored treatment variances such as cannulation problems, chest pain, clotting, high and low blood pressure, changes in procedure, machine malfunctions and patients who did not arrive for dialysis. There were a total of 2626 variations in 2016. These results were used to look at issues and make improvements where possible. We were told by the clinic manager that the chief nurse monitored this.
- Patients who did not attend appointments were also logged within the TVR system. In 2016, there were 198 variations related to patients not attending for dialysis; these ranged from seven per month to 25 per month. Staff told us that the renal consultant would also be advised and the General Practitioner would be contacted should patients continue to fail to attend.
- Additionally outcomes, which were also monitored included dialysis access, patient observations and infection control interventions.

Competent staff

- There was a comprehensive training programme available for staff. Registered nurses and dialysis assistants were required to complete a series of mandatory clinical competencies, to support their role and responsibilities.
- We reviewed the competency files of four registered nurses and two dialysis assistants based on the unit. There was evidence of up to date training records for registered nurses and dialysis assistants, attendance and sign off by senior nursing staff and mentors was evident.
- New staff were supported by mentors and time was provided to enable staff to shadow colleagues.
- For existing staff the unit provided on-going professional development opportunities for assessment and maintenance of competence, which is pivotal to the Nursing and Midwifery Council (NMC) revalidation approach. For example; annual appraisal of competence, appraisal, mandatory and statutory training, access to external training such as accredited renal courses, dialysis specific study days, E-learning and virtual classroom training. Four of the registered nurses including the clinic manager were undertaking specialist training which would lead to a renal qualification.
- Staff working in the unit received six weeks supernumerary period during induction and a six-month preceptorship period allowing time to achieve all the required competencies. Nurses we spoke with told us that supernumerary periods could be increased if the member of staff or mentor felt that this period needed to be longer.
- Dialysis assistants were given training and competency assessed to enable them to administer Tinzaparin injections (this medicine prevents patients developing blood clots or thrombosis). This followed company guidance and was intended to highlight training and development needs to discuss in annual appraisals.
- We could not see a completed annual competency assessment for the dialysis assistants but we were told by the area head nurse that a new competency training document was being rolled out in response to a previous inspection at another local dialysis unit. We reviewed this document and saw that roll out had commenced.

- There were link nurses at the unit with areas of interest; they had responsibility for updating other staff about the topic. Link nurse roles were;
  - Electronic recording link nurse who ensured supporting documents were are implemented and incorporated into practice.
  - Infection prevention and control.
  - Education and training.
  - Information Technology.
  - Health and safety.
- Fresenius had a training team who were involved in the assessment of staff competence.
- Some patients told us they felt slightly anxious about the competence of agency nurses because they did not know them but they did comment that they were aware the agency nurses were renal trained.
- We reviewed induction arrangements for agency staff and saw several completed training sheets in place for these temporary staff.
- Patients overall felt that staff were “excellent, experienced and competent”.
- One newly appointed staff member told us they had received lots of training since starting at the unit, they had also been given a preceptor to work with and felt training and support was good and had built their competence.
- The clinic manager told us that six month progression plans were completed for all new staff and that individual members of staff took on lead roles within the team for; infection prevention and control, health and safety, stock control, holidays and electronic recording database.
- The clinic manager told us that they had not completed the management development training provided by the company, however we saw there were plans to deliver this.

Multidisciplinary working

- The renal consultants based within the main renal NHS unit, had overall responsibility for patient care and visited the unit weekly to review any patients of concern. In addition to this they held a monthly clinical governance review of all patients as well as one to one reviews as part of a renal outpatient clinic within the unit. If medical staff were required outside of these arrangements the dedicated consultants were available via telephone or email and out of hours cover was provided by an on call rota of renal doctors.
- The MDT meetings were held monthly and were well attended by the relevant team members. The NHS renal consultants reviewed all patients attending the unit. The meetings were also attended by the clinic manager or deputy with supported from a senior nurse within the unit.
- Senior staff told us the company attended meetings at the local NHS trust and had positive strong relationships with the local trust.
- The dietitian and renal social worker also visited on a monthly basis.

Access to information

- Staff told us they had the information they needed to look after patients.
- Electronic records including blood results from the local NHS trust were accessible to staff on the unit and results were also recorded on paper cards, should there be any issues obtaining electronic results.
- Staff told us the patient treatment database sent information to the NHS trust. The consultant then notified the GP of any relevant changes.
- We saw the unit shared information to send with a patient when they went for treatment to another unit whilst on holiday. This was to ensure consistency of care and treatment.

