Fresenius Medical Care Renal Services Limited Scarborough NHS Dialysis Unit

Quality Report

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

Ratings

Overall rating for this location

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

Overall summary

Scarborough NHS dialysis unit is operated by Fresenius Medical Care Renal Services Limited (FMC), an independent healthcare provider. It is commissioned by Hull and East Yorkshire NHS foundation trust on behalf of the North East and Yorkshire Renal Network. All patients are managed by consultants employed at York Teaching Hospitals NHS Foundation Trust.

Summary of findings

The service is situated on the site of Scarborough NHS hospital. It is a 10-station unit comprised of nine stations in the general area and one side room, which can be used for isolation purposes.

The unit provides haemodialysis for stable adult patients with end stage renal disease/failure.

We inspected this service using our comprehensive inspection methodology and carried out the announced part of the inspection on 17 May 2017. We carried out an unannounced visit to the hospital on 19 May 2017

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

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

Services we do not rate

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

We found the following areas of good practice:

- Staff were clearly able to describe the incident reporting system and were able to provide examples of incidents and how to report them. Staff understood the classification of incidents as clinical, non-clinical and Treatment Variance Reports (TVR's).
- We observed staff working with competence and confidence and the training available in the clinic supported all staff to perform their role well. One hundred percent of staff had received induction and appraisal and two staff were completing a renal qualification.
- We observed a caring and compassionate approach taken by the nursing staff during our inspection. We observed that consent processes were in place and documentation was completed fully
- Performance indicators for December 2016 showed comparable performance against other Fresenius units nationally.
- The unit was able to provide Haemodiafiltration (HDF) 100% of the time during the 12 months prior to inspection.
- Patients were supported with self-care opportunities and a patient education process was in place.
- Holiday dialysis for patients was arranged to provide continuity of treatment and support the wellbeing of patients.
- Morale at the unit was high and staff spoke positively about the support they received from the clinic manager.
- Staff and managers demonstrated a willingness to learn and a proactive attitude to improving services and patient care.

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

- We found the incident policy did not give guidance regarding categorisation of incidents by level of harm
- When we reviewed the incident investigations / reports for these incidents, we found that one of the investigations was not robust, in that it had not identified all contributory factors or root causes.
- The medicines management and children and adult safeguarding policies did not refer to most recent guidance and policies had no review dates.
- There was a lack of re-assessment of individual patient needs and individualised care plans.
- There was no clear system to ensure staff could consistently identify and manage deteriorating patients and patients at risk of developing sepsis.
- The provider did not formally monitor or audit, arrival and pick up times, for patients who used patient transport services, against NICE quality standards.
- The unit was not meeting the 'Accessible Information Standard' (2016) or the Workforce Race Equality Standard (WRES) (2015) at the time of our inspection.
- There was no audit or assessment of compliance against the medicines management policy to ensure safe practice.

Following this inspection, we told the provider that it must take some action 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 issued the provider with one requirement notice. Details are at the end of the report.

Ellen Armistead.

Summary of findings

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.

Summary of findings

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Background to Fresenius Medical Care Renal Services Limited Scarborough NHS Dialysis Unit

Scarborough dialysis unit is operated by Fresenius Medical Care Renal Services Limited. The service opened in November 2011. It is a private medical dialysis unit located within the grounds of Scarborough General Hospital in Scarborough.

The service is commissioned by Hull and East Yorkshire NHS foundation trust on behalf of the North East and Yorkshire Renal Network. All patients are referred and managed by consultants employed at York Teaching Hospitals NHS Foundation Trust. The service does not treat children.

In the 12 months before our inspection, 30 patients were treated at the unit. There were 1453 dialysis sessions carried out for 18-65 year olds and 2704 sessions for people over 65 years of age. The registered manager of the unit is Melanie Farthing who has been in post since November 2014.

Our inspection team

The team that inspected the service comprised two CQC Inspectors and a specialist advisor. The inspection team was overseen by Amanda Stanford, Head of Hospital Inspections.

Information about Fresenius Medical Care Renal Services Limited Scarborough NHS Dialysis Unit

The Fresenius dialysis clinic at Scarborough is located as a 'standalone' dialysis unit within the grounds of Scarborough General Hospital. It provides treatment and care to adults only and the service runs over six days, Monday to Saturday. There are no overnight facilities.

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

- Treatment of disease, disorder, or injury.

The unit has 10 chairs in total. This comprised of nine stations, (bed spaces), in the main treatment area and one isolation room. There is ample storage, office space and treatment rooms. Access is ground floor to all clinic facilities and disabled car parking is available directly outside the clinic. We saw that there was no directional signage for patients approaching the unit.

The usual times for dialysing patients are between 06:50 and 12.30 hours, then between 12.15 and 18.00 hours (Monday, Wednesday, and Friday). On Tuesday, Thursday and Saturdays, the unit provides dialysis from 06:50 and closes at 12.30 hours. An average of 360 treatments sessions are delivered each month.

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

During the inspection, we visited the treatment areas where dialysis took place, and the other non-clinical areas of the unit, such as the maintenance room, and water storage area. We spoke with a range of staff including the area head nurse, a renal consultant, clinic

Summary of this inspection

manager and deputy clinic manager, registered nurses, and dialysis assistants. We spoke directly with eight patients and received 10 'tell us about your care' comment cards and letters that patients had completed prior to and during our inspection. During our inspection, we reviewed 12 sets of patient records.

There were no special reviews or investigations of the unit during the 12 months before this inspection. The last CQC inspection took place in July 2013, which found that the service was meeting all of the standards of quality and safety it was inspected against.

Activity

In the 12 months before our inspection, 30 patients were treated at the unit. There were 1453 dialysis sessions carried out for 18-65 year olds and 2704 sessions for people over 65 years of age. At the time of the inspection, there were 10 active patients aged 18-65 years and 20 patients over 65 years of age. All patients treated at the unit were NHS funded.

The unit did not employ any doctors. The unit employed 5.6 whole time equivalent (WTE) registered nurses (RN) (three full time and two part time staff). There were 1.8 WTE dialysis assistants (1 full time, one part time). There was one RN vacancy at the unit, however an appointment had been made and the candidate was going through pre-employment checks at the time of inspection.

Track record on safety

- There were no reported never events or serious injuries at this unit in the last 12 months.
- The provider categorised clinical incidents by grade of severity such as, no harm, low harm, moderate harm, severe harm and death. However, incidents reported as non-clinical and treatment variances were not graded by level of harm.
- There were no incidences of healthcare acquired Methicillin-resistant Staphylococcus aureus (MRSA),
- There were no incidences of healthcare acquired Methicillin-sensitive staphylococcus aureus (MSSA).
- No complaints were received by the CQC, referred to the Parliamentary Health Services Ombudsman, or the Independent Healthcare Sector Complaints Adjudication Service. The clinic had received two written complaints and seven written compliments from patients.

Services accredited by a national body:

The service had achieved:

- The ISO 9001 quality management system standards, based on a number of quality management principles including a customer focus and continual improvement
- The unit was accredited for ISO 14001 (Environmental Standards).
- The unit was to be audited against OHSAS 18001, which is an Occupational Health and Safety assessment in August 2017. It is an internationally applied British Standard for occupational health and safety management systems

Services provided under service level agreement:

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

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

We found the following areas of good practice:

- Staff demonstrated a clear understanding of the clinical incident reporting processes and were able to provide examples of incidents reported under the three categorisations.
- Safety bulletins were shared with staff and we saw high levels of compliance in relation to staff reading and understanding.
- There was an open and transparent culture on the unit and staff were clear when to apply duty of candour when things went wrong.
- All staff were proactively supported with their training and development needs and mandatory training compliance was high.
- Staff were able to explain what they would do in situations where vulnerable adults needed safeguarding.
- Staff worked flexibly and the rota was planned to ensure safe numbers of staff were available to meet patient need.
- One hundred percent of staff had received an appraisal in the last 12 months

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

- There were concerns regarding the completeness and effectiveness of the incident policy, the medicines management policy and the adult and children's safeguarding policy.
- There was a lack of audits to provide assurance regarding medicines management.
- We were not assured that incidents were investigated thoroughly. We saw that not all contributory factors had been considered during the investigation of a medicine incident.
- There was no system in place to ensure staff are consistently able to identify and manage deteriorating patients and patients at risk of developing sepsis. Staff had not received training regarding sepsis.
- Initial assessments of patient needs, including medical history were not revisited and care plans were not developed for patients with individuals needs outside of the usual care pathways.

