

Diaverum UK Limited (Burnley)

Quality Report

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Diaverum UK Limited (Burnley) is operated by Diaverum UK Limited. The unit is nurse led, comprising of a manager, deputy manager, five senior nurses, seven nurses, four dialysis assistants, and four healthcare assistants. The manager, deputy manager and team leader also provided clinical care.

The service has 15 haemodialysis stations (one of which is in a side room) and provides two to three treatment sessions per station per day (225 individual treatment sessions in total per week). Other facilities within the unit include a patient waiting area including male and female toilets, a weighing area, offices, clean utility, dirty utility, staff changing room and kitchen, storeroom, and water treatment plant.

The unit is located within Burnley General Teaching Hospital (the host trust) and functions as a satellite unit for the dialysis services provided by Lancashire Teaching Hospitals NHS Foundation Trust (the commissioning trust). It mainly treats patients in the Burnley area. Patients attending the unit are referred by the host trust to the specialist renal and dialysis services provided by the commissioning trust.

The unit provides haemodialysis treatment to adults aged 18 years and over, who have non-complex needs. Currently the unit provides treatment to 42 patients between the ages of 18 and 65 (6048 individual treatment sessions between February 2016 and January 2017) and to 34 patients aged over 65 years (4896 individual treatment sessions in the same period).

We inspected this unit using our comprehensive inspection methodology. We carried out the announced inspection on 7 June 2017, along with an unannounced visit to the unit 13 June 2017.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? 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:

- The unit had designated patient parking, access ramps, and secure but automatic doors, and was accessible to patients with mobility problems. It opened six days a week and appointment slots were allocated taking into account patients' individual needs.
- There was a culture of incident reporting amongst staff with lessons learning shared.
- Staff completed mandatory training which included the recognition and reporting of safeguarding concerns and we saw this process work during our inspection.
- The areas we inspected were visibly clean and tidy. Records showed hand hygiene and water cleanliness were regularly monitored and maintained. Staff observed infection prevention and control measures.
- Pain relief, food and refreshments were available if required and dietetic advice was available to patients from the dietitian who visited the unit twice weekly.
- Patients spoke highly of the staff that cared for them and were happy with the treatment they provided. This was reflected in the patient survey and the very low number of formal complaints received.

Summary of findings

- Staff we saw displayed a compassionate friendly approach to patients, and provided evidence based care in line with national professional guidelines. Staff had access to all relevant information to provide effective care and treatment.
- Treatment was individualised to each patient's prescription and was reviewed monthly by the multidisciplinary team. Staff were able to convene case conferences with other health and care professionals to understand and support patients' emotional and psychological needs.
- The unit implemented a holistic care package approach to assess patients' psychological as well as physical needs. Patients were included in discussion about their care and needs.
- The clinic manager implemented a 'memory board' to remind all staff of recurring governance actions that needed to be carried out each month.
- The provider had a clear vision and strategy with objectives to meet key aims. This supported the close working relationship between the unit, the commissioning trust and the local trust that owned and maintained the building.
- A risk register held details of risks and actions to mitigate them.
- The unit's service specification was defined and agreed with the commissioning trust to meet the need of local people, and took into account the trust's policies. Monitoring meetings with the trust reviewed the unit's performance against its service contract.
- There was a clear staffing structure and staff told us the organisation was 'a good company to work for with friendly supportive staff'.

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.
- We were not assured that staff consistently checked patients' identification before commencing treatment or administering medication.
- 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. This meant managers were not proactively assuring themselves that deaths were not related to care and treatment provided by staff on the unit for every patient death that occurred.
- Staff were not trained in safeguarding children level two.
- Sepsis training was not provided, which posed a risk staff may not always identify signs of sepsis. Necessary patient observations, including temperature, were not always fully recorded before, during and after the treatment sessions.
- The unit did not have a patient call buzzer system in place.
- Staff used relatives to help translate conversations with patients, which risked misinterpretation of information.
- Governance of policies, procedures and pathways was difficult to understand with expired and inconsistent review dates and processes, and staff sign-off sheets were unclear as to which staff members needed to read updates.

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 one requirement notice. 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 Ltd Burnley

Services we looked at

Dialysis Services

Summary of this inspection

Background to Diaverum UK Limited (Burnley)

The Diaverum UK Limited (Burnley) 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. The unit primarily serves the communities of East Lancashire.

A clinic manager was in post from October 2014; 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, and met all the essential standards of quality and safety inspected. Our last inspection 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 (Burnley)

Diaverum UK Limited operates the Burnley Dialysis Unit. It is a mixed gender 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 referring renal unit is Lancashire Teaching Hospitals NHS Foundation Trust (the commissioning trust), which provides the 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 within the grounds of the Burnley General Teaching Hospital (the host 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 15 treatment stations, one of which is a side room, offering haemodialysis but not peritoneal dialysis. Home dialysis services are not provided by staff at this unit

Access to the unit is via the host trust's main entrance. Dedicated parking for renal patients is available a short walk away and additional carpark serving the hospital's main site is close-by. Entry to the unit is secure via a video door bell.

There are nine registered nurses, four dialysis assistants and four healthcare assistants employed by the unit.

Between February 2016 and January 2017, the unit provided 10944 treatments session to adult patients. All of these treatments were NHS funded. Services are not provided to children or young people under the age of 18 years. At the time of the inspection, 76 patients received haemodialysis treatment and three patients received haemodiafiltration treatment at the unit.

During the inspection, we spoke with nine staff including; the area head nurse, the practice development nurse, the

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existing clinic manager, the new clinic manager, the deputy clinic manager, two senior staff nurses and two registered nurses. We spoke with four patients. We received one 'tell us about your care' comment card. During our inspection, we reviewed six sets of patient paper and electronic records.

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.
- No incidents occurred which triggered the Duty of Candour process.
- One patient fall was reported.
- There was one report of pressure ulcers, but no urinary tract infections or venous thrombo embolism (VTE).

- There were no cases of Meticillin-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.

- One complaint was received by the unit within this time period.

Services accredited by a national body:

- ISO 9001: accreditation for the integrated management systems.
- OHSAS 18001: accreditation for the health and safety management system.
- ISO 14001: accreditation for environmental management.

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 issues that the service provider needs to improve:

- Incidents were not categorised in terms of level of harm sustained.
- Staff, who had contact with parents and carers, had not received safeguarding children level two training.
- 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.
- We were not assured that staff were consistently confirming patients' identification prior to commencing treatment or administering medicines.
- As a result of the layout of the provider's root cause analysis (RCA) template, there was a risk the RCA report the report could omit background vital information that could contribute to identifying the root cause of an incident.
- The layout of the treatment area, which included a head-height wall in front of the nurses' station meant that patients in the centre of the room could not easily be seen by staff at the station.
- There were no call buzzers available to any treatment station in the main treatment area.
- The unit did not have any logs to provide assurances that daily general domestic cleaning had been completed.
- Whilst the unit held a portable appliance test register, important information was missing or unclear which meant we could not be assured that all relevant equipment was appropriately and routinely tested.
- 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.
- Staff were not using medicines additive labels to identify additive medication in syringes.

Summary of this inspection

- Staff were not always recording patient temperature or respiratory rates as part of the regular observations, which would be required to accurately record an early warning score for patients who were at risk of deteriorating.
- Staff did not always record that they had received and read information that was shared by the clinic manager.

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 appropriately, 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 adult 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.

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.

Summary of this inspection

- Treatment was provided in line with patients' individual treatment prescriptions which, following monthly blood tests, were reviewed 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.
- Staff were competent to provide care and treatment effectively and safely, and were supported by the provider to maintain their personal development.
- Nursing and medical staff had access to all relevant information needed to provide safe care. The unit's holiday co-ordinator worked closely with other units in the UK and abroad to ensure relevant information and results were provided before a holidaying patient was treated.

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 95% 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.
- Staff were able to convene case conferences with other health professionals to understand and support patients' emotional and psychological needs.

Are services responsive?

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

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- The unit's service specification was defined and agreed with the commissioning trust to meet the need 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, access ramps, and secure but automatic doors. Arrangements were in place for patient transport and the unit had a positive relationship with the local taxi firm contracted by the patient transport service provider.
- Patients were assessed for suitability for treatment at the unit to ensure it was able to accommodate their care needs in a safe and effective way.
- The unit was in the process of introducing a holistic care pack approach which helped staff to 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 taking into account their individual needs and, although flexibility was limited due to the small size of the unit, staff worked to accommodate requests to change appointments as required.
- The unit only received one written complaints in the reporting period. We saw evidence of shared learning from complaints and incidents that occurred in the provider's other clinics.

