

Basingstoke Dialysis Unit

Quality Report

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Date of inspection visit: 21 and 25 April 2017
Date of publication: 10/08/2017

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

Overall summary

Basingstoke Dialysis Unit is operated by Fresenius Medical Care Renal Services Limited. The unit is commissioned by a local, host NHS trust to provide renal dialysis to NHS patients. The service is registered for 24 dialysis stations. The unit has four bays. Three bays have six stations and one bay has not been used since the contract was agreed, but is set up for four stations. The clinic has two single-bedded side rooms that can be used as isolation rooms if patients have an infection risk.

The service provides haemodialysis from Monday to Saturday each week with morning and afternoon session each day.

We inspected this dialysis unit using our comprehensive inspection methodology. We carried out the announced part of the inspection on 21 April 2017, along with an unannounced visit to the unit on 25 April 2017.

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

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

Services we do not rate

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

We found the following areas of good practice:

- Staff were caring, compassionate and patients said they often went the extra mile. They were committed to providing patient-centred care.
- The unit offered haemodiafiltration as standard, which some evidence indicate delivers improved patient outcomes.
- Staff received a comprehensive induction and had good access to corporate training courses. Nurses were supported to complete external renal nurse training.
- Staff participated in annual appraisals and all staff reported in the last staff survey that they understood their roles and responsibilities.
- Staff coordinated care safely and effectively with the NHS trust consultants and dietitian.
- Staff maintained comprehensive patient records.

Summary of findings

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

- Staff did not have a good understanding of risk management and challenging practices to improve care and safety.
- There were risks associated with staff not formally identifying patients for treatment and checking patient prescriptions when giving medicines. These risks had not been identified with associated mitigating actions.
- Some staff had not completed mandated training.

- There was a lack of clarity in when to apply clean or aseptic techniques when dialysing patients with AV Fistulas, and staff did not consistently follow the Fresenius corporate policy.

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. We also issued the provider with two requirement notice(s) that affected this dialysis service. Details are at the end of the report.

Edward Baker

Deputy Chief Inspector of Hospitals

Summary of findings

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Basingstoke Dialysis Unit

Services we looked at:

Dialysis Services

Summary of this inspection

Background to Basingstoke Dialysis Unit

Basingstoke Dialysis Unit is operated by Fresenius Medical Care Renal Services Limited. The service was first registered with the Care Quality Commission in 2010. This is an independent provider of dialysis services in Basingstoke, Hampshire, and provides haemodialysis only. Basingstoke Dialysis unit also accepts patients for holiday dialysis. It serves the communities of north Hampshire and south Berkshire.

The service is registered for the regulated activity treatment of disease, disorder or injury and has had a registered manager in post since October 2010.

The service was last inspected in January 2013 using our previous methodology. Six standards were inspected and concerns were identified with consent to care and treatment and safeguarding people who use the service. A desk top review in July 2013 found the service to be compliant with these standards.

We inspected this dialysis unit using our comprehensive inspection methodology. We carried out the announced part of the inspection on 21 April 2017, along with an unannounced visit to the unit on 25 April 2017.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, a CQC manager and a specialist advisor with expertise in renal dialysis. Lisa Cook, inspection manager, oversaw the inspection team.

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.

We found the following areas of good practice:

- Staff understood the incident reporting process and reported incidents in line with the Fresenius policy. There were systems for sharing learning from incidents including from those that occurred outside the clinic.
- Most staff had completed mandatory training and there was a system for monitoring and alerting staff when they were required to undertake update training.
- There were enough staff to deliver the treatment and the unit rarely needed to use bank or agency staff
- Staff consistently followed the provider's policy for hand hygiene, and wore personal protective equipment.
- Patients with, or at risk of having blood born viruses were dialysed in one of the units two isolation rooms, on dedicated a dialysis machine to minimise the risk of cross infections.
- Staff disposed of clinical and non-clinical waste appropriately.
- The clinic environment was tidy and well organised, with sufficient storage for materials and equipment.
- Systems were in place for planned and responsive maintenance of equipment.
- The dialysis machines included automatic alarms to alert staff if the machine malfunctioned or if the patient's dialysis pathway went outside set parameters.
- The resuscitation trolley was readily available equipped with items needed in an emergency.
- Staff checked the water treatment plant and took the necessary actions if they found non-compliances with test results.
- Staff checked medicines daily and all medicines were in date and stored at the correct temperature.
- Staff followed agreed procedures to create records accessible within Fresenius and the commissioning NHS trust. Their records were comprehensive.
- There were sufficient staff on duty to support the needs of patients.
- The clinic had emergency preparedness plans for the clinic and emergency evacuation plans for each patient.

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

Summary of this inspection

- The provider had not notified the Care Quality Commission of deaths within its own clinical incident reporting policy timescale of 72 hours of the incident.
- Not all staff had completed the mandatory training.
- There was a lack of awareness of who the corporate safeguarding lead was.
- The safeguarding policies did not make reference to female genital mutilation, to enable staff to recognise and protect vulnerable individuals from being groomed for terrorist activities.
- Staff did not apply aseptic techniques in line with the Nephrocare Standard Good Dialysis Care policy, or dispose of sharps correctly.
- The clinic manager, as registered manager, was not aware of how many cycles the dialysis machines had completed and their projected replacement dates.
- When administering medicines, staff were not assured they were delivering the correct dose of the prescribed medicine to the correct patient, and recording this in line with Nursing and Midwifery Council code.
- Staff recorded some notes, such as blood results, in different folders/files. The risks associated with the practice had not been assessed.
- Staff had not risk assessed their practices of not formally identifying patients prior to dialysis.
- The risk assessments for, for example, falls or pressure ulcers were not linked to detailed care plans to guide staff in how to support patients with an identified risk.

Are services effective?

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

We found the following areas of good practice:

- The clinic staff based practices on the corporate 'good dialysis care' policy and procedure, based on internationally recognised good practice guidance.
- They used a recognised tool to assess vascular access for infection and damage.
- Most patients had arteriovenous fistulas, with the proportion in line with Renal Association standards
- The clinic offered haemodiafiltration as standard, but also provided haemodialysis when necessary.
- The unit monitored patient outcomes and contributed data to the Renal Registry.
- Patients accessed the trust's dietitian at the clinic, and said they had good support.

