Diaverum UK Limited (Accrington)

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

Ratings

Overall rating for this location

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Diaverum UK Limited (Accrington) is operated by Diaverum UK Limited and commissioned by Lancashire Teaching Hospitals NHS Foundation Trust. It is based in a building belonging to East Lancashire Hospitals NHS Trust.

The service is a nurse led unit, comprising of a manager, deputy manager, four senior nurses, two nurses, four dialysis assistants and three health care assistants. The service has 12 haemodialysis stations of which two are in a side room. Other facilities include a patient waiting area, a patient weighing area, clean utility, dirty utility, staff changing and rest room, offices, patient toilet, engineers repair room and water treatment plant.

The service provides haemodialysis treatment to adults aged 18 years and over, who have non-complex needs. Currently the service provides treatment to 24 patients between the ages of 18 and 65 and to 34 patients aged over 65 years.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 17 and 18 May 2017 along with an unannounced visit to the unit on 31 May 2017To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate. Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

Services we do not rate

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

• There was a culture of incident reporting amongst staff with lessons learning shared.

• Medicines were stored and dispensed correctly.

• Staff were appropriately trained to recognise and report safeguarding concerns and we saw this process work during our inspection.

• The areas we inspected were visibly clean and tidy and records showed hand hygiene and water cleanliness were regularly maintained.

• Staff completed mandatory training which was managed by a regional practice educator.

• Pain relief, food and refreshments were available if required

• Patients spoke highly of the staff that cared for them and were happy with the treatment they provided.

• Staff we saw displayed a compassionate friendly approach to patients.

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

• Incidents were not categorised in terms of level of harm sustained. This meant that staff may be less aware of the impact of an incident.

• Root Cause Analysis templates did not contain headings to ensure important information such as a chronology was included in line with guidance by the National Patient Safety Agency.

• Patient records were not always fully completed in relation to risk assessments and clinical observations.

Summary of findings

• Prescriptions were recorded on multiple charts rather than one and GP letters were not stored in patient record, which increased the risk that information may be missed.

• The unit did not have any records to provide assurances that daily general domestic cleaning had been completed.

• During a maintenance issue staff had difficulty obtaining a response from engineers despite calling a designated emergency number.

• Staff did not have a robust plan in place to ensure multiple patient transfers could be undertaken urgently if required.

• Main access front doors were not always secure despite the manager confirming that they should be.

• Sepsis training was not provided which posed a risk that staff may not always identify signs of sepsis.

• Not all cultural needs were met with only chaplains and celebrations undertaken based on Christian faiths.

• Staff used relatives to help translate conversations with patients, which was not robust and posed a risk that information could be misinterpreted.

• Governance of policies, procedures and pathways was difficult to understand with expired and inconsistent review dates and processes.

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

Ellen Armistead

Deputy Chief Inspector of Hospitals North

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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Diaverum UK Limited (Accrington)

Services we looked at
Dialysis Services

Summary of this inspection

Background to Diaverum UK Limited (Accrington)

The Diaverum UK Limited (Accrington) clinic has been operated by Diaverum UK Limited since 2010. It is a privately operated satellite unit for dialysis services provided by Lancashire Teaching Hospitals NHS Foundation Trust and housed in a building managed by East Lancashire Hospitals NHS Trust. The clinic primarily serves the communities of East Lancashire. It also accepts patients from outside this area who are visiting the area on holiday if capacity allows.

A clinic manager was in post from October 2010; however, the unit had not registered a manager with CQC between 2014 and the date of our inspection. At the time of the inspection, a new clinic manager had recently been appointed and was in the process of registering details with the CQC.

We last inspected this service in May 2012. The service was compliant at the time meeting all the essential standards of quality and safety it was inspected against. It did not identify any areas of concern or areas that required improvement.

Our inspection team

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

Information about Diaverum UK Limited (Accrington)

The Accrington Dialysis Unit is operated by Diaverum UK Limited. It is a mixed gender dialysis treatment unit and is registered to provide the following regulated activity to patients over the age of 18 years:

• Treatment of disease, disorder, or injury.

Diaverum have been providing services at the unit since December 2010. The main referring renal unit is Lancashire Teaching Hospitals NHS Foundation Trust which provides a multi-disciplinary team who support the unit in providing the dialysis service. It primarily serves communities in and around East Lancashire.

The unit is located in a suburb of Accrington on the site of a minor injury unit managed by a local NHS Trust. Dialysis is provided for patients six days a week from Monday to Saturday. There are no overnight facilities. Three dialysis sessions run on a Monday, Wednesday and Friday, with two sessions on Tuesday, Thursday and Saturday. Treatments start at 7am, 1pm and 6pm.

The unit has 12 treatment stations, two of which are in a side room, offering haemodialysis (HD) and haemodiafiltration (HDF) but not peritoneal dialysis. Home dialysis services are not provided by staff at this unit.

Access to the unit is outside with ample car parking. Entry to the unit is secure via door bell.

There are eight registered nurses, three dialysis assistants and three healthcare assistants employed by the unit.

Between February 2016 and January 2017, the unit provided 9295 sessions to adult patients with an average of 774 sessions provided each month. All of these treatments were NHS funded. Services are not provided to children or young people under the age of 18 years. Currently, 58 patients receive dialysis treatment at the unit.

During the inspection, we spoke with eight staff including, the director of nursing, the existing clinic manager, a new

Summary of this inspection

clinic manager, the deputy clinic manager, the regional education facilitator and registered nurses. We spoke with three patients and reviewed four patient records. We provided 'tell us about your care' comment cards for patients and visitors to complete but did not receive any completed cards.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. The most recent inspection of the unit took place in May 2012, which found that the unit was meeting all standards of quality and safety it was inspected against.

Track record on safety

• We were unable to source numbers of incidents categorised as low, moderate, severe harm or death because the unit did not record these details.

• However, between February 2016 and January 2017 there were no reported patient deaths, never events or serious incidents which occurred at the unit between February 2016 and January 2017.

• No incidents occurred which triggered the Duty of Candour process.

• No patient falls were reported.

• There was one report of a diabetic foot ulcer, but no urinary tract infections or venous thrombo embolism (VTE).

• There were no cases of Methicillin-resistant Staphylococcus aureus (MRSA), Meticillin-sensitive staphylococcus aureus (MSSA), Clostridium Difficile (C.Diff), other bacteraemia reported or blood borne virus as having occurred in the service.

• No complaints were received by the unit within this time period.

Services accredited by a national body:

• ISO 9001: accreditation for the integrated management systems.

Services provided at the unit under service level agreement:

• Clinical and or non-clinical waste removal

• Interpreting services

• Pathology

• Fire safety

• Water Supply

• Building maintenance

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

• The unit had a good reporting culture for incidents, and staff were aware of the types of incidents that needed to be recorded. Incidents were reviewed by senior staff, learning was shared, and the duty of candour was implemented appropriately when necessary.

• Mandatory training was supported by the unit's practice development nurse and compliance rates were high.

• Staff had received training in safeguarding, and we saw staff putting this into practice during the inspection.

• Infection prevention and control measures were undertaken within the unit. Staff carried out their duties in line with the provider's infection prevention policies, and machines were appropriately cleaned and disinfected between patients.

• The equipment used in the unit was appropriately maintained for the safe care and treatment of patients, and agreements were in place for the rapid repair of any faulty equipment.

• Staff appropriately monitored the quality of the pure water supply for the unit, and took appropriate action to report abnormal test readings. A second filtration unit meant that patients could continue to safely dialyse if there were any faults with the equipment.

• Medicines within the unit were ordered, stored and disposed of appropriately.

• Staffing levels were appropriate to provide safe care to patients.

• The unit had procedures to follow in the event of a major incident or loss of vital supplies. Staff were aware of their roles during such events.

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

• Incidents were not categorised in terms of level of harm sustained.

• Root Cause Analysis templates did not contain headings to ensure important information such as a chronology was included.

• Staff at the unit did not follow up patient deaths unless they occurred within the unit itself. Instead they relied upon the commissioning trust to contact them on an ad hoc basis.

Summary of this inspection

• The unit did not have any records to provide assurances that daily general domestic cleaning had been completed.

• During a maintenance issue staff were initially unable to obtain a response from engineers despite calling a designated emergency number.

• Specific batch and equipment numbers were not recorded for single-use equipment used for each patient. This meant that, in the event the numbers were needed, staff relied on obtaining batch numbers from the next available set.

• Multiple prescription charts were in use for each patient dependent upon who dispensed each medicine and GP letters were stored separately, away from each patient record. Having information spread out across different documents increases the risk of mistakes.

• Staff did not have a robust plan in place to ensure multiple patient transfers could be undertaken urgently if required.

• Main access front doors were not always secure despite the manager confirming that they should be.

• Patient records were not always fully completed with risk assessments and clinical observations missing.

• Sepsis training was not provided which posed a risk that staff may not robustly identify the signs of sepsis. Managers had difficulty locating guidance for managing patients with sepsis.