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

- Lower level concerns and complaints were not recorded, or investigated.
- Despite identifying patient transport as an area of concern, and the unit highlighting delays to the commissioning trust, a number of patients continued to express concerns about waiting times for the patient transfer service.

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 vision and strategy in place with objectives built around achieving key aims.

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- 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.
- Although a risk register was in place,

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

Dialysis Services

Safe

Effective

Caring

Responsive

Well-led

Are dialysis services safe?

Incidents

- The provider had a management of serious medical incidents policy, which set out definitions of serious incidents and staff responsibilities to report incidents including the escalation path. The policy was supported by an incident reporting procedure, which set out the process for reporting incidents via the provider's web-based information management system. The reporting system automatically generated alerts to senior staff when serious incidents were logged.
- All staff had access to the incident reporting system. Staff recorded a total of 175 incidents between January 2017 and April 2017. Of these, 141 related to patients failing, by choice, to attend their appointment or patients voluntarily shortening their treatment by more than 30 minutes.
- Staff we spoke with were aware of the policy and procedure requirements, the type of incidents that should be reported including near misses, how to report incidents, and the escalation process. Staff told us feedback and learning from incidents was shared in staff meetings and on a one-to-one basis where appropriate.
- We reviewed four root cause analysis reports of incidents that had occurred in the unit between August 2016 and April 2017. Senior staff in the unit completed the reports in line with, and using, the provider's 12 stage root cause analysis template. 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 in terms of themes and although the reporter could manually classify an incident as a serious incident, the system did not specifically categorise incidents 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. Despite this, we also saw that the reporting system automatically alerts senior management to serious incidents in line with the provider's incident reporting and management of serious medical incidents policies.
- The service reported no serious incidents, patient deaths, or never events between February 2016 and January 2017. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- The service routinely monitored incidents of patient pressure ulcers and falls. Additionally the unit monitored incidents of patient urinary tract infections, or hospital acquired venous thromboembolism (blood clots) if the patient was symptomatic on assessment.
- The unit reported one diabetic foot ulcer between March 2016 and February 2017.
- 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

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but there was no formal process in place. We were concerned that managers had not taken adequate responsibility to assure themselves following patient deaths.

- There were no incidents within the unit that required statutory notification to CQC within the same period.
- Staff we spoke to told us that learning from incidents within the unit were shared by email to all staff and were discussed with any individuals involved and in monthly staff 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 clinic manager was responsible for reviewing each update to check if it applied to the unit. Staff were required to sign to confirm they had received and read the relevant update bulletins. We viewed copies of the sign-off sheets for a range of updates, which confirmed compliance with this process. However, the sign-off sheets (which consisted of a photocopied list of the names of all staff members in the unit) did not make it clear which staff members needed to read the document. For example, although each sheet included 24 names, only 13 staff had signed to confirm they had read the clinical governance process, while 11 had signed to confirm they had read the general infection control plan.
- Learning was also shared with the provider's clinics through the quarterly regional clinic managers' meetings.
- 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.

Mandatory training

- Mandatory training was delivered through a mix of classroom and online training and was monitored by the provider's practice development nurse. Training included a range of subjects mandated by legislation and by the provider.
- The mandatory training rates for the unit were high. At the time of the inspection, all eligible staff had completed training in hand hygiene and anaphylaxis, emergency fire training, personal protective equipment training, the Mental Capacity Act 2005 (MCA) and deprivation of liberty safeguards (DoLS) training. Twelve-month rolling programmes were in place for basic life support (90% of staff completed), medicines management (58%), aseptic non-touch technique (25%) and infection control. We saw documentary evidence of mandatory training completion within the four staff files we reviewed.
- 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.
- The provider was in the process of updating its records for regular bank staff in order to understand staff background, experience and level of training. It was also undertaking a training needs analysis for bank staff. Bank staff were informed of any updates to the unit's policies and processes during their orientation session.

Safeguarding

- The provider had a policy for safeguarding adults with care and support needs and dealing with concerns, suspicions or allegations of abuse, harm or neglect. The policy set out the process for managing safeguarding concerns, and also included guidance on dealing with concerns or allegations about staff. This supported staff in identifying and reporting safeguarding concerns.

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- Staff only provided treatment to patients aged 18 and above. Safeguarding vulnerable adults training formed part of the mandatory training programme for all staff. All staff had completed safeguarding adults level two training.
- Awareness of safeguarding vulnerable children was included within the safeguarding adult training provided to staff. However, in line with the intercollegiate document Safeguarding Children and Young people: roles and competences for health care staff, all staff who have contact with parents or carers should receive level two safeguarding children training. Staff at the location had only received level one training for safeguarding children.
- By the time of the inspection, the clinic manager had completed safeguarding level three training.
- The provider's nursing director was the safeguarding lead for the service.
- Staff had contact details for the local county council safeguarding team to obtain further advice and to make safeguarding referrals when needed.
- We observed staff putting this into practice during our inspection in relation to concerns expressed about the welfare of a patient who was receiving dialysis in the unit at the time.

Cleanliness, infection control and hygiene

- The provider had 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.
- We observed all areas of the unit including the waiting and treatment areas, and staff only areas including the dirty and clean utilities, storage rooms, water treatment room, meeting rooms, toilets, and the staff kitchen. All areas were visibly clean.
- Staff from the host trust carried out the daily domestic cleaning of the unit in line with the weekly cleaning schedule. Staff told us the domestic cleaning was of a high standard and they had no concerns about this; 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.
- Although staff completed machine cleaning checklists following each treatment cycle, the unit did not carry

out any cleaning audits. This meant there was a risk that poor compliance with cleaning would not be identified or challenged. However, the new clinic manager told us they were aiming to introduce a 19 stage cleaning process.

- We observed staff carrying out their duties in line with the infection prevention and control requirements set out in the provider's policies. Staff followed hand hygiene protocols, including 'arms bare below the elbows', in line with the provider's policy. We also observed staff undertaking good practice using the aseptic non-touch technique when providing care.
- Antibacterial gel dispensers were located throughout the unit. Hand washing facilities were also located in the entrance and treatment areas.
- Posters were displayed to remind patients of the importance of washing their hands and their vascular access sites prior to commencing treatment. Staff asked patients to confirm if they had washed their access sites, and also cleaned the site with sterilising wipes before commencing treatment.
- Senior staff carried out monthly hand hygiene audits. Between January 2017 and March 2017 the unit achieved an average compliance score of 85%, which was better than the unit's target of 70%. The unit's score was an improvement on the hand hygiene score achieved through the provider's comprehensive assessment of clinic practice audit in 2016, which indicated a compliance score of 75%. An action plan was developed to address areas of non-compliance. Staff received individual and collective feedback following any audits that were carried out.
- Staff uniforms complied with the provider's policy, including appropriate non-slip cleanable footwear. Uniforms were not disposable; however, the new clinic manager confirmed that staff were required to change into and out of their uniforms within the unit's staff changing area and were not permitted to wear uniforms when travelling to or from the unit.
- Staff wore appropriate 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.
- We observed that patients were given gloves to wear during the process of removing the needles, which reduced the risk of infection at the exit site.

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- Dialysis needles and lines were single use only and were appropriately disposed of as clinical waste after use. However, staff told us they did not retain the used equipment batch numbers, which may be required for later investigation of serious incidents. Instead staff told us that if such an incident were to arise they would reference the batch number of the next piece of equipment stored in the stock room under the assumption that they would be the same as those used. This meant there was an increased risk of faulty equipment being mis-identified.
- Each machine underwent a heat disinfection cycle at the end of each treatment session. We observed staff cleaning the treatment chairs and associated equipment, and decontaminating each dialysis machine between patient treatments.
- Between March 2016 and February 2017, the unit reported no incidences of bacteriological infections such as clostridium difficile (C.diff), MRSA and MSSA. Patients who were identified as having contracted a hospital acquired infection were transferred to the commissioning trust for treatment in the isolation area. Patients were screened for MRSA/MSSA every three months. There were no reported MRSA or MSSA colonisations in the unit between March 2016 and February 2017.
- Patients with blood borne viruses such as hepatitis B and C, and HIV were treated in the unit's isolation room, which was accessible two doors away from the main area. Additional patients requiring isolation treatment were referred back to the commissioning trust.
- The provider's standard 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 MRSA and MSSA.
- Patients were screened every three months for hepatitis B and C, and for HIV in line with the provider's Hepatitis B testing, management of patients and vaccination policy. Patients with active infections were referred back to the commissioning trust's renal unit.
- Staff 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.
- Records we reviewed showed that daily checks were carried out on the unit's water system. These checks included, although was not limited to, the daily levels of chlorine in the water, the raw water pressures, the filtrated water pressures, and softeners.
- Water sampling was done according to procedure, twice monthly on different machines. Records of sampling between March and May 2017 showed that results of colony forming units (CFU's) and endotoxins remained at acceptably low levels (between zero and four CFUs and less than 0.001 endotoxins).
- Water flow on both the water systems was also tested each month. Results between March and May 2017 showed that levels of CFU and endotoxins were again within acceptable range (for example between zero and two CFUs).
- Staff carried out monthly microbiology checks and quarterly chemical analysis of the water supply. We saw evidence of these checks between January 2016 and May 2017. Staff told us analysis was carried out at the first and last water points on the water supply loop in order to avoid introducing infection risks at intermediary water points. Additional water points would be checked if the last water point test indicated a potential problem.
- Daily flushing of infrequently used taps in the unit was carried out. This reduced the risk of development of bacterial infections in water supplying sinks in the unit.