Summary of this inspection

- Staff were competent in their roles and had access to mentors and role-specific training.
- There was comprehensive induction training to assist staff in understanding their roles and responsibilities
- Staff were supported to develop their skills. Three nurses had completed the renal nurse course and another was due to complete the course in 2017.
- Staff were given lead roles to support colleagues in, for example, infection control, holiday dialysis, vascular access and nutrition.
- All staff had undertaken annual training in basic life support.
- Clinic staff worked collaboratively with the trust's consultants and dietitian, and there effective systems for sharing information.
- Patients gave to consent to treatment and staff kept documented written consent forms in patient files.
- Staff had completed training in the Mental Capacity Act 2015.
- The clinic monitored delays with patient transport.

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

- The clinical risk policy and clinical governance strategy had not been reviewed within the last three years to ensure they reflected current good practices. The corporate 'good dialysis care' policy did not make reference to recent National Institute for Clinical and Health Excellence (NICE) guidance on Renal replacement therapy services for adults.
- Staff did not have access to specific guidance on identifying and responding to sepsis.

Are services caring?

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

We found the following areas of good practice:

- Patients told us staff were caring, compassionate and treated them with respect and dignity. Our observations confirmed this, with for example, staff closing curtains to respect a patient's dignity.
- The previous patient survey result showed 98% of patients said they were treated with dignity and respect.
- Patients said they could have private discussions with staff if they requested them, in one of the consulting rooms on site.
- Staff explained the care and treatment they provided and involved patients in their care, by discussing results with them and asking their opinion.

Summary of this inspection

- Patients said they received emotional support, from staff and other patients when they attended for dialysis.
- The clinic had established a named nurse approach to foster patient- centred relationships with regular reviews.

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

- On a minority of occasions, staff did not welcome to patients onto the unit or take time to talk with them.

Are services responsive?

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

We found the following areas of good practice:

- The clinic offered a convenient location for dialysis treatment in north Hampshire.
- There was free parking at the clinic, which patients appreciated.
- The clinic was suitably designed for the delivery of dialysis services.
- Staff met the individual needs of patients, by taking account of pre-admission assessments.
- New patients could visits the clinic before they were admitted, to familiarise themselves with the environment and procedures. They also had a patient guide and welcome pack.
- Staff helped patients to arrange holiday dialysis.
- The clinic operated a 'batched' appointment system to reduce waiting times for patients.
- Patients were given the Fresenius complaints policy and procedure, and this was displayed in the waiting room.
- Staff displayed useful information for patients in the waiting room, including results of the patient survey and associated action plan.

Are services well-led?

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

We found the following areas of good practice:

- Staff said they were well supported by the clinic leadership team and by colleagues. They said they liked working at the clinic and the manager was approachable.
- Clinic and trust staff worked collaboratively to support the needs of patients.
- Staff understood their roles and responsibilities and made patient care their priority.

Summary of this inspection

- The manager attended monthly clinic manager meetings at the NHS hospital, where the trust's haemodialysis lead shared updates. He also attended regional and national meetings quarterly.
- There was a patient representative, whose role was to liaise between patients and the clinic manager.
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However, we also found the following issues that the service provider needs to improve:

- The clinic's governance arrangements did not include effective local risk management.
- The clinical governance framework did not promote frequent scrutiny and challenge of clinic performances.

Dialysis Services

Safe

Effective

Caring

Responsive

Well-led

Are dialysis services safe?

Incidents

- There had been no reported ‘never events’ or serious incidents at the unit in the 12 month period to February 2017. Never events are serious incidents that are wholly preventable as guidance or safety recommendations that provide systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.
- Records showed there had been three unexpected patient deaths in the 24 months to January 2017. Two patients died in hospital following emergency transfer and one died during dialysis. One death, following transfer to hospital, had been subject to a Coroner enquiry. The clinic manager had attended a meeting at the hospital to identify any learning from this event and it had been concluded that there was no learning to take forward.
- The unexpected deaths had been reported appropriately to the Care Quality Commission (CQC), however they were not reported within the 72 hours of the incidents, as specified in the Fresenius policy for clinical incident reporting. The CQC received the notifications about 7-10 days after the event.
- The Fresenius clinical incident reporting policy, June 2016, outlined responsibilities and actions to take when incidents, accidents or near misses occurred. The policy described the process, how to protect people from further risks, who needed to be told about the incident and how to investigate incidents. Procedures included carrying out a root cause analysis and being open with those affected, by

applying the duty of candour. The policy also defined incidents in terms of patient safety incidents (not related to clinical treatment), clinical incidents, near clinical incidents, never events and serious incidents.

- There had been three patient falls in the unit. These had been reported as non-clinical incidents as they had not been related to treatment. There had been no trends identified from the three falls.
- Staff completed treatment variance reports (TVRs) for any untoward event or intervention that occurred before, during or after dialysis, such as episodes of hypotension or access difficulties. Staff knew how to record these on the Fresenius electronic database, where they were linked to patient records. We saw a staff member record a TVR following an event on the unit, and they commented they were confident in using the system.
- The clinic manager or deputy manager recorded clinical incidents, such as a medication error or cardiac arrest on the unit, on a clinical incident report (CIR). We reviewed an incident relating to a cardiac arrest and death on the unit. The report included a full account of events and had been reviewed and signed off within the timescales laid out in the policy. The chief nurse reviewed reports to determine whether they needed to escalate it to the clinical governance lead. The root cause analysis was reviewed by clinical leads and by the medical director. The clinic service director reported the incident to the CQC.
- We reviewed a unit variance report relating to a positive Legionella result in the water supply, identified by the monthly water checks. The unit had reported this to the facilities management team and the NHS hospital, carried out a thermal and chemical disinfection and completed a risk assessment. The risks had been discussed by the clinical governance

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team and with the health and safety team. The result had not impacted on the service delivering dialysis. In response to the results, the staff carried out twice daily flushing of the domestic hot water and the facilities team reviewed the entire system. The learning was carried forward at corporate level, with the Fresenius maintenance team reviewing and revising the Legionella policy.

- Staff said they understood how to report incidents and near misses and they would speak to a senior member of staff and report the event on the Fresenius electronic reporting system. They confirmed they received feedback on the incidents at team meetings. They were able to view incident reports on the reporting system. They understood the principles of the duty of candour and being honest and open with patients if they made mistakes.
- There had been one incident of a patient given the wrong dose of anticoagulant in the weeks immediately prior to our inspection. This had been reported as a clinical incident, and documented on the system. The incident had not caused the patient harm and the dose was within an acceptable range. Staff had taken appropriate actions to support the patient after the incident.
- Bulletins were used to share learning from incidents across the organisation. Staff signed to show they had read the bulletin.
- There was a system for circulating patient safety notes and there was evidence staff reviewed and acted on these.