Consent, Mental Capacity Act and Deprivation of Liberty

- Consent to treatment means that a person must give their permission before they receive any kind of treatment or care. An explanation about the treatment must be given first. The principle of consent is an important part of medical ethics and human rights law. Consent can be given verbally or in writing.
- We reviewed consent forms in five patient files. All were found to be fully completed. We observed nurses seeking verbal consent prior to undertaking care and treatment.
- We saw that patients were asked to sign a form to say they understood the implications of finishing treatment before the end of the prescribed time and that this was done against clinical advice. We saw this form was present only in the files of specific patients.
- A previous planned internal audit report from October 2016 showed patients consent had not been signed and that further training for staff was required.

- Staff were able to describe mental capacity safeguard processes but were not able to provide us with any examples of patients who were subject to these processes.
- Staff within the unit were required to undertake three yearly DoLs training. We reviewed the training spreadsheet and saw that 10 of the 12 staff had completed this training. Dates were arranged for the remaining two staff to undertake this.

Are dialysis services caring?

Compassionate care

- All patients and relatives we spoke with told us that staff were professional, supportive and kind. We observed patients were treated with compassion, dignity and respect.
- Privacy and dignity of patients was maintained and we saw the use of curtains to screen each patient when required. There was sufficient space provided between each dialysis chair and nursing staff were able to speak with patients in a discreet manner.
- The last Fresenius national patient survey in Grimsby Dialysis Unit showed that 91% of patients would be likely to recommend the unit to friends and family in need of dialysis and patients were satisfied with the nursing staff.
- We received 28 comment cards from patients who had been using the service for up to ten years. All patients were complimentary about the care and compassion shown to them by all staff at the service. One patient told us 'the nurses show a genuine interest in their patients lives'; another described the manager as 'hands on' and 'approachable'.
- Facilities were provided for families, should they wish to have private discussions. There was a 'quiet room' and the manager's office was also available for confidential discussions when required.

Understanding and involvement of patients and those close to them

- We observed that patients deemed suitable for shared care were given a shared care questionnaire. This outlined all aspects of the dialysis treatment for the patient to answer whether they would like to take over that aspect of care. This meant that patients could be involved in shared care activities as much or as little as they wanted or felt confident about.
- We saw staff speaking with patients about their treatment and blood results. Patients were encouraged to ask questions about their care and treatment and were given direction regarding dialysis options.
- When patients first started treatment, they could come to visit the unit first with a family member or friend for a look around. There were information packs available so patients knew what to expect from the service and what the anticipated benefits and risks of treatment were.
- Relatives were not able to stay with patients during treatment due to infection prevention procedures. However, if someone had additional needs such as learning disabilities, a family member or carer could remain with them.
- Senior managers told us that a 'named nurse' was allocated to each patient to provide continuity for patients and ensure care plans and information was regularly updated. Two patients out of eight we spoke with told us they did not know who their named nurse was or what they did.
- Three patients told us that they felt there were too few nurses on the unit and that there had been a heavy reliance on agency staff. They told us on occasion there hadn't been enough attention to patient needs. For example, alarms hadn't been responded to quickly enough and staff did not always have enough time to facilitate patients wishing to self-care. One patient said on occasion there had been delays getting on and off treatment if another patient had been unwell.
- The unit sought feedback through a 'Tell us what you think' anonymous leaflet system, which allowed patients to comment on the service using freepost direct to Fresenius Head Office. We did not see specific results or actions from this feedback in the unit.

Emotional support

- Staff told us because they cared for patients frequently over a period of years, they became familiar with them and felt as if staff felt like 'family'.
- Patients were positive about the emotional support provided by nursing staff.

- One patient commented that they were treated as an individual at this unit and the support from staff has helped them to cope with what was a very physically and mentally draining treatment.
- We saw information was available for patients regarding accessing support and advocacy services.
- Two patients commented on the behaviour of other patients which they found distressing.