Are services effective?

We do not currently have a legal duty to rate dialysis services. However, we found the following areas of good practice:

• Staff provided evidence-based care in line with national guidelines from professional bodies such as the Renal Association and the National Institute for Health and Care Excellence.

• Treatment was provided in line with individual treatment prescriptions following monthly blood tests, which were reviewed regularly by the unit's multidisciplinary team.

• The unit was in the process of introducing the commissioning trust's holistic care pathway, which included the assessment of patient's pain, psychological and physical needs.

• A dietitian visited the unit twice weekly to discuss patients' nutritional needs and to provide advice

• The unit collated and submitted treatment data to the commissioning trust for inclusion in the submission to the Renal Registry.

Summary of this inspection

• Staff competencies were monitored with support provided to allow staff to maintain professional development.

• Nursing and medical staff had access to the information needed to provide care.

Are services caring?

We do not currently have a legal duty to rate dialysis services. However, we found the following areas of good practice:

• Staff provided compassionate care to patients, which was reflected in the patient survey results where 92% of patients said they had trust in the clinic team, and 91% said they felt staff improved their care.

• Patients were involved in discussions about their care and were supported to understand their treatment.

• The unit was in the process of implementing a holistic care approach to support patients both physically and emotionally, and to help staff more readily identify patients who needed referral to other relevant professionals such as the psychologist or renal social worker.

• We saw examples of staff going beyond their responsibilities to help and support patients under their care

Are services responsive?

We do not currently have a legal duty to rate dialysis services. However, we found the following areas of good practice:

• The unit's service specification was defined and agreed with the commissioning trust to meet the needs of local people, and took into account the trust's policies.

• The unit met the department of health's Health Building Note 07-01: Satellite Dialysis Unit guideline.

• The unit was accessible with designated patient parking and secure doors. Arrangements were in place for routine patient transport.

• Patients were assessed for suitability for treatment at the unit to help ensure staff could accommodate them safely and effectively.

• Staff were introducing a holistic care pack to help identify patients who required referral to other healthcare professionals such as the psychologist, renal social worker or to their own GP.

• The unit opened six days a week and appointment slots were allocated to patients and despite there being limited flexibility due to the size of the unit, staff worked to accommodate requests to change appointments to try to meet patient needs.

Summary of this inspection

• No appointments had been cancelled within the previous 12 months and 99.5% of treatments were initiated within 30 minutes of scheduled appointment times.

• The unit received no written complaints in the reporting period.

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

• We saw evidence that Christian faiths were celebrated and chaplains were available. However there was less evidence to suggest that other faiths were accommodated to the same extent.

• Staff relied on relatives of patients to help translate when a patient's first language was not English.

Are services well-led?

We do not currently have a legal duty to rate dialysis services. However we found the following areas of good practice:

• There was a clear staffing structure and staff told us that told us the organisation was 'a good company to work for with friendly supportive staff'.

• There was a close working relationship between the unit, the commissioning NHS trust and the local NHS trust that owned and maintained the building.

• A risk register was in place which held details of risks and actions to mitigate them.

• Staff could easily access the most recent version of policies and procedures.

• Monitoring meetings took place the trust to review performance against the service contract.

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

• At the time of the inspection the unit did not have a currently employed member of staff registered with the CQC as a registered manager. This is a breach of a condition of registration.

• The unit did not currently collect or publish data in line with the NHS Workforce Race Equality Standards.

• Policy and procedure review processes were not robust and did not provide assurance that they were regularly reviewed.

• The risk register did not contain details to describe how mitigating actions had reduced the level of risk.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

- An incident reporting procedure set out the process for staff to report incidents, including near misses. This was supported by a management of serious medical incidents policy. This set out definitions of serious incidents including staff responsibilities to report incidents and the escalation path to be used by staff if necessary.
- There was a culture of reporting and learning from incidents amongst staff. Staff we spoke to understood their responsibility to report incidents and gave examples of incidents they had reported.
- Reports were completed using a web based electronic system. However staff did not receive receipts to confirm an incident had been logged in the system. This meant that staff were not able to confirm that their incident had been received without checking with the manager.
- Staff told us feedback following incidents was provided on a one to one basis or via staff meetings.
- Between January and April 2017 staff reported a total of 71 incidents. These included failures to attend for treatment, shortened or interrupted treatment (by patient), hypotension (lowered blood pressure), and vascular access problems.
- Although incidents were categorised in terms of themes, incidents were not categorised in terms of the level of harm. This meant staff had less awareness of the impact of particular incidents and were less able to prioritise actions to reduce the risk of recurrence.
- Serious incidents or never events were sent to and monitored by senior managers such as the clinic manager and director of nursing. However, records showed that between February 2016 and January 2017, no serious incidents, deaths or never events occurred at the unit. A never event is a serious, wholly preventable patient safety incident that has the potential to cause serious patient harm or death, has occurred in the past and is easily recognisable and clearly defined
- Specific incidents were monitored. These included the number of falls and the number of pressure ulcers occurring under the care of staff in the unit. Between February 2016 and January 2017 the service reported one ulcer which was related to the patient suffering diabetes.
- Additionally the unit monitored incidents of patient urinary tract infections, or hospital acquired venous thromboembolism (blood clots) if the patient was symptomatic on assessment. No incidents of urinary tract infection or blood clot were recorded by staff in the reporting period.
- Deaths of patients occurring away from the unit, but who had regular dialysis on the unit were not formally reviewed by staff unless the death occurred within the unit itself. Instead senior staff relied upon the commissioning trust to contact them on an ad hoc basis but there was no formal process in place. We were concerned that managers had not taken adequate responsibility to assure themselves following patient deaths.
- Incidents reported by staff were reviewed by the clinic manager or deputy clinic manager. Root cause analysis was undertaken for serious incidents. We reviewed a root cause analysis report of a venous needle dislodgment incident. However, the template did not follow standard root cause analysis principles such as those from the National Patient Safety Agency. For example, the report did not include dates or times, or a chronology or timeline to show the reader exactly what occurred and when. Instead, each of the twelve stages was completed in tabular format which we were concerned missed vital information. When we asked the manager about this we were told that the incident

report would always be attached which gave a version of events. However we remained concerned that this process was not robust enough to provide adequate root cause analysis of serious incidents.

- Incidents were categorised by themes within the reporting system, which automatically alerted senior management to serious incidents in line with the provider's incident reporting and management of serious medical incidents policies.
- Staff we spoke to told us that learning from incidents within the unit were shared by email and discussed with any individuals involved and in monthly staff meetings. Learning was also shared with the provider's clinics through the quarterly regional clinic managers' meetings.
- The director of nursing shared safety and medicines alerts. The practice development nurse also shared lessons learnt from clinical incidents, serious incidents from all the provider's clinics. The clinic manager was also able to request additional training for staff if this was needed following an incident.
- 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.
- The unit reported no incidents of moderate or severe harm or death between February 2016 and January 2017 that triggered the duty of candour. However, the provider had a duty of candour policy, which aligned to the national patient safety agency's framework principles. The policy set out staff responsibilities and the steps to be taken to fulfil the regulatory duty.
- Senior staff in the unit were aware of the legislative requirements of the duty. Operational nursing staff we asked were able to describe the principles of the duty of being open and honest following any incidents and to explain what happened to patients and/or their carers; however, they were less able to describe the triggers of moderate or severe harm or death.

Mandatory training

- Mandatory training was delivered through a mix of classroom and online training and was monitored by the provider's practice development nurse.
- Mandatory training for staff included a range of subjects mandated by legislation and by the provider such as fire safety, medicine management, data protection and basic life support.
- Training was delivered on an annual, two yearly or three yearly basis dependent on the topic. For example, fire safety and basic life support were annual, safeguarding and anaphylaxis were two yearly and manual handling theory was three yearly with an annual practical training session.
- The majority of staff had completed their mandatory training. Between January 2016 and December 2017, compliance figures were 92% for fire safety training, 100% for hand hygiene training, anaphylaxis, data protection, basic life support, infection control and safeguarding.
- The unit used a number of regular bank staff, who were required to have renal experience. Evidence of bank staff qualifications and mandatory training was submitted to the provider's HR department prior to staff commencing working at the unit. For those who were primarily employed by the NHS, the provider had an expectation that mandatory training was undertaken in that role. Where this wasn't the case bank staff undertook mandatory training provided and monitored by Diaverum in the same way as permeant staff.

Safeguarding

- There was a policy to support staff in identifying and reporting safeguarding concerns.
- Services were not provided for children under the age of 18 years. However staff still had a duty to report safeguarding concerns.
- Staff received training to enable them to identify vulnerable adults and children. Safeguarding vulnerable adults training formed part of the mandatory training programme for all staff which also included basic training about safeguarding children. All staff had completed safeguarding adults level two training.
- The designated lead for safeguarding was the nursing director for the provider. However neither the nursing director nor the clinic manager had received higher level training. This meant that staff had no one working with them that was trained to a higher level and able to provide face to face advice. Despite this, the clinic manager was due to complete level three safeguarding training in May 2017.