Mandatory training

- The clinic manager and staff monitored completion of statutory and mandatory training, emergency training, and mandated e-learning provided by Fresenius. Staff were up to date with almost all their mandatory training, as shown by the clinic's training matrix. This included dementia awareness, safeguarding, and moving and handling. Staff were slightly overdue in completing the data security awareness level 1 course, which was new, replacing information governance. Only 2 of 13 staff had completed training in equality and human rights and conflict resolution.

- As well as showing when staff were up to date with training, the matrix showed when further training was due. The matrix also indicated which courses each member of staff needed to complete and how often.
- Many courses were provided as on-line or 'same time' training (provided for groups of staff via the internet), and staff reported good access and support for these. Fresenius offered monthly same time training, run by the training department, to encourage access.
- Staff files included training records and competencies as well as induction records. This showed there were reliable systems for recording staff training.
- If the unit needed to use bank staff, Fresenius had systems to ensure their bank staff could only work if they were up to date with their mandatory training.

Safeguarding

- Fresenius had a safeguarding adults and children's policy (May 2015) which was available to all staff members. Although the clinic only treated adults, and patients were discouraged from bring children to the unit, it was acknowledged in the policy that even though a health professional may not be working directly with a child, "they may be seeing their parent, carer or other significant adult and have knowledge which is relevant to a child's safety and welfare."
- Staff were aware of their responsibilities in relation to safeguarding adults and children and had access to guidance on the actions to take if they had concerns. This was also on display in the staffroom. All staff were up to date with their training in both safeguarding adults and safeguarding children. The training was equivalent to safeguarding children level 2.
- The clinic displayed information on safeguarding for patients and visitors in the waiting room, including contact details, to assist people in making a referral if they had concerns.
- Not all staff were aware of the safeguarding lead within the organisation, if they wanted additional guidance or information. However, they said they would refer to the clinic manager, who was the local lead. The clinic manager knew who to liaise with within the organisation for further advice on safeguarding concerns.

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- The safeguarding policies did not make reference to female genital mutilation or to PREVENT training, to enable staff to recognise and protect vulnerable individuals from being groomed for terrorist activities.

Cleanliness, infection control and hygiene

- The provider's policy on hand hygiene, the Nephrocare Hygiene Plan (July 2016), described in detail how, when and why staff should carry out hand hygiene. The guidance described how staff should carry out clean or aseptic tasks. Staff also referred to the provider's hygiene and infection control policy (February 2016). The protocols for infection control were based on the Renal Association Blood Borne Virus Infection guidelines.
- We observed staff followed appropriate hand washing techniques and washed their hands between patients. There were five hand wash basins in the three bays used by patients, which meant staff had good access to hand washing facilities. Hand sanitisers were available for staff and patients and we observed staff used these regularly and appropriately.
- Staff said they had to follow aseptic procedures when connecting or disconnecting central venous catheters (CVCs) and used clean procedures for AV fistulas. Aseptic techniques are procedures designed to prevent contamination from microorganisms and minimise the risk of infections. However, the Nephrocare Standard Good Dialysis Care policy (September 2016) stated that aseptic techniques should be used for an AV Fistula connection to prevent /reduce contamination risks. This meant staff were not following their policy and potentially placed themselves and patients at risk.
- We observed practices that were a contamination risk. For example, staff did not always change gloves between touching the patient and the clean pack. We saw staff drop gloves onto the sterile pack and contaminate the sterile area, when connecting a patient with a fistula. We saw a staff member contaminate the sterile field by the way they put on their gloves when the patient was connected to a CVC line.
- Staff did not set up the working area around the dialysis chair to promote optimal workflow. They did not arrange to have the sharps bins close to their working area when disconnecting patients from dialysis. We observed one occasion when the staff removed the dialysis needle and dropped it onto the table, as opposed to placing it directly into the sharps bin. This created an infection control risk. We raised this with the manager and saw that the working area was set up safely and more efficiently on our unannounced visit.
- We saw six sharps bins with blood spillages on the surface, which indicated a potential infection control risk.
- The unit was visibly clean and tidy. The unit had washable flooring and the cleaning checklists showed staff completed regular cleaning tasks.
- Staff were bare below the elbow and wore protective personal equipment (PPE). Most of the time, they changed protective aprons and gloves in line with their infection prevention and control guidelines, to minimise the risk of any spread of infection. They also wore visors and ensured both they and patients wore face-masks when connecting or disconnecting central venous catheters. They used the correct colour coded PPE when caring for people with an infection risk in the isolation rooms.
- Staff cleaned shared medical devices between patients, such as the blood pressure equipment and glucometers.
- The dialysis machines had built-in decontamination procedures that were part of the dialysis cycle. Staff also wiped them down between patients with ready-to-use wipes for disinfecting and cleaning medical devices.
- The unit had disposable privacy curtains between dialysis stations. These were marked with the date they were last changed (27 December 2016) and staff changed them every six months.
- Staff followed the Fresenius procedures to assess patients for blood borne viruses such as Methicillin-resistant Staphylococcus aureus (MRSA), Methicillin-sensitive Staphylococcus aureus (MSSA) and Hepatitis B and C, prior to admission for dialysis. All patients were vaccinated by their GP against Hepatitis B and C. The unit had two isolation rooms which could be used when dialysing patients with an

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infection, or if they were at risk of carrying an infection. There was also a dedicated dialysis unit for use with patients having, or at risk of having Hepatitis B. All staff were vaccinated for Hepatitis B.

- Staff ensured patients who had returned from holiday from an area with a high infection risk were dialysed in the isolation rooms. They received dialysis using a dedicated dialysis machine. The isolation rooms had entrance areas where staff accessed appropriate personal protective equipment. Staff took blood tests every two weeks to check patients for their blood born virus status.
- The clinic manager was the lead for infection prevention and control and attended annual study days. They circulated updated guidance and cascaded information from the chief nurse.
- The clinic had performed well at the last infection control audit in November 2016, where it had scored 100% for hand hygiene and 97% overall, with five actions to take, all of which had been completed. Staff also carried out regular monthly hand hygiene audits, and results for January, February and March 2017 were 100%, 90% and 91% respectively, against a target of 95%. The clinic manager raised areas for improvement with individual staff and at staff meetings.
- Staff assessed haemodialysis fluids for bacterial content in line with protocols.
- There had been one reported hospital acquired MSSA incident in the past year. The patient had a range of comorbidities and died after transfer to hospital. An investigation did not link MSSA with a lapse in infection control procedures.
- Staff disposed of waste in clinical and non-clinical waste bins. Clinical waste bins were located next to each dialysis chair and there were sufficient general waste bins. Contractors removed the waste, which the clinic stored in a secure compound. The contractors issued weekly consignment notes that indicated staff separated waste appropriately.