Environment and equipment

- The unit was located within a well-maintained modern unit in the host trust. The unit had designated patient parking, access ramps, and secure automatic doors with an entry bell system operated by staff in the reception area.
- Information, including photographs of staff members and a uniform code was displayed to help patients easily identify staff.
- Separate male and female toilets in the corridor were available for patients to use before and after treatment. A locked storeroom was also located on the same corridor.
- A small patient waiting area was located next to the unit's reception area at the end of a corridor, which approached the treatment area. The weighing area included wheelchair accessible scales. Patients took their own weight measurement which allowed staff to determine how much fluid to remove from them during

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treatment, but there was nowhere for them to record this. Instead they had to remember this information until a member of staff was ready to take it. Additionally, managers confirmed there were no back-up facilities for weighing patients if the scales were faulty. Instead, maintenance staff would be called to fix the scales which was usually completed the following day. In the meantime, staff relied on other informal means of assessing how much fluid to remove from patients such as blood pressure and respiratory measurements. We were not assured there was a robust process to ensure that patients could always be weighed or that the process for assessing fluid removal was adequate should the scales be unavailable.

- A separate waste area, including a clinical waste bin, was unlocked at the time of the inspection. We raised this with the new clinic manager who took immediate action to address it.
- Access to the treatment area, and staff only areas, was secured with staff key card access.
- A resuscitation trolley was located within the treatment area. The trolley was owned, supplied, and stocked by the host trust, which had a service level agreement with the unit to respond to cardiac arrest emergencies via the bleep call system. This meant staff attending the unit in an emergency situation were able to quickly locate the emergency equipment needed. The trolley was sealed with tamper tags, which were replaced after the trolley had been opened; a tamper tag identification log was held and completed appropriately.
- An emergency evacuation 'grab' bag was located outside the staff 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. The unit held sufficient supplies of saline to be used if patients needed to be urgently disconnected from the machines in an emergency situation.
- We reviewed the trolley checks which were carried out by staff daily. These were appropriately completed. A monthly check of the trolley was also carried out by the practice development nurse. We checked a range of equipment held in the resuscitation trolley, which was all within the manufacturers' recommended expiry dates. The emergency anaphylaxis kit was sealed and

within the manufacturer's expiry date. Pharmacy staff from the host trust replaced the anaphylaxis box when required. An oxygen cylinder was held with the trolley, and was within the recommended expiry date.

- Staff told us its contractors were responsive to requests, particularly when responding to dialysis machine failures.
- A preventative maintenance schedule was in place for all equipment used in the unit.
- We viewed the dialysis machine service logs for all 20 dialysis machines in the unit. These indicated that the machines had been tested in March 2017, and future dates for the next test had been scheduled. The logs included the number of hours each machine had been running, the replaceable parts within each machine included the calibration of each part, and confirmation of full machine cleaning.
- In the event of a patient cardiac arrest or death, a process was in place to take the dialysis machine out of service and to store it until the relevant data could be retrieved from it. Any consumables used in the treatment were also retained, labelled and stored for further analysis.
- The water plant was located in the host trust's main building, and accessed securely with a key card. A remote alarm panel was located behind the nurses' station. As such, responsibility for the operation, maintenance and servicing of the water plant lay across three organisations. Each supplier was clear about, and understood, their respective responsibilities in relation to the water plant. We saw evidence of daily engineering reviews and repair logs for the water plant.
- The clinic manager developed an easy guide for staff to follow in the event of a water plant alarm in order to identify which organisation contact and escalation details applied. The water plant included two filtration systems with automatic switching between systems when a fault was detected. An external company was contacted for any readings that were out of range. Staff told us they responded quickly when contacted.
- The unit held a portable appliance test register, which listed equipment, scheduled test dates and, where relevant, decommissioned dates. However, apart from computers within the unit, the register did not detail individual equipment numbers, rather it used item names; for example, lamp. It was unclear from the hand

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written information recorded in the register as to which testing dates had been met. This meant there was a risk that not all equipment had been appropriately and routinely tested.

- The layout of the treatment room meant that not all patients were easily visible from the nurses' station. A head-height partition wall, which incorporated the handwashing stations, was directly in front of the nurses' station. This meant that staff could not easily see the treatment stations in the middle of the room. The risk of staff not seeing deteriorating patients in this area was further increased as none of the stations in the main treatment area were fitted with patient call buzzers.
- This was a risk to patient safety and a breach of regulations. We were not assured there was sufficient mitigation of this risk in the clinic manager's view that there were always two nursing staff, two dialysis assistants and a healthcare assistant on the unit at all times. We raised this as an immediate concern with the clinic manager and the area head nurse who took action to raise the issue with the unit's suppliers with the aim of finding a solution. Until such times as appropriate call buzzers were sourced and fitted, the unit agreed to carry out 15 minute rounding checks on each patient. These checks were commenced on the same day. We reviewed the rounding check logs during our unannounced visit; all logs were fully completed.
- The dialysis machines sounded audible alarms to alert staff for a range of reasons during treatment such as issues relating to patient movement, leaks, self-test failures or other errors. We observed staff responding to audible alarms from the dialysis machines in a timely manner. We did not observe alarms being overridden inappropriately. Although it was theoretically possible for a patient to override an alarm we did not observe this occurring.
- 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.
- There were two trollies within the treatment area that held ancillary equipment such as specimen tubes, needles, syringes, dressings and tape. We checked a random range of items stored in both trollies. All items we checked were within the manufacturers' recommended expiry dates.
- Sharps boxes were available throughout the treatment area, including on equipment trollies used by nurses when setting up or attending to patients. All the sharps boxes we observed had the date of construction completed and were part closed when not in use. This meant the risk of injury was reduced.
- Boxes of equipment used for dialysis, such as the single used dialysis needle packs, and citric acid for cleaning of the dialysis machines, were held in the storeroom on shelving off the floor. All stock was clearly labelled with, and stored by, the received date. This ensured effective stock rotation and meant that the oldest equipment was used first. We checked a range of equipment within the store room which was all within the manufacturers' recommended expiry dates. However, we found two spill kits in the store room which should have been locked in the hazardous substance cabinet. We also found filters stored on the floor. We raised both of these issues with the new clinic manager who took immediate action to address the issues.
- 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. We found a container of hazardous disinfectant, with a hand-written label, left unattended on a trolley outside the side treatment room. The side-room was located within a corridor outside the secure treatment area that was accessible to any patients, carers or other visitors within the unit. We highlighted this potential safety risk to the new clinic manager who immediately removed the container.
- Clinical waste was appropriately segregated, transferred and disposed of in line with the provider's procedure on clinical waste handling and disposal. Disposal of clinical waste was carried out through a service level agreement with the host trust.

Medicine Management

- Staff used the provider's policy on medicines 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.

