

North Ormesby Dialysis Unit

Quality Report

Trinity Crescent Medical Village
North Ormesby
Middlesbrough
TS3 6LB

Tel: 01642 239090

Website: www.freseniusmedicalcare.co.uk

Date of inspection visit: 4 and 24 April 2017

Date of publication: 21/08/2017

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

North Ormesby Dialysis Clinic is operated by Fresenius Medical Care Renal Services Ltd, an independent healthcare provider. It is contracted by NHS England to provide renal dialysis to NHS patients. Patients are referred to the unit by the local NHS trust. The service is on the site of North Ormesby Medical Village in Teesside. It is an 18 station unit (comprising of 12 stations in the main area, two side isolation rooms and a four bed bay) providing haemodialysis for stable patients with end stage renal disease/failure.

We inspected this service using our comprehensive inspection methodology. We carried out an announced comprehensive inspection on the 4 April and an unannounced inspection on the 24 April.

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:

- We found that the clinic was visibly clean, arrangements for infection prevention and control were in place and there was no incidence of infection. The environment met standards for dialysis clinics and equipment maintenance arrangements were robust. Staff were aware of their responsibilities in keeping the patient safe from harm and record keeping was thorough. Mandatory training was completed by all staff.
- Effective arrangements and support from a dietitian was in place and the nutritional need of dialysis patients was a priority. There was effective multidisciplinary working and collaboration with the NHS trust renal team helped support patients' treatment and positive outcomes.
- There was a good range of comprehensive policies in place to support staff; these were accessible and understood by staff we spoke with. Policies were based on national guidance and an audit programme was in place to monitor compliance. Key performance indicators for 2016/17 showed comparable performance against other Fresenius units nationally.
- Staff described the Fresenius incident reporting system and were aware of changes being made to transfer from a paper to an electronic system. Staff reported 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. Nursing staff were experienced and qualified in renal dialysis. Over 50% of nursing staff had a specialist renal qualification. One hundred percent of staff had received induction and appraisal.
- We observed that consent processes were in place and documentation was accurate. Easy access to complex patient information in the clinic and across the trust supported treatment and care of patients in the unit.
- Effective processes were in place for the provision of medicines. These were stored and administered in line with guidance and staff completed competencies annually to ensure they continued to administer medicines correctly.

Summary of findings

- We observed a caring and compassionate approach taken by the nursing staff and named nurses during inspection. The detail in written individualised care plans was thorough and updated.
- Nurse staffing levels were maintained in line with national guidance to ensure patient safety. There was use of a specialist nurse agency when required. Staff provided additional cover during peaks in activity or during staff shortage. Nursing staff had direct access to the consultant responsible for patients care.
- The clinic provided opportunity for patients to visit prior to starting dialysis treatment as part of pre-assessment. Twice a month new patients were supported to visit to ask questions; anxieties could be alleviated by nursing staff.
- Patients were supported with self-care opportunities and a comprehensive patient education process was in place. Holiday dialysis for patients was arranged to provide continuity of treatment and support the wellbeing of patients.
- The clinic provided a satellite local service, with flexible appointment system for patients requiring dialysis and the service contract obligations were clear to senior staff. We observed a responsive approach to arranging appointments with the needs of the patient at the centre. Arrangements for contingency for appointments in an emergency was in place.
- The clinic had detailed local risk assessments in place and we observed a new operational risk register; this was being developed by the national senior team and would be reviewed through the governance committee structure prior to implementation and training to clinic staff.
- Activity was monitored closely for non-attendances of patients. The team worked flexibly to accommodate patients individual appointment needs to avoid non-attendance. Any unavoidable or emergency transfers to the NHS trust renal unit were appropriately managed by the nursing team.

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

- The grading of harm from incidents was not clearly described by staff. It was also not clear on the reporting forms. This would not support a clear trigger for the requirements of the duty of candour regulation. The incident management policy was not consistently applied in practice. Staff we spoke with told us that incident reporting was discouraged by senior staff in the clinic. Senior staff we spoke with told us that they supported incident reporting and had delivered training and support to staff.
- The classification of clinical and non-clinical incidents did not reflect the reported events, for example patients falling in the clinic were reported under 'non-clinical' incidents, to the health and safety manager, rather than the chief nurse. We did not see any investigation or sharing of lessons with clinic staff to support prevention of falls in the clinic.
- Observations were recorded regularly to assess the patient's condition, before during and after dialysis. We noted however that the clinic did not use a recognised national early warning score (NEWS) system to support the recognition of the deteriorating patient. There was inconsistent recording of temperature and no recording of respiratory rate as directed by the care plan.
- There was no formal way for staff to identify patients who were not familiar to them. We recognised that most patients were well known to the clinic team. There was frequent use of agency nurses and recruitment of new patients or holiday patients to the clinic. Staff would not always be able to identify patients when administering medicines or commencing dialysis treatment. We observed that staff did not consistently ask patients for identification formally or informally during inspection.
- Clinic staff did not have access to a designated member of Fresenius staff who had appropriate level 4 safeguarding training for advice. This training requirement was also not included in the Fresenius policy.

Summary of findings

- We did not observe a system for reporting of pain assessment for patients in the clinic who receive dialysis treatment.
- The clinic did not measure or audit any patient travel or waiting times.
- Appraisal was performed for all staff however we reviewed that the quality of the appraisal process needed improvement. In the employee survey 2016/17, over half of the staff in the clinic had reported that they did not feel their work was valued or that their training and development was identified through the current appraisal process. In five records we reviewed the appraisal notes were very brief.
- We reviewed concerns and complaints from patients with particular regard to the temperature of the clinic and comfort of patients. We reviewed action plans from the patient survey which lacked detail, timescales and responsibilities were not allocated or communicated across the team.
- The issues reported to us from a range of sources indicated that there was a culture of unprofessional display of behaviours such as shouting and confrontation in the clinic. We reviewed a range of information that indicated escalation of staff concerns in the organisation had not been acted upon. The morale of nursing staff was observed to be low at all levels during our inspection, and this was also evident in the employee survey responses..
- The 2016/17 employee satisfaction survey results showed an overall poor satisfaction response in all questions related to feeling supported by line management, or feeling stressed about work or feeling valued. We reviewed a five point action plan that did not sufficiently acknowledge or address the issues in the survey. There was a reduction in performance from 2015 to 2017 against a number of indicators in the survey.
- The clinic local team meeting was inconsistent and the agenda and content did not support governance of risk and quality at a local clinic level. The meeting briefly focussed on tasks or duties to be allocated to the team.
- The Fresenius risk management policy did not reflect the introduction of an operational risk register.

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.

Ellen Armistead

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Dialysis Services

Rating

Summary of each main service

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

Summary of findings

Contents

Summary of this inspection

	Page
Background to North Ormesby Dialysis Unit	8
Our inspection team	8
Information about North Ormesby Dialysis Unit	8
The five questions we ask about services and what we found	10

Detailed findings from this inspection

Outstanding practice	32
Areas for improvement	32
Action we have told the provider to take	33

North Ormesby Dialysis Unit

Services we looked at: Dialysis Services

Summary of this inspection

Background to North Ormesby Dialysis Unit

The service provides haemodialysis treatment to adults. The North Ormesby Dialysis Clinic opened in 2007 and primarily serves the Teesside population, with occasional access to services for people who are referred for holiday dialysis.

The registered manager has been in place since 2011 and was available on the day of CQC inspection. Fresenius

Renal Health Care UK Ltd has a nominated individual for this location. The clinic is registered for the following regulated activities; Treatment of disease disorder or injury.

The CQC have inspected the location previously in 2010, 2012 and 2013 and there were no outstanding requirement notices or enforcement associated with this service at the time of our comprehensive inspection in April 2017.

Our inspection team

The inspection was carried out by three CQC inspectors. The inspection team was overseen by Amanda Stanford, Head of Hospital Inspection.

Information about North Ormesby Dialysis Unit

The Fresenius dialysis clinic at North Ormesby is located within the North Ormesby Medical Village in Teesside. It provides treatment and care to adults only and the service runs over six days, Monday to Saturday. There are no overnight facilities. There are two to three dialysis treatment sessions a day which includes a twilight treatment session on Monday, Wednesday and Friday. This ends at 23.00hrs. Eighteen people are dialysed during both the morning and afternoon sessions and a further 18 during the twilight session.

The service commenced in May 2007. The clinic has 18 beds in total. This comprised 12 stations, (bed spaces), in the main treatment area; two isolation rooms and a four bed area that was partitioned with glass. 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 and security systems were in place.

The main referring unit is the James Cook Renal Unit, which is part of South Tees NHS Hospitals trust. The trust provides the renal multidisciplinary team, with a consultant nephrologist visited the dialysis unit once a month for the multidisciplinary team (MDT) meeting,

which are held on the first Wednesday of each month and the consultant, dietitian, and clinic manager review patient outcomes, and blood results. The named nurse for the patient also attends the MDT meeting. Medical staff are not on site with exception of MDT meetings, outpatient clinics held twice a month or occasions when patients are reviewed by referral from clinic nursing staff.