Summary of this inspection

Are services effective?

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

We found the following good practice:

- Staff followed current evidence based guidance, including National Institute of Health and Care Excellence (NICE) and The National Service Framework for Renal Services in providing care for patients.
- Staff were competent and were supported with on-going training and development needs.
- All staff had received an appraisal in the last 12 months.
- We found that 100% patients were on high flux Haemodiafiltration. High flux Haemodiafiltration may provide beneficial outcomes to patients in the long term.
- We observed effective team work and support within the unit between nurses and dialysis assistants
- We found that patients gave formal, informed written consent for dialysis treatments and for the use of anonymised clinical information.
- Staff had received training regarding the Mental Capacity Act and Deprivation of Liberty Safeguards and those we spoke to understood these principles.
- Patients overall felt that staff were experienced and competent, making them feel reassured.

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

- The provider did not formally monitor or audit, arrival and pick up times, for patients who used patient transport services, against NICE quality standards.
- The unit was not meeting the 'Accessible Information Standard' (2016) or the Workforce Race Equality Standard (WRES) (2015) at the time of our inspection.

Are services caring?

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

We found the following areas of good practice:

- We saw positive interaction between staff and patients. Staff interacted with patients in a respectful and considerate manner.
- Staff maintained patients' privacy and dignity.
- Patient feedback was generally positive and patients told us that staff explained things to them in a way they could understand.

Summary of this inspection

- The clinic manager ensured they were visible to all patients when they were on duty and gave patients the opportunity to speak to them regarding any concerns or questions they had.
- Patients were given the opportunity to visit the unit with a family member or friend prior to starting treatment.
- There was a variety of information available to patients including dietary information, holiday provision and shared care.

Are services responsive?

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

We found the following areas of good practice:

- The building met most of the core elements of provision for dialysis patients. This included level access and dedicated parking facilities.
- The unit was accessible by people who used wheelchairs. There was a hoist, which could be used if someone was unable to get on to the dialysis chair.
- The unit operated at between 93% and 95.6% capacity (November 2016 to January 2017).
- There were no cancelled or delayed sessions due to non-clinical reasons in the last 12 months.
- There was no waiting list for referrals.
- Appointment sessions were offered to patients in accordance with their personal needs and circumstances.
- Staff worked hard to accommodate patient's individual needs; including communicating with patients whose first language is not English.
- Complaints were responded to well within the 20-day standard.

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

- Psychological needs of patients were not considered as part of the acceptance criteria for referrals.
- Although one patient from the unit was a member of the corporate 'Expert Patient Board' this was held outside the local area and only on an annual basis. There was no local patient involvement group where patients could make suggestions about the service or care of patents on the unit, or where staff could share information about the service with patients.

Are services well-led?

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

We found the following areas of good practice:

Summary of this inspection

- We found that staff morale was good and there was high regard for the clinic manager.
- Staff told us the managers were supportive regarding incidents and they felt there was a no blame culture.
- We saw that the risk register contained information relating to local risks and mitigations.
- Staff were proud to work at the unit and felt patients received safe, high quality care.
- In 2015, the clinic manager had won NephroCare excellence award for the unit with the most improved effectiveness.
- We found the clinic manager and the senior team had a desire to learn and to address any issues as soon as practically possible.
- We saw views and experiences of patients had been sought through the national patient satisfaction survey 2016 and 95% of patients said they were likely to recommend the Scarborough unit to friends and family if they needed dialysis.

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

- There was a lack of systems and processes regarding; audit of medicines management, the deteriorating patient, WRES, accessible information and a number of policies required review, including the incident policy, the medicines management policy and the adult and children safeguarding policy. All policies needed to include a review date.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

· We saw the provider had a policy for the reporting of incidents including near misses. The policy did not give guidance regarding categorisation of incidents by level of harm which meant that nursing staff may find it difficult identify triggers for formal notifications of serious incidents (SIs) and may be unsure when the threshold of moderate harm has been reached, which would require 'Duty of Candour' implementation.

· Under the Health and Social Care Act (Regulated Activities Regulations 2014) 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 them with reasonable support.

· Incidents were categorised as clinical, non-clinical or as a treatment variance. Staff were able to describe examples of events, which were reported under these headings. The IT system gave drop down menus, which helped staff report incidents in the correct category.

· The provider categorised clinical incidents by grade of severity such as, no harm, low harm, moderate harm, severe harm and death. However, incidents reported as non-clinical and treatment variances were not graded by level of harm

· There had been no 'Never Events' at the unit in the 12 months before the inspection. 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.

· There were seven deaths in the last 24 months, none of these were unexpected. The deaths were not reportable to CQC.

· The service did not report any serious incidents in the 12 months before the inspection.

· There were 514 treatment variances reported in the 12-month reporting period January to December 2016. From January to May 2017, 256 treatment variances were reported, the largest numbers of incidents related to cannulation problems and hypotension.

· Numbers of patients not attending for dialysis were also captured within the treatment variance system. Staff told us that repeated missed sessions were discussed with the patient, consultant and the patient's GP if this occurred frequently and was unexplained.

· There was one patient fall reported in the last 12 months that was categorised as a non-clinical incident in line with Fresenius policy.

· We found there had been nine clinical incidents from July 2016 to May 2017, two medicine errors were reported in January and May 2017. We found that actions were undertaken to reduce the risk of these incidents occurring in the future. However, when we reviewed the incident investigations / reports for these incidents we found that one of the investigations was not robust, in that it had not identified the lack of positive patient identification as a contributory factor or root cause. The incident was a patient receiving a wrong medicine.

· We saw evidence that the patients had been informed of mistakes and although these incidents did not cause harm, staff we spoke with were aware of the principles of being open and 'Duty of Candour'.

· Information was displayed in the patient waiting area regarding health and safety incidents. The information displayed was from January 2017 to April 2017 there were

no incidents documented for this time. The clinic manager told us there had been two health and safety incidents from January 2016 to January 2017, one slip and one scald.

· Nurses were able to input the details of incidents into the electronic database and the clinic manager would review these. They would then be submitted to the area nurse and then the chief nurse to be reviewed.

· We observed a member of staff reporting an incident as a treatment variance report in line with policy.

· Senior nursing staff told us team meetings were held monthly and incidents were discussed. Staff told us that the clinic manager shared details of all incidents that had occurred on the unit.

· Staff told us they were encouraged to report incidents and there was a no blame culture when something went wrong.

· We saw that patient safety alerts and learning bulletins were held within a file in the nurse's station 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 three months before our inspections and saw that most staff had signed to say they had seen the alerts. We looked at six alerts and in each case, six out of seven staff had signed.

· Staff told us safety alerts and learning bulletins were discussed at handovers.

· The clinic manager and deputy had undergone training regarding incident reporting and root cause analysis.

Mandatory training

· All staff were required to complete a programme of mandatory training, which included basic life support, moving and handling, safeguarding, infection prevention and control, fire safety, information governance and introduction to dementia. Other training was specified according to job role.

