North Devon Satellite Dialysis Unit

Quality Report

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

Summary of findings

Letter from the Chief Inspector of Hospitals

North Devon Satellite Dialysis Unit is operated by Fresenius Medical Care and opened in November 2016.The service has 16 dialysis stations. This includes 12 stations containing either a bed or a chair and four side rooms. The unit can operate 32 sessions daily. The service is open six days a week and can operate 192 sessions weekly. The unit had a caseload of 52 patients at the time of our inspection. The service also accepts patients for dialysis who holiday in the region. The Royal Devon and Exeter NHS trust commissions the haemodialysis services provided by North Devon Satellite Dialysis Unit.

The service is a nurse led unit which provides outpatient satellite dialysis provision to patients.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 5 July 2017, along with an unannounced visit to the unit on 10 July 2017.

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

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

Services we do not rate

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

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

- There was no evidence of learning from the serious incident or actions taken to ensure this did not occur again at the unit.
- Staff did not receive feedback from incidents they reported.
- Not all staff were compliant with the mandatory training course infection, prevention and control.
- There was no assurance that actions regarding patient care and treatment were completed following the quality assurance meeting.
- There was not an appropriate policy and specific staff training for the early identification of sepsis (infection) in line with national guidance (NHS England, 2015).
- Nurses at the unit were transcribing the patient's dialysis prescription which was not in line with guidance from the Nursing and Midwifery Council (NMC, 2015).
- Non-tamper evident anaphylaxis medicine was stored on the resuscitation trolley.
- Some staff were not compliant with infection prevention and control policies and procedures and the unit was not meeting organisational compliance targets for hand hygiene audits.
- There was no assurance specific actions following the outcome of the documentation audit completed by the individual nurse responsible.
- Clinical staff we spoke with did not know which patients had a Do Not Attempt Cardio Pulmonary Resuscitation (DNACPR) in place and there was no system to ensure staff could access this information easily in an emergency situation.
- Staff were not compliant with the Department of Health document Confidentiality: NHS Code of Practice (2003) and were sharing login and password details to access patients full record from the local acute NHS trust.
- There was no evidence of compliance with the Workforce Race Equality Standard (WRES) which became mandatory in April 2015.

Summary of findings

- Staff lacked understanding regarding best practice for end of life care, when this might be appropriate to discuss with medical staff and how staff could best support patients.
- There was no assurance the risk register was monitored, regularly reviewed and a named person had ownership of the actions. The risk register was not a live document and did not have some local risks on it aligned to the unit. For example, hand hygiene and lack of compliance with organisational targets and recruitment.
- There was not an effective communication process to ensure in the provision of quality and risk information to the staff
- The audit schedule did not identify how actions following audits were to be carried out and who would oversee their implementation.

We found the following areas of good practice:

- The unit met and also exceeded the requirements of the Department of Health: Health Building notes 07-01 (2013).
- The unit had clear processes to ensure regular servicing and maintenance of equipment.
- There were policies and procedures to follow in case of a power failure or disturbance with the water supply during a dialysis session.
- Evidence based practice and the renal association guidelines were used to develop how patient care and treatment was delivered. Patient outcomes were monitored against best practice guidelines.
- The unit monitored patient outcomes and presented these to the local acute NHS trust on a monthly basis for review and discussion.
- There was a comprehensive training programme to ensure new nurses were competent to carry out their role at the haemodialysis unit. Staff were supported to develop their knowledge and skills.
- There was good multidisciplinary working and strong communication links with the lead consultant and the local NHS trust.
- Informed consent was sought and documented prior to commencing treatment.
- Patients were treated with dignity, compassion and respect and staff interacted with patients in a considerate and respectful manner.
- Staff took the time to interact with patients, and patients found staff to be supportive.
- Patients' privacy and dignity was respected in all aspects of care.
- Staff understood the importance of involving close family when they had concerns as partners in patients care.
- Staff understood the impact of the treatment on patients' emotional wellbeing and actively supported patients. This had been much appreciated by patients.
- Services were planned and delivered to meet individual patient needs and aimed to improve patients' quality of life.
- Patients had flexibility and choice as to when they could attend their dialysis session.
- Patients had access to entertainment during their haemodialysis session.
- There was a system to monitor and deal with complaints. There had been three complaints (two formal and one informal) made at the unit since January 2017.
- The clinic manager and senior management team understood the challenges to good quality care and were able to identify actions to address them.
- The clinic manager was visible, supportive and approachable.
- The unit had an initiative for succession planning, to ensure the unit maintained the right skill mix of nurses in the future and was able to promote from within.

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

Edward Baker
Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Dialysis Services		We regulate this service but we do not currently have a legal duty to rate it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

Summary of findings

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Background to North Devon Satellite Dialysis Unit

North Devon Satellite Dialysis Unit is operated by Fresenius Medical Care. The service opened in November 2016. It is an independent healthcare unit in Barnstaple, North Devon, providing haemodialysis services for the community of Barnstaple, on behalf of the Royal Devon and Exeter NHS trust. The unit also accepts patient referrals from outside this area for holiday dialysis.

The unit has had a registered manager in post since 2016.

We inspected North Devon Satellite Dialysis Unit on 5 July 2017 and carried out an unannounced visit on 10 July 2017. There had been no previous inspections at the unit.

Our inspection team

The team that inspected the service comprised a CQC lead inspector,Stephanie Duncalf and one other CQC inspector.The inspection team was overseen by Catherine Campbell, Inspection Manager and Mary Cridge, Head of Hospital Inspection.

Information about North Devon Satellite Dialysis Unit

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

- Treatment of disease, disorder and injury.

During the inspection, we visited North Devon Satellite Dialysis Unit. We spoke with 10 staff including registered nurses, dialysis assistants and healthcare assistants and we spoke with 10 patients. During our inspection we reviewed 10 sets of patient records. We also received 25 comment cards from patients telling us about their care.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the nine months before this inspection. The service had not previously been inspected.

The local acute NHS trust commissioned the services for the provision of outpatient satellite haemodialysis to patients.

- Activity (November 2016 to May 2017). In the reporting period November 2016 to May 2017, the unit carried out 2523 haemodialysis sessions. This figure also included haemodialysis sessions for holidaymakers in the area.
- The unit provided haemodialysis for both adult male and female patients from 18 to 65+ years of age. The unit opened six days weekly and could carry out 32 haemodialysis sessions daily, accommodating two sessions in the morning and two sessions in the afternoon.

The unit is nurse led and employed five full time registered nurses and eight health care assistants, working both full time and part time contracts. The unit also had its own bank staff and a consultant nephrologist providing medical support from a local acute NHS trust.

Track record on safety

There had been:

- No never events reported at the unit
- One serious incident
- Zero incidences of hospital associated methicillin-resistant Staphylococcus aureus (MRSA),
- One incidence of hospital associated methicillin-sensitive Staphylococcus aureus (MSSA)
- Three complaints made about the unit. Two formal written complaints and one informal verbal complaint.

Services accredited by a national body:

Summary of this inspection

- ISO 9001 Quality Management System in process of working towards the accreditation.
- ISO-14001 Environmental Management System Programme accreditation in May 2017.

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal
- Maintenance of medical equipment
- Pharmacy
- Dietetics
- Social worker
- Medical cover

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

Are services safe?

We found the following areas where the service provider needs to improve:

- There was no evidence of learning from the serious incident or actions taken to ensure this did not occur again at the unit.
- Staff did not receive feedback from incidents they reported.
- Only one member of staff was compliant with the mandatory training course infection, prevention and control.
- Staff did not always adhere to infection prevention and control policies and procedures with regards to the use of personal protective equipment.
- The unit had not been compliant with organisational targets for hand hygiene audits.
- Nurses at the unit were transcribing the patient's dialysis prescription which was not in line with guidance from the Nursing and Midwifery Council (NMC, 2015).
- Non-tamper evident anaphylaxis medicine was stored on the resuscitation trolley.
- There was no assurance actions from the monthly quality assurance meeting had been carried out.
- Documentation audit outcomes lacked assurance that staff had acted on the issues identified in the audit process.
- There was no policy, standard operating procedure or specific staff training to promote the early identification of sepsis (infection) in line with national guidance (NHS England, 2015).
- Clinical staff we spoke with did not know which patients had a Do Not Attempt Cardio Pulmonary Resuscitation (DNACPR) in place or have easy access to this information in an emergency.

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

- The unit met and also exceeded the requirements of the Department of Health: Health Building Notes: Planning and Design 07-01 (2013).
- The unit had clear processes to ensure regular servicing and maintenance of equipment.
- There were policies and procedures to follow in case of a power failure or disturbance with the water supply during a dialysis session.

Summary of this inspection

Are services effective?

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

We found the following areas of good practice:

- Evidence based practice and the Renal Association guidelines were used to develop how care and treatment was delivered. Patient outcomes were monitored against best practice guidelines.
- The unit monitored patient outcomes and presented these to the local acute NHS trust on a monthly basis for review and discussion.
- There was a comprehensive training programme to ensure new nurses were competent to carry out their role at the haemodialysis unit. Staff were supported to develop their knowledge and skills.
- There was good multidisciplinary working and strong communication links with the lead consultant and the local NHS trust.
- Informed consent was sought and documented prior to commencing treatment.