The clinic also hosts a twice monthly outpatient service for patients preparing for their first haemodialysis treatment.

There are on average 1000 dialysis treatment sessions delivered a month. There had been a slight increase in activity in 2016/17 and the service delivered 12,287 haemodialysis treatments to adults, around 9000 treatments are given to adults aged over 65. There was an increase from 75 to 83 people in total using the service from 2015 to 2016.

During the inspection of North Ormesby Dialysis Clinic we spoke with sixteen staff including; registered nurses, dialysis assistants, dietitian, reception staff, medical staff, and senior managers. We spoke with ten patients and

Summary of this inspection

one relative. We also received 26 'tell us about your care' comment cards which patients had completed for our inspection visit. During our inspection, we reviewed eight sets of patient records.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. The service has been inspected three times, and the most recent inspection took place in June 2013. This was the clinic's first comprehensive inspection against the new methodology.

Activity (April 2016 to March 2017)

- There were on average 1000 dialysis treatment sessions delivered a month in 2016/17.
- The service delivered 12,177 in total sessions in 2015/16 with 3721 haemodialysis sessions to adults aged 18 – 65 and 8456 sessions to adults aged over 65. The activity had slightly increased in 2016/17 to a total of 12,287.
- There were 83 people in total using the service.
- There were 63 pre-dialysis appointments in 2016.

Staffing

There are nine nursing staff and four dialysis assistants. There is one clinic manager, a deputy manager, two team leaders and one receptionist. A dietitian has approximately three sessions per week as agreed as part of a Service Level Agreement (SLA) with South Tees NHS trust.

Consultant nephrologist staff attend the clinic once a month for the MDT meetings and a further twice a month for outpatient clinics.

Track record on safety (April 2016 to March 2017)

- There were no reported never events.

- Five clinical and eight non-clinical incidents (seven of which were patient falls) were reported. We did not see a breakdown of these incidents which graded severity for the clinic, such as, no harm, low harm, moderate harm, severe harm and death.
- One serious incident was reported. One in-service death was reported and thorough reporting and investigation followed.
- No incidences of hospital acquired Methicillin-resistant Staphylococcus Aureus (MRSA), were reported.
- No incidences of hospital acquired Methicillin-sensitive Staphylococcus Aureus (MSSA) were reported.
- No incidences of hospital acquired E-Coli were reported.
- No complaints were received by the CQC or referred to the Parliamentary Health Services Ombudsman or the Independent Healthcare Sector Complaints Adjudication Service. The clinic had received one formal complaint and 11 written compliments from patients.

Services accredited by a national body:

The clinic is accredited against ISO 9001 quality management system and the OHSAS18001 health and safety system and are therefore subject to regular audit and review.

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal.
- Interpreter services.
- Grounds Maintenance
- Maintenance of medical equipment
- Pathology and histology
- Dietetics

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?

Services we do not rate

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

Are services safe?

We found the areas of good practice:

- We found that the clinic was visibly clean, arrangements for infection and prevention were in place and there was no incidence of serious infection.
- Staff were aware of their responsibilities in keeping patients safe from harm and record keeping was thorough. Staff could describe the incident reporting system.
- Nurse staffing levels were maintained in line with national guidance. The use of agency staff was monitored closely.
- Mandatory training was completed by all staff.
- Risk assessments were carried out for patients and staff were aware of escalation policies and processes for transfer of patients to NHS hospitals.
- Arrangements for contingency in an emergency were in place.

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

- The grading of harm from incidents was not clearly described by staff. It was also not clear on the reporting forms. This would not support a clear trigger for the requirements of the duty of candour regulation.
- The classification of clinical and non-clinical incidents did not reflect the reported events, for example patients falling in the clinic were reported under 'non-clinical' incidents, to the health and safety manager, rather than the chief nurse. We did not see any investigation or sharing of lessons with clinic staff to support prevention of falls in the clinic.
- We did not see consistent evidence in team meetings that local and corporate incidents and near misses were openly reported and lessons learnt. It was also reported that reporting of incidents was discouraged by senior staff. Senior staff reported that they had provided training for staff and did provide updates.
- Clinic staff did not have access to a designated member of Fresenius staff who had appropriate level 4 safeguarding training for advice. This training requirement was also not included in the Fresenius policy. There was no formal way for

Summary of this inspection

staff to identify patients who were not familiar to them. We recognised that most patients were well known to the clinic team. There was frequent use of agency nurses and recruitment of new patients or holiday patients to the clinic. We observed that staff did not ask patients for identification formally or informally during inspection.

- Observations were recorded regularly to assess the patient's condition, before during and after dialysis. We noted however that the clinic did not use a recognised national early warning score (NEWS) system to support the recognition of the deteriorating patient. There was inconsistent recording of temperature and no recording of respiratory rate as directed by the care plan.
- We noted that the use of agency staff was predominantly on twilight shifts. This cover should continue to be monitored. Some staff we spoke with told us of concerns with skill mix and levels of competence during these shifts.

Are services effective?

Are services effective?

We found the areas of good practice:

- Effective arrangements and support from a dietitian was in place and the nutritional need of dialysis patients was a priority.
- There was effective multidisciplinary working and collaboration with the NHS trust renal team helped support patients treatment and positive outcomes.
- Activity was monitored closely for non-attendances of patients and the team worked flexibly to accommodate patients individual appointment needs. Any unavoidable transfers to the NHS trust renal unit were appropriately managed.
- We observed staff working with competence and confidence and the training available in the clinic supported all staff to perform their role well. Nursing staff were experienced and qualified in renal dialysis. Over 50% of staff had a specialist renal qualification.
- Consent processes were in place, policy was robust and documentation was accurate.
- There was easy access to complex patient information in the clinic and across the trust and this supported treatment and care of patients in the unit.

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

Summary of this inspection

- We did not observe a system for reporting of pain assessment for patients in the clinic who receive dialysis treatment.
- Appraisal documentation we reviewed was brief and staff complained that the quality of appraisal did not make them feel valued or identify individual training needs.

Are services caring?

We found the areas of good practice:

- We observed a caring and compassionate approach taken by the nursing staff and named nurses during inspection.
- The clinic provided opportunity for patients to visit prior to starting dialysis treatment as part of pre-assessment. Twice a month patients were supported to ask questions and anxieties alleviated by nursing staff.
- Patients were supported with self-care opportunities and a comprehensive patient education process was in place.
- Arranging holiday dialysis for patients provided continuity of treatment and supported the wellbeing of patients.

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

- Patients complained about the temperature of the clinic.

Are services responsive?

We found the areas of good practice:

- The clinic provided a satellite local service, with a flexible appointment system for patients requiring dialysis. We observed a responsive approach to arranging appointments. These were arranged with the needs of the patient at the centre, taking into account their work and social commitments. Nurses took into account the complex care needs for vulnerable patients.
- Patients are referred for haemodialysis treatment from South Tees NHS trust renal unit by a consultant nephrologist team. The priority is to ensure that patients are assessed as physically well enough for satellite treatment and also live in the local area. We found good practice against these standards.
- Senior staff were committed to attending business and clinical meetings at the NHS trust to manage the achievement of contract obligations and key performance indicators.

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

- The clinic did not measure or audit any patient travel or waiting times.

Summary of this inspection

Are services well-led?

We found the areas of good practice:

- There was a clear leadership structure in the Fresenius Medical Care organisation and that was applied regionally to the North Ormesby Dialysis Clinic.
- Local leadership was reflected in a nominated lead consultant from South Tees renal services, a regional business manager, area head nurse and clinic manager, who was based in the clinic for 100% of the job role. The clinic manager liaised closely with the South Tees NHS trust.
- We observed positive peer support in the clinic and nursing staff spoke highly of one another. This was reflected in our observations of their teamwork and communication and in the employee survey responses.
- The Fresenius governance framework was detailed and supported with a range of comprehensive policies, a structured committee and meeting system, a strategy and vision that directed the team to deliver 'the right care to the right patient at the right time'. Senior staff were conversant with these elements of their service and senior business and governance meetings were consistently attended.

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

- The culture of the unit was reported as unsupportive, by most staff we spoke with and it was clear from our findings that not all staff exhibited professional behaviours. This was a theme reported to us from a range of sources. There was evidence that when identified, issues and concerns were not acted upon by senior staff, which led to low morale, evident in the employee survey 2016/17.
- Clinic team meetings were inconsistent and the agenda and content did not support governance of risk and quality at a local level with the nursing team. The meeting briefly focussed on tasks or duties to be allocated to the team.
- The 2016 employee satisfaction survey results showed an overall poor satisfaction in relation to staff feeling supported by line management, or feeling stressed about work or feeling valued. The reduction in performance against a number of indicators in the survey indicated that action had not been developed or had not been effective.
- A patient survey action plan was in place from 2016, however there was minimal detail of actions, allocation of staff responsibilities and timescales associated to the issues identified in the survey.