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- Staff received annual medicines management training. At the time of the inspection seven out of twelve eligible staff had completed the training for the current year. Future dates were programmed into the training calendar for the remaining five staff to undergo the training.
- Staff were supported by dedicated renal pharmacists from the commissioning trust who were available for telephone and emailed advice requests.
- There were no medicines errors reported in the period March 2016 to February 2017.
- Staff did not administer or store any controlled drugs. Medicines used in the unit that were not required to be refrigerated, were stored in a locked medicines cabinet and medicines trolley. Temperature sensitive medicines were stored in a fridge in the same area. Keys for the cabinet and trolley were held by the nurse in charge for each shift.
- The cabinet, trolley and fridge were located within a temperature-controlled room behind the nurses' station, which reduced the risk of extremes in temperature affecting medicines. The fridge temperature was checked and recorded daily using a maximum/minimum thermometer.
- We reviewed the temperature logs between January 2017 and June 2017 which indicated the maximum and minimum temperatures were all within an acceptable range. Staff told us they would contact the pharmacists in the commissioning and host trusts for advice if the temperature went out of range. This was in line with the unit's procedure on maintaining the cold storage chain.
- Medicines were organised to ensure the oldest medicines was used first. Staff monitored medicines expiration dates monthly
- We checked a sample of seven different medicines stored in the cabinet, trolley and fridge, all of which were within their manufacturers' recommended expiry dates. An oxygen cylinder stored in the treatment room was also within the recommended expiry date. We reviewed the monthly medicines expiry date log between January 2017 and May 2017, which was completed appropriately. This meant that staff could easily identify which medicines were nearing their expiry dates.
- Pre-manufactured syringes of anticoagulation medicines were obtained by staff from the medicines cabinet when needed and ready for use. We observed staff appropriately seeking a second confirmation that the correct dosage had been selected.
- However, we observed that additive syringe medicines were not identified at the treatment station by use of an additive label. This meant there was a risk that staff would not be aware of which additive medicine had been administered to the patient.
- Although additive labels were available, staff told us they were not used because the size of the labels obscured the measuring gradations on the syringe. We raised this with the area manager and practice development nurse who agreed to source appropriately sized labels.
- Any medicine needed was prescribed by the patient's consultant nephrologist. The unit did not use non-medical prescribers. A process was in place to fax urgent prescriptions to the unit with the signed hard copy of the prescription forwarded to the unit within 24 hours (or a maximum of 72 hours for bank holidays and weekends. This was in line with the provider's medicines management policy.
- We reviewed medicine prescription and administration cards held in four patient files. These were clearly written out, legible, and including relevant information including previous medical history, target weight, screening for hepatitis and HIV and access points on administration cards and dose, identification and allergies to any medicines on prescription charts.
- Safety alerts, which included alerts for medicines, were forwarded to the clinic by the director of nursing. The clinic manager reviewed each alert to determine if it applied to the unit. We saw evidence that alerts were forwarded to staff, who signed to confirm they had received and read the information.
- The unit did not hold any medicines that could be administered under a patient group directions protocol. A patient group direction, signed by a doctor and agreed by a pharmacist, enables an authorised nurse to supply or administer prescription-only medicines to patients using their own assessment of patient need, without referring back to a doctor for an individual prescription.
- One staff member told us they were concerned there was a discrepancy between the provider's policy on

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blood transfusion and the commissioning trust's policy. Whilst the provider stance was that infusion pumps were required to transfuse, the commissioning trust said transfusions could be given without a pump.

- The clinic manager acknowledged this was a known issue but that staff had been directed to follow the provider's policy. The clinic manager told us that, as the unit did not currently have this equipment, transfusions were not currently being carried out in the unit. This appeared to be supported by the documentation we reviewed which indicated that transfusions had not been carried out since staff had been updated on the provider's policy a few months earlier.

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. Paper records were stored in a locked records room within the staff only area. Paper records were managed by the host trust's secretary, and were returned to the relevant area after patients' treatments were completed.
- Patient's clinical measurements, vital observations and treatment variations before, during and after treatment were required with staff expected to record them manually on paper 'flow sheets'. These included pre dialysis, post connection, mid dialysis and post dialysis observations.
- We reviewed four sets of patient records as part of our inspection and found that other observations were not recorded as often as required. For example, in one record only nine temperature observations were recorded out of a total of 15 sheets, on another record, only six out of 20 sheets had a temperature recorded and only one flow sheet showed that pre-disconnection observations had been recorded. In a third record, four out of 15 flow sheets had no temperature recorded and ten records had no pre-disconnection observations recorded. We were concerned that without taking and recording regular observations staff were less likely to be able to identify deteriorating patients.
- Patient blood results were held within the commissioning trust's electronic renal system which staff at the unit, and the medical staff had access to. This meant that the consultant and associated

specialist in renal medicine were able to access the patient's blood results when required. Staff in the unit highlighted any issues for review by the medical staff in a communications diary.

- Consultant's clinic letters which advised of any changes in patient status, medicines, or referrals were copied to the patient's GP. These letters were also saved electronically to the commissioning trust's renal computer system which the unit had access to.
- All the paper files we viewed were structured and labelled on each page with the patient's identification details. Handwriting was clear and legible and there were no loose sheets.
- During the inspection we found patient identifiable information, which included details of patient's hepatitis B/C and HIV status within a file stored in an unlockable shelf in the shared use reception area. We raised this with the new clinic manager who took immediate action to remove the file to a secure area. Similarly, during our unannounced visit, we found patient identifiable blood results stored in a serious incident file in an unlockable cupboard in the manager's office. The office was located within the secure staff area which provided some mitigation; however, the office was not always locked when not in use.
- Senior staff carried out a monthly nursing documentation audit of ten to fifteen records care plans and dialysis records against compliance with the provider's procedure. Between January 2017 and May 2017, the unit's compliance score for care plans improved from 50% to 100%, with an overall average compliance for the period of 64%. Any actions arising from the audits were fed back to the individual named nurse for the patient, who signed to confirm completion of the actions.

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.
- Patients were already established on dialysis before attending the unit. New patients were welcome to the unit by the clinic manager and were subsequently reviewed by the associate in renal medicine.

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- We saw evidence that patients were assessed at the start to ensure they were fit to commence treatment. The patient records required the patient's weight, temperature, pulse, and blood pressure to be checked before dialysis commenced, after the patient had been connected to the dialysis machine, and after dialysis ended.
- Additional readings were sometimes but not always taken during dialysis if clinically required. For example, in two patient records we reviewed, treatment was paused due to a low blood pressure reading. In one patient, ten subsequent readings were taken. In the other we saw no documented readings for two hours 37 minutes following treatment being paused.
- Needle placement was undertaken using 'wet' rather than 'dry' techniques. This helped reduce the risk of blood spray or spillage as well as the potential harm caused should infiltration occur in surrounding tissue.
- We observed staff carrying out a handover between shifts. This meant that all relevant information, issues or concerns about patients currently, or due to commence, dialysis was verbally provided to the new shift staff members. A daily handover sheet, and communications book, was used to facilitate this discussion.
- 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. For example, staff were not recording patient temperatures as regularly as they should, 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.
- Managers were unable to provide us with any internal policies relating to the management of sepsis. Instead they relied upon the policy devised by the commissioning trust. Despite this, they were able to locate a copy for us when asked.
- Call bells were not available for patients to use. Call bells enable patients to alert staff should they suddenly feel unwell. We witnessed a patient in the department collapse during a treatment session. A member of staff witnessed the episode and was able to verbally request colleague assistance. However, the unit had never had call bells installed which would have allowed the patient to request assistance himself.
- The side treatment room was fitted with a patient call bell; however, staff told us the alarm (which sounded at the nurses' station) was difficult to hear when the main treatment area was busy. A 'back-up' solution of using an additional vision and sound monitor device had been deployed; however, during our announced inspection the monitor was not working. We raised this with the clinic manager. The unit had been repaired and was in working order when we returned for our unannounced visit.
- Staff told us that they often walked around the treatment area and could usually detect a patient that was unwell. Alternatively they relied upon other patients to raise the alert verbally. We were concerned this lack of call bells was not a robust enough process to keep patients safe and asked senior managers to take immediate action to mitigate the risk of patients being unable to request help urgently. We were particularly concerned that patients being treated in isolation away from the main area did not have the benefit of staff being in the same room at all times. To counteract this greater risk, a manager told us a monitoring system had been installed. However when we investigated further we saw that the monitor was not switched on and the charger for it was not working. We raised this as an immediate concern with senior managers who immediately sourced engineers to review the how call bells could be urgently sourced and fitted to each bay.
- The provider had a pyrexia (raised temperature) pathway for use with patients who had an increased temperature. Patients whose temperature was not lowered by medicine were transferred to the commissioning trust. However, we noted that temperatures were not always recorded as often as they should be, which limited the ability to identify pyrexia and implement the pathway.
- Patients were able to self-administer oral antibiotics if these had been prescribed by the patient's GP. Patients requiring intravenous antibiotics were referred back to the commissioning trust to receive treatment.