- Staff had contact details for the local county council safeguarding team to obtain further advice and to make safeguarding referrals when needed.
- We saw staff identify and report a safeguarding concern about a patient during our inspection. Here staff spoke to the patient, sourcing relevant details before informing the police and reporting the incident to regulatory authorities. After the incident was reported, staff took responsibility for following up the case to ensure any further actions to help protect the patient were identified.

Cleanliness, infection control and hygiene

- All the areas we reviewed including treatment and waiting areas, corridors, water treatment areas and sluices were visibly clean and tidy.
- Staff used a general infection control policy, which set out clinic manager and employees responsibilities for infection control. This was supported by a standard precautions and safe work practices policy. The policy embedded the world health organisation's five moments for hand hygiene.
- No cases of Clostridium Difficile (C.diff) meticillin-resistant staphylococcus aureus (MRSA), meticillin-sensitive staphylococcus aureus (MSSA), or blood borne virus were identified as occurring at the unit between February 2016 and January 2017.
- Domestic staff from the local NHS trust undertook daily domestic cleaning of the unit in line with a weekly cleaning schedule. Staff told us the domestic cleaning was of a good standard; however, cleaning logs were not used to confirm which areas had been cleaned. This meant the unit was not able to provide evidence that domestic cleaning had been completed as required.
- We observed staff following infection prevention and control requirements set out in the provider's policies. They followed good hand hygiene practice, including 'arms bare below the elbows' and used the aseptic non touch technique when providing care.
- Staff audited use of the 5 moments of hand hygiene monthly. We saw that between March and May 2017 the unit staff were 100% compliant with the process.
- Antibacterial gel dispensers were located throughout the unit. Hand washing facilities were also located in the treatment area. Posters explaining the World Health Organisation's (WHO) 5 Moments of Hand Hygiene were also displayed which helped make sure patients, staff and visitors adopted effective hand washing techniques.
- Other hygiene and infection control audits were undertaken which covered a range of elements including cleanliness of entrance and reception areas, waste disposal, sharps handling, decontamination and disinfection practices. However the audits did not produce an overall score. Instead staff ticked 'yes' or 'no' to answer audit questions such as 'is there a system for cleaning crockery?' and 'is the cleaner's cupboard well maintained?' we saw that in February 2017 both these questions were answered 'no', and all other questions such as 'are sterile items kept off the floor and within expiry date?' and 'are areas free from odours?' were seen to be compliant. We saw that in March the cleaner's cupboard was checked again and comments were added to confirm it was tidier. This showed that action was taken to address issues identified in audits.
- Staff wore personal protective equipment, such as aprons, gloves and visors when cleaning the equipment, and when undertaking the insertion and removal of dialysis needles. Each staff member had their own visor which should be worn when attaching patients to the dialysis machine.
- Each machine underwent a heat disinfection cycle at the end of each treatment session, which was confirmed by a machine self-test at the end of the cycle. We observed staff cleaning the treatment chairs and associated equipment, and decontaminating each dialysis machine between patient treatments.
- Although staff completed cleaning checklists following each treatment session, the unit did not carry out any cleaning audits in relation to these checklists. This meant there was a risk that poor compliance with cleaning may not be identified or challenged.
- The unit held a weekly manual log for internal machine chemical disinfection and residual disinfectant check. We viewed the log for week ending 5 May 2017; this was fully completed.
- The unit did not have an isolation facility. This meant that patient with identifiable infections were not treated at the unit. However, the provider's hygiene and infection control policy process set out the steps to be taken to minimise the risk of infection from blood borne viruses such as hepatitis B and C, and HIV, and from bacteriological infections such as MRSA and MSSA.
- Patients were screened quarterly for hepatitis B and C and annually for HIV in line with the policy requirements. Patients who had hepatitis C that was

under control were checked every three months with a PCR (polymerase chain reaction) test. Patients with active infections were referred back to the commissioning trust's renal unit.

- The unit had a process for checking patients' vaccinations status with their GP. The new clinic manager recognised there were some gaps in the data held and the unit was in the process of writing to the relevant GPs and patients to check their vaccination history and to encourage the update of vaccination booster treatment.
- Staff received hepatitis B immunisation, which reduced the risk of them contracting the infection.
- Patients were screened for MRSA/MSSA every three months in line with the referring trust policy. No cases had been identified between February 2016 and January 2017. A policy was also in place to screen patients who had returned after receiving dialysis treatment on holiday as well as a protocol for action should test results be positive.
- Patients requiring treatment in isolation (for example, to minimise the risk of infection for a period following a return from travel) could not be treated at this unit. This was because the unit did not have an isolation area. Patients requiring isolation had to travel to the nearest available isolation bed at Burnley approximately 8 miles away. Staff followed the referring trust's policy for action should patients test positive for any condition requiring isolation.
- The trust who owned the building housing the dialysis unit were responsible for waste disposal.

Environment and equipment

- The unit housed ten treatment stations in a main treatment area with two additional stations in a side room. This enabled staff to run 180 dialysis sessions each week. Nurse call bells were available at each station, including the side room, should patients require help urgently. Patients told us they were provided with call bells and we saw staff respond to a call bell alarm quickly during our inspection.
- The dialysis unit was part of an estate belonging to the local NHS hospital trust who assumed overall responsibility for building maintenance requirements.
- Dialysis machines, chairs, beds, and the water treatment plant were maintained by the provider's technicians. Remaining dialysis equipment was maintained and calibrated under contract with the individual specialist equipment providers. The unit held two spare clean dialysis machines ready for use in the event of a machine fault.
- Dialysis needles and lines were single use only. Staff showed us the process of setting up a patient on a machine. We saw that single use equipment packages were discarded prior to dialysis treatment starting and that batch numbers were not noted. This meant that should any issues be identified during treatment, staff would not be able to confirm which batch the equipment came should they need to inform the supplier. Staff explained that they would presume the batch number of items used were the same as remaining items in the stock room. However, as different batches could be stored at the same time we were not assured staff would be able to supply accurate details to suppliers should they need to.
- Water filters were changed and serviced annually and records showed that these were up to date. However calibration was also required and was due to expire within three days of our inspection. No date had been organised for calibration to take place. The manger confirmed this was due to be organised. We were concerned that there was not enough time to calibrate the machine in time for the due date.
- Water bacteraemia levels were checked each month to help make sure raised levels were identified as soon as possible. Between January and April 2017 endotoxin levels were than 0.01% and the unit had 100% compliance for appropriate levels of colony forming units. Colony forming units are the number of microbes present that are viable to multiply.
- Access to the unit and to the treatment area was via secure automatically locked doors. The manager confirmed that the entry doors should be locked at all times, however we arrived one morning to find the doors were unlocked. The manager confirmed this should not have happened and would remind the staff.
- A sealed resuscitation trolley was located within the treatment area. The trolley was owned, supplied, and stocked by the commissioing trust. Key items such as the oxygen, pulse oximeter, suction and anaphylaxis box and the seal were checked daily. A more detailed check was preformed monthly where the seal was broken and all items to secure airway, breathing and circulation

were checked before re-sealing. Records we reviewed for May 2017 showed that checks were up to date. We reviewed a range of equipment stored on the trolley which was suitably sealed and within expiry date.

- An emergency evacuation 'grab' bag was held in the clean utility, next to the treatment room. We checked the contents of the bag which included all relevant equipment needed by staff to manage patients' care safely in the event of an evacuation such as needles, gloves and saline. However we found some items were out of date including alcohol swabs and saline. The new manager immediately removed these and acted to identify and speak with staff responsible for recent checks.
- There was sufficient space between the treatment chairs to enable patients to mobilise easily into and out of the chair, and for staff to attend to the patient during treatment or emergencies. This was in line with the Department of Health's Health Building Note 07-01: Satellite Dialysis Unit guideline.
- Dialysis machines had alarms which could be used to alert staff if needles moved or if a patient's blood pressure fell outside of an acceptable range.
- External disinfection of dialysis machines was carried out with a prepared solution of strong disinfectant. The solution was made up each day from concentrate, using appropriate personal protection and staff were able to explain the process to us.
- Some medical devices were not working as effectively as they should which posed a risk that staff may be limited in their ability to care for patients. For example, managers told us that three of the four temperature sensors on the unit were not working. New sensors had been ordered.
- There was a fire warden assigned to the unit to manage any incident involving fire.
- There was a system in place to ensure equipment failures were dealt with promptly. We saw that in June 2017 a water plant failure tested this system. Staff appeared to have difficulty raising the alarm to maintenance teams due to no answer on the emergency contact numbers. However, in the meantime they implemented plans to decant patients to other centres. Shortly afterwards contact was made and the water plant was placed into emergency mode until repairs took place. Clinicians were made aware that one patient was transferred to the provider's other local unit and ten patients had reduced treatment times of three hours.