Environment and equipment

- Basingstoke Dialysis Unit is located on the ground floor of an industrial estate unit. The unit environment had been purpose designed to meet the needs of

patients. Patients and visitors accessed the unit via a secure entry pad, linked via an intercom to the reception and the nurses station. There was a large waiting area for patients, which led to offices, consulting rooms and toilets. There was keypad-controlled entry from the waiting area to the clinical area, and patients used a call bell to be let in. This meant staff monitored people as they entered the clinical area, to protect staff and patients.

- There was sufficient space around each dialysis chair for staff to attend to patients with the necessary equipment. There was space for the chairs to be moved into different positions to support safe care and treatment, and there were privacy curtains for each bed.
- The clinical area, water treatment and storage rooms were tidy and well organised. Staff kept equipment on shelves, off the floor, and items of equipment were labelled, showing expiry dates when appropriate, to support safe stock rotation. Staff reported that stock was managed to ensure sufficient supplies were available.
- The provider's own facilities management team carried out reactive and planned, preventative maintenance work, with all planned maintenance scheduled in advance. Additional dialysis related equipment was maintained under contract. Clinic staff could raise issues with the facilities management team who arranged a contractor to resolve the issue, in line with an agreed priority level.
- The clinic manager kept maintenance and calibration logs for all equipment, including the dialysis units, monitoring equipment (eg glucometers, blood pressure equipment and thermometers) and the water treatment plant. Weigh scales, glucometers and blood pressure equipment were serviced, calibrated and tested routinely, in line with an agreed schedule. Technicians had completed the last full annual service of the water treatment plant in January 2017.
- The unit had spare dialysis machines on site, should a machine need to be removed from service for maintenance.

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- Staff used disposable equipment for connecting patients to the dialysis machines. They had dedicated dialysis machines for treating patients with blood borne viruses, which were kept separately on site, and brought into use when needed.
- There was a resuscitation trolley which included an automated external defibrillator. Staff checked the contents of the resuscitation trolley daily against a checklist. We saw the checklist had been signed and dated by staff each day and the items on the trolley were well organised and within date. Oxygen was stored on site and appropriate warning signage was on display. The staff were trained in basic life support including the use of the automated defibrillator. However, the resuscitation trolley contained items the staff would not be trained to use, and no consideration had been given to this potential risk.
- The provider's facilities management team carried out annual safety testing of appliances and completed the register on site. The register was checked during the annual health and safety audit in October 2016.
- Staff completed competency assessments in the use of equipment and all the dialysis machines were of the same type, to support consistent practices. The machines had alarms to alert staff to any equipment failure.
- The dialysis machines alerted staff to any variances from pre-set operating parameters, such as trapped lines, dislodged needles or low blood pressure. These alarms included a flashing light on the top of the machine as well as an alarm bell, to alert staff. Patients also had a nurse call bell at hand, to use if they wanted assistance. We observed that alarms were responded to promptly
- The unit had maintenance schedules for all dialysis machines and chairs and for other clinical equipment such as blood pressure monitors and patient scales. The schedules included model and serial numbers. The Fresenius maintenance team monitored the replacement cycle for the machines, however the clinic manager was not in receipt of reports showing how many cycles the machines had completed and their projected replacement dates.
- The water treatment plant was well organised and maintained. The provider used its own technicians, who carried out routine maintenance according to a rolling schedule. They responded to emergency calls in line with a priority assessment. The maintenance programme reflected the Renal Association haemodialysis guidelines. These included water treatment systems, the use of concentrates, contaminants and the use of dialysis membranes.
- The registered nurses tested the water each day and sent samples to the Fresenius laboratory for monthly testing. Results of the most recent monthly water test showed a higher than acceptable level of fungal growth and as a result the unit was providing haemodialysis in place of haemodiafiltration. The laboratory tests of a repeat sample were clear and the clinic manager said he supervised the subsequent sampling to ensure staff used the correct techniques to prevent contaminating samples.
- All dialysis sets were for single use only and the provider kept a record of batch numbers as part of their quality management controls.

Medicine Management

- The Fresenius medicines management policy (June 2016) included guidance on the management and administration of medicines at the clinic. The clinic manager was the local lead for medicines.
- The medicine management policy stated the person administering the medicines must clearly identify the patient for whom the medication is intended. We observed that staff did not formally check the patient identity.
- We observed staff collect anticoagulant injections from the medicine cupboard, as a batch for the afternoon patients, and the place them on the dialysis chair tables. Staff did not check the injections against patients' specific prescriptions. This was not in line with the Fresenius medicines policy.
- We observed that staff administering medicines did not consistently check the dose required against the prescription or check the medication with a second person as per the Fresenius policy and national guidance. When dialysis assistants administered medicines, they did not always obtain and record a

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second signature from a registered nurse at the time of administration. Concerns with medicines management were reported to the clinic manager at the end of the inspection.

- Practices had improved when we carried out our unannounced inspection, with staff checking medicines, but staff still did not stop, check and record medicine administration.
- A named nurse ordered medicines each week from the NHS trust, and we saw the order forms and delivery notes were correctly signed and dated. The medicines were paid for by the NHS trust and the receptionist received the deliveries.
- We found that staff checked the medicine expiry dates each month, and a spot check showed they were all in date.
- Staff stored medicines within a suitable, safe temperature range. Staff monitored the temperature of the medicine fridge each day they were on site and checked the maximum/minimum temperatures were within the acceptable range of 2-8 degrees Celsius. The medicines cabinet was located in the clean utility room, where access was controlled, and kept locked.
- The unit had portable oxygen on site, and this was available and located with appropriate warning signage.
- The NHS trust consultants issued patient prescriptions and these were kept in patient files. The prescription were up to date and completed in full. Nurses in the unit transferred the information onto the Fresenius database, and these were also printed off for use in patient daily files.
- The commissioning NHS trust provided signed patient specific directives (PSDs) for each patient, detailing which medicines staff should give to the patient at the unit. The PSDs were in each patient's files and were signed by the lead doctor, lead nurse, lead pharmacist, clinical governance lead and the PSD committee chair. All PSDs had been signed by the relevant staff in 2017, and the PSDs included indications for the use of the medicines, contraindications, actions and action to take if the

patient declined the medicine. Nurses liaised with the trust pharmacy and consultants for advice on medicines, and also had access to a pharmacist through the Fresenius head office.

