Bridlington NHS Dialysis Unit

Quality Report

Bridlington & District Hospital
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Date of inspection visit: 5 April and 18 April 2017
Date of publication: 23/08/2017

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Bridlington NHS dialysis unit is operated by Fresenius Medical Care UK (FMC), an independent healthcare provider. It is contracted by Hull and East Yorkshire NHS trust to provide renal dialysis to NHS patients. Patients are referred to the unit by local NHS trusts. The service is situated on the site of Bridlington and District NHS hospital which was built in 1989; dialysis services began in 2008. It is a 12 station dialysis unit (comprised of ten stations in the general area and two side rooms which can be used for isolation purposes) providing haemodialysis for stable patients with end stage renal disease/failure.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 5 April 2017, along with an unannounced visit to the unit on 18 April 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:

- The process of incident reporting, investigation, escalation, and learning from incidents.
- Medicines management processes including patient identification in order to be in line with safe standards and national guidelines.
- Infection prevention and control practices which are intended to keep patients safe.
- Processes to ensure deteriorating patients can be safely and appropriately managed in line with best practice guidance and national standards.
- The processes of monitoring and ensuring staff are competent to carry out their roles.
- The mandatory training processes which ensure staff have had up to date training which is essential to their roles.
- The process for managing performance of the staff and the unit.
- The processes to ensure staff are aware of safeguarding procedures and comply with the Mental Capacity Act and Deprivation of Liberty Safeguards.
- Standards for keeping patient information safe in line with national legislation.
- To ensure a process is in place to maintain record keeping in line with professional standards.
- To ensure a process is in place where risks are placed on the risk register, so risks can be appropriately managed and action taken.
- To improve overall leadership and governance of the unit.

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

- Daily water testing was carried out by staff which was more frequent then the weekly minimum requirement for chlorine testing.
- Good standards of monitoring patients' arteriovenous fistulas to ensure they worked safely and effectively.
- All of the patients received dialysis through high flux dialysers. High flux dialysis is a form of more effective haemodialysis; it is better quality dialysis.
- Flexible staff who worked over when needed for the interests of patients.
- Caring and friendly staff who knew the patients well and looked after them with compassion and understanding.

Summary of findings

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

On 27 April 2017 we served a warning notice under section 29 of the Health and Social Care Act 2008. The warning notice related to Regulation 17, The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014- Good governance. We had serious concerns that the governance systems and process did not provide assurance that risks were identified, recorded and acted upon, to ensure patients receive safe care and treatment and were protected from risk of harm. The warning notice requires the provider to take action to ensure systems and processes are established and operated effectively to assess, monitor, and improve the quality and safety of the services provided in the carrying on of the regulated activity.

We have given the provider three months to make the necessary improvements.

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

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Background to Bridlington NHS Dialysis Unit

Bridlington dialysis unit is operated by Fresenius Medical Care Renal Services Limited. The service opened in October 2008. It is a private medical dialysis unit in Bridlington hospital in the East Riding of Yorkshire. The unit primarily serves the communities of the East Yorkshire and Hull areas. It also accepts patient referrals from outside this area.

The registered manager, Sharon Matthews has been in post since February 2009.

Our inspection team

The team that inspected the service comprised a CQC Inspection Manager Ruth Dixon, a 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 Bridlington NHS Dialysis Unit

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

- Treatment of disease, disorder, or injury.

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

The usual times for dialysing patients are between 7.00am and 12.00 hours, then between 12.15 and 18.00 hours (Monday, Wednesday, and Friday). On Tuesday, Thursday and Saturdays, the unit provides dialysis from 7.00am and closes at 12.30 hours. An average of 380 to 420 treatments sessions are delivered each month. Both male and female patients were treated in the same areas at the same times.

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 technicians' room, and water treatment plant. We spoke with a range of staff including the regional business manager, area head nurse, clinic manager and deputy clinic manager, registered nurses, and dialysis assistants. We also spoke with 8 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 on-going by the CQC at any time during the 12 months before this inspection. The service has been inspected previously, and the most recent inspection took place in January 2013, which found that the service was meeting all standards of quality and safety it was inspected against.

Activity

In the 12 months before our inspection, there were 1370 dialysis sessions carried out for 18-65 year olds and 2255 sessions for people over 65 years of age. Currently 14 patients from age 18-65 and 17 patients over 65 years of age are NHS funded and treated at the unit.

The unit did not employ any doctors. The unit employed 6.4 whole time equivalent (WTE) registered nurses (five full time and two part time staff). There were 1.8 WTE dialysis assistants (1 full time, one part time).

Summary of this inspection

Services accredited by a national body:

There were no services accredited by a national body, however the 'ISO 9001 quality management system' was was in place.

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

Services provided under service level agreement:

- Social worker provided by a health and social care agency
- Counsellor provided by a local trust
- Clinical and domestic waste SLA with a local trust
- Laundry and linen services provided by a local trust
- Cleaning provided by a private company
- Patient refreshments provided by a private company
- Security services provided by a local trust

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

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

- We were not assured that incidents were reported or investigated thoroughly. Staff used their own judgment whether to report an incident or not. Incidents which had been escalated did not have causes found and there were delays in closure of incident reports which meant learning from incidents was delayed. Medicines overdose incidents had occurred which had not been reported or escalated.
- There were unsafe methods of medicines management which increased risks to patients. There was no patient identification policy; previous medicines errors had occurred as a result of wrong doses of intravenous medicines being given to patients.
- There were unsafe practices related to infection prevention and control. This increased the risk to patients.
- Staff were unable to describe what they would do in situations where vulnerable adults needed safeguarding, and they were unsure about what level they were trained to.
- The processes for ensuring staff were competent in their role were not robust.
- Records were not always kept up to date. We also found patient information was not kept or stored in a safe way in line with national legislation.
- There was no process in place to ensure patients who deteriorated would be managed safely and appropriately in line with national guidance. There was no sepsis policy and staff had not received training to recognise or manage this life threatening condition.

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

- When alarms went off on the dialysis machines, staff checked the patients and lines before cancelling the alarm.
- 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 services.

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

Summary of this inspection

- From February to April 2017, the average number of patients with the recommended haemoglobin levels was 50%. This meant the other half of patients had haemoglobin levels which were either lower or higher than recommended. Anaemia can be a complication of renal failure and dialysis associated with increased risks of mortality and cardiac complications.
- Competency documentation relating to some staff were not fully complete. Senior nursing staff told us, and we saw that staff members regularly gave IV medicines despite not having the required competency checks.
- There was no system in place to identify who was capable to sign off other staff as being competent. Staff verified each other as being competent on the same date they had both received training. This could increase the risk of harm to patients.
- 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.
- 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).

We also found the following areas of good practice:

- We saw that policies and procedures were developed in line with NICE 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 arterio-venous (AV) fistula was higher than the national average. Having an AV fistula means dialysis is more effective.
- There were higher than average rates for clearance of certain waste products as a result of effective dialysis. Patients with these higher levels of waste reduction through dialysis have better outcomes and improved survival rates.
- In the 12 months leading up to our inspection, 100% of patients received high flux dialysis; this is better quality dialysis.
- From February to April 2017, we saw 75% of patients who attended three times a week were dialysed for the prescribed four hours treatment time. This is more than the minimum standard of 70%.