Summary of this inspection

- The Fresenius Medical Care UK strategy and vision was not well understood by the clinic team at all levels. The current governance arrangement for team meetings and lack of sharing of information from senior to nursing staff did not support the vision and strategy.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

- The clinic had a robust policy for the reporting of incidents, near misses and adverse events. Nursing staff reported incidents electronically onto a document that was saved and reviewed by the clinic manager. Staff we spoke with told us that each incident would be reviewed by the area head nurse and chief nurse for Fresenius Medical Care. The service was implementing an electronic system in pilot sites to support improvement on the paper form and data analysis of incidents with subsequent learning.
- During the reporting period, April 2015 to March 2017 there had been no never events reported. Never events are serious incidents, which are wholly preventable as guidance and safety recommendations are available that provide strong systemic protective barriers at a national level. Although each never event has the potential to cause harm or death, harm is not required to have occurred for an incident to be categorised as a never event.
- Staff we spoke with gave a mixed response to questions around incident reporting culture in the clinic. Most clinic staff could explain the reporting process but did not feel the reporting system was clear, encouraged, or information shared in meetings. Senior staff, however reported a culture of open and honest reporting to include staff reports of all near misses. We noted five clinical and eight non-clinical incidents reported in the 2016/17 timescale.
- Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 is a regulation introduced in November 2014. This Regulation requires the trust to notify the relevant person that an incident has occurred, provide reasonable support to the relevant person in relation to the incident and offer an apology. Senior staff could not clearly describe the application of duty of candour for serious harm. Staff nurses and dialysis assistants had a good understanding of the duty of candour regulation and had completed training.
- There had been one reportable incident, and one in-service patient death in the 12 month reporting period in 2016/17. There had been no serious incidents reported. We spoke with the clinic manager and consultant nephrologist who reported evidence of a thorough investigation of a patient who suffered a cardiac arrest in the clinic with no actions required from this event. The investigation was also subject to a mortality peer review that had been performed by an external NHS review team.
- Incidents were currently categorised as clinical and non-clinical and there was also a system of reporting any variance from the care pathway, known by staff as treatment variance reports or 'TVR's'. Clinic nursing staff we spoke with told us that incident reporting was discouraged by senior clinic staff. Senior staff we spoke with told us that they supported incident reporting and had delivered training to staff. The incident policy was clear but poorly applied to practice.
- The chief nurse and the health and safety officer were responsible for analysis and investigation of all incidents in the Fresenius group and they reported into a clinical governance framework and then to the clinic manager and local clinic review process.
- There was no clear grading of incidents on the 'non clinical' incident form. This lack of grading of harm or severity did not support the appropriate application of duty of candour. Triggers for the duty of candour

Dialysis Services

process starts with the recognition and acknowledgement that a patient safety incident has occurred and moderate harm, major harm, or death has resulted. Grading of incidents was clearly described in the clinical incident reporting policy.

- Staff reported patient falls as a non-clinical incident which did not trigger appropriate level of scrutiny or investigation by clinical staff. There had been seven falls in the reporting period, we did not see any investigation or actions from these incidents to prevent further patient falls in the clinic. The incident log provided by the clinic manager did not have any description of incidents. There was a record and log number with associated dates and the 'type of incident' was described only as 'patient'.
- We were told by senior staff that clinical incidents are monitored nationally with clinic updates and learning bulletins distributed by the chief nurse to support lessons learned across the organisation. We did not see evidence of any sharing of incidents in the clinic displays of information, minutes of meetings or in discussions with staff.

Mandatory training

- All new staff undergo induction which includes mandatory training in safety systems, processes and practices linked to the care and management of patients. Preceptors train new recruits and record training in their integrated competence document. This document is designed to follow key stages; Induction, fundamental skills, advancing skills and management skills.
- We observed five staff records that gave evidence of up to date training records for registered nurses and dialysis assistants, attendance and sign off by senior nursing staff and mentors was evident.
- We observed the electronic management system for training that was being upgraded and improved, it was well organised and senior staff could review and monitor individual staff training needs and were given prompts around the time for mandatory update. The tool included all aspects of training and competence sign off including medical devices.

- Staff in the clinic were reported as 100% updated with mandatory training for 2016/17. Staff we spoke with told us access and quality of training was very good. We reviewed clinic training reports and individual training records as evidence of 100% compliance.
- The mandatory training programme had a safety emphasis and included eLearning and classroom based training sessions. The programme included prevention of healthcare associated infections, waste, medicines and records management, and reporting of incidents. Senior staff attended training for root cause analysis and management of emergencies.
- All staff attended basic life support training and nursing rotas would indicate each shift where a member of the team had life support qualifications and training. All shifts would have a member of the team who had basic life support skills.
- Mandatory training records for agency nursing staff are monitored by the Flexibank administrators to ensure training is always up to date. If training lapsed the member of staff is suspended from shift allocation until evidence of completion is received. Flexibank training records are retained centrally. We did not see any evidence of staff suspension during inspection. We requested evidence of assurance that systems for checking were robust and shared with the clinic senior nursing team. Staff responded to corroborate the arrangements at a corporate level worked well.

Safeguarding

- There were systems and processes in place to keep vulnerable patients safe. All staff we spoke with were aware of their roles and responsibilities for escalation of any safeguarding concerns. We observed contacts for safeguarding leads and points of contact at the nurses station.
- The clinic manager was the designated safeguarding co-ordinator and they acted as the safeguarding lead for the clinic. There was no local designated staff who had appropriate level 4 safeguarding training. This training requirement was not included in the policy. The policy directed staff to report any safeguarding issues to the chief nurse and also into the NHS trust

Dialysis Services

safeguarding team. There had been no concerns raised in 2016/17. Staff we spoke with could not give us examples of escalation of any safeguarding concerns.

- Staff received training in the safeguarding of vulnerable people. We reviewed staff training records and saw that 100% of staff had received safeguarding adults level 2 training. The clinic manager had also trained to level 2 safeguarding for adults. Clinic staff did not have access to a designated member of Fresenius staff who had appropriate level 4 safeguarding training for advice. The training manager had level 3 children's safeguarding training. The level 4 training requirement was also not included in the Fresenius policy. They would refer to the trust lead for safeguarding.
- The clinic had a policy for safeguarding adults and children, which detailed training requirements and areas when to raise a safeguarding concern, this document did not make reference to female genital mutilation or to PREVENT training programmes for staff to safeguard people and communities from the threat of terrorism. However As part of Fresenius Medical care on-line radicalisation training, guidance is provided on how to support and identify those at risk of radicalisation and terrorism. The safeguarding children on-line training module references to female genital mutilation.

Cleanliness, infection control and hygiene

- There were comprehensive Fresenius infection prevention and control policies in place with standards audited on an on-going basis both at clinic, central and external level. Cleaning, decontamination and clinical practice was observed to be compliant with policy during inspection, to include the technique for connecting and disconnecting patients to dialysis machines.
- The Fresenius chief nurse was the lead for infection prevention and control (IPC) and had overall responsibility for providing infection prevention and control advice. On site there were link nurses, these staff received training to enable them to carry out the role.

- The clinic reported no cases of infection in 2016/17, including hospital acquired Methicillin resistant staphylococcus aureus (MRSA), bacteraemia, blood borne virus.
- Hand hygiene audit data we reviewed, which was on display, showed 93-100% compliance for the reporting period January 2017 to March 2017. Alcohol hand sanitiser was available at every dialysis station. We observed staff perform hand hygiene at appropriate times and all staff wore personal protective equipment (PPE) whilst performing clinical duties..
- Protocols were in place to screen patients returning from holiday in regions identified as high risk of infection for blood borne viruses. Screening for MRSA and methicillin sensitive staphylococcus aureus (MSSA) was also carried out.
- Procedures were in place to assess carriers of blood borne virus (BBV) such as hepatitis B and C, staff were able to describe the correct isolation requirements and actions required to mitigate the risk of BBV cross infection.
- Staff had access to two isolation rooms for nursing patients with a known or suspected infection.
- Staff were knowledgeable about the surveillance of water systems for presence of bacteria, and were able to explain the procedures required to test water samples. Staff were able to explain the procedure if a water sample came back as contaminated.
- Records we reviewed showed that staff carried out the correct procedures in regards to flushing of water outlets to prevent contamination of the water supply.
- Staff had access to clinical and non-clinical waste facilities; staff were able to dispose of waste including sharps, at the point of use.
- Staff received training on infection, prevention and control through a range of methods, face to face and through e-Learning. IPC training compliance rates for the clinic were 100%. Staff are assessed annually by the IPC coordinator, this was the clinic manager at North Ormesby Dialysis Clinic. We observed staff competence documents to be up to date.