· When we viewed the live training database, we saw that all staff were compliant with their mandatory training requirements.

Safeguarding

· Managers told us that all staff at this unit had undertaken in house adult safeguarding training at level two and that the clinic manager was to undertake level three when they had sourced this training. This action was to take place following feedback at another Fresenius unit

· Staff told us safeguarding training included; mental capacity act, deprivation of liberty safeguards, female genital mutilation, radicalisation and dementia awareness.

· All staff we spoke with told us they had received adult safeguarding training and were clear who their safeguarding lead was and which local authorities they would contact. The service lead for safeguarding vulnerable adults and children was the clinic manager and the deputy clinic manager provided this support in her absence.

· There was a single safeguarding policy in place for adults and children, which gave staff direction regarding raising alerts to relevant safeguarding teams and reporting mechanisms within the organisation. However, there was no reference to the intercollegiate guidance document "Safeguarding Children and Young People" (2014) and there was no stipulations regarding level of staff training for either adults or children.

· Although children were not treated at the unit and staff told us it was very rare for children to attend the unit; intercollegiate guidance recommends that level two competence is the minimum level required for "non-clinical and clinical staff who have some degree of contact with children and young people and/or parents/carers". Some patients at the unit were parents or carers.

· There had been no safeguarding concerns raised by or against the unit in 2016/17.

· Local safeguarding team contact numbers were displayed on the walls within the unit.

· Staff underwent disclosure and barring checks just prior to appointment but there was no policy or process in place to revisit these.

Cleanliness, infection control, and hygiene

· We found the unit was clean and tidy and patients were satisfied with standards of cleanliness.

· Patients told us that the environment was always 'clean and hygienic', which made them feel safe. They told us nurses and others frequently washed and disinfected their hands and that cleaning staff were regularly on the unit.

· We saw staff complied with bare below the elbow policy and they washed their hands at appropriate points of care.

· Infection prevention and control (IPC) audits were undertaken monthly and the results from January 2017 to March 2017 showed good compliance (98%) with environmental, waste and practice, including hand hygiene, standards. We saw that action was taken regarding any areas of non-compliance.

· 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. The chief nurse was the lead for infection prevention control.

· There was a single side room on the unit, which could be used for isolation purposes if patients had or were suspected of having an infectious condition.

· Patients were screened for MRSA (Methicillin-resistant Staphylococcus aureus) and blood borne viruses on admission to the unit and at regular intervals.

· There were no cases of healthcare acquired infection (MRSA) in the 12 months before our inspection.

· Managers told us there were monthly hand hygiene audits based on the World Health Organisation (WHO) 'Five moments for hand hygiene' guidelines and other adhoc unannounced IPC audits by the chief nurse or her deputy.

· Monthly hand hygiene and environmental audit results were displayed in the patient waiting area. The hand hygiene results showed improving compliance from 75% in January 2017 to 89% in May 2017. The environmental audit showed consistently high compliance of 99-100% January 2017 to May 2017. The target for compliance was 95%. The clinic manager told us any hand hygiene omissions, spotted during audit, were immediately fed back to the staff member and feedback for all staff was given at team meetings with a particular focus on the most commonly missed 'moment'. We saw that results had improved from the previous year and that an action plan was in place to ensure this improvement was made and sustained.

· We saw that staff used an assessment tool, which helped them observe for signs of infection at line sites. We observed good aseptic technique and infection prevention measures when attaching and removing lines.

· Beds were covered by blankets and pillows with disposable pillowcases that were changed between patients.

· Staff told us dialysis machines were cleaned between each patient and at the end of each day. They followed manufacturer and IPC guidance for routine disinfection. We saw that records were kept to show equipment was ready for use. Single use consumables such as blood lines were used and disposed of after each treatment

· Staff carried out daily water tests to monitor the level of chlorine in the water in line with the UK Renal Association clinical practice guidelines. Staff were able to describe the management of the water systems for the presence of bacteria and PH levels and could explain the procedures that were required should a water sample test be positive. 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 told us if they had any queries with test results or if there were any faults with the water plant, they could ring a water plant technician for advice or support with basic fault finding and rectification.

· Staff told us the water technician would advise over the phone what immediate actions needed to be taken and they would come to the unit to carry out any repairs necessary.

· We saw records of monthly water tests undertaken by an accredited company and we spoke with a water technician who told us they visited the unit every six months to carry out more specialist testing and routine maintenance.

· Records we reviewed showed that staff carried out daily flushing of water outlets to prevent contamination of the water supply.

· We saw that spill kits were available for staff to use in the event of a spillage of blood or bodily fluid.

· All staff were up to date with infection prevention and control training.

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. All doors were protected with a secure lock code.

· There was sufficient parking for patients at the main entrance and available bays for blue badge disabled parking.

· The unit had nine dialysis chairs / stations in the main area and a single isolation room. There was plenty of space around each station to allow for patients, staff, and equipment.

· The unit had a consulting room, staff offices, toilets for staff and patients, and a kitchen where staff prepared drinks and sandwiches for patients.

· A Fresenius facilities management team provided the clinic with both reactive and planned preventative maintenance work. Annual electrical testing was part of the clinics planned and preventative maintenance schedule provided by this team.

· The unit had maintenance plans for dialysis machines, beds and other equipment. We found these detailed the dialysis machines by model type and serial number and gave the scheduled dates of maintenance. All of the equipment testing was within the specified dates. There were two back up dialysis machines stored and ready for use in the clinic.

· Additional dialysis related equipment was calibrated and maintained under contract by the manufacturers of the equipment or by specialist maintenance/ or calibration service providers.

· 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.

· We checked the resuscitation trolley and found the equipment was correct and in date. We saw equipment checklists showed that checks were completed daily for the previous two months.

· All staff we spoke with told us there were adequate supplies of equipment and they received good support from the maintenance technicians. Staff told us breakdowns were repaired promptly.

· There were no spare weighing scales however, staff told us if they could not get them repaired quickly, they would ask the local trust if they could borrow some until repairs were made.

· There were no additional pressure relieving equipment other than the mattresses on the unit, but the manager told us if a patient needed specific item, staff could order this. The clinic manager would order this through the regional management team and gave an example of a special bed they had requested and received for a particular patient.

· All patients had access to the nurse call system and we observed that systems were working at the time of inspection.

· We saw that all dialysis machines were replaced during 2016 and that there was a regular maintenance plan in place.

· We saw that waste was handled and segregated appropriately.

Medicine Management

· There was a detailed medicines management policy; however, there was no audit of practice to provide assurance that standards of practice were monitored or reviewed by pharmacy or senior staff.

· Staff at the unit administered individually prescribed medicines; they did not use patient group directions (PGDs).

· The clinic manager had lead responsibility for medicines management.

· The unit did not use or store any controlled drugs.

· The nurse in charge who was always an experienced nurse would be 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). Stock medicine was ordered from Fresenius or Scarborough hospital pharmacy and was stored in a locked cupboard.

· Medicines requiring refrigeration were stored in fridges that recorded minimum and maximum temperatures, which were locked and the temperatures were checked daily. Staff were aware of the action to take if the temperature recorded was not within the appropriate range. The clinic manager told us that an issue with one of the fridges had occurred and had been escalated. The stock had been moved to another fridge until the repairs were made.

· Staff told us they could access pharmacy support from the local NHS trust pharmacy for advice relating to dialysis drugs. Staff also had access to the company pharmacist at head office.

· Managers told us GPs were sent letters after the monthly MDT meeting, which would include notification of any medicine changes.