Summary of this inspection

- One staff member told us they had been supported when they started at the unit. They had received a 12 week induction programme and had been supernumerary to give them the opportunity to learn.

Are services caring?

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

We found the following areas of good practice:

- We saw staff interact with patients in a respectful and considerate manner. They greeted them in a friendly personal manner on arrival, and said goodbye as patients left the unit.
- Patients received treatment in shared areas; however curtains could be pulled across if someone wanted privacy.
- 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 were information packs available so patients knew what to expect from the service and what the anticipated benefits and risks of treatment were.
- Around 70% of comment cards given to us by patients had positive comments about how they had been looked after.
- We saw nursing staff being supportive to a patient who had experienced a recent bereavement.

However we also found:

- The approach and attitude of some staff towards patients could be improved. Those staff demonstrated a lack of empathy to patients.

Are services responsive?

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

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

- There was no evidence the unit met NICE quality standards about patients being collected from home within 30 minutes of the allotted time and collected to return home within 30 minutes of finishing dialysis.
- We found patients who complained they had not been supported by senior staff. There was also no evidence action had been taken when someone complained about management of the unit.

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 at the unit where patients could make suggestions about the service or care of patients on the unit, or where staff could share information about the service with patients.

However, we also 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 which could be used if someone was unable to get on to the dialysis chair.
- The unit operated at around 87% capacity and so had spaces to accommodate for holiday treatment sessions for people stating in the local area, provided this had been medically approved and there was session availability and all relevant information was available.
- 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.

Are services well-led?

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

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

- Improvements needed to be made to the local leadership at the unit. The service was not well-led; local leadership of the unit was poor. There was a lack of assurance about leadership and guidance of the service. There had been challenges to the delivery of good quality care and safety, and action had not been taken to address issues.
- Governance processes were very poor. 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. Identified risks were not on the risk register.
- There was evidence incidents had not been escalated or investigated. There was a lack of systems and processes to

Summary of this inspection

ensure the effective recording, investigation, and learning from incidents. Staff used their own judgements in the escalation of incidents rather than following policy. The area head nurse was not kept up to date about safety or incidents within the unit.

- Unsafe methods of medicines management were in place which increased the risk of patients receiving incorrect dosages of medicines; medicines errors had repeatedly taken place and action had not been taken to improve processes to prevent this. There were failures to develop and follow policy and procedures in relation to confirming patient identify before medicine administration.
- The infection prevention and control processes were not robust and we observed some unsafe practices which could contribute to contamination and transmission of infection.
- Systems were not in place to follow national guidance around the observation of and management of deteriorating patients. Lessons had not been learned after previous patients deteriorated and needed emergency care.
- We were concerned that the culture among staff prevented actions being taken to address problems within the unit such as lack of competency and lessons not being learned.
- Senior staff told us the vision for the company was the need for it to grow and develop as a business. They did not mention safety or the quality of patient care as part of the vision for the unit. Junior staff could not explain how they contributed to the vision or strategy for the unit.
- Guidance and policy documents contained out of date national guidance, they did not have review dates on them. This meant staff did not always have the most up to date guidance to follow.

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

- There was a friendly culture, and the manager was visible and approachable.
- The area head nurse visited the unit regularly and supported new and experienced staff.
- The unit staff worked together and seemed to have supportive relationships.
- The unit staff told us their priority was to put patient care above everything else.
- We saw views and experiences of patients had been sought through the Fresenius medical care patient survey 2016 and 90% of those who replied said the atmosphere was friendly and happy.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

- There was a clinical incident policy and system in place for reporting incidents. 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.
- We were not assured that incidents were reported or investigated thoroughly. Upon discussion with staff during the inspection, we learned there had also been two medicines errors; these resulted in patients receiving an excessive dose of intravenous (IV) medicines. Both of these incidents had occurred as a result of lack of patient identification (both patients had same first name) and having more than one injection on the trolley next to the patient.
- When we asked senior nursing about the medicines incidents, they originally told us the first incident occurred in 2016. We subsequently found out this had occurred in 2015 and had been reported through the clinical incident reporting system. The incident report was sent 25 working days after the incident. A review of the incident had been carried out by the chief nurse; this was signed off nine months after the incident date. We were concerned learning from this incident had been delayed.
- The second medicines incident which occurred the week before our announced inspection had not been reported or escalated even though senior nursing staff had been aware of the incident. The area head nurse had not been advised of the recent medicines error and no clinical incident documentation had been completed at the time. The clinic manager advised us that they had forgotten to report it, or thought the deputy clinic manager had reported it.
- Information sent to us before the inspection indicated there had been no 'Never Events' at the unit. 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.
- We asked for the clinical incident register after our inspections. The information showed there had been two further clinical incidents; one had occurred in July 2016 and the other in November 2016, both related to central venous lines becoming detached. We reviewed the clinical incident report forms which were both categorised as 'moderate' incidents and saw the chief nurse had reviewed the forms, but on one of the incident forms, the root cause analysis and lessons learned sections had not been completed by the clinic manager as required by Fresenius policy. After our inspection, senior staff told us one of the incidents had not required a full root cause analysis; they said this was why the clinic manager had not completed that section or the lessons learned section.
- When reviewing the risk register, we saw the second medicines incident we had been told about had since been entered onto register as 'incorrect dose' of medicines, although this had been an overdose. There was also a further incident which had occurred on 31 March 2017, but had not been identified until 6 April 2017; this was categorised as 'dialysis prescription set up not followed', This was reported as a near miss even though it was an actual incident.
- As part of the inspection we asked what the process was for reporting clinical incidents such as drug errors to the renal consultant. We were told by senior nursing staff that they sent an email to the consultant if they felt the incident was serious enough. They also told us they

made the decision based on how serious they believed the error or incident to be. This meant staff were not following the organisations incident reporting framework.

- We were concerned about the rating of incidents. Senior staff told us actual incidents such as a drug error or a flood which had previously occurred would be classed as near misses rather than an incident.
- Senior nursing staff told us team meetings were held each week and incidents were discussed, but they had no evidence to support this. They also told us the fixed agenda which was provided by the organisation was not followed and not all meetings were documented. There was no evidence staff heard about any incidents.
- Nursing staff were able to identify clinical incident reporting procedures but were not able to give examples of learning following the incidents. Governance processes did not capture lessons learnt within the unit and there was no regular discussion of issues or concerns.
- 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 reviewed the alerts sent for the last six months before our inspections and saw that not all staff had signed to say they had seen the alerts. For example, in January 2017 six out of ten staff signed to say they had read the safety alerts.
- 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. Following the medicines 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.