Environment and equipment

Dialysis Services

- The clinic was visibly clean, tidy and well maintained. Environmental cleanliness audit scores on display showed 97-98% compliance in the reporting period January 2017 to March 2017.
- We inspected fifteen pieces of equipment including dialysis stations and suction pumps. We found all to be visibly clean. We observed staff cleaning equipment, including dialysis machines between patient sessions.
- We saw equipment being cleaned, although staff did not use labels to provide assurance to patients that equipment had been cleaned between uses, there was a cleaning rota with sign off of cleaning duties performed by staff.
- The clinic was accessed through a single entrance into a ground floor facility. Access was gained through an intercom system to reception as a security measure. Wheelchair access was provided. Entrance to the main treatment area was through a digital lock and all clinic rooms were kept locked.
- The clinic had 18 dialysis stations in four different areas. A four bedded quiet area was available with glass partition, two isolation rooms and main area consisting of 12 stations laid out in a L shape. Each bed space was spacious and compliant with Health Building Note 07-01 – Satellite Dialysis Clinics.
- Maintenance of dialysis machines and chairs were scheduled and monitored using the Fresenius dialysis machine maintenance/calibration plan. This detailed the dialysis machines by model type and serial number along with the scheduled date of maintenance. A similar plan was present for dialysis beds and other clinical equipment for example; patient thermometers, blood pressure monitors and patient weighing scales. There were two back up dialysis machines stored and ready for use in the clinic.
- The dialysis machines, chairs, beds and water treatment plant were maintained by Fresenius Medical Care technicians. The majority of additional dialysis related equipment was calibrated and maintained under contract by the manufacturers of the equipment or by specialist maintenance service providers.
- Records were maintained relating to the maintenance and calibration of all equipment used at North Ormesby. We reviewed the maintenance records which were up to date and thorough.
- There was evidence of assessment of medical device training and competence sign off and a comprehensive record of equipment used by staff. It was clear in the incident policy that a priority was given to following correct process in the event of an incident that might involve a medical device.
- In January 2017 Fresenius Medical Care brought Facilities Management (FM) in-house. A dedicated FM team, an experienced manager and two helpdesk coordinators provide the clinic with both reactive and planned preventative maintenance work. We saw evidence of staff in the clinic logging a call with the help desk regarding facilities issues. The call was allocated a job number and priority. The FM helpdesk ensures a contractor was requested to attend the clinic to resolve the issue as per the priority level. The calls were also documented in the clinic diary.
- Annual electrical testing was part of the clinics planned and preventative maintenance schedule managed by the FM team. A register is kept on-site confirming testing has taken place and was checked during annual health and safety audit. We also noted labelling to evidence that fire extinguisher checks were carried out routinely.
- We checked the resuscitation equipment and found it to be in order, with a checklist that was completed daily by staff and appropriate stock items and equipment testing. Oxygen was available and stored safely.
- Staff we spoke with said there were adequate stocks of equipment and we saw evidence of stock rotation. All single use items of equipment were found to be in date including dialysis sets.
- We observed appropriate management of alarm systems on equipment to alert staff of any potential risk, disconnection from dialysis or deterioration of patient condition. Use of alarms in the clinic was understood by nursing staff and all staff had achieved

Dialysis Services

competencies around understanding parameters and use of equipment. We observed nurses respond to alarms promptly. We reviewed sign off for competency and found reports to be up to date and as per policy.

Medicines management

- The clinic did not store any controlled drugs. Lead responsibility for the safe and secure handling and control of medicines was the clinic manager.
- The nurse in charge, usually the team leader or more senior nursing staff would be allocated duties as key holder for the medicines cabinet on a day to day basis.
- Medicines were stored securely in a locked cupboard.
- Medicines requiring refrigeration were stored in a fridge, which was locked and the temperatures were checked daily. Staff were aware of the action to take if the temperature recorded was not within the appropriate range.
- The nurses liaised with the local NHS pharmacy for additional advice relating to dialysis drugs. In addition, Fresenius staff had access to a pharmacist at head office should this be required.
- The patient's consultant prescribed all medicines required for dialysis. Access to pharmacy out of hours could be made through South Tees NHS trust on call pharmacy service, although it was rare that this was required.
- Emergency medicines were readily available and they were found to be in date in an sealed box on the bottom shelf of the resuscitation trolley. This was agreed locally and in line with Fresenius policy.
- We looked at the prescription and medicine administration records for five patients on the clinic. These records were fully completed and were clear and legible.
- We noted that staff did not have any formal method of identification of patients, such as, no wristbands or photographs in notes. No verbal checks or confirmation of identity was made with patients during our observations. This was communicated to the senior team. We recognised that most patients were well known to staff as they attended regularly for treatment, but there was a significant risk to not being able to identify patients, especially as part of

medicines and treatment management. We observed that staff did not ask patients for identification formally or informally during inspection. This practice would not be supported by other professional regulators such as, the Nursing and Midwifery Council (NMC) standards for medicines management.

- Medicine changes were posted to the patient's GP following the multi-disciplinary team (MDT) meeting each month. All medicines changes that were needed for dialysis are changed on the day of the meeting by the consultant nephrologist.
- There was a detailed medicines management policy. There was no guidance to support audit of practice to provide assurance that standards of practice were monitored and reviewed by pharmacy or senior staff. We spoke with senior staff who confirmed that currently an audit of drug expiry dates, and the use of iron and Aranesp was performed.

Records

- The Fresenius Medical Care patient treatment database automatically transferred patient data into the clinical data base of the NHS trust where the patient is under a renal consultant. Staff we spoke with described this process as working well.
- We reviewed eight sets of patient records and saw entries made pre, middle and post dialysis as well as entries made for any variances during the period of dialysis. These entries were made at appropriate times in relation to the patient pathway. We also reviewed electronic and patient paper records including care plans and pathways and saw that these had been regularly reviewed, signed, dated and updated. Records were maintained in line with the NMC Code of Professional Conduct in relation to record keeping. All entries were legible.
- We observed patient records to be stored securely with respect for patient confidentiality during inspection. There were no information governance breaches.
- On receipt of new patient transfer documentation all staff were required to document details on the form to

Dialysis Services

ensure that patient data provided was accurate. This was also cross checked for accuracy between clinic paper records, NHS trust electronic systems and Fresenius electronic systems.

- The clinic carried out nursing documentation audits monthly and we requested audit information but did not see results at the time of inspection. Eight records we reviewed showed thorough and accurate documentation.
- Each registered nurse held a case load of dialysis patients of approximately 12 patients. Staff updated patient records and care plans for patients on their caseload. Nurses had a buddy system to ensure records were updated in periods of absence. We noted care records to be individualised and detailed.

Assessing and responding to patient risk

- The satellite clinic would only admit stable and lower risk patients for dialysis. If a patient was acutely unwell Fresenius policy guided that they would receive their care and treatment at the local NHS trust renal unit. We did not see evidence of patient admission for those living with dementia. Patients with known infection had care provided in the isolation rooms.
- Staff would follow the escalation plan for an acutely unwell patient, which included a clear reference table for a range of circumstances; if a patient had an adverse drug reaction, acquired a bacteraemia, suffered a cardiac arrest in the unit or a data protection breach occurred. Staff we spoke with were aware of their roles in these circumstances and referred to the policy. Staff would contact the consultant for advice when appropriate.
- There were 104 patient transfers to another healthcare provider in the 12 month reporting period in 2016/17. Senior nursing and medical staff we spoke with told us that transfers were unavoidable and a percentage of patients would require care to be transferred to the NHS trust after initial assessment of risk on admission. Staff we spoke with knew how to access emergency transfers via local ambulance services. Fresenius staff could not benchmark transfer figures nationally at the time of inspection.
- Peoples needs were assessed and treatment was planned and delivered in line with their individual care plans. There was a comprehensive care pathway in the eight care plans we reviewed. Records contained a current dialysis prescription, dialysis summary charts and risk assessments, such as, moving and handling and Waterlow score to prevent pressure ulcers.
- Staff recorded variances during the period of dialysis in the patient records for example, falls risks, mobility post dialysis, weight recording and changes in vital signs measurements. Staff used this information to help plan the next dialysis session and to identify any themes or risks occurring during dialysis.
- The clinic did not use an early warning score system to identify the deteriorating patient. Staff we spoke with had not had any training about national early warning score (NEWS) and could therefore not describe the recognition of the patient deteriorating in the same context. Nursing staff we spoke with were experienced and able to articulate the clinical condition of a deteriorating patient. Staff could describe how they would recognise a patient that was unwell and how they would get support and escalate concerns in the absence of a NEWS system.
- There was no regular record of respiratory rate on the observation chart, although the care plan did direct the recording of this physiological parameter. It was also observed that patient temperature was recorded routinely pre and post treatment but we noted inconsistent recording across the eight notes we reviewed. Half of records did not have temperature recorded both pre and post treatment.
- There was no protocol for patient to wear an identity band or other agreed way of identifying patients, for example photographs or a name badge when they attended the clinic. Senior staff we spoke with at the unannounced inspection were aware that this issue had been added to the risk register after CQC feedback at other units. The current process was described by clinic senior staff as posing a small risk as each named nurse allocated each patient to their first session and during that session the patients details were checked. The patient data card which held all prescription information also included the name and date of birth details. These were uploaded to the dialysis machine to be checked during each session. Staff told us that the nature of the outpatient setting and the frequency

Dialysis Services

of dialysis made it very unlikely that a patient's identity would not be correctly identified. We observed that staff did not ask patients for identification formally or informally during inspection.