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

- There was no awareness of, and staff were not compliant with the Department of Health document Confidentiality: NHS Code of Practice (2003) as they were sharing login and password details to access patient's full record from the local acute NHS trust.
- The service did not follow national guidance and recommendations for patients with chronic kidney disease approaching end of life (Department of Health, 2009).
- There was no evidence of compliance with the Workforce Race Equality Standard (WRES) which became mandatory in April 2015.

Are services caring?

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

We found the following areas of good practice:

- Patients were treated with dignity, compassion and respect and staff interacted with patients in a considerate and respectful manner.
- Staff took the time to interact with patients and patients found staff to be supportive.
- Patients' privacy and dignity was respected in all aspects of care.

Summary of this inspection

- Staff understood the importance of involving close family when they had concerns as partners in patients care.
- Staff understood the impact of the treatment on patient's emotional wellbeing and actively supported patients. This had been much appreciated by the patients.

Are services responsive?

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

We found the following areas of good practice:

- Services were planned and delivered to meet individual patient needs and aimed to improve patients' quality of life.
- Patients had flexibility and choice as to when they could attend their dialysis session.
- Patients had access to entertainment during their haemodialysis session.
- Patients were supported to arrange haemodialysis at their holiday destination.
- There was a system to monitor and deal with complaints. There had been three complaints made at the unit since January 2017.

Are services well-led?

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

We found the following areas where the service needed to improve:

- The governance framework did not demonstrate how operational performance was cascaded down to staff and how actions from audits were executed to demonstrate improvements in performance and quality of care for patients.
- There were missed opportunities to identify learning from serious incidents and implementation of actions to ensure there was no reoccurrence of the event.
- The risk register was not a live document and did not provide assurance that risks were being regularly monitored and reviewed. The risk register did not include local risks to the unit such as the lack of compliance with the organisations target for hand hygiene or the challenges around recruitment of staff.
- The audit programme did not identify how actions and learning were overseen and implemented following audit results.

However

- The clinic manager and senior management team understood the challenges to good quality care and were able to identify actions to address them.
- The clinic manager was visible, supportive and approachable.

Summary of this inspection

- The unit had an initiative for succession planning, to ensure the unit maintained the right skill mix of nurses in the future and was able to promote from within.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Safe means the services protect you from abuse and avoidable harm. 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.

Incidents

- There had been no never events at the North Devon Satellite Dialysis Unit between November 2016 and June 2017. Never events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.
- There had been one serious incident at the North Devon Satellite Dialysis Unit between November 2016 and June 2017. Serious incidents can be identified as anincident where one or more patients, staff members, visitors or member of the public experienceseriousor permanent harm, alleged abuse or a service provision is threatened. The serious incident occurred when a patient fell and sustained a fracture whilst on the unit.
- We saw the investigation report and actions following this serious incident. The incident report only identified two immediate actions had taken place following the incident and did not identify any learning to ensure the incident did not occur at the unit again. Immediate actions included, a review of the patient's moving and handling plan their personal emergency evacuation plan. However, in the duty of candour letter written to the patient, the letter detailed several other immediate actions which had taken place. These included a review appointment with the lead consultant and a review by the vascular team as the fracture sustained was close to the patient's fistula. Information about the incident was provided to the staff via the daily safety huddle. There was a missed opportunity for wider learning for the unit. There was no evidence the incident had been scrutinised to identify wider learning and possible changes to practice at the unit to ensure this incident did not occur again.
- Staff were aware of their responsibilities to raise concerns, record safety incidents and near misses and report them internally. There was a policy and system in place to report incidents which was available to staff and outlined the procedure for reporting incidents. Staff provided us with examples of incidents and near misses they would report.
- There was an incident reporting policy and an electronic system in place to report incidents. Staff were familiar with how to report and incident. There had been three clinical incidents between January and June 2017. The included a venous needle dislodgement, a bacteraemia infection and bleeding from a central venous catheter.
- Clinical incident reports were reviewed by the area head nurse and then by the chief nurse to review the actions and learning. Their response to the clinical incident and actions was also documented on the clinical incident form. The form included a section for learning identified following the incident. The incident was then discussed by the senior management at the quarterly clinical governance meeting. Action plans following clinical incident reports required the name of the person responsible for ensuring actions were carried out and progress against actions was reviewed following the incident. Once actions had been completed, the clinical incident was closed.
- The unit reported on performance measures and treatment variance. Treatment variances were not incidents, but aspects of care and treatment, which could be controlled by the nurses at the unit, for example poor line flow, hypotension (low blood pressure) and short sessions. Between January and

June 2017, there had been 240 episodes of treatment variance managed by the staff at the unit during a haemodialysis treatment. For example, the most common treatment variance was procedure variances which accounted for 54 of the treatment variance reports, 31 were due to hypotension, 25 were due to needling and 27 were due to clotting problems.

- Nurses completed a treatment variance form, following each haemodialysis session, which was electronically stored on the Fresenius Medical Care reporting system. Treatment variance forms contained the clinical issue and the mitigating actions put in place by the nurses of the unit to mitigate the risk to the patient. These remained open on the system until the patient attended their next session. The nurse looking after the patient at the next session had to acknowledge the treatment variance and comment if any further actions were required. Treatment variance reports remained open until all actions had been completed and the patient was no longer at risk. There was no requirement for the clinic manager to review all treatment variance reports to ensure the actions taken were appropriate. The manager told us there would not be enough time to review each report, but if a member of staff felt the issue required escalating then the report would be reviewed. Treatment variance reports were made available to the lead consultant for review during the monthly quality assurance meeting.
- Staff did not receive individual feedback on incidents they had reported. Staff were unable to provide us with any feedback following incidents. There was also no evidence in the staff meetings minutes to demonstrate that incidents or shared learning from treatment variances incidents had been discussed.
- There was evidence of service wide learning from incidents to drive improvements in practice. We observed feedback to staff in the daily safety briefing, and noted that different equipment was being used in practice to prevent bleeding at patients central line site. This issue had been reported across Fresenius Medical Care units. Staff we spoke with told us about these improvements. Staff were able to tell us about the changes to practice following this incident trend.
- The unit received and acted upon relevant safety alerts from the Medicines and Healthcare Products Regulatory Agency. The clinic manager received any safety alerts and if information was relevant to the North Devon unit, the manager would implement any action as recommended by the alert. There had been no requirement for any action to be taken following any alerts since the opening of the unit in November 2016.
- Staff demonstrated an understanding of their duty of candour responsibilities. Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 was introduced in November 2014. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. This regulation requires staff to be open, transparent and candid with patients and relatives when things go wrong. Staff were aware of the thresholds for when the duty of candour process was triggered. There was a Fresenius Medical Care policy relating to duty of candour, which outlined actions to be taken when something went wrong and was also described in the clinical incident policy.
- We observed a completed letter to a patient following a serious incident in line with the organisations policy around duty of candour. The letter included an apology and also included the actions taken following the event to ensure the safety of the patient.

Mandatory training

- Staff completed mandatory training in safety systems, processes and practices annually. Training was divided into categories such as emergency training, nursing skills and reassessment of competencies. Mandatory training included fire training, manual handling, food safety, infection control and health and safety. The safety training also included prevention of healthcare associated infections, sharps management, waste management, medicines management, records management, risk assessment, planned preventative maintenance, incident reporting, accidents and near misses, root cause analysis and management of emergencies and information governance.
- Mandatory training was a combination of classroom and e-learning modules carried out either annually, two or three yearly. All 11 staff were issued with a training matrix which outlined what training was required and how often. At the time of our inspection three members of staff were off on long term sickness. Training records

were maintained centrally and a record was also held by the clinic manager. This ensured oversight of mandatory training to ensure all staff remained up to date and could safely carry out their role at the unit.

- Basic life support training was undertaken yearly to ensure staff were competent to deal with emergencies at the unit. Every year staff would complete an e-learning training module in basic life support and automated external defibrillator training to ensure they understood their role and responsibilities, in the event of an emergency situation. There was 90% compliance with basic life support training at the unit. The member of staff who had not completed the training was booked on a course the week following our inspection. The mandatory training matrix was unclear as to whether the clinic manager and the team leader should be trained in intermediate life support. The mandatory training matrix indicated this training was required for these two members of staff however; the box to identify their competence with this training under their initials on the training matrix contained the abbreviation N/A (not applicable).
- The majority of staff at the unit were up to date with their mandatory training. Fire safety training and practical manual handling training had been completed by 81% of staff as two members of staff were unwell on the day of the training. These members of staff, at the time of the inspection had not been rebooked onto a training course. There was also one other member of staff had been booked onto a course to attend their fire safety update. However, only 9% of staff had completed the infection prevention and control annual assessment and none of the staff had completed the yearly information governance training requirement. The clinic manager told us it had been challenging to ensure everyone had completed their mandatory training prior to commencing work at the unit in November 2016; this included those members of staff transferring their contract to a Fresenius Medical Care.

Safeguarding

- The organisation required staff to attend both safeguarding adults and children training. All staff apart from one member who had recently joined the team were compliant with this training. The new member of staff was being booked onto the next available training date for this course. Safeguarding adults level two training and safeguarding children level one training was completed every three years via and e-learning module. However, although children were not treated at the unit, intercollegiate guidance recommends that level two competence is the minimum level required for "non-clinical and clinical staff who have some degree of contact with children and young people and/or parents/carers." There was an adult safeguarding lead in the organisation. This was the teaching practitioner, part of the education and training department, who had completed adult safeguarding up to and including level three. The training and education manager was also trained unto and including level three for children's safeguarding.
- There were systems and processes reflecting relevant safeguarding legislation to safeguard adults. All staff we spoke with understood their responsibility to report safeguarding incidents. Staff would report any safeguarding issues to the local NHS acute trust and would work to support the trust with the case. There was information displayed in the unit for staff to follow if they had any concerns and needed to report a safeguarding incident.