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- The unit was supported under a service level agreement by the emergency resuscitation team from the host trust with transport from the unit to the main hospital arranged by ambulance.
- Between March 2016 and February 2017, eight patients were transferred from the clinic to another health care provider. This included transfers to the commissioning trust and to the provider's other clinic in Accrington. Any issues with emergency patient transport were fed back to the matron at the commissioning trust for discussion with the patient transport service provider.
- The clinic manager told us that prior to commencement of dialysis treatment, staff checked the patients name and date of birth and crossed checked this against the patient's prescription. Although, in many cases, staff had known their patients for a long time, this process meant the risk of mis-identifying patients was reduced. A senior nurse described the same process to us, including cross-checking against the patient prescription.

Staffing

- At the time of our inspection the unit employed a clinic manager, deputy manager, nine nurses (9.3 whole time equivalent) of which five were senior nurses; four dialysis assistants (2.9 whole time equivalent), and four healthcare assistants (3 whole time equivalent). The staffing figures were agreed as part of the unit's contract with the commissioning trust.
 - The clinic manager used a workforce planning tool to schedule staff working patterns at least four weeks in advance in line with the provider's duty roster procedure. A minimum of two registered nurses were scheduled for each shift along with a combination of dialysis and healthcare assistants. Bank and agency staff were used when needed to maintain safe staffing levels.
 - With 15 treatment chairs, the nurse to patient ratio was 1:4 with an additional healthcare assistant available. This was in line with the provider's roster management policy and the National Renal Workforce Planning Group 2002 guidance. This meant there were sufficient staff with appropriate skills on duty to keep patients safe.
 - The schedule was reviewed by the area head nurse. This ensured that all shifts complied with the unit's contracted staffing levels and skill mix.
- Between March 2016 and February 2017 one nursing staff member left the service. In the same period two nurses, one dialysis assistant and one healthcare assistant were recruited.
 - Sickness levels were monitored by the unit and were low. Sickness cover was provided by staff within the unit, which meant that no agency or bank staff were used to cover shifts within the same period.
 - The provider did not employ any on-site medical staff. However, two consultant nephrologists and an associated specialist in renal medicine, based at the commissioning trust, provided medical care and treatment to patients in the unit. The commissioning trust's on-call registrar, who was able to access the on-call consultant for emergency advice, provided out of hours cover for the unit when needed.
 - Each consultant carried out a clinic at the unit each week, while the associate specialist attended the unit three times each week to review patients. The clinic manager told us the medical staff were easily contactable and were responsive to requests for advice, often responding out of hours.
 - The unit did not have any on-site technical staff; however, under the service level agreement with the equipment supplier, staff were able to request urgent unscheduled visits from a technician to carry out work on the equipment if needed.
 - Staff in the unit undertook other roles such as the link nurses for a range of areas including, but not limited to, water plant revalidation, domestic water checks, anaemia, dialysis access, and infection prevention and control; holistic care pathway; and, patient hepatitis B record.

Major incident awareness and training

- The unit had a corporate business continuity policy in place which was supported by a procedure for the implementation of the policy. We viewed the units 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.
- The continuity plans included defined staff roles and escalation details to ensure notification of the event to

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the provider's senior management team and to the commissioning trust. A system was in place for automatically sending escalation emails as soon as a business continuity incident was triggered.

- The unit had individual continuity plans for failures of the water supply and water plant, power supply, heating, IT and telephony, and staffing shortages.
- Processes were in place to investigate, review and identify learning outcomes following business continuity incidents.
- In the event of a major incident which affected the operation of the unit, patients would be referred back to the renal unit at the commissioning trust or to other satellite units within the region to continue with their treatments. Patients temporarily transferred to this unit as a result of business continuity incidents at other local units were treated under high risk procedures to reduce the risk of infection to other patients.
- 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; however, the plans we viewed were brief and did not appear to provide a clear indication of an assessment of each patient's individual physical, mobility, and medical needs during an evacuation.

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

Evidence-based care and treatment

- The provider's policies, procedures and guidance were developed, and updated, in line with professional guidance from the Renal Association, the National Institute for Health and Care Excellence (NICE), and the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines. Clinical policies were reviewed by the provider's medical UK review group, and advice was available from the provider's medical director. The medical director held meetings bi-monthly with the practice development nurses team to discuss any clinical issues that had arisen.
- Treatment to patients was provided by staff in accordance with their individual treatment prescriptions, which were based on the Renal Association Haemodialysis guidelines (2009) and the

National Institute for Health and Care Excellence (NICE, Quality standard QS72, 2015). Prescriptions were reviewed and amended by the multidisciplinary team following monthly monitoring of patient's individual blood results. This enabled the medical team to review the effectiveness of treatment and to make improvements or changes to a patient's care plan.

- The unit provided haemodialysis and haemodiafiltration treatment. However, the unit did not facilitate peritoneal dialysis (which is a type of dialysis that uses the peritoneum in a person's abdomen as the membrane through which fluid and dissolved substances are exchanged with the blood).
- Patient treatment data was recorded manually by staff within the patient's care records before, during and after treatment. Readings then inputted manually by staff into the patient's electronic record. This increased the risk of making mistakes when recording entries. However, the manager confirmed that new machines would be arriving in August 2017 which would have the technology to electronically record readings and transfer them to the appropriate systems.
- NICE Quality Statement (QS72, 2015) was followed with regard to how staff monitored and maintained each patient's vascular access (for treatment). Approximately 78% of patients received treatment through an arteriovenous fistula (AV fistula – a surgically created connection between an artery and vein) or graft, while the remaining patients received treatment through the use of a central venous catheter. This was lower than then the Renal Association's 85% target for patients receiving dialysis treatment via AV fistula.
- Assessment of patients' vascular access was carried out before and during treatment. 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 monitored using a transonic measuring device; if any problems were identified the patient was referred to the vascular surgeons.
- The service held an ongoing register of patients with access problems which briefly summarised the problem, tests that had been carried out, and actions taken to refer the patient to an appropriate professional.
- The centre met the national recommendations outlined in the Renal Association Haemodialysis Guidelines

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(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

- 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.
- Topical anaesthetic cream was used, if needed and had been prescribed, before the insertion of the dialysis needles into the vascular access site. Local anaesthetic injections could also be provided if required; these were prescribed by the commissioning trust.

Nutrition and hydration

- Staff provided refreshments, including sandwiches, biscuits and drinks to patients during treatment. Patients were able to choose in advance the type of sandwich they wanted. Vegetarian options were available to patients that requested these.
- A dietician visited the unit twice weekly to review patients and to discuss patients' diets and to provide advice. Staff were able to contact the dietician separately if further advice was needed. The unit had a communications file to enhance communication between the dietician and staff.

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. The unit measured and reported on its effectiveness against the quality standards of the Renal Association Guidelines.
- The renal association sets out 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.

- The service 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. The registry collects, analyses and reports 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.
- 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 May 2017, and average of 93% of patients achieved the Renal Association target of more than 65% reduction. This was in-line with Renal Association guidelines. Guideline 5.3 - HD: Minimum dose of thrice weekly haemodialysis - recommends that every patient with established renal failure receiving thrice weekly HD should have consistently either urea reduction ratio (URR) > 65% or equilibrated Kt/V of >1.2 calculated from pre- and post-dialysis urea values.
- Patient blood was tested for potassium, phosphate, calcium aluminium concentrations in-line with the renal association guidelines. 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 May 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 59% of patients remained within the recommended range.
- Although the unit was unable to benchmark itself against other providers' units, its performance was benchmarked with other Diaverum UK units against a set of clinic performance measure. This data was reviewed by the area head nurse and clinic manager on a monthly basis to identify and address improvement areas.

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- The service did not participate in audits of travel time; however, it monitored the percentage of patients commencing treatment within 30 minutes of their scheduled appointment. Between January 2017 and May 2017 an average of 98% of patients commenced treatment within 30 minutes of their appointment time. The unit also monitored the number of patients who shortened their treatment times. In the same period, 3% of patients did not complete their prescribed treatment duration.