- Staff we spoke with described a process of contact for renal medic 'on call' if support was required out of hours, and it was reported that this happened each week for prescription changes. Staff we spoke with told us that it was harder to get medical on call support on Saturdays.
- We did not see evidence of any training provided to staff to support recognition of the patient with sepsis or use of sepsis toolkits.

Staffing

- North Ormesby Dialysis Clinic worked to a predetermined one nurse to four patient ratio and skill mix was defined by contract and policy agreements with South Tees NHS trust Hospital.
- There were 8.5 whole time equivalent (WTE) registered nurses (RN's). There were 3.6 WTE dialysis assistants (DA's) in post.
- At the time of inspection the clinic had 2.0 WTE dialysis RN vacancies. The turnover in the 12 months prior to inspection was reported as two staff having left the service and two staff recruited. There had also been a one WTE increase in registered nurse establishment in 2016 to cover increases in activity.
- The clinic senior nursing team ensured compliance with staffing ratios through the application of an e-rostering system. In theory this is completed eight weeks in advance by the clinic manager, however we spoke with staff who told us it was prepared four weeks in advance and occasionally changes would be made without their agreement. It was then forwarded to the regional business manager for approval. This advanced planning ensured all shifts are covered for that particular timeline.
- Rotas were further reviewed by the clinic manager on a daily basis to assess staffing levels based on the actual number of patients attending for dialysis and also for any unexpected staff shortages caused for example by sickness and personal issues which were reported by the team as 'on occasion to be unavoidable'. There had been two dialysis nurses on

sick leave and one dialysis assistant over a three month period prior to inspection. At the time of inspection staff were returning to work and shortfalls in the rota had been covered.

- Where staffing levels could not be maintained by using permanent staff employed at North Ormesby, staffing requests would be made to Fresenius Medical Care Renal Flexibank, who would arrange for cover. Where Flexibank could not cover shifts, these were then covered by external nursing agencies (approved Fresenius suppliers). The clinic's usage of dialysis nursing bank and agency staff was reported as 18 bank shifts in a three month period prior to inspection visit and 64 shifts covered by agency staff. Staff we spoke with felt that the agency staff use was high in the clinic, and it was difficult to help support them if needed, especially on twilight shifts if less experienced nurses were on duty. Often the same agency staff returned for numerous shifts and most were therefore familiar with the clinic.
- We noted that substantive clinic staff completed a health and safety training record and performed an employee notification of risk induction with temporary, bank or agency staff, however we did not have assurance that this was completed on all occasions. Handover of patients was given to promote patient safety and continuity of care.
- A fundamental part of the induction of agency staff was that they are provided with key FMC clinical policies and work instructions, which they are provided with and expected to study. The contract arrangements for agency staff clearly state the requirements for training of staff.
- We reviewed three months rota for October, November and December 2016. We noted frequent occasions of changes to staff cover on the paper copy and it was clear that the service had relied on agency nurses to provide the service in full. We noted that the team and especially the clinic manager worked frequent additional shifts or worked long days to ensure cover was provided. It was reported that the senior clinic nurse would regularly work across all three shifts, for example 6am until 11pm and we saw two occasions of this on the rota in February and March.

Dialysis Services

- The clinic did not employ any medical staff. NHS consultant nephrologists were available to review patients at MDT meetings three times a month and as part of individual reviews that could take place outside of these meetings. There was no other medical cover in the clinic.
- All clinic staff we spoke with were aware that the patients NHS consultant was contactable through telephone, e-mail, and through the consultants secretary or hospital pager.

Major incident awareness and training

- We spoke to staff about arrangements for patients if the weather disrupted their ability to attend the clinic for dialysis treatment. Staff gave good examples of when patients appointment times and transport had been rearranged to accommodate being 'snowed in', especially for patients who lived in rural or remote locations. There had been a recent power outage that had been managed well by the team through the supplier with careful rearrangement of dialysis sessions for patients whose treatment had been disrupted.
- Patients records we reviewed had personal emergency evacuation plans (PEEPS) which outlined individual assessment of patients mobility needs if they required emergency evacuation during dialysis.
- A tailored Emergency Preparedness Plan (EPP) was in place for North Ormesby Dialysis Clinic, detailing the plans for the prevention and management of potential emergency situations. All staff were made aware of this plan, and there was a requirement as part of it for training and site evacuation drills for which evidence of completion is maintained within the clinic. The plan included defined roles and responsibilities; contact details for emergency services, public services and utilities, key headquarter personnel, and neighbours. The plan addressed a number of situations that could arise.
- Clinical care was led by NHS consultant nephrologists. The clinic team we spoke with worked in partnership with the trust team and were knowledgeable and aware of the requirement to work in line with the advised UK Renal Association Standards in relation to dialysis quality outcomes and mandatory National Institute for Health and Care Excellence (NICE) renal standards.
- Individualised care pathways and treatment prescriptions were documented for dialysis patients in the clinic on the day of the inspection. These were based on relevant national guidance.
- The senior team described an established International Standards Organisation (ISO) accredited integrated management system (9001) which ensured all policies and procedures support best practice evidence. This worked alongside an annual review requirement which was stated as providing assurance that the evidence base is current.
- Monthly MDT meetings, led by consultant nephrologists, gave opportunity for staff to review all patients' blood results, their progress and general condition with the dietitian and the clinic manager or deputy. All changes to treatment parameters or referrals to other services were coordinated by the clinic manager and reported to the clinical staff for further action. Staff and patients we spoke with told us that their outcomes and changes were discussed by the named nurses and dietitian. Written information could also be provided as standard to ensure the patient has an on-going record of their treatment outcomes.
- The clinic had an audit schedule, which included patient experience, infection prevention and control, hand hygiene, patient documentation and MDT reviews, water treatment plant summaries and treatment variance reports. Nursing staff working in the clinic each had an area of responsibility to carry out the audits, however staff we spoke with told us that the audit results were not shared consistently with staff in meetings. We did not see detailed results of audits in minutes of meetings. Senior staff reported that audit results are displayed behind the nurses station for all staff and also in the area near the patient weighing scales.

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

Evidence-based care and treatment

Dialysis Services

- We saw evidence of patients being offered holiday dialysis at other clinics and it was understood that long term dialysis patients were offered home-based dialysis, although the clinic did not have examples of this at the time of the inspection.
- Dialysis patients at the end of life would receive care and treatment at the NHS trust. Patients' blood results were monitored each month as dictated by the NHS trust consultant; these bloods were individually reviewed monthly to audit the effectiveness of treatment. Action would then be taken as part of treatment.

Pain relief

- Individual pain control needs of patients were informally assessed by nursing staff and paracetamol was routinely prescribed by consultants for patients, however there was no formal assessment of patients pain control needs at the clinic.
- Patients we spoke with did not report any pain or discomfort on the day of inspection.

Nutrition and hydration

- Patients were supplied with regular hot and cold drinks, in reach, at their bedside. Patients were offered biscuits and were able to bring in snacks and food from home if they required. Patients we spoke with were aware of the dietary restriction of their illness and appreciated the support of the team and dietitian.
- We saw evidence of nutritional assessment in the care plans as the malnutrition universal screening tool (MUST) was completed in notes we reviewed. Patients were weighed pre and post dialysis treatment. This procedure contributed to assessment and the overall treatment prescription.
- A dietitian worked flexibly around the needs of patients in the clinic for 60 hours a month as per contract with South Tees NHS trust. We spoke with the dietitian during the unannounced inspection, who told us that they worked flexibly to meet the dietary and nutritional needs of individual patients in the clinic.

Patient outcomes

- Results and treatment data were captured in the clinic database with blood results feeding into the trust

electronic system. Clinic 'live' data was available to the clinic manager and consultant who monitor and audit individual patient performance month on month to identify where improvements and maintenance in achievement of national standards could be made.