Mandatory training

- All staff were required to complete a programme of mandatory training appropriate to their role. Training was divided into several categories such as basic life support and emergency training. These subjects were completed either in face-to-face training or via an electronic learning programme.
- We were provided with the annual timetable of training for the staff working on the unit which was colour coded, for example showing red where training was overdue, amber if the training was due soon, and green if the training was within date.
- There were several gaps in the mandatory training register in the information we were provided with, for example:

- Annual training for basic life support training had expired for three staff out of ten where this training was required. It was last completed for the individuals in November 2015 and February 2016.
- Annual defibrillator training had expired for two staff out of nine where this training was required. It was last completed in February 2016 and March 2016.
- Annual anaphylaxis training for two staff out of nine who were appropriate for this training was last completed in February 2016 and March 2016.
- Safeguarding adults training (3 yearly) had expired for one registered nurse, (the clinic manager) in February; it was last completed February 2014.
- The annual NephroCare standard, good dialysis care had expired for one out of eight staff where this was required; it was last completed in February 2016.
- Annual infection prevention and control assessments were out of date for two out of nine where this was required; it was last completed February 2016.
- Information governance training had expired for two out of nine where this was required; it was last completed in March 2016.
- The two yearly fire risk assessment training was out of date for one out of two where this was required.
- The three yearly Deprivation of Liberty Safeguards training had expired for one out of eight staff where this was required.

- A previous internal audit report from October 2016 showed gaps in mandatory training and the action plan detailed the need to update the training matrix. We were provided with information after our inspection which showed the training matrix had been updated.

Safeguarding

- There was a safeguarding policy in place which specified the process and responsibilities of staff. The policy did not highlight which staff should have advanced or basic safeguarding training.
- The service lead for safeguarding vulnerable adults and children was the clinic manager. No children were treated at the unit. We could not ascertain from the information provided to us what level the clinic manager was trained to, and they were also unclear what level they were trained to.
- There was no access to a nominated safeguarding lead with level four training, who staff could go to for advice or information.
- We were not assured about systems which are essential to keep vulnerable people safe. As part of our inspection, we asked staff who the safeguarding lead was. They were uncertain who this was and were unable to describe the process they would use to support patients where there may be safeguarding concerns. Staff were not able to clearly explain what they would do, for example if someone disclosed abuse to them.
- The failure of staff to understand the safeguarding policy and procedures increases the risk of them not being able to identify and prevent abuse of people who use the service.

Cleanliness, infection control, and hygiene

- There were clear infection prevention and control policies and hygiene plans for staff to follow. All staff we spoke with told us they were aware of the procedures in place. One of the registered nurses was a 'link nurse' and acted as the lead for infection prevention and control.
- There were two single side rooms on the unit which could be used for isolation purposes if patients had, or were suspected to have an infectious condition. Patients who returned from holidays to high risk areas could have their dialysis treatment in the single rooms.
- Patients were screened for MRSA (Methicillin-resistant Staphylococcus aureus). Screening did not take place for any other organisms such as Methicillin-sensitive staphylococcus aureus (MSSA).
- We were told there had been one case of healthcare associated infection (MRSA) in the 12 months before our inspection. We were told this was related to a previous hospital admission but we could not corroborate this.
- On both our announced and unannounced inspections we observed poor infection prevention and control practices. On our announced inspection we saw blood on the outside of four sharps bins in the clinical area of the unit. We pointed this out to staff who took immediate action to wipe clean the sharps bins.
- On both our inspections we observed poor aseptic technique processes when staff were connecting patients to, or disconnecting them from dialysis machines. (Aseptic techniques are methods designed to prevent contamination from micro-organisms. They involve actions to minimise the risks of infections).
- We saw staff set up sterile areas and then lean over them to reach equipment they could have had nearby.
- We observed a member of staff set up a sterile area to take a patient off a dialysis machine. They had appropriate personal protective equipment on (sterile gloves, apron, and an anti-blood- splash face shield). They started to remove the lines from the patients arm, and then picked up and moved the patient's glasses case and TV remote control. They then took the patient observations, touched the screen on the machine to record the results, and continued to remove the lines without changing their gloves or washing their hands.
- Blood pressure cuffs and tourniquets in use were made of fabric. Staff cleaned them with antiseptic wipes in between patients, but it is difficult to effectively remove bacteria from fabric using this method.
- Monthly hand hygiene audits were carried out based on the World Health Organisation (WHO) 'Five moments for hand hygiene' guidelines.
- Hand hygiene audit results for January to December 2016 showed an average of 75% compliance. The target for compliance was 95%. Monthly compliance varied and ranged from 8%, to 36%, 60%, and 81%. There were three months in 2016 were 100% compliance was achieved.
- An action plan had been put in place to address the results of the audits and 'barriers to effective hand hygiene' were noted. Examples included:
- Staff touching machine keys then moving to the next patient without washing their hands or using alcohol hand rub;
- Busy periods of time when patients need immediate care;
- Telephone calls answered, and staff not washing their hands or using alcohol gel before returning to the patient;

- Touching the screens on machines with gloves on and not wiping the screen.
- We found all of the above were occasions when effective hand hygiene had not taken place rather than barriers to this happening.
- Infection prevention and control audit results for January to April 2017 were provided to us after our inspection. Results ranged from 71% to 90%; the average for the four months was 82%. This was an improvement on the overall results from 2016.
- Staff did not know the results of the hand hygiene audits; however they told us they could access them if they needed to.
- The action plan related to these results showed opportunities for hand hygiene had not always been followed. The action plans were not clear and reliable systems were not in place to follow infection control policies and procedures. This increased the risk of contamination and transmission of infection to patients.
- There was no system to show equipment was cleaned and ready to use. There were no stickers or a sign in place to indicate equipment was clean.
- Staff told us they performed disinfection of dialysis machines between each patient and at the end of each day. Single use consumables such as blood lines were used and disposed of after each treatment. However we did not see them clean the dialysis chairs or pillows in between patient use.
- We saw none of the pressure relieving mattresses had sheets or covers on, and plastic pillows without pillowcases were in use. This meant patients skin was in contact with plastic surfaces. We asked patients if they minded this, and were told it had always been that way, so they did not question it. We also asked staff, and they told us the unit didn't previously have linen supplied to them. This was still the case now, but they told us patients did not mind. After our inspection, senior staff told us disposable sheets and pillowcases were available if required.
- 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 and chlorine levels and were able to explain the procedures that were required should a water sample test positive.
- During our inspections staff told us the unit had failed monthly water quality tests carried out by an accredited laboratory; there was a problem with the reverse osmosis water system (this is the method used to purify water used for dialysis). This had been reported and investigated, and work had been carried out to replace part of the water system.
- The unit was unable to provide haemodiafiltration so this treatment was suspended; haemodialysis treatment still took place. The water quality tests had repeatedly failed, but this was not on the risk register.
- Training compliance figures for infection prevention and control indicated 25% (two staff out of eight for whom this was required) had not completed the annual reassessment of competence task.