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

Service planning and delivery to meet the needs of individual people

- The Grimsby dialysis unit had been in operation since January 2018 and was commissioned by a local NHS trust. It was one of seven Fresenius units that provided renal dialysis across the region. The unit was one year in to an eight-year contract to provide this service.
- Dialysis services were commissioned by NHS England. The contract for the unit was renewed in April 2016 as part of an eight year service specific contract by the acute NHS Hospital trust renal team.
- We found there was a good relationship between the service and the contract management team at the trust. The trust told us there was an open and honest relationship and the service had informed them immediately of feedback from the inspection of other commissioned units. The trust was supportive of the service and was aware of planned actions to make improvements in the areas identified by other inspections.
- Patients were referred for haemodialysis treatment from the main renal unit and consultant nephrologist team. We saw criteria for referrals were in place and patients were assessed as physically well enough for satellite treatment, had functioning haemodialysis vascular access and lived in the local area. All staff told us that it was important that patients were 'stable' in terms of their renal care and commenced treatment within the NHS hospital before being referred to the local satellite clinic for on-going dialysis treatment.
- Patients who had additional needs such as those living with severe dementia, or who had challenging behaviour were not treated at the unit.
- Patients were provided with free Wi-Fi and each station had a ceiling mounted TV for individual patient use.
- The building met most of the core elements of provision for dialysis patients. (Department of Health Renal care Health Building Note 07-01: Satellite dialysis unit).This included level access and dedicated parking facilities. There was space for transport services to drop off and collect patients.
- NICE quality standards (QS72- standard 6) indicate that adults using transport services to attend for dialysis are collected from home within 30 minutes of the allotted time and collected to return home within 30 minutes of finishing dialysis. The quality standard indicates dialysis providers should collect evidence at unit level to ensure the standard is being met.
- The clinic manager told us that the staff on the unit spoke regularly to the local patient transport liaison office if they had any issues, but there was no formally monitoring of patient arrival times and pick up. We were not able to see if senior if managers maintained any regular dialogue with local transport providers.
- The unit did not monitor travel or waiting times for patients. This meant they were not assured that patients they did not wait for treatment after arrival and for transport or were delayed returning home after treatment. Staff told us that transport was usually 'regular' and they would contact the local patient transport liaison office should there be any.
- Two patients spoke positively about the flexible deployment of staff and that staff had swapped shifts to accommodate patients.

Access and flow

- We saw that there were 20 cases where patients were transferred out to another health care provider. These patients transferred for care and treatment and not due to deterioration or emergency care.
- There was no waiting list for treatment at the unit and staff we spoke with said that this was consistent.
- Referrals for admission were directed by the consultant nephrologist team at the local NHS trust Renal Unit who would contact the clinic, usually the clinic manager, to inform the team in the Grimsby dialysis unit that there were new patients for admission.
- The unit was currently being extended at the time of inspection and the numbers of dialysis chairs would

increase by an additional six, offering in total 18 stations. This planned extension was in response to growing referral numbers and increased demand for NHS dialysis services.

- The unit had an established appointment system, which promoted structure, timeliness and minimised delays. Staff we spoke with told us that they facilitated a flexible approach to the patient's dialysis sessions and would change the day of patients dialysis, and/or times as far as possible to accommodate external commitments and appointments or social events the patients may have. Sometimes patient's treatment sessions were transferred to the main renal unit to accommodate such requests.
- The utilisation of capacity in the unit in the three month reporting period was as follows: November 91%, December 94% and January 90%. Staff told us that the unit did not cancel patient appointments.
- Access to the unit was adequate and dedicated patient car parking spaces were provided. A nurse told us that occasionally car parking spaces were taken by staff outside of the dialysis unit and the security officers were contracted for the local hospital and were unable to monitor the unit grounds.
- Four patients told us of issues with transport, which included lateness and not turning up on bank holidays. The patients told us they needed to be at the unit 30 minutes before their treatment time if their treatment was to start on time. Late transport meant their treatment started late and this had a knock on effect throughout the day for other patients and meant nurses finished work late. There was one positive comment about transport from the four patients who spoke with us about it.
- Patients indicated they were not aware of what the service was doing to improve transport services and there was no transport user group for patients.
- The clinic manager told us about a recent issue the patient transfer services. The unit had received a call that to advise that a patient would be arriving late the following day (Saturday) for their appointment. The manager raised this as a concern with the ambulance office and the transport issue was immediately rectified.
- Three patients commented that start times were often delayed even when they were an early morning start; the reasons given were transport and machines not ready. We did not see any action plans or development work to improve this.