Cleanliness, infection control and hygiene

- Staff did not always adhere to infection prevention and control policies and procedures. Staff were bare below the elbow to enable effective and thorough cleaning of their hands between patients. We also observed effective handwashing and the use of hand gel. There was good access to personal protective equipment (equipment that protected the user from health and safety risks at work) around the unit. However, we observed one member of staff assist a colleague with needling technique (the insertion of a needle into an arteriovenous fistula) without wearing an apron or personal visor. We also observed another member of staff leave a patient while continuing to wear personal protective equipment, including gloves, to collect consumables from a central trolley.
- Hand hygiene audit results for January to June 2017 showed an average of 72.5% compliance. The target for compliance was 90%. Monthly compliance varied and ranged from 64% in January 2017 to 87.5% in June 2017. The area most frequently identified with poor compliance was hand hygiene after patient contact and touching patient surroundings. An action plan had been put in place to address the results of the audits. Actions included ensuring more hand gels were made available

for staff, discussing results of the audits at handover and monitoring staff with poor performance and advising on missed opportunities. Between January and March 2017, the action plan had been unsuccessful and demonstrated a lack of oversight of the actions due to the same action appearing the following month and the scores not improving. Not all staff were aware of the non-compliant hand hygiene results and we did not see these displayed anywhere in the unit. The area head nurse became involved in April 2017 and completed the audit and action plan with the clinic manager. From April 2017, results had gradually started to improve although; the unit was still not meeting its target.

- Infection prevention and control audits covered included for example, environmental aspects of infection, prevention and control. Results for this audit between January to April 2017 were provided and demonstrated an improvement and plateau between February and April 2017. Results ranged from 91.7% to 95.9%. Action plans related to the results and identified the need for ensuring the correct procedures are followed when using personal protective equipment, for example, removing personal protective equipment when leaving a side room and the use of gloves to hold the patient's fistula post haemodialysis. The use of personal protective equipment in line with company policy was still a problem which we observed during our inspection.
- The premises were visibly clean, tidy and free from clutter. There was sufficient space for staff to access patients from both sides of the chair and each dialysis chair had disposable curtains which could be drawn to protect patients' dignity. These were all marked with the date they were last changed and tied back when not in use. Curtains were changes every six months according to company policy unless they became contaminated and required changing immediately. Staff used disposable linen such as pillow cases and mattress covers, which were single patient use.
- The flooring in the unit was in good condition and visibly clean. It was made of a hardwearing material and extended six inches up the wall, which allowed for effective cleaning and decontamination.
- The reclining dialysis chairs in the clinic were of a wipe clean material. They were visibly clean and in good condition at the time of our inspection. We observed nurses cleaning the chairs with disinfectant wipes before and after the haemodialysis session, and we saw this was recorded on the daily cleaning rotas, which were all completed and up to date.
- The unit had provision in place for the decontamination of equipment and maintained a record to demonstrate compliance. The was a policy for the disinfection of haemodialysis machines, which outlined specific instructions for the safe decontamination of the equipment used for haemodialysis. This was embedded in the NephroCare hygiene standards, a document produced for dialysis centres run by Fresenius Medical Care. This policy was based on best practice guidelines from European renal best practice guidelines and the Kidney Disease Outcome Quality Initiative guidelines.
- There were procedures to assess patients as carriers of blood borne viruses and methicillin-resistant Staphylococcus aureus (MRSA). The unit had protocols available in regard to infection control practice for monitoring MRSA. Swabs were taken from each patient monthly for analysis and three monthly for methicillin-sensitive Staphylococcus aureus (MSSA). The consultant received the results and discussed any actions necessary following the results of the test. This ensured patients attending the unit were free from infection and enabled infection prevention and control process to be adequately maintained. There had been no episodes of methicillin-resistant Staphylococcus aureus (MRSA) and one episode of methicillin-sensitive Staphylococcus aureus (MSSA) bacteraemia at the unit since the unit opened in November 2016. This had been investigated however; there was no learning identified to prevent bacteraemia in the future.
- The unit had four isolation rooms for patients with infections or who had compromised immunity, in line with the recommended requirements set out in the Health Building Notes 07-01 (2013. The unit had two spare dialysis machines and could therefore isolate a machine for a patient with a blood borne virus as required. There were standing operating procedures for staff to follow to ensure safe dialysis care of patients with infection diseases such as hepatitis.
- The chief nurse was the infection control lead for the organisation. Staff at the unit could liaise directly with the infection prevention and control lead for advice if required.
- Staff used recommended aseptic non-touch techniques to attach patients to their dialysis machines. We

observed good compliance with aseptic non-touch techniques This was completed through either the insertion of large bore needles into an arteriovenous fistula/ graft or central line. Arteriovenous fistulas are an abnormal connection or passageway between an artery and a vein created through vascular surgery specifically for haemodialysis. Grafts are artificial veins inserted for haemodialysis, and central lines are larger cannulas that are inserted for long periods for haemodialysis.

- The unit had a policy to ensure ultra-pure water. These were found in the NephroCare hygiene standards (the Fresenius Medical Care hygiene standards document). The guidelines for water testing and disinfection of the water plant were available to staff at the unit.
- Water used for dialysis was tested and specially treated to reduce the risk of contamination in patients. There was a large water treatment room. Nursing staff monitored the water supply and water testing was completed daily and weekly to ensure that water used during dialysis was free from contaminants. This was in line with national/manufacturer's guidance on the monitoring the quality of treated water and dialysis fluid. We saw the record log that recorded test results. Staff were aware of the processes for obtaining samples, and actions to take if results showed some contaminants. There had been no reported incidents of contamination. All staff underwent a competency check to ensure they were competent to carry out the water testing. Fresenius Medical Care had a facilities management team who carried out maintenance within the water treatment plant.
- Staff also completed daily tap flushing to ensure water used for handwashing was free from contaminants and bacteria. These checks formed part of the daily cleaning tasks, and records we looked at confirmed this was consistently carried out.

Environment and equipment

- The environment and equipment met patients' needs. The unit provided 16 dialysis stations, including four isolation rooms. The unit had the capacity to provide 20 dialysis stations, however this had not been commissioned at the time of our inspection. The main dialysis area was arranged with two centrally placed nurse's stations to ensure nurses could observe all patients receiving haemodialysis.
- The environment met the Department of Health: Health Building notes 07-01 (2013). The dialysis area met and exceeded recommended ratio of sinks to dialysis stations as each station had its own sink with lever operated taps, soap, antibacterial gel and pedal operated bins for disposal of both clinical and non-clinical waste.
- Each dialysis station had a reclining chair, dialysis machine, nurse call bell, height adjustable table, and television with remote control. This provided patients with their own individual environment and direct access to the nurses on duty at the unit.
- The unit had emergency equipment in case of medical emergencies and in accordance with national guidance (Resuscitation Council, 2015). This included automated defibrillators, which staff were trained to use. All staff had access to the medical emergency policy, which outlined what to do in the event of and an emergency. The resuscitation trolley was checked daily by staff and was found to be safe to use and records we saw were complete and up to date. Anaphylaxis medicine (medicine to treat a severe and potential life threatening allergic reaction) was stored on the resuscitation trolley, were not tamper evident There were also a cardiac arrest medicines supplied by NHS pharmacy (medicines to be used in the event of a cardiac arrest). However, no member of staff at the unit was trained to be able to give this medicine if required. No member of staff was trained in immediate life support despite the mandatory training matrix identifying the clinic manager, deputy clinic manager and the team leader should all have this training.
- All dialysis sets used at the unit were single patient use and were all CE marked (CE marking defines how the equipment met the health, safety and environmental requirements of the European Union).
- Sharps bins were stored in line with the National Institute of Health and Care Excellence guidelines, Healthcare Associated Infections: Prevention and Control in Primary and Community Care (CG139).The sharps bins remained closed via a flap mechanism. The sharps bins were in good condition and not overfilled.
- Waste was managed correctly and we saw closed clinical and non-clinical waste bags stored in a clinical waste bin. Bins were not overfilled and were emptied regularly. The dirty utility area was organised and tidy.
- The store room appeared clean and tidy with shelving for all equipment and had direct access outside. Fluids were stored on pallets meaning they were raised off the floor, although, some boxes were stored on the floor

which made cleaning of the floor difficult. Stock was delivered weekly and staff told us there were adequate supplies to ensure that the service could continue for two days if there was a delay with stock delivery. In addition, staff could arrange delivery of additional consumables as required which could be delivered on the same day. Stock orders were reviewed every seven weeks to ensure efficient stock level management. Staff monitored the ambient temperature of the stock room daily to ensure this did not exceed recommend levels for the safe storage of consumables.