Medicine Management

- The unit used the provider's policy on medication handling, storage and disposal, which was supported by staff training in medicines management. The clinic manager was responsible for the safe and secure handling of medicines within the unit.
- Medicine compliance targets were included in the contract with the commissioning NHS trust which included having up to date prescriptions. Between January and April 2017 the unit scored 100% compliance.
- Staff received annual medicines management training. In April 2017 we saw that seven out of eight eligible staff were up to date with this training.
- There were no medication errors reported in the period March 2016 to February 2017.
- A range of medicines were available to staff caring for patients. The unit did not administer or store any controlled drugs. Medications used in the unit that were stored in a locked medicines cabinet and medicines trolley.
- Temperature sensitive medications were stored in a fridge in the same area however this was not locked due to a faulty seal. Staff confirmed that since reporting the fault in September 2016, no one from the local estates team had come to fix the issue. Staff confirmed they had not taken any further action to chase the team responsible but the deputy clinic manager confirmed contact would be made with the team to report the issue again.
- Fridge and room temperatures where medicines were stored were checked daily to ensure temperatures were in line with manufacturer instructions. Records we checked confirmed this.
- A dedicated pharmacist was available for staff at the unit to contact via email or telephone. Medicines were ordered monthly or more frequently if required using a stocklist with instructions detailing required stock levels.
- Keys for the medicine cabinet and trolley were held by the nurse in charge for each shift.
- We checked a sample of two different medications both of which were within their manufacturers' recommended expiry dates.

- Any medication needed was prescribed by medical staff, who visited weekly and reviewed each patient individually each month. The unit did not use non-medical prescribers. Urgent prescriptions could be authorised verbally by the medical staff; however, these were subsequently followed up in writing by fax within 48 hours or 72 hours if over a weekend or bank holiday.
- We reviewed four medication prescription and administration cards held in patient files. These were legible, and included information such as the dose, frequency of administration, prescriber's signature, and checked by signature, and initials of the staff member administering the medication. However, three different prescription charts were used dependent on where the medicines being prescribed were sourced from. We were concerned that this disjointed process could lead to errors rather than using a streamlined singular prescription process.
- Staff providing medicines to patients had to be sure of their identity to help reduce the risk of administering medicines to the wrong patients. Staff confirmed that even though patients were well known to them in the majority of cases, they used name and date of birth to check identify as well as using guidance by the Nursing and Midwifery Council. The deputy clinic manager explained that photographic identification had been discussed with the commissioning trust but was not instigated.

Records

- Management of patient records was supported by the provider's medical records policy and information governance policy. Staff received annual training in data protection.
- The unit used a mixture of electronic and paper records. For example, care plans were paper based and historical treatments were stored electronically. Paper records were stored in a locked records room within the staff only area. Other information was stored away from individual patient records in folders marked 'GP letters' for example. Storing elements of records in different places increased the risk that important information may be missed, particularly if the member of staff is unfamiliar with the different areas of storage.
- Electronic details were dependent upon manual entries made by staff from the paper records. This posed a risk of errors being made when entering details such as blood pressure readings. However the clinic manager confirmed that new dialysis machines due to arrive in August would help minimise this risk as details would be recorded automatically.
- All regular patients were under the care of the local NHS Trust specialist renal centre. At the time of our inspection dialysis staff did not have access to the system used by this trust. However this was due to be implemented at the clinic and we saw evidence of progress during our inspection. Working with one system would increase the access staff had to medical information about the patients they were caring for.
- We reviewed a sample of four paper patient records. These contained important information needed to care for patients safely such as known allergies, prescriptions, treatment 'flow' sheets, consent and individual risk assessments. The records were legible and structured with no lose sheets. The folders also had clearly assigned named nurses, who had responsibility for maintain the paper records.
- Despite this, we also found some elements were not included in the records that should have been. For example, risk assessments including those for falls, moving and handling, venous dislodgement and post-operative risks were not fully complete in all four records. We were concerned that without recording risks, staff were less sighted on the needs of their patients in order to keep them safe.
- The records contained 'patient flow sheets' which recorded observations and notes during each treatment session. Approximately 12 paper sheets were kept on file, the details of which were also added manually to the electronic record. However, the paper sheets contained a number of omissions. For example, on one record, seven out of 14 flow sheets did not document a temperature at all during treatment. In another record only six out of 12 flow sheets had a temperature recorded. In minutes of unit meetings held as far back as January 2016 temperature observation recording was listed as a 'repeated issue'. We were also concerned that staff would be unable to fulfil the requirements of the provider policy relating to patients with a high temperature because this observation was not being consistently monitored.

Assessing and responding to patient risk

- Staff undertook a detailed assessment of patients prior to commencement of their treatment at the unit. This

included reviewing the patient's demographic, their clinical details including allergies, diagnoses and vascular access type, past medical history, their existing medicines and current dialysis prescriptions, virology results, and any special needs or mobility requirements.

- The unit used the national early warning score system (NEWS) to manage patients who were showing signs of deterioration. NEWS uses a range of vital sign observations including respiratory rate, oxygen saturation levels, temperature, blood pressure, heart rate, and level of consciousness to assess and respond to acute illness. However, we were not assured the observations recorded were sufficient to enable staff to accurately implement the NEWS system. This was because staff were not recording patient temperatures or respiratory rates as part of the regular observations, which meant it was not possible to accurately calculate a NEWS score or to know when escalation of care needed to be triggered. The clinic manager told us that the NEWS system was being reviewed in order to ensure it was appropriately tailored to the needs of renal dialysis patients.
- Emergency care was available should a patient's condition deteriorate. This was done using the 999 system. Staff used a mobile phone which was kept on the resuscitation trolley and charged each night, to ensure they could make the call whilst by the patient's side if required.
- Should patients require urgent but not emergency intervention, there was an urgent care centre on the same site as the unit and staff gave examples of occasions when patients were escorted to the centre for further assessment.
- Needle placement was undertaken using 'wet' rather than 'dry' techniques. This helped reduce the risk of air embolus, blood spray or spillage as well as the potential harm caused should infiltration occur in surrounding tissue.
- Managers confirmed that policy or protocols relating to the identification and early treatment intervention for sepsis was not used routinely. However the commissioning trust's policy could be used if required. Despite this, managers took several hours to locate a policy because they had to contact the trust to obtain it. Not having a policy or procedure displayed, readily available or used regularly left us concerned that sepsis was not given as much consideration as it should have been and that potential cases of sepsis may go unrecognised.
- The practice educator confirmed that staff were not trained to identify or initiate action to treat sepsis, other than recognise symptoms of possible infection in line with basic nursing principles. These principles included recognising when a patient's temperature was higher than it should be which may indicate infection. However, when we checked patient records we saw that temperatures were not always recorded which posed a risk that the indicators for infection were not always recorded, lessening the opportunity to identify infection early.
- Between February 2016 and January 2017, eight patients were unexpectedly transferred to another hospital from the dialysis unit. However this number included patients who were transferred between two local dialysis units for particular treatments such as transfusions or isolation.
- Although there was a process in place to risk assess patients in areas such as falls, needle dislodgment and moving and handling we saw evidence that these were not always completed. (see subheading 'records' for details). Managers told us that risk assessments had been introduced recently and that staff were in the process of completing them. Without an established process we were concerned that risks had not been properly considered in patients prior to this.
- We saw care pathways in place to help manage high risk scenarios such as patients with pyrexia (a high temperature) or chest pain. However, the chest pain pathway did not align with the competencies of this unit. For example, the pathway instructed staff to undertake an electrocardiogram (ECG). However the unit did not have access to an ECG machine and staff were not trained to interpret the readings.
- We were also concerned that the instruction to request emergency assistance was not properly stipulated. Instead the pathway instructed staff to 'arrange transfer to A&E' which did not adequately describe the nature of the transfer (emergency or routine). The transfer was also listed someway in the process rather than being done urgently. For example, after undertaking an ECG, staff were then instructed to make contact with the renal unit at the commissioning trust rather than

arranging the transfer. This left us concerned that a patient suffering with a potentially life threatening cardiac complaint may wait longer than they should for staff to summon emergency care.