Meeting peoples individual needs

- The unit was accessed through a dedicated external door, which was considered the main entrance; this led into the waiting area where the receptionist was based. An intercom system was also in place in reception as a security measure. There was also a rear door to the unit which had access inside the local hospital. All doors were protected with a secure lock code.
- Patients had access to Wi-Fi, personal televisions in each chair space and reading materials. Patients were able to bring anything in from home, such as electronic tablets, to help pass the time during their dialysis sessions.
- Patients were provided with a nurse call system and nurses ensured that the call bell could be reached by patients during dialysis. We observed the call system in use and we saw that nurses responded to alarms promptly.
- One patient told us that the headphones provided by the unit were not working and had not been replaced. Other patients were happy with the facilities provided.
- We asked nursing staff if patients were provided with any other activities or stimulation. We were not given any examples of any form of activities for patients.
- There was sufficient parking for patients at the main entrance and available bays for blue badge disabled parking and wheelchair access was provided.
- The unit had a quiet room, staff offices, toilets for staff and patients, and a kitchen where staff prepared drinks and sandwiches for patients.
- There was a range of information and magazines available in the waiting area regarding dialysis, such as healthy eating, supported holidays and self-care information.
- We asked the clinic manager if literature and support was available to patients for whom English was not their first language. We were told that leaflets were available and the unit had access to an interpreter service should it be required. Staff told us they could use 'big word' telephone translation services. Interpreters could also be accessed upon request.
- Staff we spoke with told us that patients were allocated a dialysis appointment times to fit in with social care and work commitments. For example, day appointments for elderly or vulnerable patients with more complex care needs or evening appointments for working patients.

- The clinic manager told us that two patients had been started on a self-care programme. All unit staff told us they actively encouraged patients to be involved in self-care if able.
- The unit was accessible by people who used wheelchairs. There was a hoist, which could be used if someone was unable to get on to the dialysis chair and personal evacuation plans in plans for those patients with mobility needs.
- Staff told us about adjustments which could be made for someone with learning disabilities or who were living with dementia; they could have someone with them during treatment.
- Patients had access to dietitian services through the local NHS trust. In addition a social worker employed by Fresenius, could be contacted if necessary.
- The unit was not meeting the 'Accessible Information Standard' (2016) at the time of our inspection. The standard aims to make sure that people who have a disability, impairment, or sensory loss are provided with information that they can easily read or understand and with support so they can communicate effectively with health and social care services. The Fresenius management team had placed this on the corporate risk register and actions were to be taken by the training and education manager. Locally the unit had taken actions to ensure the service met the needs of relevant patients.

Learning from complaints and concerns

- The clinic manager told us they were committed to dealing with the '4 Cs' (compliments, comments, concerns and complaints) in a sympathetic and understanding way. They recognised that lessons for continuous quality improvement for patients may develop as a direct result of a concern or complaint.
- We saw a "Tell us what you think" poster displayed in the waiting area, which explained how patients could raise concerns, leave a compliment or make a complaint.
- It was the responsibility of the clinic manager or deputy clinic manager to ensure all complaints were sympathetically dealt with within maximum 20 working days.
- Data provided by the unit indicated that there had been seven written complaints in the 12 months prior to the inspection. We reviewed the details of each complaint and saw there were no reoccurring themes.
- There were 18 compliments for the unit in the same time period.
- One patient told us that when they had concerns about an agency nurse's competence, their concerns had been taken seriously and acted upon.
- Another patient told us 'I would rather just speak to the staff rather than have to put concerns in writing'.
- We reviewed four electronic complaint files and found that only one of these files held the original complaint letter. We were told that complaint letters were held in a paper complaint file however, we did not review this. The clinic manager told us, a system had been introduced where the complaint letter was scanned and held with the response letter.
- We saw that the complaint investigations demonstrated patients' concerns seriously and the service had responded appropriately within the policy guideline of 20 working days. The clinic manager told us that all complaints were discussed face to face with patients prior to sending a formal written response but this was not explicit in all of the complaint letters we reviewed.
- Although letters indicated there had been actions taken as a result of complaints there was no formal action plans or evidence within the letters to indicate a wider sharing of concerns and actions taken.
- One patient told us how staff had responded to ensure suitable snacks were available to meet their dietary needs.
- There was no patient involvement group where patients could make suggestions about the service or care of patents on the unit, or where staff could share information about the service with patients.

Are dialysis services well-led?

Leadership and culture of service

- There was a clear leadership structure in the Fresenius Medical Care organisation and that was applied regionally to the Grimsby Dialysis Unit. There was a clinic manager, deputy clinic manager and two team leader's in the unit. Senior managers were present during inspection. The clinic manager was also present during the unannounced inspection.
- The clinic manager for the unit was promoted to the post from a deputy position in June 2016. The lead role was part clinical and part managerial. The clinic manager for the unit was supported by an area head

nurse who was responsible for the oversight and management of this and six other units. There was also a regional business manager and a managing director and chief nurse at corporate level.