Cleanliness of premises

- We reviewed the clinical and non-clinical waste areas, which were generally clean, tidy and well maintained. Monthly hygiene audits had been carried out; from January to April 2017 the audit showed the unit was not clean, tidy, nor free from clutter. Action plans included speaking with cleaning staff to ask them to clean dusty areas. Improvements were made for the days of our inspections.
- New stock was organised and labelled clearly and stored off the floor on shelving.
- The floor areas in the clinic had tape over them to temporarily cover holes and cracks. Audits in January, February, March, and April 2017 noted flooring was in need of repair. Records on 13 March 2017 indicated plans to replace the defective flooring had been declined at a corporate level. Records also showed the need for floor replacement was under review by a senior manager on 10 April 2017.

Environment and equipment

- 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. 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.

- The unit had a consulting room, staff offices, toilets for staff and patients, and a kitchen where staff prepared drinks and sandwiches for patients.
- The unit had 12 dialysis chairs / stations in three different areas. There was a two station area, and two areas each with four stations. In addition there were two individual isolation rooms. There was plenty of space around each station to allow for patients, staff, and equipment. Each station had a ceiling mounted TV for individual patient use.
- 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. All the equipment testing was within the specified dates.
- 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. A dedicated FM team, an experienced FM Manager and 2 helpdesk coordinators provided the clinic 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.
- We checked the resuscitation trolley and found the equipment was correct and in date. There were first line medicines which could be given by the hospital emergency 'crash' team. Equipment checklists available which showed the previous five 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. There were two spare dialysis machines kept in the maintenance technician room which were ready to use if necessary.
- All patients had access to the nurse call system and we observed that systems were working at the time of inspection.
- During our announced inspection we found the clean clinic room was unlocked and needles were stored in an unlocked cupboard within the room. We pointed this out to senior staff at the time as the room could be accessed by patients if staff were not nearby. When we carried out our unannounced inspection two weeks later, no changes had been made to the security of the room or the cupboard door.
- 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, but this was not sent to us.

Medicine Management

- 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; 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 clinic 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). The EPO injections were supplied by the local trust, other stock medicine was ordered from Fresenius.
- There were no arrangements for a pharmacist to visit the unit, pharmacy audits were not carried out. Pharmacy support was available from the local NHS trust pharmacy for advice relating to dialysis drugs. Staff also had access to the company pharmacist at head office.
- We observed staff administering IV medicines to patients. There were failures to follow procedure confirming patient's identities before administering the medicine, which increases the risk of harm to patients and was not in line with national Nursing and Midwifery Council standards (NMC). We pointed this out to senior staff at the time.
- After our inspection we asked for evidence of the patient identification (ID) policy. We were told the company did not have a policy for this. This meant have there was no Fresenius policy or procedure for staff to follow when administering medication that reflected current

legislation and guidance. Senior staff told us they would normally follow the respective NHS trust on such key policies. The lack of a patient ID policy was entered onto the risk register following our inspection.

- During our announced inspection, we observed a member of staff remove a batch of several IV pre filled syringes of Tinzaparin (an anti-coagulant drug) from the medicines cupboard, according to a pre-printed, colour coded list kept in the clinic room. This list was not a written prescription.
- The staff member took out all the injections at the same time rather than getting them out for each individual patient as their medicine was due. Previous drug errors had occurred at the unit related to non-individual practices. This was not a safe method of medicines management and was not in line with internal policies and procedures or NMC professional standards.
- Dialysis assistants administered IV medicines to patients. The NMC standards for medicines management states:
- Wherever possible two registrants (registered nurses) should check to be administered intravenously, one of whom should also be the registrant who then administers the intravenous (IV) medicine.
- FMC medicine management policy stated 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 medicines administration.
- We checked the staff competency booklets and saw a member of staff had been observed for competency twice instead of the required five times. Senior nursing staff told us the staff member regularly gave IV medicines despite not having the required competency.
- Medicines requiring refrigeration were stored in a fridge; the fridge was locked and the temperatures were checked on a daily basis. The fridge was not alarmed, so staff would not be aware of the temperature had increased and then reduced again in between the daily checks. The record sheet we saw did not have an escalation process outlined about what to do if temperatures were outside of normal safe ranges. We spoke with staff who told us that changes in temperature would be escalated to the nurse in charge.

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. Paper records were stored on open shelves according to the day and time patients would have treatment. The shelving unit was behind a desk.
- When not in use, the files were kept in the same shelving unit. There was no way to secure the records. After our inspection senior staff told us the shelving unit was lockable but this was not apparent to us at the time of inspection.
- When patients commenced treatment at the unit an initial nursing assessment should be carried out and care plans produced. During our inspection we saw incomplete paper records. There was evidence of a lack of nursing assessment and re-assessment of patients in 40% of records we looked at (four out of ten records). An internal audit report from October 2016 showed further training was required for documentation due to gaps and lack of detail in nursing documentation.
- Staff showed us electronic care plans which they updated on hand held devices or the computers, but initial nursing assessment had not been carried out for some patients who had been attending the unit for several years.
- Two nurses told us patients were not routinely reassessed during the course of their dialysis treatment. Variances in care such as falls, illness, or changes in vital signs were recorded but there was no protocol to determine when reassessment was carried out.
- These standards were not in line with the NMC Code of Professional Conduct in relation to record keeping.
- During our announced inspection we observed two Information Governance breaches. Patient names and results of body composition tests had been left on a trolley in the maintenance technician room; there were also four sets of pathology results which contained patient identifiable information on top of a filing cabinet in the consulting room. We pointed this out to senior

managers at the end of our announced inspection. The Information Governance breaches contravened company policy and national legislation regarding personal data.

- 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 audit results for the six months before our inspection. In October and December 2016 there were no errors or omissions found. In November 2016 there were three errors or omissions for one set of records, and two omissions on each of the other records (allergy status and missing signatures).
- In January 2017, there were four issues of non-compliance for one set of notes checked. In February 2017, one check indicated a patient's temperature had not been taken before and after treatment; all other checks were compliant. In March 2017 all three records checked had omissions for drug administration completion; other checks were compliant.
- There were blank action plans attached to the audit sheets. This meant there was no evidence the issues had an action plan to remedy the problems.
- None of the audit sheets had evidence that issues had been reported to the clinic manager or deputy clinic manager within seven days, which is the requirement according to Fresenius policy.
- Results of blood tests carried out at the local NHS trust were sent to the unit electronically.