Staffing

- An up to date policy and procedure for staffing and rostering were available to support staff involved in this area of work on the unit. These detailed arrangements for minimum staffing, annual leave and clinical versus administrative time for those with management duties. There was also a policy for managing temporary staff such as those from established agencies.
- There were 8.0 dialysis nurses, 4.4 whole time equivalent (WTE) dialysis assistants and 2.5 (WTE) healthcare assistants employed by the service. There were no vacancies for any staff at the time of our inspection.
- Day to day, two or three nurses, one dialysis assistant and one healthcare assistant worked in the unit. We saw the rota between April and May 2017, which confirmed this. The ratio of qualified staff (nurses and dialysis assistant mix or all nurses) to patients was 1:4, which was better than the ratio of 1:5 recommended by the National Renal Workforce Planning Group 2002.
- Where staffing fell to below required levels, bank or agency staff were sourced to work instead. Between November and January 2017, no bank or agency staff worked on the unit. However, should temporary or agency staff be required, they were introduced to the unit by staff who went through a checklist to ensure they were aware of important details. These included procedures and locations for fire and evacuation, information governance and occupational health details.
- Handovers between staff took place each morning. Here a senior nurse went through patients individually to make sure any important details were discussed. Handovers also took place between the clinic manager and deputy manager on a weekly basis. Records showed that specific patients, clinical issues, facilities and health and safety were all discussed.
- Annual leave was monitored and planned in advance. The longer the requested time period, the more notice was required which helped minimise the impact on staffing levels day to day.
- No medical staff were employed directly; however one consultant and one associate specialist doctor were responsible for patients at the unit. They were available via mobile or email during office hours. Out of hours staff could contact the on call registrar or consultant at the commissioning NHS trust if necessary.
- The consultant visited patients on the unit once each month and the associate specialist held a weekly clinic as well as attending on two further days each week.
- Technical staff were available to maintain equipment including dialysis machines, dialysis chairs and medical equipment. A corporate policy supported this process. Technicians were also available to help staff using new machines which were due to arrive in August 2017.

Major incident awareness and training

- The unit had a corporate business continuity policy in place which was supported by a procedure to support implementation of the policy. We viewed tailored business continuity plans for information technology, power supply, water supply and water treatment plan failures. The unit also had plans in place for telephone systems failures, loss of heating and staff shortages.
- One of the actions involved transferring patients to other local units to allow them to continue treatment. However, the manager told us there was no agreement in place with the local ambulance service to facilitate this should it be required. Instead the manager suggested patients would drive themselves or rely on relatives. We were concerned that this was not robust enough to ensure patients could receive the support they might require under these circumstances.
- The continuity plans included defined staff roles which were displayed on the staff noticeboard and escalation details to make sure the senior management team and commissioning trust were informed promptly. A system was in place for automatically sending escalation emails as soon as a business continuity incident was triggered.
- Processes were in place to investigate, review and identify learning outcomes following business continuity incidents.
- Staff were aware of their roles in an emergency, and this was tested through evacuation scenario exercises every six months. The last exercise was held in March 2017.
- Personal emergency evacuation plans were in place for all patients attending the unit. As the plans were only introduced during the inspection they were not yet sufficiently embedded for us to assess their robustness.

Dialysis Services

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

Evidence-based care and treatment

- Treatment was provided in accordance with professional guidance from bodies including the Renal Association and National Institute of Health and Care Excellence (NICE). This was supported by corporate policies, procedures and care pathways to support staff providing care such as managing pyrexia (high temperature), assessing central venous catheter exit sites and screening for patients returning from holiday.
- However, despite these being in place, we were unsure how often they were reviewed. For example, despite managers telling us care pathway reviews were two yearly, we saw no evidence to support this. The chest pain pathway displayed an issue date of 2012 but the review date was 2016 in one area and 2019 in another. We saw no evidence that the document had been reviewed in 2016 because the version number of this document (01) indicated it was still the original. The manager confirmed that the system was not clear and agreed that it appeared not to have been reviewed. Despite this we were told that a new system for reviewing these documents was being formulated and would be introduced in the near future.
- The unit measured and reported on its effectiveness against the quality standards of the Renal Association Guidelines. It submitted data monthly to the commissioning trust for inclusion in its overall submission to the UK Renal Registry. The data was reviewed quarterly at a monitoring meeting with trust. Annual data on patients' age, gender, access and modality was also sent.
- An average of 87% of patients were dialysed through arteriovenous fistulas. This was in accordance with the NICE Quality Statement (QS72) statement 4 (2015): 'Dialysis access and preparation'.
- Assessment of patients' vascular access was carried out before and during treatment. Vascular access is the term used for access into a vein, for example, a dialysis catheter. Continuous monitoring by the dialysis machine meant that nurses were alerted by a machine alarm to any potential issues that could relate to poorly functioning fistula. Fistulas were also monitored every three months using a transonic measuring device; if any problems were identified the frequency increased to monthly and the patient was referred to the vascular surgeons. This was in line with the NICE Quality Statement (QS72) statement 8 (2015): 'Haemodialysis access-monitoring and maintaining vascular access'.
- Vascular access review meetings were held quarterly. These were attended by the renal consultants, a vascular consultant, a consultant radiologist, and a member of the unit's nursing team. The meeting reviewed patient X-rays and vascular access problems for individual patients.
- Some clinical observations such as weight, temperature, pulse and blood pressure were taken at the beginning and end of dialysis treatment and we saw some evidence of monitoring during sessions, but the evidence was not robust because staff did not always record the details in the patient record.
- The centre met the national recommendations outlined in the Renal Association Haemodialysis Guidelines (2011). For example, Guideline 2.3: 'Haemodialysis equipment and disposables' and Guideline 6.2: 'Monthly monitoring of biochemical and haematological parameter (blood tests)'.

Pain relief

- Patients were prescribed analgesia on an ad hoc basis by the doctor and a prescription for this was held on each patient's paper record.
- Paracetamol was supplied to the unit by the local NHS trust available should patients experience any pain whilst receiving treatment.
- None of the patients we asked told us they had experienced significant pain during their treatment sessions. However, the patients confirmed that paracetamol would be provided by nursing staff if they were feeling mild pain or headaches.
- Assessment of pain, against a pain thermometer, formed part of the holistic care plan approach being rolled out in the unit.

Nutrition and hydration

- Patients had access to hot drinks and biscuits during their treatment.
- A dietician from the commissioning trust visited the unit twice a week to see patients, discuss their diet and provide advice.
- Patients we spoke to were happy with the food and drinks that were provided.

Dialysis Services

Patient outcomes

- Information about the outcomes of patients' care and treatment was collected and monitored by the service to ensure good quality care outcomes were achieved for each patient. The unit measured and reported on its effectiveness against the quality standards of the Renal Association Guidelines. Electronic treatment data collected by the unit's dialysis machines was submitted to the commissioning trust for inclusion in its overall submission to the UK Renal Registry.
- The registry collected, analysed and reported on data from the UK adult and paediatric renal centres. The data submitted included patients under the direct care and supervision of the unit; it did not include information on the unit's patients undergoing dialysis elsewhere during holiday periods. As the unit's data was combined with the trust's data, the unit was unable to benchmark its outcomes against other providers' clinics.
- Patient blood was tested for potassium, phosphate, calcium aluminium concentrations in-line with the renal association guidelines. The renal association sets outs guidelines for dialysis units to follow based on evidence and research. The guideline promotes the adoption of a range of standardised audit measures in haemodialysis; promote a progressive increase in achievement of audit measures in parallel with improvements in clinical practice, to achieve better outcomes for patients.
- Patients' blood results were monitored and available within the commissioning trust's electronic system for review each month by the trust's nephrology team. This enabled the unit to review the effectiveness of treatment and implement changes to patient's prescriptions and care plans to improve outcomes. Ninety per cent of patients attended for dialysis three times a week, with the remainder attending twice a week.
- The service used standard methods of measuring dialysis dose. Urea Reduction Ratio (URR) is the most widely used index of dialysis dose used in the UK. URR is the percentage fall in blood urea achieved by a dialysis session and studies have shown the URR should be at least 65%. Data provided by the unit showed that between January 2017 and April 2017, an average of 89% of patients achieved the Renal Association target of more than 65% reduction. In the same period, and average of 92% of patients achieved the equilibrated urea reduction value of Kt/V greater than 1.2 calculated from pre-and post-dialysis urea values.
- Pre dialysis serum potassium in patients' blood was monitored on a monthly basis. Renal Association guidance suggests that pre-dialysis serum potassium should be between 4.0 and 6.0 mmol/l in HD patients. Between January 2017 to April 2017 an average of 88% of the unit's patients maintained their potassium levels within this range. Patient haemoglobin (HB) levels were measured to ensure that they remained within 10.5-12.5g/dl target range. In the same period, an average of 52% of patients remained within the recommended range. An average of 98% of patients achieved a ferratin range of more than 100 nanograms per millilitre. However, the target for patient blood pressures before treatment were not consistently met, with an average of only 46% of patients within target range.
- When we asked managers what was done to better meet targets, they told us that many of the results were dependent on variables which they struggled to control, such as patient diet and fluid intake prior to treatment. To try to ensure they kept measurements within range dieticians gave them advice about diet and fluid intake.
- Treatment waiting times were monitored. Between February 2016 and January 2017 no dialysis treatment sessions were delayed due to equipment failures or for other non-clinical reasons. Between January and April 99.5% of appointments were held within 30 minutes of their scheduled start time.
- Audits to assess how well staff taped needles to help prevent dislodgement during treatment were undertaken. These took place every three months and between January and April 2017 the unit staff scored 100% compliance with good practice.