Competent staff

- Four staff, including the clinic manager and deputy manager held renal nursing qualifications. One further staff member was undertaking a renal qualification at the time of the inspection. Six staff had completed a mentorship course. Dialysis assistants were trained to national vocational qualification level three. The provider supported opportunities for other staff to undertake other qualifications if they wished.
- One dialysis assistant had attended a validated 'shared-care' course and was in the process of capturing information about tasks each patient was able to undertake, for example setting up the treatment trolley, self-needling and setting up the dialysis machine. A practice development nurse worked across the region to maintain and provide education and training for staff. This was supported by the provider's corporate education plan which incorporated mandatory and role specific training. The practice development nurse supported the clinic manager to provide additional training to staff on an ad-hoc basis if needed.
- Staff underwent a range of initial and annual competency checks. We reviewed four staff files which included competency records. However, we noted that, as a result of the inadvertent destruction of staff competency records in 2014, the initial competency records had been recreated with staff self-certifying competency skills. These records appeared to be completed 'in bulk'; however, the clinic manager had reviewed and signed them off.
- 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.
- All staff were expected to have an up to date disclosure and barring service certificate. As these were held centrally by the provider's human resources department we did not review them during the inspection. However, the clinic manager had assured themselves that all staff had a valid certificate.
- Existing staff were supported in maintaining their professional development and in revalidation with their professional body.
- New staff members underwent an induction and orientation programme. This included a range of 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.
- Staff competencies were reviewed and signed-off by their mentor. 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.
- Staff competencies included the understanding and administration of the medicines used within the unit. We saw evidence of this within four staff files that we reviewed.
- All staff were trained in the provision of basic life support (BLS) which included the use of the automated external defibrillator.
- The unit achieved an award in 2015 from the host trust in recognition of the work it carried out in mentoring student nurses. Three staff members had achieved individual certificates for being 'the best cadet mentor'.
- The clinic manager was notified of any updated policies and procedures by the director of nursing. The clinic manager reviewed each new policy and identified which staff members were required to read the updated document. Staff signed to confirm when they had done so.
- 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.

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- 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.
- 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. All staff had received their annual appraisal between March 2016 and February 2017. Staff we spoke with confirmed they had received an appraisal in the past 12 months.
- The clinic manager, and the provider's human resources department, regularly monitored and checked nursing staff professional registration and revalidation status. At the time of the inspection this has been carried out for all nursing staff in the unit.
- The clinic manager introduced a 'memory board' system which informed 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.
- All staff had access to the provider's online learning centre. Staff told us the unit supported continual development.

Multidisciplinary working

- There was effective multidisciplinary working in place.
- Overall care of patients at the unit remained with the consultant nephrologists. Multidisciplinary team (MDT) meetings were held three times a month to review each patient's progress, their care plans, monthly blood results, vascular access, and any patient follow-up care requirements.
- The consultant nephrologists, the associate specialist in renal medicine, the clinic manager, and the dietitian attended the meeting. The team could also access additional psychological and social work support if needed, although these individuals did not routinely attend MDT meetings. Communication across the MDT team was effective.
- The vascular consultant visited the unit every Monday to review and discuss any patient vascular access problems. Patients who required urgent assessment and intervention were referred back to the commissioning trust for review by the vascular consultant.

- An on-call registrar from the commissioning trust was available to provide emergency prescriptions or changes to the care plan in emergencies.
- The MDT reviewed the patient's treatment records and care plan. Any changes to patient's care and prescriptions were recorded for each named nurse to initiate the agreed actions. Changes as a result of the MDT were discussed with all patients by the named nurse.
- Clinic letters were copied to patients' GPs and a copy of letters was kept electronically. Staff were able to contact patients' GPs separately as and when necessary, for example to enquire if a patient had been admitted to hospital if they failed to attend their dialysis session.
- A communications book was used to enhance communication between the nursing and medical staff.
- Staff we spoke with were aware to contact the vascular access team in the commissioning trust for any suspected central venous catheter infections.

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.
- 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.

Consent, Mental Capacity Act

- All staff received annual mandatory training in the Mental Capacity Act 2005, which included awareness of equality and diversity issues.

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- At the time of the inspection 20 out of 21 eligible staff had completed this training. A further training session was planned to train the remaining member of staff. Staff knowledge was supported by a quick reference guide for applying the mental capacity act to decisions made when staff suspected a patient lacked capacity.
- 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.
- The unit did not have any patients living with dementia or learning disabilities at the time of the inspection. Patients living with dementia were usually cared for in the commissioning trust. However, where staff had any concerns about a patient's capacity to consent they referred the patient to the medical team for a capacity assessment.
- Consent forms were held within all four of the paper records we reviewed. The form detailed consent for treatment, screening procedures and then ongoing treatment. The name of the professional taking the patients consent and the patient's signature were recorded.
- The unit's catchment area had a diverse population, which was reflected in the patient group. Although the high usage capacity of the unit meant that there was limited flexibility, the clinic manager told us the unit would try to accommodate patient's requests to change or swap treatment slots for cultural or spiritual needs.
- Staff supported patients who wished a chaperone to be present during consultations or intimate treatment.
- Patients were able to access the chaplaincy services of the host trust if needed.
- The clinic manager told us staff assisted patients with other health needs, such as arranging or rearranging GP and other clinic appointments. Staff had also arranged for the collection of medicines from local pharmacies for elderly patients; for example, antibiotics for chest infection. This meant patients were able to start their medicines in a timely way to reduce the impact on their health.
- Patients took part in the provider's twice-yearly national 'I want great care' patient satisfaction survey in 2015. Of those patients who responded, 95% 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 patient transport, delays in commencing treatment, availability of information and staff shortages. The action plan was displayed in the unit for patients to view in line with the provider's patient engagement and experience policy.

Are dialysis services caring?

Compassionate care

- Staff 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.
- We observed staff interacting with patients in a compassionate and caring manner.
- One patient we spoke with said they felt safe in the unit and told us "staff are very caring and it feels like a family here" and confirmed that they were able to see the doctor and dietician regularly.
- The unit did not have privacy curtains around each treatment station; however, portable privacy screens were used to maintain patient dignity when providing care for patients with central venous catheters, and when patients were ill. One patient told us that staff will spend extra time with ill patients and confirmed the use of privacy screens.
- The provider supported the use of 'Patient View', an online system which enabled patients to view their latest test results. This enabled patients, who wished to use it, to be more involved in their care and treatment. Of those patients that responded in the October 2016 patient survey, 85% said they felt they were involved in their dialysis treatment and decisions.
- Staff took opportunities to promote 'self-care' with all patients in the unit. While the majority of patients chose not to self-care, three patients had expressed an interest following a recent roadshow hosted at the unit.
- One patient we spoke with told us they were due to start an education programme for self care at home and staff in the unit were arranging training for them. The patient

Understanding and involvement of patients and those close to them

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saw home self-care as a benefit given the amount of time taken in travelling to and from the unit, which could be compounded by delays in commencing treatment.

- All of the patients we asked told us staff involved them in discussion and explanations about their care, including their blood results. Patients also confirmed they were seen by the dietitian and were able to discuss their diet. One patient wrote on the patient survey that “the staff at Burnley do an excellent job”.

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.
- Nursing staff were able to refer any patient to the commissioning trust’s psychology service, to the community social services team, or to the patient’s GP if any specific needs were identified. Staff and patients also had the contact details for the renal social worker for help and advice.
- Staff were able to arrange case conferences with relevant professionals where it was felt patients may require additional support. Staff told us of an example where a case conference had helped to identify the root cause of one patient’s repeated non-attendance at the unit. The conference enabled staff to make adjustments to the patient’s prescription and treatment times in order to more easily facilitate the patient’s personal and family needs. As a result, the patient’s attendance compliance improved.
- The Kidney Patient Association was actively involved in the unit and were able to provide emotional support services for patients, their families, or carers.
- Although there was no specific ‘quiet room’ in the unit, there was a consultation room which could be used to undertake confidential discussions with patients. This was situated within the staff only area of the unit which reduced the risk of conversations being overheard.
- Staff on the unit supported patients who wished to go on holiday.
- Staff attended patient funerals whenever possible.

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 contract, and service specification, was defined and agreed directly with the commissioning trust’s renal team. As such the unit had no direct link with the commissioners in planning its services. However, performance against the contract was monitored by the commissioning 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 host trust; the unit was located next to a number of the hospital’s carparks. Eight designated dialysis parking bays were located close to the unit. For patients who required transport, this was arranged through the local ambulance service, which contracted patient transport to a local taxi firm. Staff told us the unit had a good rapport with the taxi drivers.
- The patient transport services provider was contracted by the commissioning trust and provided its service through a local taxi firm. The commissioning trust monitored performance against the service specification, which detailed that patients should not wait more than 90 minutes to be collected prior to, or after, treatment sessions with travel time being no longer than 60 minutes.
- The clinic manager reported any late pick-ups by the taxi service as an incident to the commissioning trust’s matron; however, the unit did not routinely collate data on patient transport waiting times.
- Staff participated in a patient transport user group, which evaluated the transport service against defined performance indicators. Feedback from the groups was provided to the local commissioning groups to aid improvement of the service.
- The October 2016 patient survey highlighted a number of concerns relating to dissatisfaction with the patient transport services, and associated waiting times before and after treatment. This reflected in the patient survey with only 75% of patients satisfied with the waiting time before commencement of treatment.