- All staff were trained to use specific dialysis machines and to ensure they were competent to carry out disinfection of the machines. This was part of the competencies completed by staff at the unit. The organisation used the same type of equipment in all clinical areas, so staff transferring between units would be familiar with the equipment. We saw that equipment training records showed 100% compliance for all staff. This ensured all staff were competent and could use the machines and equipment provided at the unit to keep patients safe.
- During the inspection, we saw that dialysis machine alarms were responded to within a few seconds. Alarms would sound for a variety of reasons, including sensitivity to patient's movement, blood flow changes and any leaks in the filters. Nurses attended all alarms promptly and dealt with any problems which arose. No patients at the unit cancelled their own alarms.
- Staff were aware of the escalation process for the reporting of faulty equipment to ensure patients did not experience delays or sessions were cancelled. The centre had two spare dialysis machines, which rotas demonstrated were cleaned daily to ensure they would be fit to use in an emergency. We observed staff transferring a patient onto a spare machine, due to a message being displayed which staff were unfamiliar with and which identified a fault with the machine. Staff were aware of the procedure to follow and how to report the fault.
- Maintenance of the dialysis machines and chairs was scheduled and monitored using the Dialysis Machine Maintenance/Calibration Plan; this detailed the dialysis machines by model type and serial number along with the scheduled date of maintenance by technicians. The additional dialysis related equipment was calibrated and maintained under contract by the manufacturers of the equipment or by specialist maintenance/ or calibration service providers. All the equipment testing was within the specified dates.
- In January 2017 Fresenius brought facilities management in-house. A dedicated facilities management team, and experienced facilities management manager and two helpdesk coordinators provided 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 helpdesk ensured 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. The facilities management team arranged both the planned and reactive maintenance work at the unit in North Devon.
- The facilities management team carried out electrical testing work at the unit as part of the planned and preventative maintenance schedule. The unit maintained a register to demonstrate all equipment had been tested and was in date. Electrical testing of equipment was also monitored during the yearly health and safety audit.
- There was a system to ensure the phased replacement of older haemodialysis machines. The organisation had a replacement programme for their haemodialysis machines in line with the Renal Association guidelines. The recommendation for machine replacement was either every 7 years, or after 45,000 hours of use. The machines at the North Devon Satellite Unit were seven months into their life cycle. An asset register was maintained at head office and the business manager would be informed well in advance of any machines requiring replacement.

Medicine Management

- The unit had processes in place for the safe management of medicines. Patients attending would receive prescribed medicines for their dialysis or continuing treatment only.
- The unit had a service level agreement with a local acute NHS trust to ensure the provision of some medicines to the unit. Other medicines were provided by Fresenius Medical Care who held a pharmacy license. A weekly order of stock items were ordered from the pharmacy and delivered to the unit by a courier. Nursing

staff completed monthly medicine stock level audits when the amount of and expiry dates of medicines were checked. Staff told us stock was also rotated during the monthly stock audit. Records showed this was carried out consistently from January to June 2017.

- Medicines were stored in a locked clean utility room, away from the main treatment area. There were a small number of medicines routinely used during haemodialysis, for example anti-coagulants and intravenous fluids. The unit also had a small stock of regular medicines such as erythropoietin, (a subcutaneous injection required by renal patients to help with red blood cell production).
- Medicines, when in not in use, were stored in locked cupboards or in a locked, wheeled medicines cabinet. Medicines that were temperature sensitive were monitored closely. We saw that staff monitored the room temperature daily as well as the minimum and maximum fridge temperatures. These had been maintained within the recommended parameters. There was guidance for staff if temperatures were outside of the recommended range. Staff told us if temperatures were outside of range, they would escalate this to the nurse in charge who would discuss the medicines with the pharmacist to determine if they could still be used. Controlled drugs (requiring extra security of storage and administration) were not used or available on site.
- The unit had arrangements for pharmacist support to gain additional advice relating to dialysis drugs. The nurses at the unit could liaise with the pharmacy at the local NHS acute trust.
- Safe prescribing and review of medicines was undertaken for patients on haemodialysis by the patients lead consultant at the local NHS trust during the patient's quarterly follow-up appointment. The unit had access to a renal pharmacist as part of the contract with the local NHS trust, but senior staff told us they had regular email contact with the consultant and could raise any medicine queries directly with them. We reviewed 10 medicines prescription charts and saw that prescription charts were clearly written, showed no gaps or omissions and were reviewed regularly. The prescription chart also covered medicines for staff to give to patients as required, these included medicines such as paracetamol and oxygen prescriptions. If staff contacted the local acute NHS trust with concerns a patient had a raised temperature or a fever, they followed a set procedure set out in the complication, reactions and clinical emergency policy. In the event a patient at the unit required a prescribed medicine, the on call registrar would add to the patient's electronic record at the local acute NHS trust which the nurses had access to. Two nurses would acknowledge the instruction and the antibiotics would be checked by two nurses prior to administration.
- Nurses at the unit were transcribing the patient's dialysis prescription which was not in line with guidance from the Nursing and Midwifery Council (NMC, 2015). Transcribing is defined as any act by which medicinal products are written from one form of direction to administer to another. The lead consultant reviewed and if required, optimised the patient dialysis prescription monthly and inputted this onto the lead acute NHS electronic patient record. The nurse at the unit then entered the information onto the unit's electronic record for each patient and printed this prescription off to be held as an updated record in the patients file. Information had to be inputted onto the unit's electronic system to upload the information to the patient's card which was inserted into the scales and dialysis machines to transfer prescriptions onto the dialysis machine. At the time of our inspection the electronic system used by the local acute NHS trust and the electronic system used by the unit were not linked. The NMC (2015) guidance states this should not be undertaken routinely, and only in exceptional circumstances. The NMC (2015) guidance also states there should be a rigorous policy for transcribing that meets local clinical governance requirements. There was no process to audit or ensure the prescriptions were aligned.
- Staff ensured the safe administration of intravenous medicine to patients in line with guidance from the Nursing and Midwifery Council (NMC, 2015). We observed two nurses checking the anticoagulant provided was in date and correct for the patient. We also observed the nurses formally identify the patient's date of birth against the anticoagulant prior to administration. Dialysis assistants were allowed to administer prescribed anticoagulant medicines via the haemodialysis set and only once this was checked by a registered nurse. The dialysis assistants received training from registered nurses and were assessed as

competent. This competence was identified on the mandatory training matrix for annual reassessment by the clinic manager. The first reassessment would be required in November 2017.

- Intravenous fluids were administered to patients if their blood pressure dropped during dialysis. Staff followed a hypotension pathway, which set out actions to follow including the administration of intravenous bolus (pure water via the dialysis machine). Staff recorded this as a treatment variance via the electronic patient record system.

Records

- Patient care records were written, managed and stored in a way which kept patients safe. The unit used a combination of paper and electronic records. Nurses at the unit used an electronic record system to input patient data following the haemodialysis session. The paper records included the dialysis prescription, patient, and next of kin contact information, and GP details. There were also nursing assessments, medicine charts, and patient consent forms. Records were kept at the unit until a patient stopped dialysing, at which point the records were archived. All patient records were kept in a locked office overnight to ensure patient confidentiality.
- On receipt of new patient transfer documentation there was a mandatory requirement to document on a dedicated section of the transfer form, an acknowledge that data quality confirmation checks had been undertaken to ensure patient safety. This ensured that data provided reflected accurate patient information and was cross checked between paper records and NHS trust.
- Documentation audits were carried out on a monthly basis, however the audit process was not always completed and there was no assurance actions were always taken and followed up by the staff. The organisation required 10% of patient records to be audited monthly. Twenty seven aspects of documentation were looked at each time; (for example legibility, signature, clear prescription, care plan in place).We reviewed documentation audits from February to June 2017. Audits demonstrated that three out of the five audits had not been fully completed with regards to reviewing documentation on the electronic system. We also found across the five months, actions had been identified but staff had not completed the process of signing and dating when the named nurse had been informed, and the named nurse had not signed and dated to identify when they had completed the action required.
- Consultants managing patients who attended the unit were able to access the patient's record and blood results via the local NHS trust computer system.
- Staff at the unit were able to access patient's NHS clinic letters. All clinic letters following patient's appointments with their consultant were electronically stored on the local trust's central renal database which could be accessed by staff from the unit. Information such as blood results, medication lists, recent clinic letters, multi-disciplinary planning and all demographic and identity information was also held on this system. This ensured staff remained fully informed about the ongoing medical input and any changes to treatment or status of the patients attending the unit to ensure their safe ongoing care and treatment. Also, following patients outpatient appointments, the unit was copied into a letter, written by the consultant which contained information about medical history, current medications and the outcome of the appointment, including changes made to the care and treatment of the patient. This arrangement also ensured the unit was fully informed about the patient.

Assessing and responding to patient risk

- Effective systems were in place to assess and manage patient risks. Only stable patients were dialysed on the unit; if someone was acutely ill they were treated at a main NHS hospital. This was to ensure that patients who required additional support received their treatment at the local NHS trust to ensure patient safety.
- Nursing staff completed a full patient assessment based on the activities of daily living to identify the patient baseline condition on referral to the centre. The assessment included past medical history, mobility assessment and a skin integrity assessment. This information was used to plan care and treatment at the unit.
- Patients were required to insert a personal card into the weighing scales on arrival for their dialysis session. These individual patient cards were held at the unit to ensure patients did not forget their card when attending for dialysis. The card was inserted into the dialysis machine and enabled access to patient's dialysis prescriptions via the dialysis machine. We observed staff

confirming the patient's date of birth before they could move on to the treatment screen to commence set up for treatment. All treatment data was stored and transferred electronically to the electronic patient record. This ensured current and up-to-date data was monitored and stored. Staff also completed a paper record to ensure information was available in the event of electronic system failure.