- All dialysis assistants had completed training and competency assessment in administering medicines.

Records

- Staff created paper and electronic patient files. Staff completed electronic patient records on the Fresenius electronic records system and this automatically transferred patient data into the NHS trust's clinical database. This meant the hospital consultants and renal team could access patient records created during dialysis treatment.
- Patient admission files were structured and contained admission details, consent records, patient treatment plans and relevant care pathways and risk assessments. The files included a signed, dated patient admission checklist and clinic letters. These files were mostly up to date however we found one care plan where the staff had recorded an incorrect patient name in one place. We drew this to the attention of the clinic manager. Staff had not included the pre-printed patient identification sticker on all the paper records, to minimise the risk of errors.
- Staff recorded daily observations within paper records, kept in files by each patient on their dialysis stations. These included the up to date dialysis prescriptions and medication charts. We observed that a medicine dose given to one patient was recorded, with the time of administration, in the medication chart, but not signed or checked. This indicated that staff did not always sign the record at the time of medicine administration.
- Staff completed electronic records for each patient during their dialysis treatments. Registered nurses set up these electronic records on admission, from the patient referral documentation provided by the hospital. The Fresenius policy for 'patient referral and acceptance for treatment (UK Cl 09 26)' does not require a second staff member to check these entries. Staff were required to sign the data quality confirmation document to confirm they had checked their entries against the pre-transfer data.

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- Staff recorded daily notes onto the Fresenius electronic patient records. Staff cared for about three patients per session, and it was their responsibility to complete the records for those patients. Entries included observations and summary notes, including inspection of the catheter site. Some of the information was automatically transferred onto the trust's electronic patient record, such as information about the catheter access, dressing changes and moving and handling guidance.
- The dialysis machines were electronically linked to the Fresenius information system, so that many of the observations were automatically captured and recorded from the machines. In addition, staff manually added into the system patient observations, such as temperatures, fluid changes and any deviations from the treatment plan.
- Staff maintained two additional, separate folders; the clinic folder for the renal consultants to share information with the unit and the blood results folder, with the monthly blood results for all the patients. This meant there was a need to transfer information from a range of folders into other formats, to ensure patient records were complete, and a potential risk of creating errors.
- The renal consultants had access to patient records including blood results. They received their patient's blood results each month and wrote notes in the clinic folder, or emailed advice, to share updates and directions with the unit staff. For outpatient appointments at the service, they accessed electronic medical records from their NHS hospital information system and from the Fresenius system, to inform treatment planning. The unit also requested hard copy hospital medical records in advance of the clinic, so the consultant had the full set of patient notes.
- The clinic manager showed us the patient records audits, which were carried out by the deputy manager, approximately monthly. They raised any non-compliances with the staff involved and staff and the clinic manager signed to show when audits were completed. About 10% of records were reviewed at each audit. No trends had been identified.
- Patient admission files were stored in locked filing cabinets, where they were accessible to staff.

Assessing and responding to patient risk

- There was no formal identification of patients prior to dialysis. Staff told us that they knew the patients and they did not feel it appropriate to request formal identification each time patients arrived. On arrival, patients picked up their treatment cards in the waiting room, which displayed their initials and normal dialysis chair number. The clinic kept these cards in batches, according to the dialysis treatment sessions. Patients used these cards to record their weight when they used the walk-on scales. Patients were let into the dialysis clinical area and knew which dialysis chair to go to, but there was no formal procedure for checking patient identity and we did not observe any formal checks of prescription against the machine settings. We were told that if two patients had the same initials, they added further information, such as additional initials, to reduce the risk of confusion. However, this overall process had not been risk assessed.
- However, staff had conversations with the patients and generally referred to them by name and the card system meant the dialysis machine were programmed to the individual patient prescription.
- The clinic manager said the referring nephrology consultant risk assessed patients suitable for dialysis at this satellite location, and only referred patients to Basingstoke if they were stable on dialysis and assessed as a low risk. The trust did not generally refer patients to the unit who had challenging behaviours or dementia. Patient admission documents showed they had been assessed as suitable for care at the dialysis unit.
- The clinic staff also carried out their own assessment of new patients for their suitability for dialysis. For example, on the day of our inspection, the clinic had admitted a new patient but staff assessed the patient as not stable and they were observing the patient in the isolation room before starting dialysis treatment. When they had concerns, they immediately referred these to the consultant.
- Staff created care plans for patients on admission, based on risk assessments. Patient allergies were noted and flagged in their records. Records included patient medical history, blood borne virus status, consent to treatment and information on whether the

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patient had an advance directive or a 'do not attempt cardiac pulmonary resuscitation' agreement. These had been signed by the admitting nurse and the patient. In addition, each patient file included an emergency evacuation plan, a care pathway for catheter care and dialysis care pathway. The patient specific direction booklet, prepared by the referring trust, was also kept on file.