· Staff told us that one of the doctors did any prescription changes needed during their weekly visits to the unit. If any medicines needed to be prescribed at other times then nurses told us they called the renal registrar on call or signposted the patient to their GP or A&E if the patient's condition required urgent treatment.

· Staff were clear about the process to follow if they required a prescription change or new prescription. The consultant or registrar would give a verbal instruction to a registered nurse who would transcribe onto a prescription form. The nurse faxed this to the doctor who would check and sign the prescription and fax back. The nurse stapled the temporary sheet to the full prescription card and used this until a doctor next visited the unit. At the next visit, the doctor would prescribe the required medicine onto the full chart and remove the temporary sheet.

· Patients we spoke with said they took their regular medicines at home, prior to coming to the unit or when they went home.

· The clinic manager told us there had been two recent drug errors, one in January 2017 and a second one in May 2017. We found that immediate action had been taken to report these incidents and to inform the patient involved, their lead consultant and the area lead nurse. Actions were also taken regarding further training and reassessment of competence of the staff involved. The incidents were shared with the other unit staff for learning and reduction of risk of recurrence. The drug errors were of different types and unrelated to each other.

· Managers told us they were tightening up on patient identification checks following CQC feedback at another unit; however, there had not been enough time since the feedback to review the patient identification and medicine administration policies and processes. Although the medicine management policy referred staff to Nursing and Midwifery Council (NMC) guidance, regarding patient identification, there was no detailed procedure for staff to follow regarding patient identification at the point of medicine (including dialysis) administration.

· Nurses told us they asked patients to confirm their name before administering medicines. We observed a registered nurse checking a patient's identity when administering medicine and two nurses checked the medicine given, in line with policy.

· Fresenius medicines management policy allowed dialysis assistants to 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 medicine administration. We saw from training files that dialysis assistants had received training and been assessed as competent. We saw from their training files that these staff had undergone an annual medicine competency re-assessment in the last 12 months.

· We looked at the prescription and medicine administration records for 12 patients on the clinic. These records were fully completed and were clear and legible.

· We saw that stock checks were undertaken monthly and medicines were stored using a first expired first out principle.

· If any in-patients from the local NHS hospital were receiving dialysis treatment, ward staff provided their medicine.

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.

· There were IT security measures in place to protect patients' records and paper records were stored at the nurses' station when not in use. Although these were on open shelves there were no unauthorised personnel in this area and were visible to staff within the unit.

· The paper records included the dialysis prescription, patient, and next of kin contact information, and GP details. There were also nursing assessments, medicine charts, and patient consent forms. Records also contained standardised pathways for Haemodiafiltration (HDF) and management of arteriovenous (AV) fistulas and grafts.

· We saw that the electronic records contained patient medical history, referral letters, consent, dialysis treatment prescription and treatment plan, notes of multi-disciplinary team meetings and daily nursing notes. From within a patient record, outcomes could be tracked and treatment variances and incidents could be viewed and monitored. As the system interfaced with the trust IT system this also allowed the nurses to see if a patient was in hospital or on holiday and had received their dialysis elsewhere. Nurses manually entered patient observations from before, during and after treatment so this could be monitored over time.

· We looked at 12 sets of records and found that all patients had regular observations recorded pre, during and post treatment with few gaps noted. Records contained a new patient admission assessment that included a short review of 'activities of daily living'. We did not see that holistic assessments had been re-assessed despite most patients using the service for over 12 months.

· We saw risk assessment documentation for manual handling, pressure ulcer risk and nutrition. However, we did not see individual care plans for patients with needs outside of the usual pathways / care plans for anaemia, risk of anaemia and fistula management. We saw one patient was diabetic but there was no corresponding assessment of needs and care plan relating to this issue. We did however see care plans for patients with anaemia, at risk of anaemia and regarding fistula management. We found that one patient had language needs that staff had taken individual steps and made plans to address for ongoing treatment reviews and training around self-care, however this information was not documented as a care plan but did appear as individual record entries when actions were taken.

· Individual patient preferences were not recorded at any part in the patient assessment process. We asked two nurses if patient's likes and dislikes were recorded and we were told 'no not recorded but it does come up in conversation'.

· Documentation audits were carried out on a monthly basis. Three to five 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). The clinic manager told us there had been two omissions found in the April 2017 audit; one of them was a prescription omission and one a missing care pathway. The issues were rectified and discussed at the next staff meeting to raise staff awareness.

· We looked at audit results for the six months before our inspection. We saw generally good standards were maintained and any omissions were discussed at team meetings.

Assessing and responding to patient risk

· Only clinically stable patients were dialysed on the unit; if someone was acutely ill with renal problems they were treated at a main NHS hospital.

· Patients who had additional needs such as those living with severe dementia, or who had challenging behaviour were not treated 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 how much excessive fluid had built up in between treatments.

· Observations of vital signs such as blood pressure and pulse were recorded before, during and after dialysis treatment.

· Managers told us there were referral and escalation criteria in use for staff to follow should a patient's condition or results deteriorate. They told us that poorly patients were escalated to the renal consultant on-call and an email was sent to the patient's own consultant to ensure they were aware of any changes in condition.

· Staff told us they just contacted the hospital switchboard to be put through to the on-call renal registrar. They also told us of a recent 'crash call' and that the medical team had arrived very quickly.

· There was a guidance document, 'complications, reactions, and other clinical event pathways' but no specific system such as an early warning score (national 'NEWS' or modified) was in place to identify deteriorating patients. We saw that this was on the unit risk register with action to be undertaken by the Fresenius chief nurse to look at potentially developing a modified tool for use in dialysis settings.

· There was no sepsis toolkit or pathway in use at the unit. This was not in line with the National Institute for Health and Care Excellence (NICE) guideline (NG51) for recognition, diagnosis, or early management of sepsis. We spoke with staff about the lack of a sepsis pathway who told us that they would follow their guidance pathway for patients suspected of having an infection. The clinic manager had received training regarding sepsis at the managers meeting in December 2016 but other staff had not received training.

· Staff told us the service held emergency resuscitation simulations every six months. We saw that the last simulation completed was May 2017. The clinic manager told us the trust crash team and an A&E consultant from the trust had been involved and the response time had been two minutes.

· There was an agreement with the local NHS trust that patients who became ill would be transferred to the hospital. The clinic manager told us the last emergency transfer had been in September 2016, when a patient needed to be transferred to A&E.

· We saw that the unit had received a safety bulletin dated 12 May 2017 regarding 'dry needling' a practice which carried the risk of introducing air into the patient's bloodstream, this practice was to be stopped immediately. All staff in the unit had seen this bulletin and signed to say they had read and understood the information. Dry needling was not carried out at this unit and staff told us this had been stopped several years ago following publication of guidance regarding this practice.

· We saw that all patients had personal emergency evacuation plans in place and these had been updated within the last three months.

· One patient told us how the staff on the unit had responded with speed and expertise to their medical emergency and of their transfer to an acute hospital.

· Staff told us that if patients had non-urgent medical needs they would advise them to attend their GP. We observed a RN advising a patient to see their GP about a persistent cough.

· The clinic manager told us of a recent occasion when a patient had not wanted to come in for dialysis as they had been suffering from diarrhoea and was concerned about infecting other patients. The clinic manager had arranged for the patient to have their dialysis at the trust where isolation facilities were available so the patient did not miss their treatment.

· We saw posters displayed to highlight to patients the need to ensure their vascular access was visible to others in an effort to reduce the incidence of these becoming dislodged.

Staffing

· The unit was generally staffed to a 1:4 registered staff to patient ratio; trained dialysis assistants were not included in the ratio with registered nurses at this unit. Managers told us there was always a minimum of two RNs on duty and that skill mix was usually around 67% registered nurses to 33% dialysis assistants. We reviewed three months of staffing rotas, which confirmed planned staffing levels and ratios were achieved.