- Nursing staff used risk assessments to review patients on a regular basis. Staff reviewed care plans in line with company policy. Reviews enabled staff to identify any deterioration or changes in patients' physical condition. Staff completed two care plans: mobility and pressure care. The mobility care plan was completed on the patient's initial session and every six months. The organisations guidelines stated a care plan required an update if the patient's general health or mobility status declined, the patient fell or following any hospital admission. We saw evidence of a care plan being reviewed following a patient's recent hospital admission and change in mobility status. The guidelines also stated for any Waterlow scores greater than 10 should be reassessed monthly until all nursing measures were in place. All 10 records we reviewed had completed and up to date care plans. We also saw an example of where a care plan had been reviewed and updated in line with company policy. We noticed all of the care plans had an initial assessment from June 2017. The clinic manager told us a recent audit had identified a lack of compliance with keeping up with the care plan, therefore the unit had started again and completed new care plans for all patients and added dates for review in line with company policy.
- Patients were observed throughout their haemodialysis session. This included an assessment of patient's pre and post haemodialysis to ensure patients did not suffer an adverse effect, which may impact upon their safety. Patients had clinical observations recorded prior to commencing treatment. This included blood pressure, pulse rate and temperature. The nurse reviewed any variances prior to commencing haemodialysis, to ensure the patient was fit for the session. Where necessary the nursing staff consulted with the consultant or on call renal doctor for clarification. Staff checked patients' clinical observations half way through dialysis, just before disconnecting the patient from dialysis and again before the patient left the dialysis chair or bed. However, the service did not use an early warning system to alert staff if a patient was deteriorating.
- The unit had a policy for 'complications, reactions and other clinical events pathways.' This included simple flow charts for staff to refer to in a variety of scenarios to guide treatment and clinical decision making. The policy contained flow charts outlining procedures to follow in specific circumstances, for example, if a patient had an adverse drug reaction, acquired clostridium difficile, suffered a cardiac arrest or death in the unit or a data protection breach occurred.
- There were no policies or standard operating procedures at the unit which made direct reference to the management of sepsis in line with national guidance (NHS England, 2015). Staff had also not received any specific sepsis training. There was no system to ensure staff took appropriate action if the suspected a patient had sepsis.
- There were systems to ensure treatment was optimised for patients. However, the system, introduced by the registered manager and in use at the unit was not fit for purpose and did not provide assurance that actions from the quality assurance meeting had been completed to ensure the safe care and treatment of patients. The consultant attended the monthly quality assurance meeting. At this meeting, the patient's monthly blood results were reviewed and the consultant made amendments to the patient's dialysis prescription or medication to ensure treatment was optimised for patients. We looked at records of these meetings from January to June 2017. The records had actions, such as changes to treatment documented from discussions held at the meetings. Many entries where nurses had to sign and date to state the actions had been completed were left blank. We followed through two unsigned actions, which despite being left blank and unsigned, had been completed.
- No member of staff was trained in immediate life support despite the mandatory training matrix identifying the clinic manager, deputy clinic manager and the team leader should all have this training.
- The unit liaised directly with the patient's GP if required. Routine communication with the patient's GP regarding medicine or dietary changes were communicated via the lead consultant for the patient at the unit. We observed staff recommend a specific type of dressing to

a patient, which would help blood coagulate once the needle was removed after dialysis treatment. This dressing was not routinely part of dialysis prescriptions and should therefore be prescribed by the patient's GP. Staff communicated this with the GP via fax and ensured the patient could pick up the prescribed dressings before the next dialysis session.

- The unit had a procedure to ensure patients who self-needled and dialysed were safe to do so and ensured risks were mitigated. The unit had a competency assessment for patients who dialysed themselves to complete prior to doing this independently. We saw a completed record at the unit which assessed the patient carrying out the haemodialysis process from beginning to end. The unit requirement was that patients had to be observed three times and signed off to be competent prior to carrying out their treatment independently. The one patient who self-dialysed at the unit had been assessed according to company policy and the competency document was held in the patient's paper record. Staff continued to monitor the patients and recorded their observations throughout their treatment to ensure their safety.

Staffing

- The unit based it staffing levels on guidance set out by the Renal Workforce Planning Group 2002, on the service level agreement set out with the local trust and patient dependency. The unit used one nurse to four patients, with a 50:50 skill mix of five registered nurses and four dialysis assistants and three health care assistants. In addition, one healthcare assistant was also available during each shift. The unit employed five registered dialysis nurses and eight healthcare assistants, with both full time and part time contracts.
- The unit used a bespoke electronic system to ensure compliance with staffing numbers as set out by the local NHS acute trust and the Renal Workforce Planning Group. The electronic staff rota was completed eight weeks in advance by the clinic manager and approved by the regional business manager. This method of planning ensured all shifts were covered for the specific week to ensure staffing levels were safe for the patients attending the unit.
- At the time of our inspection there was one staff vacancy at the unit. However, there were three members of staff were off on long-term sickness (one registered nurse, one dialysis assistance and one healthcare assistant). However, two of these posts had been covered. A member of staff had been permanently recruited for the team and another member of staff had been brought in to provide short term cover for the absence.
- The unit had a plan to cover for any absences such as annual leave or sickness. The unit would look to fill the shift with a permanent member of staff from the unit. If this was not an option, the unit would look to cover the shift using Fresenius Medical Care flexibank staff and then Fresenius Medical Care approved agency nurses. The organisation's requirements for agency staff were that they had renal experience or a renal qualification. The unit also would also try to ensure continuity of agency staff if required to work at the unit to minimise disruption to patients.
- Bank and agency staff underwent a comprehensive induction programme prior to working at the unit. This ensured staff understood how the unit worked and their role and responsibilities, which helped to minimise disruption to patients. The induction consisted of a training shift and a competency assessment which ensured the member of staff was as competent in their role and procedures as the permanent members of staff. Agency staff were required to undertake a health and safety temporary worker induction checklist. This included familiarisation with emergency equipment and were also provided with company policies and work instructions to ensure they understood what was expected whilst they were working at the unit.
- Staff at the unit had a qualification in renal nursing. At the time of our inspection, three nurses held qualifications in advanced renal nursing, including the clinic manager. There was one member of staff also looking to develop and enrol on this course. The unit was supporting the member of staff to do this.
- New members of staff joining the unit were provided with support until they were competent and were able to carry out their role proficiently. A new member of staff would be allocated two mentors (trained nurses already working at the unit), who provided support with completing training and competencies during the supernumerary period. The duration of the supernumerary period was dependent upon the individual nurse and reviews were carried out at one, three and six months after joining the unit. This enabled managers to monitor progress with development and training.

- Medical support and advice was provided by the consultant nephrologist managing patients who attended the unit. The consultant also attended the unit once weekly. Over three weeks the consultant held a clinic for patients and the other week they attended the monthly quality assurance meeting at the unit to discuss patients to ensure treatment was optimised for patients. Nurses were able to contact the consultant directly by telephone, or email with any concerns about patients attending the unit.
- There was a contingency plan in place in the event of absence of the patient's named consultant. The unit were able to contact the on call renal consultant at the local NHS trust or the renal registrars. The nurses called the switchboard and asked to be connected to the consultant.

Major incident awareness and training

- The unit had an emergency preparedness plan for the unit which provided plans for the prevention and management of emergency situations. Staff were aware of the emergency preparedness plan and participated in site evacuation drills to ensure their familiarity with procedures. The emergency preparedness plan provided prevention plans for fire, loss of electricity and loss of computer systems and data. The plan also addressed other situations which could arise such as, service failure, fire or minor and major water leaks. The emergency preparedness plan defined the roles and responsibilities of the staff during an emergency situation and key contact details. This was available to staff and displayed on the unit.
- Staff told us the dialysis machines had a 15 minute battery back-up so in the event of a power cut, the patient's own blood could be recirculated and returned to them. There was also a backup water treatment plant at the unit in case one plant failed.
- Each patient had their own individual patient emergency evacuation plan which ensured each patient had been assessed to determine what help they would require in the event that the unit needed to be evacuated. The patients physical ability was documented along with the support required from a member of the nursing team to ensure their safety. This form was kept in the patient's paper record and was completed at the patient's initial visit to the haemodialysis unit.
- The unit planned to carry out a fire drill every six months to ensure patients and staff understood their role and what was required in the event a fire broke out at the unit. The drill was carried out in June 2017. Patients were warned of the drill and one patient who agreed remained on the haemodialysis machine to provide a scenario based learning opportunity. The information to demonstrate staff had participated in the drill was recorded on the board in the manager's office. The manager was unsure where this information was the formally captured and whether this information needed to be held centrally by Fresenius Medical Care. We saw an email to the area head nurse to clarify this.

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

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.

Compassionate care

- Staff interacted with patients in a respectful and considerate manner. We observed interactions between staff and the patients. Staff remained courteous and polite during all interactions with patients.
- Staff treated patients with kindness, dignity, compassion and respect. Patients we spoke with during the inspection were highly complementary of the care and treatment they received at the unit. Quotes from patients we spoke with included, "cannot be faulted, " "excellent," and "amazing care."
- Patient's privacy and dignity was maintained at the unit. Each station had curtain which could be drawn to provide patients with privacy. We observed good use of these curtains when staff hoisted a patient onto a bed and helped a patient with poor mobility up from a dialysis bed in order to maintain their dignity during this transfers.
- Staff demonstrated a supportive attitude to patients at the unit. We observed staff checking regularly to ensure the patient was all right and how attentive staff were when patients needed support to get on the scales at

the unit. We observed staff carrying bags for patients and linking arms with patients to support them with their mobility when walking across the unit to the reception area.