- Staff completed moving and handling risk assessments and recognised tools for assessing skin integrity risks. However, these risk assessments were not always linked to clear care plans, for example describing how best to support people with moving and handling to minimise the risk of harm to patients and staff.
- At the start of each shift, staff assessed the health and wellbeing of each patient before starting their routine dialysis treatment. They carried out the daily dialysis assessments (such as blood pressure, glucose levels, weight), observed the patient's appearance and, in most cases, asked patients how they felt. Staff did not start to dialyse patients if these assessments gave results outside agreed parameters. If patients were not sufficiently stable to start dialysis, staff raised concerns with the nephrology consultants at the hospital and took their advice.
- We noted that staff observed patients' footwear and commented when someone was wearing new, stable, comfortable footwear, which indicated staff were aware of the hazards associated with falls.
- There had been 12 patient transfers to an NHS hospital in the last 12 months. The clinic manager explained they called emergency services to transfer ill or deteriorating patients, and they noted these as incidents or TVRs in the patient records. Fresenius had a patient transfer policy in place and emergency transfers were carried out using emergency services, by calling 999.
- Patients said staff responded promptly to any alarms automatically generated by the dialysis machines. We observed this to be the case during our visit. When one patient experienced hypotension, the staff acted quickly, efficiently and appropriately to support the patient and the patient's condition stabilised.
- The Fresenius policy on 'complications, reactions and other clinical event pathways' (November 2016) included a detailed set of algorithms for staff to follow if patients became unwell. Such events included anaphylaxis, catheter dislodgement, cardiac arrest, falls and an air embolus. The algorithms included symptoms, possible causes and instructions on what actions to take.
- The clinic did not use a standard warning score assessment to identify a deteriorating patient. Staff explained their observations and alarms meant there was a continuous, sensitive monitoring system in place to show deviations in vital signs such as blood pressure, heart rate and oxygen saturation. If a patient showed signs of deterioration, staff said they monitored the patient more closely, to determine whether dialysis should be discontinued and whether they needed to transfer the patient to an acute hospital via emergency services.
- Although Fresenius did not use the sepsis pathway to assess patients for septicaemia, staff assessed patients on arrival and monitored their temperature, oxygen saturation and blood pressure before starting dialysis. Staff also assessed the intravenous catheter for signs of infection, using the multi-racial visual inspection catheter tool (Mr VICTOR). This guide provided nursing staff with a consistent and recognised description of the condition of the fistula. If necessary, staff were able to administer intravenous antibiotics if prescribed. Corporately, we were told Fresenius were planning to introduce a formal approach for assessing patient for sepsis
- During dialysis, staff carried out routine observation checks each hour and noted the results in the patient records, to help inform any subsequent treatment plans.
- Staff also carried out monthly blood tests and took quarterly blood samples for blood borne virus screening. The consultants reviewed these results and advised on any changes to the patient treatment plan.
- At the end of dialysis treatment, staff checked patients were stable before they left the unit. This included ensuring their blood pressure had stabilised.

Staffing

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- The contract with the commissioning NHS trust required a ratio of one staff to three patients, and a 70:30 ratio of nurses to dialysis assistants. The clinic monitored and reported on the staffing levels and was able to adhere to the agreed level. The regional business manager monitored staffing levels and the off duty plan.
- Staff and patients said there were enough staff to meet people's needs, and the contracted staffing levels were appropriate. Staff said they were usually allocated to work with specific patients on each shift and this worked well.
- The clinic manager used an e-rostering system to plan the staffing levels four weeks in advance, which the manager and deputy reviewed daily to manage any issues. There was a low rate off staff sickness and zero use of bank or agency staff in the period November 2016 – January 2017. Staff tended to cover for unfilled shifts, and the clinic manager and regional business manager monitored staff working hours.
- The unit had access to trained staff via the Fresenius Flexibank, or if necessary, approved agencies. These resources were rarely used at this clinic.
- The unit did not employ medical staff. The commissioning NHS trust employed the two nephrology consultants treating patients at this unit. The consultants visited the clinics at least twice a month for clinics. Staff reported good access to consultants for advice and support. They were able to call the hospital at any time and request to speak with a renal registrar. In addition, staff knew when members of the renal hospital team were on site at the unit, for immediate advice if appropriate.
- Consultants planned patient care and the NHS dieticians visited the unit to meet with patients and discuss their dietary needs. Patients said this was a good service.
- Staff held daily handover meetings, which were well organised and informative. They enabled staff to review each patient, discuss any recent analytical results and adjust treatment as needed. Staff also maintained a communications book, which included corporate message as well as information required locally for that day or week.

Major incident awareness and training

- The clinic had an emergency preparedness plan (EPP) which included details on how to manage a range of potential emergency events. These included instructions for site evacuation and emergency contact numbers. The staff carried out emergency evacuation drills twice a year and this was monitored.
- Each patient had a patient personal emergency evacuation plan on file, and this was summarised to show specific support requirements in the EEP.
- The plan also covered prevention plans for loss of IT and power. The dialysis machines had automatic backup systems, which gave staff 15 minutes to disconnect if there was a power failure.
- Other events covered by the EPP included fire, utilities leaks and the impact of adverse weather.
- If the water treatment plant failed, the unit had contingency plans to dialyse patients at buddy units, following liaison with trust consultants and patients.

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

Evidence-based care and treatment

- Fresenius had produced their own 'Good Dialysis Care' policy and procedure document for all their clinics, which was compliant with European Renal Best Practice (ERBP) and the Kidney Disease Outcome Quality Initiative (KDOQI) guidelines. It contained instructions for staff in how to use the specific dialysis equipment and there was clear referencing to other policies and best practices. The Good Dialysis Care policy excluded medicine management guidelines for units in the UK, as Fresenius had created a separate UK medicines policy in accordance with the UK Nursing and Midwifery Council Standards.
- At a corporate level, Fresenius reviewed policies and procedures yearly, in compliance with the ISO quality management system. The 2016 QMS audit demonstrated compliance in monitoring out of date policies. However, we noted that the clinical risk policy and clinical governance strategy were last updated in 2009 and 2010. Also, the NephroCare standard good

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dialysis care policy and procedures (September 2016) did not refer to recent NICE guidance such as the NICE Quality Standard 72, 'Renal replacement therapy services for adults', November 2014, updated January.

- All patients had their weight, temperature, pulse and blood pressure checked at the beginning and end of dialysis, in line with the Good Dialysis care policy. The guidance detailed how to carry out each step of patient monitoring, and what the information indicated. Staff ensured the results were included in the electronic patient record.
- Staff monitored patient vascular access for infection and damage, using the recognised Mr Victor scoring tool. This is a universal tool that uses pictures to help staff identify infections in patients with different skin colours. This was in line with the principles of the NICE Quality Standard 72 Statement 8 'Haemodialysis access – monitoring and maintaining vascular access'.
- Patients had an arteriovenous fistula (AVF) or a central venous catheter (CVC) depending on their specific access assessments. Where clinically indicated, functioning arteriovenous fistulas are regarded as the best form of vascular access for adults receiving haemodialysis (NICE Quality Standard 72 statement 4 (September 2015) 'Dialysis access and preparation'). Consultants at the NHS trust were responsible for assessing and establishing vascular access and the clinic had an appointed vascular access lead to liaise with the nephrology consultants at the NHS hospital. At the time of inspection, 57% of patients had an AVF, against a corporate target of 76%. In March 2017, there were 11 patients who were clinically unsuitable for an AVF, some patients had new fistulas not ready to use and some patients with CVCs were awaiting surgical reviews.
- Basingstoke clinic provided haemodiafiltration as standard, which promotes the efficient removal of large as well as small molecular weight solutes from blood. They can also provide haemodialysis when this is required in a patient's care plan. There is some clinical evidence that haemodiafiltration achieves better outcomes for patients.
- The referring NHS trust did not refer patients to this clinic who needed support with home dialysis. Patients were only referred to Basingstoke clinic for

haemodialysis/haemodiafiltration. As part of their assessment however, patients were assessed for suitability for inclusion on the kidney transplant list. Talking to patients and reviewing records showed patients could choose not to be put forward for a kidney transplant.