Assessing and responding to patient risk

- Only stable patients were dialysed on the unit; if someone was acutely ill with renal problems they were treated at a main renal unit. 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 who had additional needs such as those living with severe dementia, or who had challenging behaviour were not treated at the unit. However, staff told us of a situation where a patient with challenging behaviour had to continue treatment at Bridlington as there were no treatment slots available at the local NHS hospital. Following our inspection, senior staff told us the patient lived locally and had a preference to continue treatment at the unit.
- 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. The electronic card reader was not working on our announced inspection, so staff manually recorded patients' weight. Observations of vital signs such as blood pressure and pulse were recorded before, during and after dialysis treatment.
- During our unannounced inspection we saw one patient had significantly high blood pressure before their dialysis. We asked a staff member if there was an algorithm or NEWS (national early warning score) in place to support staff decision making, and to standardise the assessment of patients if their vital signs were abnormal. They told us there was no early warning tool in place; in such circumstances, the patient would be kept at the unit until their blood pressure returned to normal and staff would contact the renal registrar by phone if they felt this was necessary.
- There was a guidance document, 'complications, reactions, and other clinical event pathway' but no system was in place to ensure that care was delivered in line with national guidance from the Department of Health or the National Patient Safety Agency which related to deteriorating patients. This meant there was a risk that deteriorating patients may not be managed appropriately.
- There had been a previous incident in 2016 where a patient was found to have very low blood pressure part way through their treatment. The blood pressure was not re-recorded, and an hour later the patient was found to have deteriorated and become unresponsive. Staff took urgent action to stabilise the patient and spoke with the renal registrar by phone. They were advised to send the patient to an acute hospital.
- A non-urgent ambulance was called as this was deemed appropriate at the time. Three hours later the patient had deteriorated further and staff did not speak directly to the registrar on that occasion; instead a message was passed via nursing staff in the acute hospital. An emergency ambulance was called and the patient was

transferred to hospital where they were treated and recovered. Lessons had not been learned from this, there was no pathway in place for the management of deteriorating patients.

- There was no sepsis toolkit or pathway in use at the unit. Staff were not trained to recognise or take action about sepsis. 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 after our inspection.
- 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, 12 patients had been transferred to the acute trust. This was less than the national average.

Staffing

- The unit employed 6.4 whole time equivalent (WTE) registered nurses (five full time and two part time staff). There were 1.8 WTE dialysis assistants (1 full time, one part time).
- Staff worked longer hours on a Monday, Wednesday and Friday when the unit had two treatment sessions; they worked half days on Tuesday, Thursday, and Saturday. If patients were delayed commencing treatment due to transport problems, the staff were flexible and worked over.
- Senior staff told us the clinic manager worked 34% of their time in the clinical area and had 66% of time set aside for management.
- The staffing rota was planned by the clinic manager in advance so that there was one registered nurse to four patients. We checked the rota for the month before our inspection, but were not able to establish how many patients had received treatment on those days. Staff told us if someone was sick from work at short notice they had to carry on with the available staff as they couldn't cancel treatment sessions. There were no staffing vacancies at the time of our inspection.
- When staff shortages were identified, staff were flexible and covered extra shifts. If staffing levels could not be maintained by permanent staff, requests were made to FMC Renal Flexibank, who arranged for cover. When Flexibank could not cover shifts, external nursing agencies (approved by FMC) were used.
- In the three months before our inspection, no bank nurses had been used. There had been 13 shifts covered by agency nurses. We could not ascertain from records if regular agency staff worked or different ones each time.
- The average sickness at that time had been 9% 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 1.2%. This is lower than average sickness which is around 3- 4%.
- 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:

- A link nurse who was responsible for ensuring electronic documents were are implemented and incorporated into practice;
- Infection prevention and control link nurse;
- Education and training link nurse;
- EuCliD link nurse (EuCliD was the IT database);
- Health and safety link nurse.

- The unit did not employ any doctors; the renal consultant attended the unit once a month. If doctors were needed outside of this, renal doctors at the NHS trust could be contacted by phone or email.
- Patients had access to dietitian services through the local NHS trust. In addition, a social worker from an independent agency could be contacted if necessary.

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.

- 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

- We saw that policies and procedures were developed in line with guidance and standards from NICE and the UK Renal Association, and had been incorporated into the organisations 'NephroCare standard for good dialysis care'.
- Treatment was led by an NHS Consultant; staff told us that treatment was prescribed to ensure best patient care outcomes.
- We looked at 11 policies, these all had included a date they became effective, but did not have a date to indicate when the policy expired or would be reviewed.
- The local NHS trust was responsible for the creation of fistulas; staff at the clinic 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 National Institute for Health and Care Excellence (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 therefore better than the Renal Association guidance of 85%.

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 Bridlington unit was combined with the NHS Trust data and submitted as one data set.
- This data set included patients under the direct care and supervision of the Trust i.e. it would not include for example those patients undergoing Dialysis away from either the trust or Bridlington unit. Due to the inclusion with the trust, the unit could not benchmark the effectiveness of its service to other dialysis providers.
- Clinical outcomes for renal patients on dialysis can be measured by the results of their blood tests. The blood results were monitored on a monthly basis as directed by the NHS trust. Results were collated on the EuCliD database used at the unit. The data was available for the clinic manager and consultant to review so they could see individual patient outcomes.
- The results show how the unit performed in the achievement of quality standards based on UK Renal Association guidelines. We reviewed results of blood tests for three months from February to April 2017. These comprised of a number of standards, for example:
- Two standards we looked at show how much waste products are removed from the patient and how effective the dialysis is;

- the rate blood passes through the dialyzer over time, related to the volume of water in the patient's body (expressed as 'eKt/V >= 1.2,h');
- the Urea Reduction Ratio (URR).

- On average just over 80% of patients had effective dialysis based on the first standard. We could not establish how this compared to a national average.
- For the URR, Renal Association guidelines indicate a target of 70%. The average URR for the patients at Bridlington from February to April 2017 was 96%. Patients with these levels of waste reduction through dialysis have better outcomes and improved survival rates.
- We also looked at the standards indicating patients' haemoglobin (Hb) was at safe levels. Anaemia can be a complication of renal failure and dialysis associated with increased risks of mortality and cardiac complications. From February to April 2017, the average number of patients with the NICE recommended target of Hb (100-120 g/l) was 50%. This meant the other half

of patients had Hb levels which were either lower or higher than recommended. Where patients had low levels they were given injections of a stimulating agent to help their body produce more blood cells.
- Potassium levels in the blood are monitored as part of a renal association standard. From February to April 2017, an average of just 3.5% of patients had high levels of potassium (greater than 6.0 mmol/l). If potassium levels are higher than 6mmols, it can cause acute cardiac problems. This means around 97% of patients had potassium levels within acceptable ranges.
- In the same timeline, outcome standards for the unit showed 95% of patients received haemodiafiltration (HDF) treatment. We were not clear about these results as senior staff told us they had suspended HDF treatment as a result of failed water tests.
- From February to April 2017, we saw 75% of patients who attended three times a week were dialysed for the prescribed four hours treatment time. This is more than the minimum standard of 70%.
- In the 12 months leading up to our inspection, 100% of patients received dialysis through high flux dialysers. High flux dialysis is a form of more effective haemodialysis; it is better quality dialysis.
- 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. These results were used to look at issues and make improvements where possible.
- In 2016, there were 28 variations related to patients not attending for dialysis; these ranged from one per month to eight times per month. We did not ask staff what actions they carried out of patients who did not attend.

Pain relief

- Senior staff told us the unit kept a stock of paracetamol and all patients were prescribed this to have if they needed it. If any in- patients from Bridlington hospital were receiving dialysis treatment, ward staff provided their medicines.
- Patients told us it could be painful when the needles were first inserted into to their fistulas, but the pain went away quickly.

Nutrition and hydration

- Patients who have renal failure require a strict diet and fluid restriction to maintain a healthy lifestyle.
- Patients were offered hot and cold drinks and pre prepared sandwiches or biscuits while they were having their treatment.
- 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.
- We did not see any nutritional assessment tools in use at the unit; it was not clear from national guidance if assessment tools were recommended.