- Staff at the unit quickly built up a rapport with patients who attended the unit for treatment and interacted with patients in a respectful manner. Staff put patients at ease and communicated with them like friends. Patient's told us a 'feeling of warmth and welcome is apparent' and 'nothing is too much trouble.'
- Nursing staff maintained patients comfort through the use of additional pillows. We saw many patients brought their own blankets and comforters.
- All patients we spoke with talked about the care provided by the unit staff. Patients told us the care provided was "brilliant," "of a very high standard," and one patient told us they felt 'very fortunate to be treated at the unit.'

Understanding and involvement of patients and those close to them

- Staff communicated with patients to ensure they understood their care and treatment. Patients told us the nurses would always explain what was happening with their care and treatment and would identify any changes set out by the patients lead consultant. Patients told us they felt comfortable to ask questions about their care and treatment to the nurses, however, five patients told us they did not always feel staff had enough time to answer them because they were so busy. Eight patients also commented on how busy the staff were. Some patients felt more staff were needed at the unit to support the nurses. One patient told us they were reluctant to ask questions because they knew the nurses were busy and did not want to delay them. However during our inspection we observed staff interacting with patients and felt they had enough time to do this.
- Staff understood the importance of involving family members and close relatives as partners in patients' care. Staff told us they communicated with relatives particularly if they had concerns about patients. For example, staff told us about a patient who had displayed symptoms of confusion which was unusual. Staff spoke with the consultant nephrologist and as there were no signs of dialysis related infections, staff advised the patient to see their GP and also phoned their relative to inform them and ensure this was arranged.
- Nursing staff told us that as they saw their patients frequently they were familiar with their moods and were able to identify when patients were having a bad day or were feeling unwell. This enabled them to spend additional time with the patients as necessary to support them with their treatment, or assist with any concerns they may have.
- On referral to the centre, patients were encouraged and invited to visit for an initial assessment and a look around. Patients and their relatives were encouraged to spend time with the staff and other patients to ensure that they were satisfied with the unit before agreeing to start treatment.
- Patients had ongoing education provided by the nurses to ensure they and their family were able to make informed choices about the future of their treatment. Nurses ensured patients understood their kidney condition and how this related to other medical problems they may have, which impacted upon the life choices made by patients. The unit had a 'patient and carer shared/self-care training check list' but most patients did not want to carry out any part of the treatment themselves. We spoke with a few patients who took an active part in their dialysis including setting up the dialysis machine and priming the dialyser. Patients told us that they were asked and encouraged to participate in their care.
- The majority of patients felt informed about their blood results and were given the opportunity to discuss any treatment changes made by the consultant. Nurses discussed the meaning of the results with each individual patient and any changes to their treatment which the consultant had made following the blood results. The majority of patients told us they understood what was happening and felt clear about the status of their condition, following an explanation of their blood results. Five patients felt the nurses did not have enough time to explain things to them.
- Staff spoke openly about the treatments provided, the blood results and dialysis treatment plans. Many of the patients were observed speaking to staff and discussing their treatment as the nurses were setting them up for treatment.

Emotional support

- Staff recognised the broader emotional wellbeing of the patients under their care. One patient told us how they still experienced emotional ups and downs with regards to their condition treatment. The patient told us that nurses had taken the time to speak to them and provide reassurance when they were feeling low which they greatly appreciated.
- One patient told how they were new to dialysis and had been recently diagnosed with their condition. The patient told us how the nurse's kindness, consideration and friendliness had helped them come to terms with their condition. The patient told us they felt they could go to the nurses about anything and knew they would be supported.
- Staff understood the impact on a patient's condition, care and treatment and how this affected their family and relatives. Some patient's attended The North Devon Kidney Dialysis Group which met once a month for lunch and once a month for a meeting. The group was in the process of making arrangements for a patient advocate to hold clinics in the unit for patients who may need advice of help and support available for people with chronic kidney disease.
- Nurses discussed and sign-posted patients to where they could gain support about their condition. We saw that the centre provided details of support networks for patients and their loved ones. This included organisations such as the Kidney Patients' Association who held social events, and had support networks for patients and their loved ones and newsletters provided by kidney charities.

Are dialysis services caring?

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

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- One patient told how they were new to dialysis and had been recently diagnosed with their condition. The patient told us how the nurse's kindness, consideration and friendliness had helped them come to terms with their condition. The patient told us they felt they could go to the nurses about anything and knew they would be supported.
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Dialysis Services

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

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.

Service planning and delivery to meet the needs of individual people

- The Royal Devon and Exeter NHS Foundation Trust commissioned Fresenius Medical Care to provide haemodialysis treatment to service users in and around the Barnstaple area at the North Devon Satellite Dialysis Unit.
- The local acute NHS trust responsible for commissioning the North Devon Satellite Dialysis Unit owned the building in which the unit was situated. The local acute NHS trust provided detailed specifications for Fresenius about the facilities they required to ensure the environment was responsive to the needs of the patients attending and to enable safe and effective haemodialysis treatment to take place. Fresenius were responsible for providing the fixtures and fittings within the unit. For example, the local acute NHS trust had requested a sink was located at each patient station and that the unit also had hospital beds as well as dialysis chairs. The organisation met this requirement requested by the local acute NHS trust.
- Services were planned to account for the needs of different people. The unit had four side rooms which were allocated to patients who may need isolating, for example due to infection, post chemotherapy, or post radiation therapy. The unit also had 12 stations available for patients in the main treatment area. The side rooms were also in use for haemodialysis patients who benefitted from dialysing in a private room rather than out on the main floor.
- The unit had arrangements available to patients attending the unit with individual care needs. There was access to a hoist, dialysis specific chairs, hospital beds and single rooms for isolation.
- A named nurse was allocated to each patient on starting treatment at the unit which provided patients with better continuity and gave them a point of contact if they needed support or advice. This role was still in its early stages and the clinic manager was looking to develop it as staff became more settled at the unit. However, it was unclear at the time of our inspection how this system was working in practice.
- Monthly quality assurance meetings provided a forum for the unit manager and lead consultant for the unit to ensure services were planned and tailored to meet the needs of the individual patients attending the unit. Concerns or issues around a patient's treatment were brought to the meeting and professionals determined the best ways to ensure the quality of the care and treatment provided for individual patients met the standards set out by the Renal Association. For example, discussions were held about each patient's monthly blood results, to ensure treatment was optimised for each patient.
- Services were planned and organised so patients could participate in their own care if they chose to do so. There were some patients who participated actively in their own care. Patients were encouraged to participate in their treatment for example; patients were encouraged to weigh themselves. The unit also had a competency framework available for patients who wanted to self-needle and manage their own treatment session. At the time of our inspection, three patients self-needled or managed their own treatment at the unit.
- The unit had access, via the local NHS trust, to psychological support or counselling for patients who attended the unit for treatment, to ensure their psychological wellbeing. If the nurses at the unit had concerns about the psychological wellbeing of a patient, they would raise concerns at the monthly quality assurance meeting which the lead consultant attended. It was the responsibility of the lead consultant to make a referral.

Access and flow

- The North Devon unit had the capacity to provide up to 1152 haemodialysis sessions per month. The number actually varied every week dependent upon the needs and demands of patients. There were 52 patients who currently attended the service. Between January 2017 and March 2017, the unit was operating between 66%

and 69% of its total capacity. The unit and the local acute NHS trust were looking to increase the numbers of patients attending the unit. There was no pressure or a set timeframe in which this had to happen.

- Patients could access dialysis care and treatment at a time to suit them. The unit had, up to the time of our inspection, been able to accommodate patients' needs in this respect. The unit was open six days weekly and provided a choice of morning or afternoon sessions. Patients had the choice of session which would be best suited to their lifestyle and which would least impact upon their quality of life. At the time of our inspection, there was no waiting list of patients to attend the haemodialysis unit. The unit manager spoke with the dialysis co-ordinator at the local acute NHS trust on a weekly basis to keep informed about any potential patients which may want to attend the unit.
- Patients were assessed for their appropriateness to attend the centre by the local NHS trust. Patients with acute kidney disease were treated at the local NHS trust and only chronic, long-term dialysis patients were referred to the unit for treatment.
- When a patient was identified as being suitable to attend the centre, a referral was completed by the local acute NHS trust. Patients could attend the unit to have a look around and meet staff. Staff told us of occasions where this had occurred in the past.
- There had been no appointments cancelled or treatment start times delayed between November 2016 and July 2017 at the time of our inspection.