- The consultants responsible for patient care and referring patients to this satellite unit for dialysis had the discussions with patients about end of life care and advanced planning decisions. The outcomes of these discussions were documented in the patient records on admission. Staff liaised with the consultants if they observed changes in patients which might indicate the need for end of life discussions. Staff described circumstances where end of life care plans had been developed for patients.
- Staff performed observations on all patients before and during dialysis, in line with the Good Dialysis Care policy. If a patient appeared unwell or showed signs of deterioration staff monitored more closely and would either continue monitoring, or discontinue the dialysis as per guidelines.
- Staff did not follow specific guidelines for identifying and responding to sepsis, however the provider had already identified this for further consideration. Staff used evidence from the dialysis observations and surveillance protocols to identify potential sepsis.
- The clinic monitored when the waiting time for transport exceeded 45 minutes. The National Institute for Health and Care excellence (NICE) guidance, 'Renal replacement therapy services for adults,' states adult patients should be both collected from home and returned home within 30 minutes of their allotted time. Minutes of the staff meetings showed the clinic monitored issues with transport, for example by recording the times when patients came off machines and when their transport collected. The clinic reported delays to the commissioning NHS trust, which held the contract with patient transport. The trust had regular meetings with patient transport services to review and improve performance.

Pain relief

- The unit did not provide pain relief for patients. The service did not use patient group directions (PGDs) for pain relief and staff made this clear to patients on

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admission. A PGD allows some registered health professionals (such as nurses) to give specified medicines (such as painkillers) to a predetermined group of patients without them seeing a doctor.

- Patients were responsible for any analgesia they required.

Nutrition and hydration

- The unit offered patients a hot drink and a biscuit during dialysis. Many patients brought in a snack to eat during their treatment.
- Patients said they received good support from the dietician, from the NHS trust, who offered advice on foods to eat and to avoid. The dietician visited them at the unit, and patients could request appointments.
- There was a link nurse for nutrition, and the clinic displayed information about this in the waiting room.

Patient outcomes

- The unit contributed patient outcome data to the Renal Registry, however the data was part of the 'hub' NHS trust's total patient data. This meant that the unit could not identify its performance and benchmark themselves against other providers. The clinic produced monthly reports on patient outcomes for internal review and sharing with the hospital.
- At the time of inspection, 57% of patients had an AVF, against a corporate target of 76%. In March 2017, there were 11 patients who were clinically unsuitable for an AVF, some patients had new fistulas not ready to use and some patients with CVCs were awaiting surgical reviews. The unit reported on this data monthly as part of their quality monitoring programme.
- There was no waiting list for dialysis at the unit. The trust made referrals when appropriate and the unit was staffed to support the current caseload.
- The unit reported 8 out of 52 patients experienced a collection delay over the three months to February 2017, with two patients delayed on two occasions. The clinic monitored and reported on reasons for delays, and the most common reason related to a failure to communicate the booking effectively.
- The clinic manager reported on patient outcomes in the clinic review report. The review included data on a

range of parameters, including the efficiency of dialysis, vascular access management, and patients' hydration and nutrition. The report showed monthly trends and outcomes against targets, to highlight areas for improvement.

Competent staff

- All staff had completed an annual appraisals and the clinic manager monitored and reported on staff training.
- Staff carried out annual self-assessments of their competence and used these to inform their training and development plans. Senior staff members then formally competency assessed more junior staff, and for nurses, this was the clinic manager. Dialysis assistants said they were assessed by team leaders, and team leaders by the deputy manager or clinic manager. Staff said they found the competency assessments thorough and useful, and if they had questions or concerns, they would be confident to ask for guidance.
- Staff files showed evidence of their annual competency assessments. These showed the assessments covered safe use of the dialysis machines, recognising and reporting patient's vital signs, medicine administration, assessing dialysis catheters and adhering to the NephroCare Standard Good Dialysis Care Guide.
- Consultant feedback indicated a high level of confidence in staff competence, and they commented that staff received a thorough induction in dialysis techniques.
- Staff said the induction training was good, with a mix of on line training, shadowing and completing course books. Induction training included training in safety systems, such as corporate induction and the 12 week nurse training programme for nurses new to renal nursing. Staff said they felt well supported and were not expected to work on their own until their induction had been signed off and they had been assessed as competent and confident in their roles. They had protected time to work as supernumerary staff, for six weeks, and they worked with mentors during this time, having regular reviews. New staff had a six-month probationary period to ensure they achieved the required level of competency.

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- Three of the eight registered nurses had completed the renal course and another nurse told us they planned to complete the course in 2017. Staff reported they were well supported by their colleagues and manager in developing their knowledge and skills.
- All clinic staff had completed annual basic life support and anaphylaxis training. This was e-learning. In addition, the area head nurse set up an unannounced annual cardiac arrest simulation exercises, and gave feedback and support to staff. Staff at this clinic were not required to be competent in immediate life support, in line with their commissioning requirements.
- Different members of staff held lead roles within the unit, for example there were leads for vascular access, nutrition, infection control and prevention, health and safety and water treatment. The provider provided annual training for representatives. At this clinic, the training matrix showed the representatives had not all completed this training.
- The Fresenius staff handbook (April 2016) states that employees must notify their manager if they are convicted of a criminal offence or receive a caution. All new staff undertook criminal records checked at recruitment.

Multidisciplinary working

- The commissioning NHS trust operated a 'hub and spoke' model for dialysis with patients attending local 'spoke' dialysis clinics if they were assessed as stable.
- The NHS nephrology consultants maintained overall responsibility for patient care. Two consultants had responsibility for patients at this clinic. They monitored patient outcomes remotely, via records created by clinic staff which transferred onto the NHS records system. They also visited the clinic monthly for outpatient clinics. Each patient received a full medical review once a quarter, with more frequent reviews as results indicated.
- Consultants reported prompt information sharing with staff at the clinic, and effective management of blood samples. This meant the blood results were consistently available for consultant review.
- Staff at the clinic and consultants shared information relating to patients mostly via email or telephone,

rather than through face to face, group meetings. For example, the clinic manager, consultants and dieticians emailed patient results and requests for actions. Consultants referred patients to the counselling service contracted by their NHS trust when necessary.