- The clinic manager had applied to be the registered manager for the service at the time of the inspection and was awaiting the registered manager interview. The manager actively covered the unit and fulfilled the role according to the requirements of the registered manager. A senior manager was also registered at the time in order to maintain regulatory compliance. We saw that a unit induction had been completed and the clinic manager was supported into the role by the head nurse.
- Morale within the unit was good and all staff we spoke with told us that they enjoyed their job. One nurse told us 'I am very happy here. We support each other'. Three nurses told us they felt they were well supported by the clinic manager. We also asked staff about the level of support provided by senior managers but they were less confident regarding the consistency and visibility of the senior managers.
- There was a friendly culture, and the manager was visible and approachable. The atmosphere was relaxed and we saw positive dialogue between staff and patients.
- The clinic manager carried out patient rounds on all shifts to ensure all patients had the opportunity to speak to her regarding any concerns or questions they had.
- A commissioning manager from the local commissioning group described professional and positive working relationships with the clinic manager and the team.

Vision and strategy for this core service

- Fresenius medical care is a large international organisation and had core values of quality, honesty and integrity, innovation and improvement, and respect and dignity. The strategy of the organisation was to grow as a company, enhance products and treatment and to create a future for dialysis patients.
- The Fresenius Clinical Governance strategy document described a framework that the team used to deliver 'the right care to the right patient at the right time.'
- We asked the clinic manager what the vision for the unit was. We were told they had a strategy to develop the unit capacity and objectives were in place to improve treatment compliance.
- All staff told us their priority was to put patient care above everything else. They could not describe the corporate vision or strategy but were clear regarding the expansion of the unit and the patient outcomes that were measured.

Governance, risk management, and quality measurement

- Governance is a term used to describe the framework, which supports the delivery of the strategy and safe, good quality care. We were not assured there was an effective governance framework in place. Systems were not in place to effectively manage risk and safety. There was a lack of understanding by senior unit staff and corporate processes had not been put in place or maintained.
- An organisational manager told us they were moving to an integrated governance framework but it was not clear what this process would involve and when it would be fully implemented. A new post, Quality and Risk manager had been implemented as part of this process.
- Monthly performance measures included; clinical patient outcomes; compliance; staff usage retention, absence, accidents and training; waste, water and electrical consumption and other costs. The clinic manager looked at this information monthly and was expected to discuss results and improvements that could be made with the area lead nurse on a quarterly basis. We did not see any evidence to corroborate this.
- At the time of inspection we saw that risks were categorised into three headings; Clinical, Operational and Technical. The clinical risk management policy was detailed about risk management principles and risk assessment processes.
- The provider had also introduced a patient concerns register to highlight any particular safety issues for patients receiving care and treatment.
- We were told by the area head nurse that a draft risk register was in place in addition to the above, following feedback from a recent inspection in a local dialysis unit.
- There was evidence following incident investigations that communication regarding patient escalation was

not completed to the standard the company expected. This meant there was a risk that deteriorating patients may not be managed appropriately. This was not included anywhere on the risk register.
- Staff were unable to tell unable to tell us how they learned from incidents but explained that the clinic manager shared all information with them following an event.
- We saw within the risk register that there were two clinical risks identified. These were damp areas following low level plastering and a delay in the resuscitation policy implementation. Areas of improvement identified in clinical investigations were not included on the register.
- The clinic manager identified their top risks as the on-going building work, the transfer of the old to new water treatment plant and ensuring rotas were covered by experienced staff to support new starters.
- There were failures to develop and follow policy and procedures in relation to confirming patient identify before medicine administration. Practice was not in line with NMC guidance and increased the risk of harm to patients from incorrect medicines being administered. There was no patient identification policy. This was put on the draft risk register following feedback from a similar inspection.
- As part of our inspection we asked for evidence the unit met the 'Accessible Information Standard'. From 1st August 2016 onwards, all organisations that provide NHS care were legally required to follow the Accessible Information Standard. The standard aims to make sure that people who have a disability, impairment, or sensory loss are provided with information that they can easily read or understand and with support so they can communicate effectively with health and social care services.
- Senior staff told us the unit had no evidence of meeting this legal standard. After our inspection the lack of an accessible information standard was placed on the risk register.
- We saw none of the corporate policies had review dates on them. This meant there was a risk that up to date guidance and legislation would not be incorporated into the organisations policies.
- The Workforce Race Equality Standard (WRES) is a requirement for organisations, which provide care to NHS patients. This is to ensure employees from black and minority ethnic (BME) backgrounds have equal access to career opportunities and receive fair treatment in the workplace. We acknowledged the local area had low numbers a of black and minority ethnic population (BME).
- WRES has been part of the NHS standard contract, since 2015. NHS England indicates independent healthcare locations whose annual income for the year is at least £200,000 should have a WRES report. This means the unit should publish data to show they monitor and assure staff equality by having an action plan to address any data gaps in the future.