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- One patient commented on the survey that following a transfer of the patient transport contract to another provider 'the waiting time [for the taxi] has gone up tremendously. I have waited more than one hour on numerous occasions after treatment'. Another patient commented 'transport never arrives on time both coming to dialysis and going home'.
- Managers acknowledged these concerns on the patient survey action plan, but noted that it was unable to take complaints on behalf of patients to the patient transport provider as the unit did not hold the contract. However, the unit was monitoring the number of late pick-ups and drop-offs which it provided to the commissioning trust.
- 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, by the entrance to the host trust and was accessible for patients living with mobility issues. Access to the unit was via a secure remote locking door system, which was operated from the unit's reception area.
- The patient waiting area was situated next to the reception desk. Patients were able to hang their coats in a small area, which included the weighing scales and individual boxes used to store items such as tape. We were told of a theft from a patient's coat in this area. Although the risk of a similar situation occurring was low, patients were unable to mitigate against this as there were no separate lockers for patients to store their belongings.
- Accessible male and female toilets were located close to the reception area.
- The unit had one isolation room, which included one machine used solely within this room. This isolation machine was clearly identified in the relevant maintenance records. However, as the unit had only one isolation room, this meant if more than one patient required isolation treatment the additional patients were referred back to the commissioning trust.
- 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.
- Staff provided treatment to 42 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 7.15am and 10.30pm. 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 exclusion criteria. The commissioning trust's consultants made the decision on patient suitability for the unit; however, the new clinic manager told us the future aim was to include unit nursing staff in the decision making process.
- The acceptance criteria included patients being stable with established and functioning venous access with no history of adverse reactions to treatment, and all virology tests completed.
- The unit did not have separate treatment stations for patients on holiday. However, the unit was able to accept patients on holiday if there was capacity for the dates required. This was subject to receipt of fully completed documentation, and medical approval and acceptance. This included consideration of any risk posed by the incoming patient on the resident patient cohort, for example isolation requirements.
- 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 where 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.

Access and flow

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- Between March 2016 and February 2017, the unit did not cancel any dialysis treatment sessions due to machine breakdown or failure and there were no cancellations as a result of non-clinical reasons. In the same period the unit had one treatment sessions delayed due to dialysis equipment failure.
- Arrangements were in place to ensure continuity of patient treatment where treatment sessions had to be cancelled. This included opening the unit on Sundays and/or referring patients to use treatment sessions in the provider's other nearby units or NHS dialysis units.
- The unit recorded that 154 treatment sessions were missed between March 2016 and February 2017 because patients did not attend their scheduled appointment. Missed appointments were recorded as an incident. We saw evidence of staff contacting patients or relatives to encourage attendance and discussing the risks of missing treatment. Staff also alerted the consultants to patients who had missed treatments.
- In the same period staff recorded 196 incidents where patients requested to shorten their treatment. Staff recorded the reasons and advice given to patients on the risk of doing so. Where necessary, staff also referred the patient for discussion at the multidisciplinary meeting. Patients were required to sign a disclaimer if they voluntarily shortened treatment.
- 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.
- Staff requested detailed information about patients prior to acceptance of their care. This was to ensure the patient met the admission criteria and that the unit could meet their individual care needs in a safe and effective way. The unit was able to accommodate visits by new patients and their relatives prior to the start of treatment. This meant that patients were familiar with the unit, its facilities and the staff.
- The allocation of appointment slots for dialysis treatment took into account patient's individual and clinical needs, including any domestic, social care or work commitments, level of mobility, other medical conditions and the patient's age. For example, diabetic elderly patients living alone were offered afternoon appointments to ensure they arrived home safely before dark and were able to eat in accordance with their diabetic status and needs for medicine and carers attendances. Patients who work were given priority for evening treatment slots and parents with young children preferred morning slots.
- Once a patient was established the unit would aim to accommodate patient choice if other slots became available, or through swapping slots by mutual agreement with another patient. The clinic manager told us of a situation where the unit temporarily opened a Tuesday, Thursday and Saturday twilight shift for an individual patient who, for a specific reason, could only dialyse at those times.

Meeting people's individual needs

- The unit was located on the ground floor of the host trust by the entrance to the hospital. This meant the unit was easily accessible for patients living with mobility difficulties or for those using a wheelchair. The entrance to the unit was through a secure, but automatic, door into the reception corridor, which included separate male and female toilets for patients to use if needed prior to commencement of treatment.
- Access to the treatment area was through a proximity card secured door. There was sufficient space between, and around, the treatment station for patients and staff to move safely. Each station had a television for patients to watch, although staff told us the unit had experienced problems with TV remote controls going missing.
- An induction loop system was fitted within the treatment area to assist patients who used hearing aids.
- The unit had Wi-Fi facilities for patients' use and each treatment station had a television.
- In line with the provider's 'admission and discharge of patients' procedure, patients were invited to visit the unit before starting their first treatment. Patients with learning disabilities were encouraged to bring their hospital passport.
- 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, medicines and living with haemodialysis. This provided patients with the opportunity to discuss any questions or concerns they had.
- Staff were in the process of introducing the commissioning trust's holistic care plan approach, which incorporated patient self-assessment of mood

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through a 'stress thermometer'. This tool assisted staff to identify patients that needed additional support or referral to other professionals such as the psychologist or renal social worker.

- The unit accepted 'holidaying' patients when there was a treatment slot available and the appropriate paperwork and records had been received.
- The provider developed a travel guide for renal patients, which provided advice to patients going on holiday, suggested destinations in Spain including the contact details for the provider's local clinics in each area, and information about hotels, restaurants and areas for sightseeing.
- Staff supported patients to go on holiday and had a link nurse responsible for co-ordinating, and preparing the relevant paperwork. Consultant to consultant agreement for holiday treatment was obtained and patients were screened for infection before confirmation of the treatment.
- Patient treatment session slots were not guaranteed for patients returning from holiday. This meant patients were only able to return to the unit if there was capacity to do so. Where there was no existing capacity in the unit, the commissioning trust co-ordinated referrals to other satellite dialysis clinics within the area. We were concerned that this produced difficulty for patients who wanted to travel to higher risk countries but felt unable to because they risked losing their place in the unit.
- Staff were able to access advice from a psychologist and a social worker if this was needed. However, patients with more significant psychological, bereavement support or counselling needs were referred to their GP to access the relevant services.
- The demographics of the patients attending the unit reflected the diversity of the local population. This meant that a number of patients attending the unit did not use English as their first language. However, the unit had proactively worked with a patient to translate signs and posters throughout the unit. Information was published in different languages to help make sure it was accessible to patients from a range of ethnic backgrounds.
- The provider's admission pathway encouraged patients whose first language was not English to bring a relative to the first appointment to assist in translating information and we saw evidence of this practice in a patient record. This was not in line with draft guidance from NHS England (2015) which 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". However, the unit had access to a telephone interpretation service, which was used when required.

- Despite this, we saw that staff reviewed the communication needs for new patients. They checked a box to confirm whether patients had communication requirements such as an interpreter and we saw evidence of this in the records we reviewed.
- Staff supported patients who wished to break their fast during the period of Ramadan. The clinic manager told us that staff will bring food in during celebratory times.