Competent staff

- A regional practice educator worked across the region to maintain competencies by providing education and training for staff. Regular updates were sent to the clinic manager to help ensure they were aware of compliance.
- Staff were trained to provide basic life support as part of their role.
- Dialysis assistants were trained to level three of the National Vocational Qualifications (NVQ).

- New staff received an induction and a tailor made training package to ensure they were competent in their role. Training was individually tailored using a standard questionnaire, from which topics were selected and sent to the staff member to complete. Training included e-learning and face-to-face training, along with supervised clinical practice. As part of this supervised practice, staff were supernumerary for eight weeks under the guidance of a mentor while undertaking their induction and competency checks.
- Link nurses (nurses with a particular interest such as diabetes or infection control) worked in areas such as Hepatitis B.
- Staff competencies were reviewed and signed-off by their mentor. Topics included device training, administration of intravenous iron and heparin, aseptic non touch technique. The clinic manager undertook final interviews and sign-off for new staff. During the six-month probationary period new staff were able to consolidate their skills and clinical practice.
- The practice educator confirmed that no training was provided for staff in relation to sepsis. We were told that staff used basic nursing skills to identify patients with possible infection such as those with a high temperature. There was a risk that by not providing training for sepsis, staff may be less able to identify cases of infection in their patients.
- Appraisals were undertaken annually which gave staff the opportunity to discuss their employment and any other issues on a one to one basis with their manager. Between February 2016 and January 2017, 100% of staff received their annual appraisal.
- Nurses approaching re-validation were supported by managers.
- Nursing and midwifery council (NMC) registration was checked monthly by the clinic manager and we saw evidence to support this during our inspection. This helped make sure that nurses were appropriately registered in their role when caring for patients.
- New bank and agency staff were required to undertake an induction programme. This included an introduction to staff and patients, orientation to the unit including health and safety familiarisation and risk assessment verification, location of the resuscitation trolley, oxygen and suction equipment and emergency number, signatory confirmation of receipt and understanding of personal protective equipment and infection control guidelines. We saw evidence that this has been completed.
- The provider's specification for agency staff required staff to have renal experience. The agency provided evidence of staff qualifications and mandatory training prior to staff working at the unit.
- All staff had access to the provider's online learning centre. Staff told us the unit supported continual development.

Multidisciplinary working

- There was an effective multidisciplinary approach to caring for patients.
- Overall care of patients at the unit remained with the consultant nephrologists. Other staff including the clinic manager, nurses and administrative staff liaised closely with the commissioning trust renal staff to ensure patients received the care they required. Communication books were used to assist staff in effective communication with the multidisciplinary team.
- We saw evidence that staff liaised with patients' GPs to ensure they were aware of the care and treatment needs of their patients and that important information such as vaccination status was discussed. Clinic letters were copied to patients' GPs and a copy of letters was kept electronically
- Multi-disciplinary team meetings were held at the unit each month. Here the consultant, associate specialist, dietitian and unit staff met to review care plans, blood results, vascular access, bone disease, transplant status and follow up care. Psychologists and social workers from the commissioning trust were also available to attend if needed.

Access to information

- Staff had access to all the relevant information they needed to provide effective care to patients. This included previous treatment records and current observation records, up to date prescriptions, and patient's clinic letters from the renal team to their GPs. All these details were discussed each month at multi-disciplinary team meetings. Named nurses attended these meetings to maintain knowledge of their patients.

- Patient's blood results were held on the commissioning trust's electronic renal computer system, which was accessible by all staff in the unit including the renal consultants and the associate specialist in renal medicine. This meant the medical and nursing teams had the latest information available for patients undertaking dialysis.
- The medical team copied clinic letters to the unit and the patient's GP.
- The clinic manager and holiday co-ordinator reviewed all requests for acceptance of a holidaying patient in line with the provider's policy. This ensured that all the relevant information was available to staff to provide care for the patient, and included the transfer letter from the referring consultant, the patient's blood test results, dialysis prescription, medicines, virology screening information and arrangements for transport.

Equality and human rights

- The provider had an equality and diversity policy statement, which applied to all staff, patients and visitors to the provider's units. The policy aimed to promote diversity, equality of opportunity and to challenge discrimination.
- Staff training on the mental capacity act included awareness of equality and diversity issues.
- Patients were seen based on their clinical condition and whether there was space on the unit to accommodate them, irrespective of backgrounds such as race, religion, sexual orientation or marital status.
- Information was published in different languages to help make sure it was accessible to patients from a range of ethnic backgrounds.

Consent, Mental Capacity Act and Deprivation of Liberty

- All staff received annual mandatory training in the Mental Capacity Act 2005. At the time of the inspection 12 out of 15 eligible staff had completed this training. Two of the three staff who had not completed training were on long term absence.
- General consent to treatment was obtained from all new patients when their care transferred to the unit, and this was repeated on an annual basis. Staff obtained patient consent for taking blood samples, and carrying out other procedures; this included implied consent where appropriate.
- Consent forms were held within all four of paper records we reviewed. The form detailed the type of treatment including the risks and benefits, confirmation of any advance directives or do not attempt cardiopulmonary resuscitation orders, confirmation of agreement to data protection and research analysis, and any requirement for interpretation. The name of the professional taking the patients consent and the patient's signature were recorded.
- Where staff had any concerns about a patient's capacity to consent they referred the patient to the medical team for a capacity assessment.
- The unit did not have any patients with advanced dementia or learning disabilities at the time of the inspection. Despite this the provider had a policy to help staff care for patients which included using a 'health passport' or generating a provider health passport if the patient did not already have one. (A Health Passport is a resource tool that can be used to help healthcare professionals understand and make reasonable adjustments to the care and support they provide).
- Staff rarely cared for patients with dementia, as these patients were usually cared for in the commissioning trust premises. There were no situations in the reporting period where it was necessary for the unit to apply for a deprivation of liberty safeguards order.

Are dialysis services caring?

Compassionate care

- The unit operated a named nurse system and this was noted in the records for each patient. This system helped to ensure continuity of care for each patient. Patients in the unit knew who their named nurse was.
- In the most recent patient survey (October 2016) staff were described as 'friendly cheerful people' and 'superb'.
- We observed staff interacting with patients in a compassionate and caring manner.
- We saw examples of staff providing care which was compassionate. In one case staff helped a patient source their prescription and even went to collect this for them to allow them to start treatment for an infection early.

- One patient told us 'if I need anything the staff will help me'. Another said that they receive 'a high standard of care' and that 'the staff treat me and other patients with dignity and respect and are very caring'. Overall they reported the care received as 'very very good'.
- The unit took part in the provider's twice-yearly national 'I want great care' patient satisfaction survey in 2015. Of the 38 patients who responded, 92% said they had trust in the clinic team, and 91% said they felt staff improved their care. The unit created an action plan to address areas of concern highlighted by the survey, which included concerns about televisions and staffing levels.
- We saw that one patient had written a poem to express how staff comforted them with a friendly smile during treatment.

Understanding and involvement of patients and those close to them

- The provider had a new patient information handbook, which was supported by a detailed information leaflet. The handbook included knowledge checks on treating kidney failure, vascular access, food and drink, test results, medication and living with haemodialysis. This provided patients with the opportunity to discuss any questions or concerns they had.
- We saw examples of patients being involved in their own care. Where appropriate patients were encouraged to undertake self-care if they felt comfortable. Two patients chose to self-care to some degree and staff helped them with the elements of care that they did not wish to do for themselves such as placing needles.
- In the most recent patient survey we saw comments like 'the staff are very helpful and answer any questions raised if they can. If not they find out and get back to you'.
- Patients told us that staff explained things to them in a way that they could understand.

Emotional support

- Staff understood the importance of building a strong and friendly rapport with the patients in their care, a number of whom had received care at the unit for many years. Staff were aware of the impact of chronic kidney disease on their patients and how long-term dialysis affected their individual needs.
- As part of a new approach to care, staff were undertaking holistic care plans for each patient. These included helping patients complete a 'distress thermometer' which helped quantify how well a person was doing psychologically. Staff made referrals to the commissioning trust psychologist, social worker or GP if needed. In one case, staff referred a patent to the GP following high scores. In another, staff liaised with a patient's GP to request an assessment to support the acquisition of a stair lift at home.
- We saw examples of staff recognising the need for sensitivity and taking action to ensure patients were given time to process the loss of people they knew from the unit. For example, following the loss of a patient representative, staff identified that patients needed time to grieve before sourcing another representative after speaking with them.