Public and staff engagement

- We saw views and experiences of patients had been sought through the national Fresenius patient survey 2016. Twenty two patients had responded, the results were;
  - 97% said the atmosphere was friendly and happy.
  - 87% of patients thought the unit was well maintained and clean.
  - 91% of them said they would recommend the unit to friends and family in need of dialysis.
  - 91% of patients said they had complete confidence in the nursing staff.
  - 73% thought the unit was well organised.
- The action plan following this survey was displayed in the reception area of the unit. We did not review the action plan.
- One patient told us they believed there were to be changes to transport services in June 2017 but they did not feel there had been consultation around this and they did not feel well informed regarding what was happening.
- Patient satisfaction results and "you said we did" actions were displayed on the notice board in the patient waiting area. These included;
  - making information available to patients regarding the difference between dialysis and diafiltration.
  - making further copies of fistula care and patient guides available in the reception area.
  - staff have been made aware of the importance of giving monthly bloods feedback sheets and explanations to patients regarding the effectiveness and length of their treatment.
  - staffing ratios increased in response to patients comments that nurses spent insufficient time with them during their treatment.

- Staff and patients were fully informed about the refurbishment and expansion project and were kept up to date with developments. Patients were unclear as to how much information they had been given about this.
- A staff survey was carried out in November 2016; senior managers told us 58% (8 respondents) of staff responded. Of those that replied;
  - 50% (four people) said they would recommend the unit to friends and family who needed dialysis.
  - Around 50% (four people) said they would recommend their organisation.
  - Around 100% (eight people) said their training helped them to do their job.
  - Around 50% (four people) would recommend the unit as a place to work.
- Senior managers told us the survey would be repeated next year. We were unable to ascertain if there was an action plan based on the previous results as the number of participants was so small.
- There was a policy and process in place to enable staff to raise concerns at work through a nominated compliance officer. The policy also detailed how staff could access support or raise concerns outside of the organisation through 'Public concern at Work'. Poor practice concerns could also be raised through this policy, which was introduced following an NHS peer review in August 2016.
- The corporate human resources (HR) lead told us they visited the dialysis units periodically to make checks regarding things like; follow up actions from the staff satisfaction survey, although there were plans to improve this process to corroborate data submitted from each unit.

Innovation, improvement and sustainability

- The service was undergoing an expansion and refurbishment project to increase capacity from a 12 to an 18 station facility. This included the upgrading of the water treatment plant and addition of an extra consultation room for outpatient use. It was anticipated that the works would be completed by the middle of June 2017.

Areas for improvement

Action the Provider MUST take to improve:

- The provider must ensure that investigation process and policy following incidents are thorough and include the assessment and, monitoring of risks to improve the quality and safety of the services they provide.
- Ensure patient identification processes are in place in relation to the safe administration of medicines, which are reflective of current legislation and guidance.
- Provide additional safeguard training for the registered manager and unit staff in accordance with the intercollegiate document 2014.

Action the provider SHOULD take to improve:

- The provider should ensure that a recognised early warning score reflecting the risks of the dialysis patient is implemented to prompt recognition of the deteriorating patient.
- Learning from incidents and investigations should be collated consistently to enable trends and themes to be shared regularly with staff.
- The provider should ensure that the Workforce and Race Equality Standards (2015) and 'Accessible Information Standard' (2016) are implemented appropriately.
- Ensure patients receive a comprehensive assessment as part of the initial consideration for acceptance at the Grimsby Dialysis Unit.
- Care plans are developed which reflect the care and treatment required to support patients with medical and health needs.
- Include medication audits as part of the provider audit programme.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • The provider failed to develop and follow policy and procedures in relation to confirming patient identify before medicine administration. Practice was not in line with NMC guidance. • The provider failed to ensure incidents were reviewed and investigated consistently.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 18 HSCA (RA) Regulations 2014 Staffing • The provider failed to provide appropriate training for the registered manager as safeguarding lead.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The provider failed to review the incident reporting policy to ensure incident investigations were monitored consistently and reflect the severity of the incident to support the application of duty of candour.