· The unit employed 5.6 whole time equivalent (WTE) registered nurses (RN) (three full time and two part time staff). There were 1.8 WTE dialysis assistants (1 full time, one part time). There was one RN vacancy at the unit; however, this had been appointed to and pre-employment checks were being carried out at the time of the inspection.

· The clinic manager worked 40% of their time in the clinical area and had 60% of time set aside for management.

· In the three months before our inspection there had been 79 shifts covered by agency nurses. The manager told us there had been a number of vacancies at the unit during this time but all vacancies had been filled and the unit did no longer need to use bank or agency staff to cover shifts, although delivering the correct ratios and skill-mix was an ongoing challenge.

· When permanent staff could not maintain staffing levels, requests were made to the Fresenius Flexibank, who arranged for cover. When Flexibank could not cover shifts, approved external nursing agencies were used.

· A patient commented that the unit had survived on agency staff who were experienced but did not know them as individuals.

· The average sickness for the past 12 months had been 3.7% for RNs. There was no reported sickness for DAs at this time.

· There were link nurses at the unit with responsibility for updating other staff about their topic. Link nurse roles were; infection prevention and control, education and training, EuCliD (the IT database), health and safety and vascular access.

· The unit did not employ any doctors. Renal consultants from York Teaching Hospitals NHS Foundation Trust were clinically responsible for patients' treatment. Managers told us consultant staff visited the unit weekly and formally reviewed patients at monthly MDT meetings. They told us consultants could be contacted at any time for advice or support regarding individual patients and that they would undertake individual reviews as necessary if a patient's condition or results changed.

· Patients had access to a dietician and social work services through the trust. In addition, a renal social worker was available when necessary.

Major incident awareness and training

· The unit had an 'Emergency Preparedness Plan' in place. This detailed the plans for the prevention and management of potential emergencies, such as fire, loss of electricity or water leaks.

· Staff were knowledgeable about what to do in case of emergency.

· All patients had personal emergency evacuation plans.

· 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 they could be safely disconnected within this time.

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

Evidence-based care and treatment

- Treatment protocols were based on national guidance including the Renal Association Guidance and National Institute for Health and Care Excellence (NICE) standards. A key document for staff to refer to was the 'NephroCare standard for good dialysis care' (2016). This encompassed European Renal Best Practice (ERBP) and the Kidney Disease Outcome Quality Initiative (KDOQI) guidelines.
- Within the policy guidance, staff followed current evidence based guidance, including National Institute of Health and Care Excellence (NICE) and The National Service Framework for Renal Services in providing care for patients. For example, the Standards of good Dialysis care guideline 2016. This guidance was incorporated into the local NHS and Fresenius (NephroCare) guidelines.
- We looked at 11 policies, these all had a date they became effective, but did not have a date to indicate when the policy expired or should be reviewed.
- Senior staff told us as part of a provider presentation that the Scarborough unit was up to date with the review of new policies and work instructions. We saw that new policies were in a folder at the nurses' station and most of the staff had signed to say they had read the new documents.
- Patients came to the unit with fistulas for vascular access already created at the local NHS trust. The staff monitored the patients' vascular access/ fistula site in line with the NICE quality standards.

Pain relief

- Staff told us that local anaesthetic was prescribed for patients who found the commencement of treatment particularly uncomfortable.

- Nurses told us they did not formally assess pain levels but they asked patients about their comfort during interventions. They told us they would give patients paracetamol if they complained of headache or other pain during their treatment.
- The prescription charts we reviewed showed patients were prescribed 'as required' paracetamol. Nurses told us this was routinely prescribed for all patients and that they would report excessive pain to the renal consultant on-call if necessary.
- Two patients told us they received paracetamol when they needed it.

Nutrition and hydration

- Patients who have renal failure require a strict diet and fluid restriction to maintain a healthy lifestyle. The renal dietician visited the unit on a monthly basis to give support and advice.
- Staff told us there was a contract in place with a local food supplier to provide sandwiches for patients receiving treatment in the unit.
- Patients were offered hot and cold drinks and pre prepared sandwiches or biscuits while they were having their treatment and there was a cold-water dispenser in the reception area.
- Several magazines and leaflets were displayed in the reception area, which provided nutritional advice for patients.
- Patients told us they regularly saw a dietitian and they were able to bring their own food into the unit.

Patient outcomes

- The unit monitored clinical outcomes for patients receiving dialysis similar to the Renal Registry data. Patients' blood results and vascular access management were reviewed monthly at the multidisciplinary meeting led by the NHS consultant.
- The clinic data management system provided customised reports and trend analysis to monitor and audit patient outcomes and treatment parameters. The multidisciplinary team used this to improve outcomes and in turn quality of life. The report provided specific unit scores in areas such as infusion / volume, albumin, weekly treatment, vascular access, and haemoglobin. This was referred to as the 'balanced scorecard'.
- The clinic manager told us they looked at their unit's patient outcome reports on a weekly basis to keep a close eye on the unit's performance and patient outcomes. They told us that this was a more formal process on a monthly basis when they would print off the reports to review at the monthly MDT. On a three monthly basis, this would be reviewed with the area lead nurse.
- Renal Association guidelines to monitor the quality of dialysis include measurement of the urea reduction rate (URR) and Kt/v. From April 2016 to May 2017 the proportion of patients meeting the standard of URR >65% fluctuated between 75% and 96% and between 57% and 86% of patients met the standards of Kt/v >1.2. Between 70% and 91% of patients had 240 minutes or more on dialysis.
- Other comparative data was that 42% to 76% of patients had haemoglobin within the recommended range (100-120), 67% to 96%had calcium in the recommended range of 2.1-2.5 and 40% to 63% had phosphate levels in the recommended range of 1.1-1.7.
- Data from April 2017 showed that Scarborough dialysis unit had 21 patients out of 30 (70%) had an arteriovenous fistula (AVF) and nine (30%) patients had a central line access. The renal association standard for the proportion of patients with an AVF or AVG is 80%. An AVF is the formation of a large blood vessel usually in the arm, created by surgically joining an artery to a vein, this form of vascular access is considered the best form of access for haemodialysis. An AVG is a connection of the artery to a vein using a looped plastic tube.
- We were told that the organisation produced patient outcome reports every six months, which were shared with the clinic manager. These reports showed how the unit performed in the achievement of quality standards based on UK Renal Association guidelines and was used to internally benchmark Fresenius units against each other. We reviewed the December 2016 report and saw that the Scarborough unit had mixed performance with most indicators being middle table. The Ktv score was at the lower end of the table but the unit scored well for effective weekly treatment time.
- We found that 100% patients were on high flux Haemodiafiltration. High flux Haemodiafiltration may provide beneficial outcomes to patients in the long term.
- The unit did not directly submit data to the UK Renal Registry. The data from Scarborough unit was combined with, and submitted with York Teaching Hospitals NHS Foundation Trust data.