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

Service planning and delivery to meet the needs of local people

- The unit's service contract, and specification, were defined and agreed directly with the commissioning trust's renal team. Performance against the contract was monitored by the trust through key performance indicators, regular contract review meetings, and measurement of quality outcomes including patient experience.
- There was adequate patient parking with the grounds of the unit for those patents that travelled by car. At the time of our inspection there were no car parking charges but staff and patients told us there were plans to introduce these in the future.
- For patients requiring transport, this was arranged through the local ambulance service, which subcontracted the majority of transport to a local taxi firm.
- The clinic manager reported transport delays on a designated log and sent this to the commissioning trust's matron; however, the unit did not routinely collate data on patient transport waiting times, however transport performance was measured against the service specification by the commissioning trust. The

specification stated that patients should not wait more than 90 minutes to be collected prior to, or after treatment sessions and that travel time should not exceed 30 minutes.
- The unit's design and layout, including the water plant, adhered to the recommendations of the Department of Health's Health Building Note 07-01: Satellite dialysis unit. The unit was located on the ground floor, with a designated entrance which was accessible for patients living with mobility issues. Access to the unit was via a secure remote locking door system. However, we saw that on two occasions this door was unsecured which posed a risk of unauthorised entry.
- The patient waiting area was situated adjacent to an area that included the weighing scales and individual boxes used to store items such as tape. The unit did not have spare scales for use in the event of a fault. Accessible male and female toilets were also located in the waiting area.
- The unit had no isolation rooms, which meant patients requiring isolation had to be cared for at Burnley or at the commissioning trust unit.
- The unit's high usage levels meant there was limited flexibility in meeting patient's preferred choices; however, staff at the unit aimed to facilitate temporary and permanent 'shift swaps' wherever possible to meet patient's personal or work needs.

Access and flow

- The unit provided treatment to 24 patients between the ages of 18 and 65, and 34 patients aged over 65. The unit opened six days a week Monday to Saturday between 7.00am and 11.30pm. Three dialysis treatment sessions were scheduled for each treatment station on a Monday, Wednesday and Friday with two sessions scheduled for each station on the remaining days.
- Responsibility for the management, referral and prioritisation, of new patients requiring dialysis remained with the commissioning trust. As such, the unit did not hold a waiting list.
- The commissioning trust's patient co-ordinator held a weekly call with the unit to discuss current inpatients, discharge dates, transient patients, holiday capacity, planned admissions and general capacity. However, the unit was operating to capacity, which meant it was limited in its ability to accept new patient referrals at the time of the inspection.
- The criteria for referral and acceptance of new patients were set out in the provider's criteria for patient admission policy, which also set out acceptance criteria. This was also discussed during the weekly call.
- The acceptance criteria included patients being stable with established and functioning venous access, and all virology tests completed and the capacity to provide consent to treatment.
- Patients with blood borne viruses such as hepatitis B and C, and HIV were referred to the commission trust for treatment. The unit had high utilisation rates. Rates were 99% for the three months between December 2016 and February 2017. The high utilisation rates meant there were limited opportunities for patients to change their treatment sessions at short notice; however, staff aimed to accommodate patient requests or to co-ordinate swapping treatment sessions were possible. A process was in place with communication between the consultants, lead renal nurse and the clinic to determine which patients would receive priority if capacity was exceeded.
- Treatment cancellations were monitored. Between February 2016 and January 2017 no dialysis treatment sessions were cancelled due to equipment failures or for other non-clinical reasons. Between January and April 99.5% of appointments were held within 30 minutes of their scheduled start time.
- Treatment sessions where patients failed to attend were also monitored. Between January and April 2017 an average of 0.5% sessions were not filled for this reason. The provider required all clinics to have less than 2% fail to attend rates.

Meeting people's individual needs

- Dialysis services were provided only at the unit rather than patients having the option to receive dialysis treatment at home.
- However, on site services were planned so that patients could be involved in their own care if they wished. Two patients were undertaking 'shared care' at the time of their inspection. They told us they were happy and felt supported by staff who completed other elements of care as required such as needle insertion.
- The unit was located in an area with a diverse population, of which approximately 30% were from ethnic backgrounds such as south Asian. This was

reflected in the range of patients who attended the unit. We saw that the majority of written information was in English which we were concerned would be unsuitable for patients whose first language was not English.

- When we asked senior staff about language interpreters they told us that a telephone service could be organised via the commissioning trust but this was rarely used. Instead staff relied upon relatives to translate conversations. NHS England (2015) draft guidance states: "The use of an inadequately trained (or no) interpreter poses risks for both the patient and healthcare provider. When this occurs neither the healthcare provider nor patient can be assured that accurate and effective communication is taking place. The error rate of untrained interpreters (including family and friends) may make their use more high risk, than having no interpreter at all".
- Whilst we were told that catholic chaplains could be arranged and that Christmas celebrations took place, we were less assured that chaplains from the Muslim faith were made available or that other ethnic religious festivals were celebrated, because managers told us that no other religions were catered for.
- Staff told us that they did not have any patients with complex needs or a learning disability at the time of our inspection. They said the majority of these patients would be cared for at the trust site. This was because patients had to be able to understand their treatment and provide informed consent. However, some patients may develop dementia and as long as they still had an understanding of their care staff worked to provide extra support such as allowing relatives to sit with them, should this be required.
- Any requirement for additional support was identified and made available to vulnerable patients. For example, staff referred one patient to the National Kidney Association after they identified challenging social circumstances. Following this referral a grant was provided which improved the patient's circumstances.
- Counselling support could be sourced by staff who referred patients to the trust psychologist, renal social worker or GP if required.
- Holiday places were available for patients wishing to receive dialysis treatment whilst on holiday. However these were only available if a space became available, for example if a patient receiving regular dialysis was also on holiday away from the unit.
- A member of staff acting as the holiday coordinator had recently left and the clinic manager was fulfilling the role until a new member of staff could be assigned to take over. The coordinator helped ensure that all relevant documentation was gathered prior to receiving holiday patients. This included transfer letters from referring consultants, consent to treatment, details of allergies, blood screens, medical prescriptions and arrangements for transport. We spoke to one patient who had travelled abroad and told us the process worked well.

Learning from complaints and concerns

- The complaints management policy and procedure set out the process and staff responsibilities for handling compliments, comments, concerns and complaints. The policy defined the severity of complaints and set out a 20 working day timescale for the response to complaints and concerns. The clinic manager was responsible for ensuring complaints were responded to within the policy's timescales.
- Information about the complaints process was included in the new patient handbook. Patient complaints could be made verbally, in writing, by email or online.
- The unit received no formal complaints in the period February 2016 to January 2017. This meant we could not comment on the unit's timeliness for responding to complaints; however, complaints were included as an agenda item in staff meetings to enable learning to be shared.
- Staff told us they aimed to identify and where possible respond to patient concerns face to face. This meant that concerns were dealt with before they escalated to formal complaints or required formal investigation. Although this was a positive, proactive approach, the provider's corporate complaints policy indicated that complaints "can result from any type of deficiency identified in products, equipment, the services received in our clinics or supplied to our clinics, and in the clinic processes." With this in mind, we were not assured that the unit was capturing and recording all relevant complaints including low level and informal concerns and complaints in a way that would enable the unit to identify trends.

Are dialysis services well-led?

Leadership and culture of service

- There was a clear staffing structure to help support staff delivering care in the unit. Area managers had responsibility for clinics in the North, Midlands or South of England. The clinic manager, who had several years' management and supervisory experience, was responsible for this and one other local unit but this was due to change to individual management when the new clinic manager was due to start in August 2017. Supporting the manager were practice development nurses, deputy managers, senior nurses, staff nurses, dialysis assistants and a ward clerk.
- At the time of the inspection, the new clinic manager had been appointed and was undergoing induction in readiness to take over responsibility for the clinic. To support this, the current manager had developed a guide showing new managers what was required from them each month.
- At the time of the inspection the unit did not have a member of staff registered with the CQC as a registered manager. This is a breach of a condition of registration. However we saw that the new clinic manager was progressing with their application to become the new registered manager.
- One staff member told us the organisation was 'a good company to work for with friendly supportive staff' and that 'they [leaders] will do anything they can to help'. Another said that team work was encouraged amongst the team, who respected and supported each other. They felt supported with structured learning which was tailored to suit individual needs.
- Local senior staff were visible and approachable. Staff were aware of, and knew the area head manager and director of nursing.
- We saw that members of staff in employment came from different ethnic and religious backgrounds. However, the unit did not currently collect or publish data in line with the NHS Workforce Race Equality Standards.
- The unit did not report on the Workforce Race Equality Standard (WRES). This is a requirement for organisations, which provide care to NHS patients. This is to ensure employees from black and minority ethnic (BME) backgrounds have equal access to career opportunities and receive fair treatment in the workplace.
- WRES has been part of the NHS standard contract, since 2015. NHS England indicates independent healthcare locations whose annual income for the year is at least £200,000 should produce and publish WRES report.