Meeting the needs of local people

- Dialysis services were commissioned by NHS England. The contract for the unit was set up for 2016 and the service specification was defined by the acute NHS hospital trust renal team in conjunction with the requirements and needs of the local community. Patients were referred to the unit by the local NHS trust.
- Information about the needs of the local population was used to inform the planning and development of the dialysis service. When the service was planned in 2016, the provision of NHS dialysis services at the old unit did not have the capacity or facilities to meet the needs of the patients attending the unit for treatment. North Devon Satellite Dialysis Unit was chosen as a suitable location, due to it being central within the region of North Devon and there was effective transport links within the area to enable patients to easily access the unit for treatment. Not having to travel long distances has been shown to help improve a dialysis patient's quality of life.
- The dialysis service reflected the needs of the population served and provided flexibility and choice for patient care. Patients were able to access the unit six days a week and had the choice of either the morning or an afternoon session to receive their treatment. Patients were able to receive their treatment at a time which suited them.
- Services were planned to take into account for the needs of different people, to enable them to access care and treatment. Admission criteria was set out, so all patients irrespective of age, gender, race, religion, belief or sexual orientation could access the services. Patients were required to be haemodynamically stable, have established fistula or central venous catheter access and reside in the local area.
- There were processes in place to ensure a patient new to haemodialysis was provided with information to ensure their understanding of the nature and purpose of the treatment. Patients were provided with information booklets about haemodialysis treatment and other common subjects such as vascular access, diet and infection control on starting their treatment at the unit. Information was set out clearly and simply for patients to follow.
- The unit had access to interpreter services via the local acute NHS trust. Although at the time of the inspection no patients had attended the unit who had required interpreter services.
- There was provision for patients to be able to use the toilet prior to commencing treatment at the unit. Patients had access to two toilets at the unit. The toilet facilities had a different coloured rails and toilet seats to make them easily identifiable to patients with disabilities. At the time of our inspection, the unit had not been required to treat any patients with complex needs or a learning disability.
- The unit had designated parking and disabled parking adjacent to the dialysis unit for patients who travelled independently to the unit for treatment. There was convenient and safe access to the dialysis unit for ambulant and disabled patients.
- Patients had access to entertainment or activities during their haemodialysis session. Each station had its own individual television, a call bell and a height adjustable

table. Patients could access the Wi-Fi at the unit to access the internet via laptops and other personal electronic devices. One patient attending the unit was able to continue working whilst receiving treatment at the unit.

- There were provisions to ensure patient comfort during treatment sessions. Staff offered patients pillows for their session and ensured patients were comfortable and their privacy respected throughout the session. Patients were also provided with a drink and biscuits during their session. Patients told us the unit was as comfortable as it could be for the treatment it was providing.
- The unit had a specific procedure to follow and paperwork to complete when patients booked to receive treatment at the dialysis unit during their holiday in the area. The unit also provided each holiday patient with an electronic card and information was recorded in line with the unit's requirements.

Learning from complaints and concerns

- People using the service knew how to make a complaint and felt they could raise any concerns with the clinical staff. The complaints procedure was made available to all patients at unit and information about how to make a complaint was provided in a leaflet displayed in the reception area at the unit.
- There was a comprehensive complaints procedure to ensure all complaints were handled effectively and confidently. The organisation told us they were committed to handling complaints using the 4Cs (compliments, comments, concerns and complaints) in a sympathetic and understanding way. The procedure required complainants to receive a timely response, acknowledgement in two working days and a full response in 20 working days.
- The unit had received three complaints between January 2017 and June 2017. Two formal written complaints and one informal verbal complaint. Two complaints had been about the quality of care patients had received and one was categorised as 'other' but was a complaint about the air temperature at the unit. The unit had provided one letter of response to the patient which took 33 days. However, this was not in line with company policy which stated a response was required within 20 days. The complaint regarding temperature was closed following the unit manager having a discussion with the patient at the unit about what had been done and the patient was satisfied with the outcome and the problem had been resolved. The last complaint was ongoing at the time of our inspection.
- Learning from complaints was not disseminated to staff. We saw no evidence from staff meetings that information regarding the two closed complaints had been discussed with staff working at the unit.

Are dialysis services well-led?

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.

Leadership and culture of service

- The manager at the unit had experience in renal nursing, but was new to a management role and at the time of our inspection was developing managerial skills. We observed the clinic manager's motivation and enthusiasm to develop their knowledge and skills within this area, willingness to learn and dedication to making a success of the new unit. The clinic manager had worked in renal nursing for seven years and had an advanced qualification in renal nursing. The organisation had recognised the unit manager required more support to develop knowledge and skills within the management role. Support had been provided from the senior management team since the opening of the unit in November 2017 to develop the manager's ability to carry out the role effectively. The manager had been given the opportunity to spend time with more established managers from other units and had built strong relationships with other managers from nearby units and received good telephone and email support from them. The senior management team had the skills, knowledge, experience and capacity to lead effectively. The area head nurse supporting the unit had working in renal care with Fresenius since 2003, held and advanced qualification in renal nursing and had worked his way up through the organisations ranks to achieve their current position of area head nurse.
- Leaders understood the challenges to good quality care and were able to identify actions to address them. The clinic manager explained the aim was to have the clinic running effectively seven days a week, particularly at the

weekend, when the clinic manager was not usually present. The clinic manager told us how he was looking to develop members of the team into more senior positions, into roles such as deputy clinic manager and how he was doing this. At the time of our inspection, the clinic manager was working closely with a member of staff, who had expressed an interest in developing their role within the organisation.

- The senior management team also understood the challenges to good quality care and the need to ensure the new unit in North Devon was running effectively. The organisation faced challenges as the haemodialysis units covered a large geographical area across the country. Therefore, they were not able to be present at the units every day. The area head nurse had been visiting the unit very frequently when the new unit opened and at the time of our inspection, had reduced his visits to fortnightly. The regional business manager had also been visiting the unit frequently. These visits provided support for the unit manager and staff at the unit, whilst ensuring they maintained oversight of the running of the new unit. The unit manager had valued the area head nurse and regional business manager's support over the past few months.
- The unit manager was visible, approachable and supportive. Nurses told us how supportive the unit manager had been since the move to the new unit. Staff told us they felt comfortable to discuss any concerns with the manager.
- Staff were proud of the patient care they provided and felt the unit was a "nice place to work now things had settled down" since the move in November 2016. Staff had found the transition and move to the new unit challenging. This was for several reasons, for example, due to them having to care for four patients each session, rather than three at their previous unit. Staff felt like they had less time to spend with each patient due to the increased workload. However, staff felt they worked well as a team to support each other.
- The senior management team and manager of the unit maintained a strong working relationship with the local NHS trust, to ensure the safety and well-being of the patients attending haemodialysis at the unit. The unit manager and regional business manager met with the lead consultants and local NHS trust monthly to discuss the contract and the service provided. The manager of the unit had regular telephone and email contact with the consultant. The manager told us the consultant was very helpful and they felt they had built a strong, effective working relationship. We received feedback from the lead consultant for the unit who described the communication with the unit as "excellent."

Vision and strategy for this core service

- There was a clear vision and set of values for the dialysis unit. The vision of the unit focused on safety and quality, excellence in patient care, independence for patients and innovation. The values included quality, honest, integrity, innovation, improvement, respect and dignity. However, staff were unaware of the vision and values of the organisation.
- There was a realistic strategy, looking towards developing and expanding the organisation, and developing treatment by creating a future for dialysis patients. The unit manager talked about increasing the number of patients attending the unit to improve the utilisation and the facilities with the view to eventually look towards increasing the choice of session times for patients by offering a twilight session. At the time of our inspection, there was no timeframe for this. The unit had steadily increased the numbers of patients attending the unit for treatment since it opened in November 2016. The clinic manager was also keen to develop the service so as patient numbers grew, there was a stable management structure to ensure effective and seamless running of the unit. The clinic manager was looking to develop the nurses working at the unit and offer a deputy clinic manager role. All staff were aware of their role and responsibilities in providing effective and safe care to all patients.

Governance, risk management and quality measurement

- There was an organisational governance framework in place to support how risks and quality issues were monitored and managed. However, the governance framework required some improvement to provide assurance operational performance was discussed along with documented actions to improve performance and quality of care for patients. The governance structure demonstrated how communication and performance at the unit flowed up to the senior management team. At a local level this

involved the area head nurse monitoring the unit against the organisations key performance indicators, but, there was a lack of information being fed down to staff at the unit via team meetings.