- The clinic data management system provided customised reports and trend analysis to monitor and audit patient outcomes and treatment parameters. This highlighted the opportunity to improve outcomes and in turn quality of life. The following outcomes were audited; achievement of quality standards (Renal Association Guidelines), patient observations, dialysis access specific data, treatment variances, infection control interventions and body composition monitoring.
- In addition, each month a report summary for each dialysis clinic was produced for all clinics by the clinic head office as part of a 'balanced scorecard'. The data collected, as part of the Treatment Variance Report (TVR) was monitored and reviewed by clinic staff. This included monitoring or prescribed and delivered treatment times, fistulae and catheter care, admission to hospital and quality standards for monitoring of patients' blood results. Within Fresenius, the dataset was shared monthly with the area head nurse who worked with the clinic manager to address any improvement areas.
- A clinic review process further captured overall month on month clinical effectiveness and improvement areas. As part of the Fresenius 'Clinical Governance Review' and reporting, a report defining the clinics achievement of the Renal Association standards is sent to the NHS trust consultants.
- Submission of clinic data to the UK Renal Registry was undertaken by the NHS trust. The clinic data was combined with the NHS trust data and submitted as one data set. This data set, however only included patients under the direct care and supervision of the trust therefore it would not include those patients undergoing dialysis in satellite clinics.
- As the UK Renal Registry data is representative of all 'parent' NHS trust patients this does not permit the review of patients and outcome trends specifically treated within North Ormesby Dialysis Clinic. Therefore data, specific to the clinic, is available

Dialysis Services

through the clinic database. Senior staff told us that this is used to benchmark patient outcomes both as an individual clinic and nationally against all Fresenius Medical Care UK clinics. We did not have opportunity to review national benchmarked data, clinic staff could not describe the benchmarked position against other similar dialysis clinics.

- It was reported to us that there was a small percentage of patients who refused the prescribed four hours treatment durations. There was also a small percentage of patients who were prescribed less than four hours for example in April 2017, 82% of patients achieved the full 720 minutes of dialysis treatment time, and this included the patients prescribed less than four hours. This was an improvement since reports in November 2016 which showed an underperformance against dialysis adequacy management targets such as, effective weekly treatment times, infusion and blood volume targets.
- The clinic did not monitor travel or waiting times for patients to be assured that they did not wait for treatment after arrival and for transport home after treatment. There were no issues reported from staff and we were told by senior clinic staff that there were no delays. It was reported that if delays occurred for the first patient in treatment, this would be accounted for by delaying the next patients appointment time and transport pick up would be rearranged.
- There had been 27 non attendances in the clinic in 2015/16. These were for a variety of reasons; some patients chose not to attend, also some numbers may have been attributed to hospital in-patient stay, but the clinic was not informed. When patients persistently did not attend staff described that they had changed their appointment times to support appointment attendance.

Competent staff

- We observed a clinically competent and confident team on the day of inspection. Staff we spoke with were experienced dialysis nurses and we observed care and treatment being delivered by a caring and knowledgeable team of nurses and dialysis assistants.
- In the 12 month reporting period prior to inspection 100% of dialysis nurses had received an appraisal and had their professional Nursing and Midwifery Council (NMC) registration checked by the clinic manager. Nurses were supported with revalidation processes.
- We reviewed an inconsistent level of detail in staff appraisal documentation in the five records we checked. We noted some nurse appraisal documentation was very detailed with a range of objectives and others had been performed and written in brief. There was little detail to support evidence of continuous professional development and updated individual objectives, although other evidence of this, certificates for example were in the personnel file.
- In the employee satisfaction survey only 44% of staff stated that their appraisal left them feeling their work is valued by Fresenius, with the same figure reporting that the appraisal identified training, learning and development needs.
- Staff we spoke with described access and support for training. We reviewed five personnel files that gave evidence of a thorough induction program which included emergency procedures, training and supervision of clinical practice and sign off of competence. Each member of staff had training & education file, staff we spoke with told us that there was good access to internal and external study days, and access to the Fresenius learning centre. We reviewed evidence of full competence assessment during staff probationary period for RN's and DA's.
- We noted a 'Training and Education Progression Plan' which outlined a commitment to induction for new staff, it provided an overview of the first year of employment within the clinic defining objectives for the following phases; Supernumerary, probation, supervised practice, consolidation of knowledge and skills and then onto consolidation of managerial practice where appropriate. Staff we spoke with confirmed this arrangement.
- For existing staff the clinic offered ample on-going professional development opportunities for on-going assessment and maintenance of competence which is pivotal to the Nursing and Midwifery Council (NMC) revalidation approach, for example; annual appraisal

Dialysis Services

of competence, appraisal, mandatory and statutory training, access to external training such as accredited renal courses, dialysis specific study days, E-learning and virtual classroom training. There were five registered nurses with a recognised renal qualification, which was over 50% of nurses.

- Staff working on the clinic received six weeks supernumerary period during induction and a six-month preceptorship period allowing time to achieve all the required competencies. Nurses we spoke with told us that supernumerary periods could be increased if the member of staff or mentor felt that this period needed to be longer.
- A mentor was allocated to support junior staff and sign off the competence records. Senior staff and policy stated that working as a mentor was supported to be supernumerary during the induction period.
- Nurses require a mentorship qualification to support student nurses. Staff we spoke with told us that they would be allocated a student nurse to mentor despite not having the qualification.

Multidisciplinary working

- Staff we spoke with during inspection told us that there was good multi-disciplinary team working relationships and commitment to the service amongst the MDT.
- The MDT meetings were held monthly and were well attended by the relevant team members. The NHS renal consultants reviewed all patients attending the clinic.
- The dietitian, who covered the service as part of a service level agreement, we spoke with told us that they visited around three times a week and were present on the day of unannounced inspection.
- Nursing staff we spoke with told us that they liaised with patients GP's and advised them of any changes to patient treatment.
- Patients that were referred from South Tees NHS trust were referred with a full medical history, personal details and blood results. Staff in the clinic would

contact the person initially by phone to prepare them for their first visit. The clinic manager told us that they had introduced in 2016 these specific appointments for pre-dialysis patients to visit the clinic.

Access to information

- The Fresenius Medical Care patient treatment database EuCliD automatically transferred patient data into the James Cook University Hospital South Tees NHS trust clinical database system PROTON. Staff we spoke with described this process as working well.
- The service was able to offer dialysis to patients from out of area who may be on holiday. Arrangements for referrals are through Fresenius head office or through the patient's own clinic to the dialysis clinic. The clinic manager provisionally allocates dialysis availability subject to receiving completed documentation and medical approval and acceptance. An Incoming Holiday Patient Form (UK-CR-03-40) is used to ensure all relevant information is gathered relating to the holiday patient, to reduce risks to all patients e.g. isolation requirements.
- We spoke with the dietitian who told us that the paper records were stored securely. The team used a consistent document template across the clinic and NHS trust. They had access to EuCliD and PROTON.
- The clinic manager ensured all clinic letters were signed by named nurses and the dietitian. Staff we spoke with told us that named nurses would contact the GP services by telephone if they felt the patient needed to be referred for extra care such as, chiropody, or wound dressing clinics.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- 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 and this was clear in the Fresenius consent policy.
- We reviewed eight patient consent to dialysis forms and noted all to be accurate. There was policy and

Dialysis Services

systems in place to gain consent and review consent from people using the service. We observed staff asking for informal consent prior to giving care and treatment.

- One hundred percent of staff had received Mental Capacity Act (2005) training, and Deprivation of Liberty (DoLS) training (both attended 3 yearly). At the time of inspection all patients attending the clinic for dialysis had capacity to make decisions in relation to treatment and care. Staff we spoke with did not describe clearly the application of the MCA or DoLS in practice.

Are dialysis services caring?

Compassionate care

- We observed a caring and compassionate approach by the nursing staff during inspection.
- Patients had access to a nurse call system and staff were careful to place the handset to the side not connected to the dialysis machine, this ensured patients were able to call for help if they required. During the inspection, we saw that staff answered patients' needs promptly, including alarms on dialysis machines. The staff assisted patients with warmth and compassion and gave reassurance where needed.
- The privacy and dignity of patients was prioritised. The curtain and screen system and space around the bed spaces was more than was needed to ensure conversations were not overheard and patients had privacy.
- We spoke with patients who told us that 'staff were fantastic', and 'would go out of their way to help with anything.' Of 26 'tell us about your care' cards, there were 17 positive responses with comments, 'the staff are very caring and helpful and always make time to explain anything I may be unsure of', 'all staff are first class and prepared to go that extra bit, from reception to cleaner to nurses, hygiene is excellent, care is first class, any problems staff will discuss with you'.
- The clinic had consultation rooms where patients could have confidential discussions about their care with any members of the multidisciplinary team should they so wish.