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 the registered nurses and dialysis assistants based on the unit. We saw that competencies relating to two staff were not fully complete. Competency documentation stated five observations of practice were required to confirm competency. Only two signatures were in place and not the five required. Senior nursing staff told us the staff members regularly gave IV medicines (Tinzaparin and saline) despite not having the required competency checks.
- There was evidence in another staff folder of only one competency observation out of the required five.
- We reviewed the investigation notes relating to the first medicines error we were told about and saw that the member of staff involved was advised to repeat the competency to give medicines. We did not see any evidence to state that this had occurred and senior staff were unable to provide a clear explanation why this had not happened.
- There was no system in place to identify who was capable to sign off other staff as being competent. The process for verifying each other was not robust. Two staff had verified each other to be competent on the same date they had both received training. This meant competency checks were not carried out in line with company policy. This could increase the risk of harm to patients.
- No staff had received training to recognise sepsis in patients despite the patients being a high risk group. This was not in line with NICE guidance (NG51 sepsis recognition, diagnosis, and early management).

- We spoke with a staff member who told us they had been supported when they started at the unit. They had received a 12 week induction programme and had been supernumerary to give them chance to learn. We were also provided with information which indicated core induction training for 100% of staff to be given within one month of joining the organisation had not been possible due to reduced supernumerary time for new starters and late access to the Fresenius learning centre. After our inspection, senior staff told us there had been a delay in new staff receiving log in details to access electronic learning. We were told this had since been rectified.
- Staff performed annual self-assessments of competence. This followed company guidance and was intended to highlight training and development needs to discuss in annual appraisals. We saw evidence in staff files of completion of annual competency declarations.
- We asked for evidence that staff had received an appraisal in the last 12 months before our inspection; we were not sent this information, however we were sent a plan to show all staff had an appraisal booked for 2017.
- Three staff out of the required ten staff had not undergone annual basic life support training. Two staff had not had their annual reassessment of competencies for infection prevention and control.
- One registered nurse (out of three for whom this was required) had not had their annual re assessment of competence for registered nurse dialysis units.

Multidisciplinary working

- Staff told us the renal consultant had overall responsibility for patient care and visited the unit every month to carry out a clinical review of patients.
- Senior staff told us a colleague from a nearby Fresenius dialysis unit attended meetings at the local NHS trust and were responsible for discussing issues related to Bridlington. They were unable to provide us with evidence of this.
- The dietitian 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.
- 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 care and treatment could continue.

Equality and human rights

- 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.
- 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.

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.

- As part of our inspection we checked consent forms in six sets of records. One patient record showed the consent form had not been signed; the patient had been coming to the unit for over three years. There was no evidence the procedures had been explained to them or that verbal consent had been given.
- A previous internal audit report from October 2016 showed patients consent had not been signed and that further training for staff was required.
- The Deprivation of Liberty Safeguards (DoLS) are part of the Mental Capacity Act (MCA) 2005. The safeguards aim to make sure that people are looked after in a way that does not inappropriately restrict their freedom.
- Staff told us about a dialysis patient who lacked capacity and had one to one supervision to keep them safe during dialysis. Standard authorisation had not been applied for; therefore the appropriate DoLS legislation had not been applied or followed. There was a lack of understanding about mental capacity and DoLS and there was no robust system in place to ensure the legal requirements of the MCA and DoLS were being followed.

Are dialysis services caring?

Compassionate care

- We saw staff interact with patients in a respectful and considerate manner. They greeted them in a friendly personal manner on arrival, and said goodbye as patients left the unit.
- There was a 'quiet room' where patients could have confidential discussions about their care with member of staff.
- Patients received treatment in shared areas; however curtains could be pulled across if a patient wanted privacy.
- Senior managers told us a 'named nurse' approach was used so that patients could be cared for by staff they were familiar with. Two patients out of eight we spoke with told us they did not see their named nurse. Other patients told us they knew all the nurses and were well looked after by all of them.
- We viewed comment cards we had sent to the unit to be anonymously filled in by patients before our inspection. Out of 20 cards, 14 were positive (70%), one card (5%) had both positive and negative comments on, and five cards (25%) had negative comments on.
- The positive comments were praiseworthy of the compassionate attitude of staff. The negative comments related to lack of continuity for patients, waiting for an hour to start treatment on several occasions, and not being able to participate in self-care.
- We saw the approach and attitude of some staff towards patients could be improved. Those staff demonstrated a lack of empathy to patients.

Understanding and involvement of patients and those close to them

- We saw staff speaking with patients about their treatment and blood results. Patients were encouraged to ask questions and were given answers 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 were information packs available so patients knew what to expect from the service and what the anticipated benefits and risks of treatment were. However two patients told us they had not seen or received these packs.
- Relatives could not stay or visit patients during treatment due to infection prevention procedures. However, if someone had additional needs such as learning disabilities, a family member or carer could stay with them.

Emotional support

- Staff told us because they cared for patients frequently over a period of years, they became familiar with them and could tell when a patient was having an 'off day' or were worried. They said they would spend more time with the patients if they could.
- We saw nursing staff being supportive to a patient who had experienced a recent bereavement.
- Senior staff told us the unit worked in partnership with a social worker and renal psychologist who were based at the main renal unit. They could arrange for relevant support for patients.

Dialysis Services

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

Service planning and delivery to meet the needs of individual people

- Dialysis services were commissioned by Hull and East Yorkshire NHS trust. The contract for the unit was renewed in April 2016, and the service specification was defined by the acute NHS Hospital trust renal team. Patients were referred to the unit by the local NHS trust. Senior staff told us the corporate team met with commissioners in order to plan services for patients.
- 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.
- The unit operated at around 87% capacity (November 2016 to January 2017) and so had spaces to accommodate for holiday treatment sessions for people stating in the local area, provided this had been medically approved and there was session availability and all relevant information was available. The receptionist at the unit was involved in the coordinating of holiday dialysis.
- 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. This standard wasn't met by the Bridlington unit. After our inspection we asked senior managers for evidence of this. They told us transport services were the responsibility of the local NHS trust business team.
- Senior staff told us they did not have a transport user group. They were unaware of how long patients waited to be collected for dialysis or waited to be taken home again. We asked senior staff what would happen if transport did not come to collect someone and the unit was due to close. They were unable to answer this.
- Patients who attended the Bridlington unit were referred if they were medically stable enough for treatment at a satellite unit, had vascular access, had been prescribed to have dialysis treatment, and they lived in the local area wherever possible.

Meeting peoples individual needs

- There was sufficient parking for patients at the main entrance and available bays for blue badge disabled parking.
- 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.
- 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.
- If translation or interpreting services were needed, for example, for someone who was deaf and used British Sign Language to communicate; or a non-English speaker, this would be arranged by the local NHS trust. Staff told us they could use 'big word' telephone translation services for patients who did not speak English.
- Facilities were provided to support patients comfort. These included electrically operated dialysis chairs which could be adjusted, and pressure relieving mattresses were on the chairs. Wheeled tables were positioned at each station for ease of use.
- We were provided with information which indicated the unit was dedicated to upholding equality and diversity, however staff were unable to tell us how the service took account of the needs of people with protected characteristics such as gender, sexual orientation or religion.