- There was not an effective communication process to ensure in the provision of quality and risk information to the staff. Staff did not receive information about quality, performance, safety or risks at the unit. We observed the minutes of staff meetings which had taken place in January, May and June 2017. The agenda for the meeting was under development and regular topics for discussion to be decided. The minutes of two out of the three meetings did not demonstrate any conversation about risk, safety or the unit's performance. June's minutes demonstrated the hand hygiene audit results had been feedback to the staff and the minutes identified the balance score care had been discussed. These minutes contained no detail as to the depth of conversations held, therefore, we were not provided assurance about the quality of the information passed onto staff. The minutes of the meetings would not provide any staff member who did not attend, with any useful information about the discussions which had taken place.
- There were missed opportunities for learning following the bacteraemia infection incident and the serious incident. Immediate actions following the incidents had been identified to demonstrate how the unit had managed the incident and ensured the safety of the patient, and there was no evidence of how the incident was scrutinised for wider learning at the unit or evidence of any actions taken to ensure this incident did not occur again.
- There were systems and process to identify and manage risks and mitigating actions, however we were not provided with assurance that the risk register was monitored, regularly reviewed and a named person had ownership of the actions. The risk register had been newly introduced to the unit in April 2017, but the content contained corporate risks rather than risks specific and live to the North Devon Satellite Unit. Examples of risks on the risk register were major incidents to the power or water supply, the lack of a sepsis pathway and national early warning score. Risks were rated according to company policy and identified mitigating actions for each risk, but, there was no evidence risks were regularly discussed and the mitigating actions reviewed. The risk register did not identify a named person responsible to manage and oversee each risk. The risk management policy did not state how often the risk register should be reviewed. The risk register was not a live document. During the inspection, we identified the lack of compliance with hand hygiene. Although the results from May 2017 had started to improve, the unit had not achieved the organisations target of 90% which had occurred since January 2017. This was a current and live risk for the North Devon Satellite Unit due to them also having an incident of a bacteraemia infection in February 2017; however, this was not on the risk register. Recruitment was also a challenge for the unit and this was also not on the risk register.
- There was a systematic programme of clinical and internal audit used to monitor quality and identify where actions needed to be taken. However, repetitive problems following monthly audits demonstrated a lack of oversight to ensure actions were completed. The unit had a programme of monthly audits which were set out for the year. The results of these audits were captured on the audit schedule matrix which had started in January 2017. The audit programme included water testing, incident reporting, infection prevention and control audits. We reviewed, the dialysis unit hygiene audit. The unit had scored 91.8% in January 2017 and 95.8% in February. March and April 2017. Similar comments regarding the appropriate use of personal protective equipment had been made for three out of the four audits. We did not see any evidence in staff meeting minutes this information had been fed back to the staff to ensure improvements were made. The action plan identified what needed to be done to make improvements, but lacked the detail with regards to how this was going to be done. We found similar problems with the hand hygiene audit.
- There was a comprehensive assurance system to provide the organisation and the local acute NHS trust with information regarding patient outcomes and performance at the unit. The unit monitored patient outcomes and reported these on a monthly basis to the trust, at the request of the trust. The unit also monitored performance indicators which covered infection control, complaints, venous access problems, infection and clinical variances. This information was readily available for the trust if they were to request it. Information was

also available and present at each monthly quality assurance meeting involving the lead consultant for the unit in case the consultant wanted to review any other performance indicators for the unit.

- The consultant involved with patients attending the unit attended monthly contract review meetings and was part of the strategic management of the commissioning arrangements provided by the local acute NHS trust. The contract for the provision of services at the North Devon unit was discussed at these meetings along with the performance of the unit. Topics such as patient treatment parameters, workforce, equipment and maintenance and patient statistics and governance were discussed and the discussions minuted. Since the opening of the unit in November 2016, there had been monthly contract review meetings since January 2017. The plan was to then make these meeting quarterly once the content of the meeting became routine. There was no timeframe for this happening at the time of our inspection. The unit manager and area head nurse felt they had a good relationship with the trust.
- The registered manager did not have any knowledge of the Workforce Race Equality Standard (WRES) and Equality Delivery System (EDS2). This became mandatory in April 2015 for services which deliver £200,000 or more of NHS-funded care. WRES looks at the extent to which black and minority ethnic (BME) background employees have equal access to career opportunities and receive fair treatment in the workplace. Services are required to collect, report, monitor and publish their WRES data and take any required action to improve workforce race equality. Whilst corporate reports could be written, information should have been collected and reported at local level. We acknowledged the local area had low numbers a of black and minority ethnic population. Workforce Race Equality Standard had been identified on the risk register and was being looked into and developed corporately.

Public and staff engagement

- Patient's views and experiences were gathered and acted on to shape and improve services. The Fresenius Patient Group had been involved with the development of the patient satisfaction survey and every year patients are able to complete a patient satisfaction questionnaire. The unit was due to carry out its first annual patient satisfaction survey in November 2017.
- The move to the North Devon Satellite Dialysis Unit had been challenging for all of the staff, patients and the unit manager involved. Both patients and staff had been involved in an extensive consultation process prior to the move to the new unit. Both staff and patients had been given the opportunity to visit the new unit prior to its opening to get a feel for the new environment prior to the move.
- The organisation carried out a yearly staff satisfaction survey. Due to the unit opening in November 2016, the first staff survey is due to be completed in November 2017.

Innovation, improvement and sustainability

- The unit had an initiative for succession planning, to ensure the unit maintained the right skill mix of nurses in the future and was able to promote from within. The unit provided a comprehensive training and development programme for staff. Staff were also given the opportunity to develop and encouraged to complete a course in advanced renal nursing. The unit manager was also looking to ensure there were established team leader and deputy clinic manager roles at the unit to ensure succession planning for the future. At the time of the inspection, the unit manager was also working with a member of staff at the unit to who had expressed an interest in developing their role to move into a more senior post at the unit.
- There were initiatives in place for green nephrology and sustainability. The unit had obtained ISO-14001 Environmental Management System Programme accreditation in May 2017. This accreditation reflects that the unit complied with a set of criteria to demonstrate their environmental management systems to ensure these were sustainable.

Outstanding practice and areas for improvement

Outstanding practice

- Staff had the opportunity to spend time at the local acute NHS trust to improve their competence in particular areas of their role. The dialysis assistants had spent time with the vascular access team at the local acute NHS trust to develop their knowledge and skills in this area. The vascular nurse had also visited the unit to provide further training about the electronic vascular monitoring device use by the unit to monitor a patient's vascular access.

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure there is an appropriate policy and specific staff training for the early identification of sepsis (infection) in line with national guidance (NHS England, 2015).
- The provider must ensure the nurses at the unit are not transcribing the patient's dialysis prescription and are working in line with guidance from the Nursing and Midwifery Council (NMC, 2015).
- The provider must ensure there is compliance with infection prevention and control policies and procedures.
- The provider must ensure staff are compliant with the Department of Health document Confidentiality: NHS Code of Practice (2003) and not share login and password details to access patients full record from the parent trust.
- The provider must ensure the risk register is monitored, regularly reviewed and a named person had ownership of the actions.
- The provider must ensure there is an effective communication process to ensure the provision of quality and risk information to the staff.
- The provider must ensure actions and learning from the audit schedule were overseen and implemented following audit results.
- The provider must ensure there are systems and processes in place so staff have access to all the information they require to provide care and treatment for patients.

Action the provider SHOULD take to improve

- The provider should ensure learning from serious incidents to ensure this did not occur again at the unit.
- The provider should ensure staff receive feedback form incidents they report.
- The provider should ensure all staff are compliant with the mandatory training course infection, prevention and control annual assessment.
- The provider should ensure compliance with organisational targets for hand hygiene audits.
- The provider must ensure medicines held on the resuscitation are either tamper evident.
- The provider should ensure processes are completed to provide assurance that actions regarding patient care and treatment are completed following the continuous quality improvement meeting.
- The provider should review staff understanding regarding end of life care and take action to ensure treatment and care given is in line with best practice.
- The provider should ensure processes are completed to demonstrate actions following the documentation audit have been completed.
- The provider should review processes to ensure all staff know which patients had a Do Not Attempt Cardio Pulmonary Resuscitation (DNACPR) in place.
- The provider should ensure they have knowledge of and evidence compliance with the Workforce Race Equality Standard (WRES) which became mandatory in April 2015.
- The provider should ensure staff understand the vision, values and strategy for the organisation.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment 12(2)(g) the proper and safe management of medicines 12(2)(h) assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are healthcare associated. 12(2)(g) Nurses at the unit were transcribing the patient's dialysis prescription which was not in line with guidance from the Nursing and Midwifery Council (NMC, 2015). 12(2)(h) Staff did not always adhere to infection, prevention and control policies and procedures and did not use personal protective equipment effectively. There were no policies or standard operating procedures at the unit which made direct reference to the management of sepsis in line with national guidance (NHS England 2015). Staff had also not received any specific sepsis training.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance 17(2)(a) assess, monitor and improve the quality of services provided in the carrying on of the regulated activity (including quality of the experience of service users in receiving those services.)

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Requirement notices

17(2)(b) assess, monitor and mitigate the risk relating to the health, safety and welfare of the service users and others who may be at risk which arise from the carrying on of a regulated activity.

17(2)(d) maintain securely such other records as are necessary to be kept in relation to – (i) persons employed in the carrying on of regulated activity, and

(ii) the management of the regulated activity.

17(2)(a)

There was not an effective process to ensure clinical staff had access to patient DNACPR information or access to the patients electronic record held by the commission trust.

There was not an effective process to ensure in the provision of quality and risk information to the staff. Staff did not receive information about quality, performance, safety or risks at the unit.

17(2)(b)

We were not provided with assurance that the risk register was monitored, regularly reviewed and a named person had ownership of the actions. The risk management policy did not state how often the risk register should be reviewed. The risk register was not a live document. During the inspection, we identified the lack of compliance with hand hygiene. Although the results from May 2017 had started to improve, the unit had not achieved the organisations target of 90% which had been occurring since January 2017. This was a current and live risk for the North Devon Satellite Unit due to them also having an incident of a bacteraemia infection in February 2017; however this was not on the risk register. Recruitment was also a challenge for the unit and this was also not on the risk register.

There was a systematic programme of clinical and internal audit used to monitor quality and identify where actions needed to be taken. However, repetitive actions following monthly audits demonstrated a lack of oversight to ensure actions were completed.

17(2)(d)

Staff used the clinic manager's log in details and password to gain access to patient's full medical records

This section is primarily information for the provider

Requirement notices

which were held at the commissioning trust. This was not in line with the Department of Health document Confidentiality: NHS Code of Practice (2003). The document stats staff must not share log on details and if access is required by other members of staff, appropriate access should be arranged.