- The provider did not formally monitor or audit, arrival and pick up times, for patients who used patient transport services, against NICE quality standards. Dialysis patients should be collected from home within 30 minutes of the allotted time and collected from the unit within 30 minutes of finishing dialysis.
- The clinic secretary told us when they were on duty they logged ambulance pick up times and chased them up when patients had been waiting more than 30 minutes, they also told us that there were very few problems with lengthy delays.
- The clinic manager told us they would contact the local patient-transport liaison officer if there were any issues. There was no formal transport group but the clinic manager told us they had previously had a good response from the liaison officer when issues had arisen.
- The clinic manager told us that patient transport issues could be discussed as part of the contract review meetings with the trust, as the trust also commissioned the patient transport service, if there were persistent issues. The regional business manager attended these meetings on behalf of the unit.
- A patient told us that their treatment had been very positive and had given them a new quality of life

Competent staff

- New staff were provided with an induction programme and a six-week period of supernumerary practice. This was followed by a six-month preceptorship period with an identified mentor to ensure staff became confident and competent in carrying out their role. A relatively new member of staff confirmed they had undertaken this probationary period and that this had been very helpful when they came into post.
- There was a 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.
- Dialysis assistants were given training and were competency assessed to enable them to administer Tinzaparin injections, which prevent patients developing blood clots or thrombosis. We saw a newly developed competency assessment, specific to the administration of medicines, was in place following feedback from a previous inspection at another unit.
- We looked at four training files, which showed all staff had received initial training and showed that assessment of staff competence was assessed against clear practical and knowledge based assessments. There was evidence of up to date training attendance, and sign off by senior nursing staff and mentors was evident.
- Training was divided into several stages, which included induction, fundamental skills, advancing skills and management skills. Management skills were specific to nurses and not the healthcare assistants.
- Staff we spoke with told us that Fresenius provided them with on-going professional development opportunities for improving and maintaining their competence. Two of the registered nurses were undertaking specialist training which would lead to a renal qualification.
- Fresenius had a training team who were involved in the assessment of staff competence.
- Patients overall felt that staff were experienced and competent, making them feel reassured.
- The clinic manager told us that individual members of staff took on lead roles within the team for; infection prevention and control, health and safety, education, vascular access and the electronic recording database.
- Managers told us that the organisation was rolling out management development training across the organisation but the clinic manager at Scarborough had not had this yet.
- Data submitted by the provider indicated that all relevant staff had received an annual appraisal. We reviewed appraisal documentation and found it was thorough and staff progress was well documented. Documentation indicated progress meetings and assessments were held at three and six months following appointment.
- The clinic manager told us the organisation supported excellence through appraisals, supervision and competency assessment. The clinic manager told us, staff participated in one to one supervision and had held peer support sessions regarding NMC revalidation.
- We saw that all registered staff had current NMC registration and the clinic manager had a process in place to ensure she was aware when staff needed to revalidate.

Multidisciplinary working

- We observed effective team work and support within the unit between nurses and dialysis assistants.
- The patients treated on the unit remained under the care of their NHS consultant. Staff we spoke with said

they had excellent links and access to the medical team at the NHS trust both for routine and urgent contact. They also had ready access to the dietitian and renal social worker.
- There were monthly multidisciplinary team meetings to review the patient outcome reports where changes to treatment, medicines and diet were discussed and agreed. GPs were sent a monthly review letter following these meetings and named nurses shared any information directly with patients at their next treatment.
- Senior staff told us the company attended meetings at the local NHS trust and had positive strong relationships with the local trust.
- The dietitian visited the unit weekly and the renal social worker visited the unit on a monthly basis.
- Patients told us they had regular contact with dietitians and social workers when they were needed.

Access to information

- Staff told us they could easily access guidelines and policies through the service IT system.
- Staff told us they had the information they needed to look after patients.
- Results of blood tests carried out at the local NHS trust were sent to the unit electronically and were accessible to staff on the unit. Results were also recorded on paper cards, should there be any issues obtaining electronic results.
- Staff told us the patient treatment database sent information to the NHS trust, which was accessed by the consultant who then notified the GP of any relevant changes.
- We saw the unit had a process in place to share information for patients going to other units for holidays or for acute care and vice versa.

Equality and human rights

- The unit was not meeting the 'Accessible Information Standard' (2016) at the time of our inspection. The standard aims to make sure that people who have a disability, impairment, or sensory loss are provided with information that they can easily read or understand and with support so they can communicate effectively with health and social care services. The Fresenius management team had placed this on the corporate risk register and actions were to be taken by the training and education manager. Locally the unit had taken actions to ensure the service met the needs of relevant patients.
- The unit was not meeting the Workforce Race Equality Standard (WRES) (2015) at the time of our inspection. This is a requirement for locations (providing care to NHS patients with an income of more than £200,000) to publish data to show they monitor, assure staff equality, and have an action plan to address any data gaps in the future. The risk register indicated that although Fresenius had not produced a WRES report, race equality formed part of their wider approach to ensure equality for all employees.

Consent, Mental Capacity Act and Deprivation of Liberty

- We found that patients gave formal, informed written consent for dialysis treatments and for the use of anonymised clinical information.
- We reviewed consent forms in 12 patient files. All were found to be fully completed. We observed nurses seeking verbal consent prior to undertaking care and treatment.
- We found that patient consent was also recorded on the EuCliD database.
- We saw that patients were asked to sign a form to say they understood the implications of finishing treatment before the end of the prescribed time and that this was done against clinical advice.
- Staff had received training regarding the Mental Capacity Act and Deprivation of Liberty Safeguards and those we spoke to understood these principles. Staff were not able to provide us with any examples of patients who were subject to these processes as they told us it was very rare that they received patients with impaired capacity.

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.

- We reviewed the patient satisfaction survey results from 2016, which showed that 95% of patients felt that the unit staff were caring.
- All patients and relatives we spoke with told us that staff were professional, supportive and kind. We observed care interactions and saw patients were treated with compassion, dignity and respect.
- Privacy and dignity of patients was maintained and we saw screens were available if patients required them. There was sufficient space provided between each dialysis chair and nursing staff were able to speak with patients in a discreet manner.
- Patients were provided with a nurse call system and nurses ensured that patients could reach the call bell during dialysis. We observed the call system in use and we saw that nurses responded to alarms promptly.
- We received 10 comment cards / letters from patients who had been using the service for several months up to eight years. All patients were complimentary about the care and compassion shown to them by all staff at the service. One patient told us 'that nothing was too much trouble for the staff." Another said the staff were attentive, very understanding and pro-active in looking after patients. Patients told us the staff knew them well, treated them with respect and they felt well looked after.
- The clinic manager carried out patient rounds on all shifts to ensure all patients had the opportunity to speak to them regarding any concerns or questions they had.
- Senior managers told us a 'named nurse' approach was used so that patients could be cared for by staff they were familiar with. One patient told us they had a good relationship with their named nurse although not all patients understood what 'named nurse' meant.
- Patients told us there was a family atmosphere on the unit and they sometimes were invited to social events with staff and other patients.
- We observed a staff member taking a phone call from a patient who was having difficulty collecting a prescription, the nurse made a couple of calls and arranged with the pharmacy to deliver the medicine to the patient's home and rang the patient back to tell them what was happening.

Understanding and involvement of patients and those close to them

- There was a range of information and magazines available in the waiting area regarding dialysis, such as healthy eating, supported holidays and self-care information.
- We observed that patients deemed suitable for shared care were given a shared care questionnaire. This outlined all aspects of the dialysis treatment for the patient to answer whether they would like to take over that aspect of care. This meant that patients could be involved in shared care activities as much or as little as they wanted or felt confident about.
- We saw staff speaking with patients about their treatment and blood results in a way they could understand. Patients were encouraged to ask questions and we observed staff checked their understanding.
- When patients first started treatment, they could come to visit the unit 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.
- Patients told us that nurses answered their questions sensibly in a way they could understand. They told us they felt listened to and involved
- We spoke with a patient who would like to undertake self-care but because he had a line rather than a fistula, he had not been allowed to do this. The patient understood that other units allowed patients with lines to undertake aspects of self-care.
- Another patient felt he had received conflicting information and this had led to a breakdown of trust in the staff- patient relationship. Staff were aware of this and were sorry this situation had arisen.