Access and flow

- Staff told us they were happy to welcome patients to visit the unit prior to commencement of treatment to familiarise themselves with the facilities and routine.
- Staff told us they were flexible as far as possible to accommodate patient wishes and other commitments for the days or sessions they attended for treatment. One patient told us they wanted to attend in an afternoon rather than coming early in a morning, but there were no available slots for them at the moment.
- Referrals for treatment were controlled by the main renal unit who informed the unit they have new patients

they wanted to transfer to the Bridlington unit. If patients were not stable or did not fulfil other requirements of the eligibility criteria, they could not be accepted for treatment at the unit.
- Senior staff were not sure what occupancy they worked towards; the unit utilised 77% of treatment slots in November 2016, in December it was 87%, and 83% in January 2017.
- Staff told us there was no waiting list for treatment and there had been no cancellations of treatment in the 12 months before our inspection.
- Staff told us patients were not delayed in treatment starting when patients arrived at the unit, however this was not audited. Patients spoke to us about delays, and there was evidence in the waiting area that staff had taken action to address delays on the 'you said- we did' poster.

Learning from complaints and concerns

- There was a complaints policy in place. A senior 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 customers may develop as a direct result of a concern or complaint.
- 'Tell Us What You Think' leaflets were in the patient waiting area to encourage comments, concerns, or compliments to be shared.
- 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. One patient had anonymously shared concerns with us before our inspection. They were concerned about the skills and capabilities of staff and no doctor being available on the unit.
- During our inspection, patients told us they had verbally complained to senior staff in the unit about a transport issue and had not been supported. They told us they were made to feel as though they were to blame for raising concerns. They said they had to pursue the complaint before it seemed to be taken seriously.
- There had been three verbal and two written complaints in 2016; one was about unit management (there was no evidence that action was taken as a result of this).
- Three complaints were about the quality of care (one about staff and two about lateness of treatment); the area head nurse apologised to patients and took action following these. The fifth complaint was categorised as 'other'; an apology was given and the complainant did not wish to take the matter further. We could not ascertain from complaints information which was sent to us, how quickly complaints were dealt with.
- In 2017 there had been one complaint in January and three in March. We did not know what these were in relation to, nor what action or learning which may have taken place afterwards.
- 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.

Are dialysis services well-led?

Leadership and culture of service

- The service was not well led. There was a lack of assurance about leadership and guidance of the service. There had been challenges to the delivery of good quality care and safety, and action had not been taken to address issues.
- There had been reviews of the performance of the unit but risks were not mitigated. There was evidence of staff appraisal however we were not assured about the quality of these. The area head nurse was not kept up to date about safety or incidents within the unit.
- There was a friendly culture, and the manager was visible and approachable, but the unit did not look outwards for ways to challenge standards and improve. There was a small number of staff who all worked together, they told us they were also friends outside of work; we were concerned this prevented actions being taken to address problems within the unit such as lack of competency and lessons not being learned.
- Staff told us the area head nurse visited the unit regularly and supported new and experienced staff. There was transition between leaders on the unit; the deputy clinic manager was being upskilled to take over when the clinic manager retired later in the year.
- The unit staff worked together and seemed to have supportive relationships.

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.

- We asked senior staff what the vision for the unit was, they told us as a business it needed to grow and develop. Senior staff did not highlight safety or the quality of patient care as part of the vision and strategy.
- Junior staff told us their priority was to put patient care above everything else. They could not describe their role in achieving the aims of the unit or organisation.

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 in senior unit staff and corporate processes had not been put in place or maintained.
- Processes involving medicines administrations were not safe and errors had repeatedly taken place. Processes were not in line with internal policies or Nursing and Midwifery Council (NMC) professional standards. For example, there were no ID checks and staff gave IV medicines without having the required competencies to do so.
- There was a lack of systems and processes to ensure the effective recording, investigation, and learning from incidents. For example; incidents had not been escalated to the area head nurse and staff used their own judgements in the escalation of incidents rather than following policy. They were unable to tell unable to tell us how they learned from incidents.
- Processes for assuring staff were competent in aspects of their role were not followed. For example, staff signed each other as competent on the day they both received training for a subject; there was no way to tell who was a competency assessor.
- There was a failure to follow infection control policies and procedures; there was no robust system in place which increased the risk of contamination and transmission of infection and some practices we observed were unsafe. For example, we saw poor aseptic techniques carried out when connecting or removing patients from dialysis treatment. Hand hygiene audit results were well below the target throughout 2016.
- Systems were not in place to follow national guidance around the observation of and management of deteriorating patients. For example there was no system to guide staff on what to do if someone's vital signs were abnormal. A patient had previously needed emergency treatment when they deteriorated and improvements to recognising and acting on such events were not in place. Staff used their own judgement about what to do in similar circumstances.
- There were no systems in place related to patients who may develop sepsis. There was no policy and staff had not had training on how to recognise or manage this life threatening condition.
- There was a lack of a robust system to keep patient information safe. For example we found identifiable patient information left in two areas of the unit.
- We were not assured that the risk register reflected known risks or that they were accurately categorised. For example water quality tests had repeatedly failed, but this was not on the risk register. Actual incidents and risks such as procedures not being followed were categorised as near misses.
- There was a lack of awareness in senior staff about the risks to the unit. For example they told us the top risk was an increasing older population rather than anything related to the unit.
- There was no process to ensure national legislation was followed around meeting the Accessible Information Standard. After our inspection the lack of an accessible information standard was placed on the risk register.
- We were not assured that up to date guidance and legislation was incorporated into the organisations policies as there was no review date on any polices we saw. For example the FMC medicines management policy referred to NMC guidance from 2007. This had since been superseded by NMC guidance in 2015.

Public and staff engagement

- There was no patient involvement group at the unit where patients could make suggestions about the service or care of patients on the unit, or where staff could share information about the service with patients.

After our inspection, senior staff told us that there was senior Fresenius representation at the Humberside renal association meetings which were held every other month.

- However, we saw views and experiences of patients had been sought through the Fresenius medical care patient survey 2016. Twenty patients had responded, the results were:
- 90% said the atmosphere was friendly and happy;
- 88% of patients thought the unit was well maintained and clean;
- 79% of them said they would recommend the unit to friends and family in need of dialysis;
- 70% 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.
- A staff survey was carried out in November 2016; senior managers told us 79% of staff responded, unfortunately this was just three staff members so the results were less valid. Of those three staff that replied:
- Three staff said they would recommend the unit to friends and family who needed dialysis;
- Two staff said they would recommend their organisation as a place to work;
- Two staff said their training helped them to do their job;
- Two staff would recommend the unit as a place to work.
- Senior managers told us the annual survey would be repeated. We were unable to ascertain if there was an action plan based on the previous results as the number of participants was so small.