Understanding and involvement of patients and those close to them

- We observed the use of a named nurse approach and nurses had a caseload of patients and built relationships over a long period of time. This fostered familiar yet professional communication between patients and staff in the clinic. The named nurse was responsible for ensuring patients had updates about their treatment plans and blood results after the monthly MDT meeting or at any other review by consultant staff.
- Patients who were new referrals to the clinic were invited to a pre-assessment clinic led by the consultant and also attended by the clinic nurse and dietitian. These were held twice a month and gave patients opportunity to see the environment and ask questions about treatment that would alleviate any anxieties about planned treatment. Patients were given written information about dialysis and treatment. To date 63 patients had attended the clinics since starting in 2016.
- Staff told us that patients were encouraged to be as involved in treatment as possible. There was a comprehensive Fresenius Medical Care, 'patient and carer shared and self-care training checklist' which guided three supervised assessments by a nurse with the patient of each step of treatment. It included clear consent and sign off of understanding in the document. We did not review any patients using the shared care process during the inspection but observed patients being offered opportunities to be involved in their care such as, removing needles after treatment and self-weighing prior to treatment
- We spoke with a patient who had been an inpatient in the local NHS trust after emergency surgery. Care and support was described as being very good and all arrangements and changes to support dialysis treatment had been explained at each stage of recovery, including the return to clinic for dialysis treatment.
- The clinic collected 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. There had been no leaflets sent to the Chief Nurse from the clinic.

Dialysis Services

Emotional support

- Staff we spoke with were aware of how to access additional support for patients and liaised in partnership with the consultant nephrologist and a social worker allocated to the renal unit at South Tees NHS trust, who arranged for the relevant support for patients.
- We spoke with staff who gave examples of when they had taken patients individual needs into account and had contacted a patients GP to help plan and support circumstances at home with the patients partner who had become unwell. This situation had an impact on the patients general wellbeing and staff had been concerned. The circumstances had said to improve after the interventions of the nurse.
- Care plans, and care pathways were individualised in detail with assessment of patients emotional, social, cultural, spiritual, psychological and physical needs. It was clear that nurses took opportunity to keep patients informed about their care, involving them and their families in decisions and ensuring that they have the opportunity to participate in their own care.

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

Service planning and delivery to meet the needs of local people

- Patients are referred for haemodialysis treatment from South Tees NHS trust renal unit and consultant nephrologist team. The priority is to ensure that they are assessed as physically well enough for satellite treatment and also live in the local area. Patient treatment was established at the NHS trust renal unit and they then referred to the local satellite clinic, with close liaison across the service and team. The clinic provided a flexible service to local people.
- Fresenius Medical Care and North Ormesby Dialysis Clinic were commissioned by the local clinical commissioning group (CCG) and contracted by South Tees NHS trust to provide satellite dialysis as part of a

defined specification. Senior clinic staff attended business and clinical meetings at the trust to manage the achievement of contract obligations and key performance indicators

Access and flow

- Referrals for admission were directed by the consultant nephrologist team at South Tees NHS trust Renal Unit who would contact the clinic, usually the clinic manager, to inform the team in North Ormesby Dialysis Clinic that had new patients for admission.
- There was no waiting list for treatment at the clinic and staff we spoke with said that this was consistent.
- North Ormesby Dialysis Clinic had an established appointment system, which promoted structure, timeliness and minimised delays. Staff we spoke with told us that they facilitated a flexible approach to the patient's dialysis sessions and would change the day of patients dialysis, and/or times as far as possible to accommodate external commitments and appointments or social events the patients may have. If necessary a dialysis session would be relocated to South Tees NHS trust renal unit. Staff and patients we spoke with gave us evidence that the patients' needs were always central to any decisions made.
- The utilisation of capacity in the clinic in the 3 month reporting period was as follows: November 91%, December 92% and January 88%. The clinic did not cancel any treatments for people. There was a three shift system over a six day week, Monday to Saturday.
- The clinic had opened the two additional bed spaces on twilight shifts to accommodate patient referrals made by the trust. The clinic had been commissioned to have 16 open beds during twilight shifts and it was reported and observed that 18 had been opened by the clinic manager, which in 2016 had put pressure on staff resources prior to the appointment of additional staff.
- There had been 104 patient transfers to the NHS trust renal unit. Staff we spoke with told us that the transfers were all unavoidable as all patients had required consultant assessment. We noted details of transfers, collated by the clinic manager and evidence of discussion in governance meetings with the trust MDT.

Dialysis Services

- Access to the clinic was good, as part of the North Ormesby Medical Village the car parking was convenient and safe during the day. The village staff would close security gates after 11.30pm and staff described concerns about occasions where they had not been able to leave the complex at the end of the twilight shift, if a patient session had run over. The senior manager reported that after contacting the company responsible for the gate security there had been no repeat incidents. We did not see this issue in the clinic risk register, or any incident reporting.

Meeting people's individual needs

- Staff encouraged and supported patients to arrange dialysis away from base and welcomed patients to the clinic for temporary holiday treatment providing medical approval was given and all pre-assessment checks had been made, in addition to having dialysis session availability.
- We observed good access to facilities in the clinic, which was spacious and modern in design with good provision for people with individual needs. We observed wheelchair users being supported with access to treatment and facilities.
- Patients had access to Wi-Fi, personal televisions in each bed space and reading materials of their choice. Patients were supported to bring anything in from home to alleviate any boredom during their dialysis treatment session.
- North Ormesby Dialysis Clinic provides haemodialysis treatment to patients by following an individualised treatment prescription. Changes to prescriptions are made during multi-disciplinary meetings. The outcome of the meetings and changes to care are discussed with the patients and provide a responsive approach.
- Patient information was available in four main languages but staff we spoke with said they were able to obtain information in other languages or larger print if required. Access to interpreter services was made through South Tees NHS trust switchboard and staff we spoke with knew how to access when needed.
- The clinic had an acceptance criteria and policy which was designed to be open and inclusive, accepting patients over 18 years, had functioning haemodialysis

vascular access, were clinically stable for satellite treatment and had medical approval. Staff requested these details as part of pre-transfer assessment to ensure all care needs could be met and transfer to the clinic was safe with full communication with the patient and carer or family.

- Patients did visit the clinic as part of the pre-assessment clinic prior to commencement of treatment to familiarise themselves with facilities, staff and routine.
- Senior and junior nursing staff we spoke with told us that the patient would be allocated a dedicated dialysis appointment time which considers: Social care and work commitments, day appointment availability for the elderly, vulnerable or those with more complex care needs, length of journey to the clinic and number of hours or days of dialysis the patient was prescribed as part of their care plan.
- Staff we spoke with told us they had adapted simple communication tools for patients who could not express themselves verbally, such as alphabet cards.

Learning from complaints and concerns

- The clinic received 11 written compliments and one formal complaint in 2016/17. The complaint was managed formally under the complaints procedure, timescales for responses were met and upheld. It highlighted issues around the temperature of the clinic and that the main clinic area was too cold. Dialysis patients may be susceptible to cold. Actions involved the clinic manager reporting with the human resources business partner and all clinic staff to agree that the air conditioning system would not go below 21 degrees.
- Two further complaints were made at the time of inspection, and the issue was reported in the patient satisfaction survey, about the clinic being cold, indicating that this is not successfully resolved to provide patients with the comfort that they need during four hour dialysis treatments.
- There was a clear process and complaints policy. The team recognised that lessons for continuous quality improvement for people using the service may develop as a direct result of concerns or complaints. The approach was said to mirror the NHS approach. Seventy five percent of patients responded that they felt complaints were taken seriously.

Dialysis Services

- The Fresenius complaints process was displayed in the waiting area. The patient advice and liaison service (PALS) at the NHS trust had produced leaflets and posters to guide patients about the complaint process and these were visible in the reception area.

Are dialysis services well-led?

Leadership and culture of service

- There was a clear leadership structure in the Fresenius Medical Care organisation and that was applied regionally to the North Ormesby Dialysis Clinic. Local leadership was reflected in a regional business manager position and an area head nurse, who would be clinic based approximately once or twice a week. The clinic manager was based in the clinic for 100% of the nursing job role, with the exception of duties performed across South Tees NHS trust. There was a deputy manager and two team leaders in senior positions in the clinic. Senior staff were present during inspection. The clinic manager was also present during the unannounced inspection.
- Morale amongst nurses was described to be low. A culture of blame was said to exist in the clinic if staff made any mistakes, which did not contribute to an open reporting culture. After the inspection senior staff responded to us that the team had met with the Fresenius Medical Care Human Resources business partner to give staff opportunity to discuss concerns. They expressed that staff had left the meeting with all parties 'feeling positive'. Concerns were reported to inspectors from nursing staff about the behaviours of senior clinic nursing staff, staff reported that they had witnessed behaviours that were described as unprofessional and intimidating, to include shouting in the clinic, in front of patients and staff.
- Staff responses to questions around leadership visibility and involvement with day-to-day activity of the clinic were that they did not always feel supported by management, and were less confident about support from higher management.
- The clinic senior management team said they held regular team meetings, staff we spoke with said these were inconsistent. Meeting minutes we reviewed which spanned 2016/17 confirmed some of the issues expressed at the time of inspection. A small number of the employee survey results were discussed. The minutes of the meeting did not reflect a collaborative open discussion, that could have contributed to a meaningful staff survey action plan.
- Eleven staff responded to the 2016/17 employee satisfaction survey. Only a small selection of results were raised in the team meeting and none were disclosed to inspectors by senior staff during interviews. In 2016/17, 91% of staff reported that they felt unwell in the last 12 months as a result of work related stress.
- Staff described their peers in a positive way and spoke about them supporting each other. We observed good working relationships and professionalism in the clinic amongst the nursing staff.
- We spoke with senior staff who told us that they supported staff at times when the clinic was busy or short staffed. The Area Head Nurse had been visible in the unit during a six week period where the clinic manager was absent to provide additional support to the team.
- Consultant and dietetic staff from South Tees NHS trust described professional and positive working relationships with the clinic manager and the team at North Ormesby Dialysis Clinic. No concerns were raised about leadership or patient safety.