Emotional support

- We observed a nurse providing care and treatment to a patient who had specific emotional and mental health needs. Counselling services and the mental health services were contacted as a matter of priority and we observed a nurse explaining what support was to be provided, in a caring and understanding manner.
- The patient survey 2016 showed that 100% of patients felt the atmosphere in the unit was friendly and happy.
- Patients were positive about the emotional support provided by nursing staff.
- We saw information was available for patients regarding accessing support groups and advocacy services.
- Patients had access to psychological support through a renal counselling service.

Dialysis Services

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

Meeting the needs of local people

- The Scarborough dialysis unit has been in operation since November 2011 and was commissioned by Hull and East Yorkshire NHS foundation trust.
- Performance of the unit was monitored at contract meetings with the commissioning trust (monthly) and the local trust (quarterly), managers told us this was their opportunity to discuss with commissioners how services needed to be delivered and developed to meet patients' needs.
- Patients were referred for haemodialysis treatment from York teaching hospitals NHS foundation trust. We saw acceptance criteria for referrals were in place. Patients needed to be 'stable' in terms of their renal care and have functioning vascular access, which was commenced within the NHS hospital before being referred to the local satellite clinic for on-going dialysis treatment.
- The building met 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

Access and flow

- At the time of inspection, the service had 30 registered patients receiving active treatment. Ten of these were in the age group 18-65 and 20 were over 65 years old.
- In the 12 months leading up to the inspection 1,453 sessions were delivered to patients aged 18 – 65 years and 2,704 sessions were delivered to adults aged over 65 years.
- The unit operated at between 93% and 95.6% capacity (November 2016 to January 2017). This meant the unit and staff were always busy and holiday dialysis could only be arranged around regular patients and vacant capacity.
- There were no cancelled or delayed sessions due to non-clinical reasons in the last 12 months.
- Referrals for admission came from the consultant nephrology team at the commissioning trust. Admissions were arranged directly between the referring team and the clinic manager or deputy. Patients needed to meet acceptance criteria to have dialysis at the satellite unit.
- There was no waiting list for treatment at the clinic and staff we spoke with said that this was consistent.
- The unit had an established appointment system, which promoted structure, timeliness and minimised delays. Staff we spoke with told us that they facilitated a flexible approach to the patient's dialysis sessions and would change the day of patients' dialysis, and/or times as far as possible to accommodate external commitments and appointments or social events. The clinic manager told us they could liaise with nearby units to accommodate requests if they were unable to do this themselves.

Service planning and delivery to meet the needs of individual people

- We saw in the reception area that there was a variety of information available for patients. Leaflets and magazines included information on holiday dialysis arrangements, support and advocacy, making the right choices and signposting information to social networks, support groups and involvement activities such as the 'dialysis games'.
- Patients had access to Wi-Fi, personal televisions in each bed space and reading materials. Patients were able to bring anything in from home to help pass the time during their dialysis sessions.
- We asked nursing staff if patients were provided with any other activities or stimulation. We were not given any examples of any form of activities for patients.
- We asked the clinic manager if literature and support was available to patients, whose first language was not English. We were told that leaflets in other languages and formats could be obtained on request and they had access to telephone and face-to-face interpreting services when needed. Leaflets in some languages could be downloaded from the Fresenius website.
- The clinic manager told us that they regularly booked an interpreter for one patient when treatments changed and that this was planned to take place when the staff started to teach this patient aspects of self-care. The clinic manager told us that staff had also used communication flash cards to help with communicating with this patient.

- Staff we spoke with told us that patients were allocated dialysis appointment times to fit in with social care and work commitments and that they would change these if a patient's needs required it.
- The clinic manager told us that two patients had been started on a self-care programme and there were plans to start a third patient.
- The unit was accessible by people who used wheelchairs and there were personal evacuation plans in place for all patients, which took into account mobility needs.
- General signposting upon the approach to the unit was poor but the receptionist advised that patients were provided with a welcome letter advising where the unit was within the grounds of the local hospital.
- The receptionist told us that parking permits were allocated to patients wishing to travel by car.
- Facilities were provided for families, should they wish to have private discussions. There was a 'quiet room' and the manager's office was available for confidential discussions when required.
- Relatives were not able to stay with patients during treatment due to infection prevention measures. However, staff told us that if someone had additional needs such as learning disabilities, a family member or carer could remain with them.
- One holiday placement was available for patients per week, should it be required, however this needed to be accommodated around vacant capacity as the unit was running at over 90% occupancy.

Learning from complaints and concerns

- There had been two written complaints in the last 12 months (two were from January to May 2017). We reviewed the details of the complaints. The complaint investigations demonstrated patients' concerns were taken seriously and the clinic manager had responded appropriately, well within the policy guideline of 20 working days. The clinic manager told us that all complaints were discussed face to face with patients prior to sending a formal written response.
- There were four written compliments for the unit in the same period.
- Although letters indicated there had been actions taken because of the complaints there was no formal action plans or evidence within the letters to indicate a wider sharing of concerns and actions taken.
- The clinic manager told us they were committed to dealing with the '4 Cs' (compliments, comments, concerns and complaints) in a sympathetic and understanding way. They recognised that lessons for quality improvement could develop as a direct result of a concern or complaint.
- We saw a "Tell us what you think" poster displayed in the waiting area, which explained how patients could raise concerns, leave a compliment or make a complaint.
- There was a policy in place for unresolved complaints and escalation to the Parliamentary Health Service Ombudsman.
- Patient satisfaction results and "you said we did" actions were displayed on the notice board in the patient waiting area.
- Although one patient from the unit was a member of the corporate 'Expert Patient Board', this was held outside the local area and only on an annual basis. There was no local patient involvement group where patients could make suggestions about the service or care of patents on the unit, or where staff could share information about the service with patients. The patient representative was happy to take local patient issues to the board and was happy to share feedback with other patients at the unit. Unfortunately, the patient was unable to attend the 2016 meeting but was planning to attend the next meeting. The patient received minutes when not in attendance.
- Senior staff told us any concerns would be discussed at their local team meeting so that staff could learn from these and improvements could be made. Although we did not see minutes of meetings, other staff confirmed team meetings were held and items such as complaints and incidents were discussed.

Are dialysis services well-led?

Leadership and culture of service

- The clinic manager, who was also the registered manager for the unit, led the Scarborough dialysis unit. The clinic manager worked 60% of their time undertaking management duties and 40% of their time undertaking clinical duties as part of the team delivering direct care to the patients.

- The clinic manager was supported by a Deputy clinic manager from within the nursing team and by the area lead nurse who was responsible for the oversight and performance management of this and six other units. There was also a regional business manager, a managing director and chief nurse, at corporate level, who were available to provide support when needed.
- The clinic manager told us they carried out monthly clinic reviews, which looked at key performance indicators, with the area head nurse. These joint reviews were to focus on what the clinic was doing well and areas for improvement.
- The clinic manager told us they received support and training regarding their management role at the regional managers meeting which was held every four months and at the six monthly national meetings. The agendas from the last two national meetings indicated that training was provided regarding management development, clinical updates, performance management and continuous improvement. We also saw that patient stories were shared and good practice and success stories were shared from across the organisation.
- The clinic manager told us they had received on the job training and support from the area lead nurse when they were new in post. The clinic manager told us they had received some training, regarding human resource (HR) management, and they could contact the HR personnel easily for advice or support.
- We found that staff morale was good and there was high regard for the clinic manager. Staff told us they were well supported by the clinic manager.
- Staff told us the managers were supportive regarding incidents and they felt there was a no blame culture.
- The average rate of sickness over the three months before the inspection was 3.7%. This was in line with the national average.
- Patients told us that staff worked well as a team.