Innovation, improvement and sustainability

- The unit took part in research programmes based at the local trust, and four patients were currently involved in clinical trials.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

The following were found to be areas for improvement:

- The process of incident reporting, investigation, escalation, and learning from incidents.
- Medicines management processes including patient identification in order to be in line with safe standards and national guidelines.
- Infection prevention and control practices which are intended to keep patients safe.
- Processes to ensure deteriorating patients can be safely and appropriately managed in line with best practice guidance and national standards.
- The processes of monitoring and ensuring staff are competent to carry out their roles.
- The mandatory training processes which ensure staff have had up to date training which is essential to their roles.
- The process for managing performance of the staff and the unit.
- The processes to ensure staff are aware of safeguarding procedures and comply with the Mental Capacity Act and Deprivation of Liberty Safeguards.
- Standards for keeping patient information safe in line with national legislation.
- The process for maintaining record keeping in line with professional standards.
- The processes for ensuring risks are placed on the risk register, so risks can be appropriately managed and action taken.
- Overall leadership and governance of the unit.

Action the provider MUST take to meet the regulations:

- The provider must ensure governance systems are in place and established effectively in order to assess, monitor, and improve the quality and safety of the services provided to patients.
- The provider must take prompt action ensure incidents are reported and investigated thoroughly in a timely way and that staff follow incident reporting policies.
- The provider must take prompt action to ensure safe methods of medicines management and administration are put in place and embedded into everyday practice.
- The provider must take prompt action to ensure safe infection prevention and control practices are put in place and monitor these practices.
- The provider must take prompt action to ensure a process is put in place so that deteriorating patients can be safely managed in line with national guidance.
- The provider must ensure staff receive sepsis training and know what to do to manage patients with sepsis.
- The provider must ensure systems are established in relation to safeguarding so that staff are aware of their level of training and what to do and who to report to if they become aware of safeguarding situations.
- The provider must ensure processes are in place so staff can comply with the Mental Capacity Act and Deprivation of Liberty Safeguards.
- The provider must ensure staff are suitably skilled and competent to carry out their role.
- The provider must ensure patients are assessed and that care plans are updated and contain enough detail to enable staff to reduce risks to patients.
- The provider must ensure processes are in place to keep patient information safe.
- The provider must ensure processes are in place so patients who have a disability, impairment, or sensory loss are provided with information they can easily read or understand in line with the legal requirement of the Accessible Information Standard.

Action the provider SHOULD take to improve

- The provider should take action to increase the average number of patients with recommended haemoglobin levels in order to reduce potential complications and associated risks to those patients.
- The provider should take action and to meet NICE quality standards (QS72- standard 6) in relation to patients who use transport services.
- The provider should ensure all staff display supportive and respectful attitudes to patients and that all patients are given enough support.

Outstanding practice and areas for improvement

- The provider should collect and produce workforce data (Workforce Race Equality Standards) in order to comply with the NHS contract to ensure staff equality and fair treatment in the workplace.
- The provider should consider sharing results of audits such as hand hygiene audits with staff so they can be aware of where improvements need to be made.
- The provider should consider the use of stickers or notices to demonstrate equipment has been cleaned and is ready for use.
- The provider should consider the structure and content of staff meetings to foster an open learning culture
- The provider should consider forming a patient involvement group where patients could make suggestions about the service or care of patients on the unit, and where staff could share information about the service with patients.
- The provider should consider how it takes account of the needs of people with protected characteristics such as gender, sexual orientation, or religion.
- The provider should put a process in place which is in line with the Accessible Information Standard; to ensure that people who have a disability, impairment, or sensory loss are provided with information that they can easily read or understand.
- The provider should consider fitting an alarm to the medicines fridge so staff could be made aware if the temperature went outside safe ranges in between checks.
- The provider should consider securing either the clinic room door or cupboard inside the room where needles are stored.
- The provider should consider putting a process in place to ensure guidance and policy documents contain up to date advice for staff to follow.

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 12 (1) Care and treatment must be provided in a safe way for service users. (2) (a) assessing the risks to the health and safety of service users of receiving the care or treatment; (b) doing all that is reasonably practicable to mitigate any such risks; (c) ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely; (g) the proper and safe management of medicines; (h) assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated. **How the regulation was not being met:** • Medicines were not being managed or administered in a safe way. • Staff administered IV medicines when they were not signed off as being competent to do so. • Incidents were not always reported or escalated, and steps were not taken to reduce risks of incidents reoccurring. • There was no patient identification policy and no positive patient identification checks in place. • There was no process to manage the risks to deteriorating patients. • Poor infection, prevention, and control practices were in use. • There was no sepsis policy and staff were not trained to recognise or take action about sepsis.

This section is primarily information for the provider

Requirement notices

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment 13(2) Systems and processes must be established and operated effectively to prevent abuse of service users. (5) A service user must not be deprived of their liberty for the purpose of receiving care or treatment without lawful authority. **How the regulation was not being met:** • Staff did not know what level of safeguarding training they had. They could not explain what they would do if someone disclosed abuse to them. There should be someone with level 4 safeguarding training who the staff could contact for advice or information. • Dialysis patients who lacked capacity had one to one supervision to keep them safe during dialysis, however, standard authorisation had not been applied for; therefore the appropriate DoLS legislation had not been applied or followed. • There was a lack of understanding about mental capacity and DoLS overall and there was no robust system in place to ensure the legal requirements of the MCA and DoLS were being followed.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance 17 (1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. (2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to--

This section is primarily information for the provider

Requirement notices

(a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services);

(b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity;

(c) maintain securely an accurate, complete and contemporaneous record in respect of each service user, including a record of the care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided;

(e) seek and act on feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity, for the purposes of continually evaluating and improving such services.

How the regulation was not being met:

- There were no robust processes in place to effectively manage risks and safety related to:
- incidents;
- medicines management;
- staff competency assurances;
- deteriorating patients;
- the management of sepsis.
- Documentation including assessments and care plans were not always up to date.
- Records were not locked away when not in use.
- Patient identifiable information was not securely maintained.
- Feedback from patients who used transport services was not sought or acted upon.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **17. Good Governance** The provider did not fully establish processes to ensure compliance with the regulation. (1)Systems and processes must be established and operated effectively to ensure compliance with the requirements in this part. (2)Without limiting to paragraph (1), such systems or processes must enable the registered person, in particular, to- (a)Assess, monitor, and improve the quality and safety of the services provided in the carrying on of the regulated activity; The provider did not fully assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others. (b)Assess, monitor, and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity; The provider did not securely maintain an accurate and contemporaneous record about the care for each person who used the service, or about decisions taken in relation to that care. (c) Maintain securely an accurate complete and contemporaneous record in respect of each service user, including a record of their care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided; (d) Maintain securely such other records as are necessary to be kept in relation to-

This section is primarily information for the provider

Enforcement actions

(i) Persons employed in the carrying on of the regulated activity, and(ii) the management of the regulated activity;(f) evaluate and improve their practice in respect of the processing of information referred to in sub-paragraphs (a) to (e).