Vision and strategy for this core service

- The organisation mission was 'to improve the quality of life for renal patients'. The vision was to be 'the first choice for renal care'. Three values stemmed from these two elements which were 'competency, inspiration and passion'.
- In order to achieve the mission and the vision, the organisation had five priorities which included focusing on improving quality of life, pursuing operational efficiency and being a 'great' place to work. While staff were able to briefly describe the priorities, the manager was able to explain the background of each priority to us. For example the priority to be a great place to work stemmed from previous staff survey results.
- Staff worked with an emphasis on improving quality of life which we saw as we observed them caring for patients.

Governance, risk management and quality measurement

- There was a governance framework in place to support staff delivering care and managing units. For example, the clinic manager was overseen by the nursing director, quality manager and operations director. Overall responsibility was held by the country manager.
- Staff were mostly clear about their roles and what they were accountable for. For example, staff we spoke with were clear about their roles in providing care and treatment for patients, and in supporting the unit in additional lead roles such as arranging holiday dialysis for patients. However there was a disconnect between the responsibility of both the clinic manager and the human resources directorate in relation to registered manager status. Neither the clinic manager nor human resources staff had ever received confirmation of registered manager status or taken steps to follow this up. This had led to the unit breaching their registration requirements for approximately three years.
- There was a close working relationship between the unit, the commissioning NHS trust and the local NHS trust that owned and maintained the building. Patients

who attended the unit were referred by the local NHS trust to the specialist renal and dialysis services provided by the commissioning trust. The unit functioned as a satellite unit.

- Monitoring meetings took place the trust to review performance against the service contract. Other working arrangements were in place with companies who maintained and replaced equipment, provided medicines and removed waste.
- There was a risk register in use. The register separately held 11 risks in total, which reflected the risks we saw during the inspection. These were categorised as two risks for employee wellbeing, patent safety and facilities management, one for recruitment and business interruption, and one for supplier management. Two were awaiting categorisation. Each risk also included a description, assessment of likelihood and severity of the risk, overall risk level, mitigating actions, target for completion of actions, risk status and responsible persons.
- Although planned completion dates were identified for outstanding control actions, there was no separate reassessment of the risk score/level applied to the additional control mechanisms to understand whether or not they were likely to reduce the risk sufficiently.
- The unit had achieved ISO 9001 accreditation for an information management system (IMS). All staff had access to an information management system, which held all current policies and procedures. This meant staff could easily access the most recent version of these documents. However, the version control information on a number of the documents we received during the inspection was unclear. The clinic manager and practice development nurse told us all the provider's policies and procedures were being reviewed and updated for inclusion in the launch of the new IMS system. The launch of the new system was expected imminently.
- Staff were required to sign to confirm when they had read policy updates. Each signature sheet was prepopulated with the names of 24 staff members, was photocopied and attached to each policy.
- The clinic manager introduced a 'memory board' system which informed senior staff of which recurring actions or activities such as audits, equipment checks, or reports needed to be carried out each month. This helped to ensure timely completion of appropriate tasks.

Public and staff engagement

- The provider had a patient engagement and experience policy, and implemented twice yearly patient surveys. The policy focused on a number of factors including involving patients in their care; actively encouraging self-care; facilitating adjustments to patient schedules to enable patients to participate in patient support group; using the results of the survey to improve patient experience; and ensuring the involvement of hard to reach patient groups such as those with sensory impairments or diverse languages.
- The unit had one patient advocate. The clinic manager told us the patient advocates had moved away from requesting formal advocacy meetings as the advocates preferred to raise any issues on an ad-hoc basis.
- Staff told us that patients, through their own choice, did not tend to engage with external advocacy groups. However, the local kidney patient association funded annual social events for patients and their families, including Christmas dinners, raffles, and days out.
- The unit carried out an annual patient satisfaction survey. The results were the fourth best amongst the provider's other clinics nationally. Thirty-eight patients responded to the survey in October 2016 which indicated an average overall satisfaction score of 91%, with 92% of those who responded indicating they had trust in the clinic team. The most frequently mentioned concern by those who commented related to issues with staffing, and televisions or the remote controls. The issues relating to televisions were reflected in the action plan subsequently developed by the unit but staffing levels were not. However the clinic manager told us these had been temporary issues which were not evident at the time of inspection.
- The unit carried out an annual 'My Opinion Counts' staff satisfaction survey. The most recent published results were from the October 2016 survey, which was carried out in February and March 2016. Twelve staff responded to the survey, which indicated an average overall satisfaction score of 70%.
- Of those staff who responded, 90% said they knew what was expected of them in their job; 69% said they felt 'motivated to use our strengths at work' and 71% said they 'felt motivated to improve the quality of services for patients'. The scores were supported by staff comments

which included: “I feel I am supported in my day to day role”; “I feel I work with a very strong team”; and, “I enjoy working at Diaverum because of the staff and the lovely patients”.

- However, staff also commented “the only thing we can do to improve is have a couple of extra staff so we aren’t constantly worried about someone ringing in sick or having no cover” and “every day at present is constant fire-fighting. Staffing levels and skills mix are poor leading to most shifts being stressful”.
- In response to staff survey findings, managers produced an action plan which detailed that recruitment was in progress and new starters were currently in training.

Innovation, improvement and sustainability

- The unit was due to commence a phased replacement programme for all its dialysis machines in August 2017. This posed benefits such as reducing the risk of errors when manually entering clinical details onto the system because details would be automatically stored by the new machines.
- A mobile phone application had been developed which staff were referring patients to use if they wished. The application was an educational tool for patients being treated by the provider.
- One of the organisations priorities was for focus on improving quality. This was achievable through a range of initiatives including the purchase of new machines and staff development.

Outstanding practice and areas for improvement

Outstanding practice

- Managers implemented a 'memory board' to remind all staff of recurring governance actions that needed to be carried out each month.
- Staff comforted one patient with a friendly smile during treatment as a result of which the patient wrote a poem to express how this had helped.

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure all staff who have contact with parents or carers in the unit, are trained in safeguarding children level two.
- The provider must ensure that risk assessments are fully completed and updated at regular intervals, and that temperatures and other necessary observations are recorded pre-connection, post connection, pre disconnection and post disconnection.
- The provider must have a process in place to ensure that should patient deaths occur (whether within or outside of the unit itself), they have a process in place to assure themselves that care or treatment provided was not a contributory factor.
- The provider must ensure that staff are suitably trained and aware of the stages of sepsis and the actions required to ensure treatment is provided as soon as possible
- The provider must review procedures, policies and/or pathways relating to caring for patients with chest pain and ensure these are appropriate for a unit without ECG capabilities. The provider must also review and provide assurance that sourcing emergency assistance is clearly stipulated at an appropriate stage in the process.
- The provider must ensure that a registered manager is in place at all times and that appropriate notifications of change or absence are made to the regulation body. This is a breach of the condition of the provider's registration.

Action the provider SHOULD take to improve

- The provider should ensure that incidents are categorised to help identify the level of harm sustained.
- The provider should take actions to implement systems to record what cleaning activities have been done in each area.
- Staff should take actions to ensure the necessary maintenance support is available without delay when required.
- The provider should consider reviewing the procedure for potential transfers of patients with involvement from the local ambulance service or designated relatives or friends for patients who are not able to drive themselves to another unit if required.
- The provider should continue with plans to introduce a more robust way of governing the policy and procedure process with review dates clearly defined and adhered to, and evidence of this and any changes clearly documented.
- The provider should ensure front doors are secured at all times and not left open.
- Staff should refrain from using relatives to assist with translation and instead use a recognised translation company
- The provider should ensure that chaplains from a range of faiths are available for patients.
- The provider should review whether a more streamlined process for recording prescriptions could be sourced rather than using three separate charts.
- The provider should review and improve the process to ensure batch numbers of equipment could be accurately recorded and reported should it be required.
- Staff should review whether GP letters should be stored with the patient record to reduce the risk that items stored separately may not be seen.
- The provider should consider introducing celebrations covering all religious and cultural backgrounds of patients.

Outstanding practice and areas for improvement

- The provider should take action to monitor and publish data with regards to the Workforce Race Equality Standard (WRES).
- Consider how it can ensure implementation of the requirements of the NHS accessible information standard.

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 1. Care and treatment must be provided in a safe way for service users. 2. Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include: a. assessing the risks to the health and safety of service users of receiving the care or treatment; b. doing all that is reasonably practicable to mitigate any such risks; c. ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely; This was because: Risk assessments were not fully completed Regulation 12(2)(a) And; There was no process in place to ensure that should patient deaths occur (whether within or outside of the unit itself), staff could assure themselves that care or treatment provided was not a contributory factor. Patients' clinical observations were not being recorded as regularly as they should be. Staff were unable to follow plans and pathways for helping patients with chest pain because the process involved using equipment that the clinic did not hold and was not trained to use. It also made no reference to requesting emergency assistance. Regulation 12 (2)(b And;

This section is primarily information for the provider

Requirement notices

Staff were not trained in safeguarding children level two.

Staff had received no training to help them identify and take action to initiate treatment for sepsis.

Regulation 12 (2)(c)