Vision and strategy for this this core service

- Fresenius Medical UK in partnership with South Tees NHS trust renal unit had a clear vision and strategy with quality and safety at the top of its priority. It was expected that this was cascaded to the local team at North Ormesby through business and clinical meetings, and staff training and updates. 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 senior team at regional and local level were aware of the strategy and values for achieving priorities and delivering good quality care, however staff we spoke with in the clinic did not have a clear understanding.

Dialysis Services

There was no consistent approach to communicating or display of the values and strategy, and a lack of opportunity taken in team meetings in the clinic to discuss.

- The business strategy meeting was well attended at South Tees NHS trust and the clinic manager was involved in monitoring progress in delivering the strategy. The use of dashboards had been recently introduced for monitoring of performance and had not been embedded into practice or cascaded to all staff.

Governance, risk management and quality measurement

- The clinic had a newly developed risk register, which appeared comprehensive and a much improved approach. This was part of a process that was being developed at a corporate level in Fresenius Medical Care UK. We reviewed comprehensive risk assessments that were complete and in date and thorough. The risk assessments reflected most risks and issues at the clinic. Senior staff we spoke with did not have an understanding of the risk register as it was still under development.
- The clinical risk management policy was detailed about risk management principles and risk assessment processes, however there was no evidence in the policy to suggest that there was a corporate or local risk register.
- The clinic local meeting was inconsistent and the agenda and content did not support governance of risk and quality at a local level with the nursing team. The meeting focussed on tasks or duties to be allocated, it briefly directed business around infection control, health and safety and environmental issues.
- There was a nominated consultant nephrologist clinical lead for North Ormesby Dialysis Clinic from South Tees NHS trust. The team met quarterly to review clinic performance against key performance indicators (KPI's), we reviewed one set of KPI's from November 2016 which gave good detail of both achievements and areas of underperformance. The meeting was attended by the regional business manager, area head nurse and clinic manager, along with key trust staff.

- There was a clinical governance committee as part of the Fresenius Medical Care group strategy. The clinic manager was responsible for monitoring and leading on delivering effective governance and quality monitoring in the dialysis clinic, supported by the wider Fresenius management team. Data was collected by the clinic manager and reported monthly to the trust team where it was input to the UK renal registry. It was through this process and shared meetings that validation of audit results and benchmarking occurred
- 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 of black and minority ethnic population (BME).
- WRES has been part of the NHS standard contract, since 2015. NHS England indicates independent healthcare locations whose annual income for the year is at least £200,000 should have a WRES report. This means the unit should publish data to show they monitor and assure staff equality by having an action plan to address any data gaps in the future.

Public and staff engagement

- Fresenius Medical Care performs both an annual patient and employee satisfaction survey which has also been reviewed by the Fresenius patient group, which is a patient representative group set up by the service. In 2015/16, results and action plans gave evidence of 90% of patients would be likely to recommend the clinic to friends and family in need of dialysis and 95% of patients were satisfied with the nursing staff. In 2016/17 results were comparable with 88% of patients likely to recommend the clinic to friends and family in need of dialysis and 93% of patients were satisfied with the nursing staff.
- Fresenius performed annual patient and employee satisfaction surveys. Senior staff reported that these resulted in actions being implemented in order to continuously improve. We did not see any clear evidence of completed actions from 2015 or 2016 reports.

Dialysis Services

- The 2015 patient and staff survey action plans were available for staff to review progress in the staff room of the dialysis clinic. However the results from the 2016 staff survey were not displayed and were significantly worse in some areas of concern expressed clearly by staff.
- The 2016 staff survey results showed an overall poor satisfaction response in all questions related to feeling supported by line management, or feeling stressed about work or feeling valued. Higher scores were mostly associated to patient care and staff feeling that they were providing high quality care and doing their job well. Results were slightly lower than comparable NHS results, for example 64% of Fresenius staff would recommend the unit, against 69% in the NHS.
- Patients expressed in the 2016/17 survey that improvements could be made with attending to their comfort during treatment (69%), the level of information given to patients could be improved especially on induction (63%), and only 75% of patients felt that any concerns or complaints were taken seriously. In contrast 98% of patients felt confidentiality was respected and the clinic was a happy friendly place. The survey also indicated that patients felt that staff were helpful and explained treatment and patients did respond that they felt safe during dialysis. One concern from feedback taken from comments cards was around issues with patient confidentiality. Another patient recognised that staff 'often worked short staffed'. Only 75% of patients felt that dialysis started on time and 73% of patients did not know how to raise a complaint as well as feeling that complaints were taken seriously.
- Of 26 comments cards we received back from patients on the day of inspection, 17 were positive, however nine patients expressed complaints with examples such as;
 1. A patient who had recently been referred to the clinic stated that they had been cared for by a different nurse at each visit, and stated it would be nice to be treated by regular nurses so they could get to know one another
 2. Two patients complained about TV access, although it seems to be satisfactory during the inspection at each bed space.
 3. Two responses detailed that the clinic was too cold and had been told by staff that 'they get too warm.' The response further expressed that they thought the temperature in clinic was for patients benefit and not the nursing staff. The same patient expressed that the 'chairs were too hard after four hours' we did not see any use of pressure relieving mattresses in the clinic during inspection.

Innovation, improvement and sustainability

- The consultant nephrologist told us that the clinic would be included in clinical research trials, based at the NHS trust in 2017.
- Pre-assessment clinics had been introduced in 2016 and were noted to be working well for patients with chronic kidney disease attending the clinic for the first time for dialysis treatment.
- We observed evidence of regular resuscitation simulation training sessions that were provided by Fresenius staff in the clinic.
- One nurse working on the clinic had been recently been awarded 'the most popular nurse with patients' voted by dialysis patients from the North East region.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- Ensure that incident reporting is clearly graded for severity of harm to support the application of the duty of candour regulation.
- Ensure clinic staff have access to a nominated safeguarding lead with level 4 training at a provider level in the organisation.

Action the provider **SHOULD** take to improve

- Ensure staff in the clinic have support from the senior team and review behaviours which impact on morale and culture within the unit. Effective action must be taken to respond to concerns and feedback from staff.
- Ensure that the plans for implementation of the new risk register are carried out and this system is embedded to reflect the local and organisational risks. The Fresenius risk management policy should be updated to reflect the introduction of a risk register.
- Implement a system to ensure staff positively identify patients prior to them receiving treatment and medicines to reduce the risk of patient harm.
- Implement a recognised early warning score system to support the recognition of the deteriorating patient. Consider the value and implementation of sepsis toolkits in line with national guidance.

- Nurse staffing levels should be managed safely and consistently as per policy. Nurse to patient ratio should meet four to one on all three shift patterns across the day and the skill mix on the twilight shift should be as consistent as during the day shifts. The use of agency staff should continue to be monitored.
- Implement a system for reporting of pain assessment for patients.
- Undertake audit of travel and waiting times for patients as a way of assuring that quality of the service provided was achieved.
- Ensure staff are supported through effective appraisal, development, supervision and support.
- Patient concerns and complaints should be taken seriously with an appropriate level of action, for example the temperature of the clinic and warmth and comfort of patients who were immobilised whilst receiving treatment for over four hours. Action plans from the patient survey must be detailed and meaningful with timescales and responsibilities allocated and communicated across the team.
- Implement the policy for workforce and race equality standards (WRES) at a clinic level.

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

Treatment of disease, disorder or injury

Regulation

Regulation 20 HSCA (RA) Regulations 2014 Duty of candour

20 (1) A health service body must act in an open and transparent way with service users in carrying on a regulated activity. (7)

How the regulation was not being met:

There was no grading of 'moderate' harm in incident reporting systems and policy. This means that the duty of candour would not be triggered for moderate harm that requires (a) a moderate increase in treatment, and (b) significant but not permanent harm.

Regulated activity

Treatment of disease, disorder or injury

Regulation

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

How the regulation was not being met

There was not a member of staff who had received training in safeguarding at level 4 for the team to contact for advice and escalation of safeguarding concerns within the organisation.