Vision and strategy for this core service

- Fresenius Medical Care (FMC) Renal Services Limited is a large international organisation and had core values of quality, honesty and integrity, innovation and improvement, and respect and dignity. The strategy of the organisation was to grow as a company, enhance products and treatment and to create a future for dialysis patients.
- The mission of the service was centred on "the health and welfare of the human being" which linked to four key pillars "patients, shareholders, community and employees".
- All staff told us their priority was to put patient care above everything else and were clear regarding the expansion of the unit and the patient outcomes that were measured.
- The clinic manager told us that their immediate aims for the unit were; to upskill the unit staff; and to develop and implement training for more patients to become involved in self-care.

Governance, risk management, and quality measurement

- The Fresenius Clinical Governance strategy document described a framework that the team used to deliver 'the right care to the right patient at the right time.'
- The organisation had recently moved to an integrated governance framework, led by FMC head office, and included a risk register. The register was split into three categories: clinical, operational and technical risks associated with the delivery of the service. We saw that risks were rag rated red to green with current controls in place to support the rating.
- There was a corporate risk register, which was divided into three sections, clinical, operational and technical. Managers told us that a new format risk register had been introduced following inspection feedback from another unit and that clinic managers were expected to review the corporate document against local practice and concerns.
- We saw that the register from the Scarborough unit had some local additions and mitigations. For example, skill mix was an additional risk, actions had been implemented regarding medicine management to reduce medicine administration errors and there were some local mitigations regarding an individual patient in relation to the 'Accessible Information Standard'. We were told that local changes would be reviewed by the corporate quality assurance and risk manager and presented to the corporate integrated governance committee before acceptance onto the corporate document.
- It was acknowledged that there had been some additions to the risk register following CQC inspections

at other units in relation to patient identification, sepsis and identifying deteriorating patients. The clinic manager planned to review these risks in the context of this unit.

- We found that managers had clear responsibilities and had a good understanding of risk.
- Performance measures were monitored and action taken to make improvements.
- The clinic manager told us they looked at their unit's patient outcome reports on a weekly basis to keep a close eye on the unit's performance and patient outcomes. They told us that on a monthly basis they would print off the reports to review at the monthly MDT. On a three monthly basis, this would be reviewed with the area lead nurse to identify areas for improvement.
- The clinic manager told us their biggest risks were skill-mix and training needs as they had a number of inexperienced staff.
- The clinic manager felt that the corporate team were proactive about managing risk and that they were easily able to escalate any risks or concerns through either their area lead nurse or regional business manager. Risks and concerns could also be discussed at the regional managers meeting which was held every four months.
- Managers told us that a new process was due to commence later this year, this would involve any member of the senior management team carrying out a unit review visit. This would enable managers to review units from differing perspectives and may identify issues that had not been considered previously.
- We found some areas for concern relating to governance.
  - For example, an investigation of medicine errors had not identified that a lack of positive patient identification was a contributory factor in the incident occurring.
  - There was no audit or assessment of compliance against policies such as medicines management.
  - The medicines management and children and adult safeguarding policies did not refer to most recent guidance and policies had no review dates.
  - There was no clear system to ensure staff could consistently identify and manage deteriorating patients and patients at risk of developing sepsis.
  - Managers told us that inspections at other locations had highlighted some risks previously unrecognised and that these were being included into the risk register. However, assessment of the risks was just starting and action plans needed to be developed to address them. The clinic manager was aware of the feedback from other units and the areas for improvement that had been identified.
  - The unit was not meeting the 'Accessible Information Standard' (2016) at the time of our inspection.
  - The unit was not meeting the Workforce Race Equality Standard (WRES) (2015) at the time of our inspection.
- The clinic manager was aware of the majority of these concerns as they had received feedback from other inspections and planned to evaluate each of these concerns in relation to their own unit. As the concerns had been highlighted very recently there were no firm plans or actions in place, to address these concerns yet.
- The clinic manager showed us the monthly checks they made and records they had in place regarding checking where staff were at with training, appraisals, and whether NMC registration was nearing expiry or revalidation due.
- The Fresenius health and safety inspection October 2016 showed good levels of compliance with a small number of minor actions that were all addressed immediately.
- The clinic manager told us there had been a recent ISO 9001 audit and that the verbal feedback for the unit had been very positive, with only seven actions. The ISO 9001 quality management system is a standard based on a number of quality management principles including a customer focus and continual improvement. They told they would develop an action plan around the audit recommendations and when the actions were implemented, they would receive re-accreditation.

Public and staff engagement

- We saw views and experiences of patients had been sought through the national patient survey 2016. There was a response rate of 33% (20 patients) for this unit, the results were;
  - 100% said the atmosphere was friendly and happy.
  - 95% of them said they would recommend the unit to friends and family in need of dialysis.
  - 95% said staff were caring.
  - 92% of patients said they had complete confidence in the nursing staff.
  - 90% thought the unit was well organised.

  - 90% of patients thought the unit was well maintained and clean.
- We saw there was an action plan developed to improve the areas where patients had been less satisfied. These areas were patient comfort, self-care for fistula/ graft site and timeliness of treatment start time.
- The unit sought feedback through a 'Tell us what you think' anonymous leaflet system, which allowed patients to comment on the service using freepost direct to Fresenius Head Office. We did not see specific results or actions from this in the clinic.
- A staff survey was carried out in November 2016; however, senior managers told us, just three staff members of staff from this unit responded. All of the staff who responded said they would recommend the unit to friends and family who needed dialysis. All three said their training helped them to do their job and they would recommend the unit as a place to work.
- There was a policy and process in place to enable staff to raise concerns at work through a nominated compliance officer. The policy also detailed how staff could access support or raise concerns outside of the organisation through 'Public concern at Work'. Poor practice concerns could also be raised through this policy. This was introduced following an NHS peer review in August 2016.
- Staff we spoke with told us they felt they were welcomed into the unit when they were new and that the team worked well together. Staff were proud to work at the unit and felt patients received safe, high quality care.
- Managers told us of annual events for sharing of good practice and celebrating achievement where annual awards were given to high performing individuals and units. The clinic manager told us of an occasion when they had received a phone call from the corporate governance lead when the unit's outcomes had improved.
- Staff receive £25 per quarter for 100% attendance and £100 per year for continuous 100% employment. In addition to this, they receive a £25 voucher for a Christmas Celebration. Rewards are also given for long service.

Innovation, improvement and sustainability

- In 2015, the clinic manager had won NephroCare excellence award for the unit with the most improved effectiveness.
- The clinic manager told us that capacity issues and expansion were currently under review and undertook a visit to the main dialysis unit as an aid to planning this development.
- We found the clinic manager and the senior team had a desire to learn and to address any issues as soon as practically possible.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must take action to address the concerns regarding the medicines management policy in relation to being in line with up to date guidance and the lack of audits to provide assurance.

Action the provider SHOULD take to improve

- The provider should consider reviewing how incidents are investigated to ensure all contributory factors are identified to maximise learning points and highlight areas for improvements.
- The provider should review the incident reporting policy to ensure staff are better supported in their judgements regarding level of harm and when to make notifications and implement Duty of Candour.
- The provider should review the adult and children's safeguarding policy to bring it in line with up-to-date guidance, specifically the intercollegiate document 2014.
- The provider should take action to ensure staff are consistently able to identify and manage deteriorating patients and patients at risk of developing sepsis.
- The provider should ensure care plans are developed to support patients with their individual health needs.
- The provider should take action to ensure patients are provided information appropriate to meet their needs, in line with the Accessible Information Standard (2016).
- The provider should take action to implement the requirements of the Workforce Race Equality Standards (2015).

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The service did not carry out medicines management audits to assess and monitor the proper and safe management of medicines. Care and treatment must be provided in a safe way for service users. The registered person must ensure the proper and safe management of medicines. Regulation 12 (1)(2)(g)

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.