Learning from complaints and concerns

- The provider's corporate complaints management policy was supported by a complaints procedure which 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. Details of how to complain, including contact details for senior management team members, were displayed within the unit's waiting area. Patient complaints could be made verbally, in writing, by email, online, or through the unit's feedback boxes.
- The unit received one formal complaint in the period April 2016 to March 2017, which related to an incident on the unit that was not related to the operation of the unit or the care and treatment received. The complaint was dealt with, and responded to, in line with the provider's policy.
- Patient concerns about the patient transport service, raised in the October 2016 patient survey, were dealt with as part of the survey action plan, rather than as part of the complaints management process.
- 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

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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

- The clinic manager was responsible for this unit and one of the provider's nearby clinics. The clinic manager, who was supported by a deputy clinic manager, did not undertake clinical duties. The manager had approximately 30 years management experience. At the time of the inspection, a new clinic manager had recently been appointed and was undergoing induction in readiness to take over responsibility for the clinic.
- The area manager who had responsibility for the performance of a number of clinics in the region reported through the operations director to the county manager. The nursing director and the practice development nurse also supported the unit.
- Staff told us that local senior staff were visible and approachable. Staff were aware of, and knew the area head manager and director of nursing.
- One staff member told us the unit "was a nice place to work. It is light and bright and lifts the mood". The unit was described as "a family" and that the "best thing here is the care for the patients. It's a very friendly atmosphere". Another staff member told us it was a "very friendly team. Support is there; there is always someone to go to"; although the same staff member recognised there had been challenges in the previous year due to staff shortages.
- In contrast, one staff member was concerned that there was a lack of support from the clinic management team. This was echoed by another staff member who commented that the health care assistants would benefit from additional support and being made to feel more part of the team. The staff member indicated the apparent lack of support may have been a symptom of

previous staff shortages and the clinic manager splitting their time between two clinics; both of which situations had since been resolved. Despite the concerns expressed, during the inspection we observed a supportive and friendly atmosphere within the unit.

- 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.
- 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 Workforce Race Equality Standard (WRES) is a requirement for organisations, which provide care to NHS patients. This is to ensure employees from black and minority ethnic (BME) backgrounds have equal access to career opportunities and receive fair treatment in the workplace.
- 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. 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. We saw that reminders to switch off lights were displayed to help achieve another priority for operational efficiency.
- Staff we spoke with were aware the provider had a strategy and values. Although staff were unable to

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discuss these in detail, they were able to describe the objective of improving the quality of life for their patients. Staff were aware of how their roles contributed to achieving this objective.

Governance, risk management and quality measurement

- The provider's country manager retained overall responsibility and accountability for governance. The clinical governance process set out clinic staff responsibilities to collate and report monthly and quarterly governance information.
- 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 consultant nephrologist was the clinical lead for governance in the unit.
- Staff we spoke with were clear about their roles in providing care and treatment for patients, and in supporting the unit in their additional lead roles, for example the holistic care approach co-ordinator.
- The clinic manager introduced a clinic 'memory board' which was displayed within the medicines room. This displayed actions, including audits that needed to be carried out each month. This encouraged staff compliance with monthly requirements and ensured the timely completion of monthly audits, reports and other action.
- The new manager had an understanding of the challenges to providing good quality care in the unit and was able to tell us how these were being addressed. For example, the manager said random sickness was a challenge at times. To measure this effectively the manager was using the Bradford Factor Scoring system (a tool to measure frequent short-term absenteeism) to monitor the impact. Sickness rates were falling at the time of inspection.
- There was a close working relationship between the unit and its NHS stakeholders; the commissioning trust and the host trust. Patients who attended the unit were referred to the specialist renal and dialysis services provided by commissioning trust. The unit therefore functioned as a satellite unit for, and under contract to, the commissioning trust. Monitoring meetings were held with the commissioning trust to review performance against the unit's contract.
- The area manager undertook a monthly checklist of the unit which reviewed issues around people, finance, quality, facilities, patients and trust feedback. Comments and actions were recorded where appropriate; however, action owners and target deadline dates were not recorded on the checklists between October 2016 and February 2017.
- The unit had achieved ISO 9001 accreditation for its information management system (IMS) and OHSAS 18001 accreditation for its health and safety management system.
- All staff had access to the IMS 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. Some documents appeared to be a number of years old with next review dates in the past. The clinic manager and practice development nurse told us 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 photocopied signature sheet was prepopulated with the names of all 24 staff members and attached to each policy. However, the sheet did not specifically identify which members of staff, of those listed, were required to read and sign. Of the policies we viewed we were not assured that all the relevant and eligible staff had signed. This was because out of the 24 names on the sheet 12 staff had signed the roster management policy, 11 had signed the general infection control plan and the hepatitis B testing, management of patients and vaccination policy (11 staff had signed), and eight staff had signed the duty of candour policy.
- There was a risk register in use. In the document sent to us by unit managers, we saw there were three patient safety risks listed. These included regular patient non-attendance for treatment; the inaudible side room patient alarm; and lack of patient call bells in the main treatment area. The last two risks were added to the register following our inspection. We were not therefore assured that the unit had identified all relevant risks.
- Each risk included a description, assessment of likelihood and severity of the risk, overall risk level,

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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.

Public and staff engagement

- The provider had a patient engagement and experience policy, and implemented twice yearly 'I want great care' patient survey. 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 three patient advocates. 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 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. Thirty-five patients responded to the survey in October 2016 which indicated an average overall satisfaction score of 87%, with 95% 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 the patient transport. This was reflected in the action plan subsequently developed by the unit. The clinic manager told us that following feedback from patients regarding wait times for treatment, the unit conducted a two week time and motion study which led to changes being made to schedule times and transport provision.
- Staff we spoke with appeared to be engaged with the unit and the service as a whole. However, some staff expressed views that given the clinic manager split their time with another provider's unit impacted on the amount of support available.
- There were incentives provided for staff such as extra annual leave and a shift allowance for staff who worked unsociable hours.
- 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. Fourteen staff responded to the survey, which indicated an average overall satisfaction score of 81%.
- Of those staff who responded, 89% said they 'like to go to work'; 88% said they know what was expected of them in their job; 86% said they felt 'motivated to improve the quality of services that we provide' and the same numbers said they 'contributed to the achievement of the companies goals'. The scores were supported by staff comments, which included "Working with staff, as we are a very good team, providing support and care for patients"; "Culture of high standards caring attitude, helpfulness of colleagues"; and, "Team work staff are amazing meeting different patients throughout the day learning something every day. Enjoy working in the unit".
- However, of those that responded, 73% said they felt they "had everything [they needed] to do the job well", knew the strategy of the provider, felt that the provider supported their training and development, and would recommend the provider as a good place to work. One staff member commented, "I think [the provider] is a good company to work for. However frequent staff shortages is putting extra strain on staff who are already struggling to carry out their daily task, leaving them having to stay back to carry out task like bloods and care plan reviews etc. in their own time."

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.
- The unit had recently received authorisation to donate their old machines abroad. A local chaplain would be facilitating this process.
- 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.

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- 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.

Outstanding practice and areas for improvement

Outstanding practice

- The unit implemented a 'memory board' to remind all staff of recurring governance actions that needed to be carried out each month.
- The unit was in the process of introducing the holistic care package approach to assess patients' psychological as well as physical needs.

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure there is an active and effective patient call buzzer system to enable patients or those near to them to alert staff to any immediate needs or distress.
- 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 completed, 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 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 conditions 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 consider how it can evidence daily compliance with the domestic cleaning programme.
- The provider should consider how it can audit, identify and address any non-compliance with machine cleaning.
- The provider should ensure that weighing scales are always available for patients to weight themselves prior to and following treatment.
- The provider should consider how it can ensure accurate and up to date testing of portable electrical appliances is recorded and maintained.
- The provider should consider how it can implement a more robust system for accurately identifying and retaining equipment numbers and batch numbers of single-use dialysis equipment.
- The provider should consider how it can ensure additive medicines are clearly identifiable to staff during patient treatment.
- The provider should consider how it can ensure lower level concerns and complaints are logged, investigated and responded to at an appropriate level.
- The provider should consider how it can more clearly record which staff are eligible and required to sign confirmation for documentary updates.
- The provider should consider how it can improve the identification and recording of risks to the safe operation of the unit on the risk register.
- The provider should take action to monitor and publish data with regards to the Workforce Race Equality Standard (WRES).

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	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>Regulation 12 HSCA 2008 (Regulated Activities) Regulations 2014</p> <p>Safe care and treatment</p> <ol style="list-style-type: none">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:<ol style="list-style-type: none">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; <p>This was because:</p> <p>Risk assessments were not fully completed.</p> <p>Regulation 12(2)(a)</p> <p>And;</p> <p>Call buzzers were not available for patients to alert staff should they require urgent assistance. This increased the risk that staff may not be aware when patients require urgent assistance.</p> <p>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.</p> <p>Patients' clinical observations were not being recorded as regularly as they should be.</p>

This section is primarily information for the provider

Requirement notices

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;

Staff were not trained in safeguarding children level two.

Staff had not received training to help them identify and take action to initiate treatment for Sepsis

Regulation 12 (2)(c)