Access to information

- Staff and consultants reported effective information sharing between the clinic, the consultants and patient GPs. Letters between consultants and GPs relevant to dialysis were in patient files. Both consultants and staff said they had good access to patient GPs. For example, the consultants wrote to GPs for specific patient prescriptions.
- The clinic staff knew when to take blood samples these were dispatched promptly to ensure staff had timely access to blood results.
- The clinic supported patients with holiday dialysis. In most cases, staff supported patients from this unit to go on holiday and attend dialysis at other locations. Staff coordinated this effectively, by liaising with the holiday dialysis site and sharing the necessary clinical and non-clinical details about the patient.
- The unit could also receive patient on holiday dialysis, and this was coordinated centrally based on local capacity. Staff completed 'incoming Holiday Patient Forms' to ensure all relevant information is gathered relating to the incoming patient, such as their prescription and risk factors.
- The Fresenius electronic patient records included any events, such as incidents and communications from consultants. For example, if consultants requested a reduction in a patient's target weight, this request (often by email) was logged in the patient record and the entry alerted staff to take appropriate action.

Equality and human rights

- There was information provided in different formats which related to patients with differing cultural, physical or learning disabilities.
- There were different language options for the patient guide and interpreters were available via the NHS trust.

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- There were individual patient specific evacuation risk assessments, which, in the event of fire, detailed any additional help the patient would need if they had disabilities.
- The clinic's patient guide (September 2016) was also available as DVD.

Consent, Mental Capacity Act and Deprivation of Liberty

- We observed 'patient consent to treatment' documents in all the files we reviewed. These were signed and dated by the patient and the nurse completing their admission. Wording on the consent form showed the nurse signed to confirm they had discussed the treatment with the patient, the patient had no further questions and they wished to accept treatment at the unit. The consent forms also included consent to data management and protection. It also documented if patients had an advance directive and if they had (or did not have) a 'do not attempt cardiopulmonary resuscitation' (DNACPR) agreement in place.
- Only one patient attending the unit had a DNACPR on their file. We saw this was a shared decision, made and signed by the patient and their consultant.
- The staff had access to the Fresenius policy for consent to examination or treatment (October 2014). The policy made reference to and explained the Mental Capacity Act 2005, and the protection it gives to patients who lack capacity to make decisions in relation to their care and treatment. At the time of the inspection, staff said all patients had capacity to make decisions about their care.
- All staff had completed the three-yearly training in the Mental Capacity Act and its associated Deprivation of Liberty Safeguards.
- The staff demonstrated a clear understanding of the right of a patient to decline treatment or request a shorter dialysis time. They recognised that for different reasons, patients sometimes wanted to leave the clinic earlier and they supported patients to make reasonable adjustments to the dialysis schedules.

Are dialysis services caring?

Compassionate care

- All the patients we spoke with said staff were kind and treated them with respect. They said they had sufficient privacy and could always ask for the curtains to be closed if they wished. One person described how staff had managed a difficult situation calmly and with thought to all patients in the clinic environment. Patient comments on feedback forms included:

'The staff are very caring, professional and have always treated me with respect',

'My care over the past year has been outstanding and I am always treated with dignity; my views are respected and my opinions always taken into consideration' and

'Staff always treated me with the utmost respect and dignity...they always listened to what you have to say and explain everything'.

- The clinic's 2016 patient survey results showed 85% of patients would recommend the unit to friends and family in need of dialysis and 98% of patients were satisfied with the nursing staff. Ninety six percent of patients said they were treated with dignity and respect.
- Almost all patients said this was a friendly unit and they felt part of a family when they attended.
- We observed that staff closed the curtains when providing intimate or personal care, to respect the patient's privacy and dignity.
- The unit had two side rooms, primarily intended for patients with infections, or at risk of having infections. Patients and staff said those who preferred to be dialysed on their own could use the side rooms, if there was capacity.
- Staff and patients said they had opportunities for private discussions with staff and visiting consultants in the consulting rooms. However, some patients said they were happy to have these discussions whilst they were in the dialysis chair.
- Although most staff were encouraging and supportive, we observed that sometimes staff did not offer patients a warm welcome to the unit or take time to

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talk with them. Feedback from one patient said they found some staff hard to understand when English wasn't their first language. This was not observed during our inspection.

Understanding and involvement of patients and those close to them

- Patients said they understood the treatment they were receiving and felt they had enough information from the outset. They said they were prepared for dialysis before they attended this clinic, whilst in hospital, and they found the routines at the clinic easier, with more personalised care. They were encouraged to visit the unit before their first dialysis session, so they knew what to expect.
- They knew that staff reviewed their care each session, at handover meetings, and they were confident that staff adjusted care based on analytical results and observations.
- Patients reported good liaison with their consultants.
- We observed staff discuss observations, vital signs and blood results with patients, fully involving them in their dialysis treatment. Patients asked questions and staff answered them clearly and professionally. Staff asked patients for their opinions, thereby involving them in decisions about their care.

Emotional support

- Patients were complimentary about the emotional support provided by staff. They particularly welcomed the help in arranging dialysis holidays. We received feedback from patients with comments such as; 'The staff always great me with a smile', 'The staff are friendly, helpful and totally competent' and '[The staff's] sense of humour helps to calm my nerves'.
- We observed that staff provided reassurance and calm explanations when one patient experienced hypotension and required prompt support.
- The clinic had set up the named nurse approach to encourage patients and staff to develop a supportive relationship. As most of the patients attended the clinic for dialysis over long period, staff and patients got to know each other well. Patients found emotional

support from other patients as well as staff, and most said they felt part of a family when they attended the unit. One person commented that staff made them feel comfortable and at ease.

- Patients said the NHS consultants coordinated support from renal psychologists or a social worker when staff recognised a need with individual patients.

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

Service planning and delivery to meet the needs of local people

- The commissioning NHS trust, a tertiary centre for renal dialysis, first commissioned this service in 2009, as a 'spoke' unit, based on a hub and spoke model. By commissioning this unit in Basingstoke, patients living in north Hampshire had the opportunity to access services locally instead of travelling over 40 miles, which improved their quality of life.
- The initial contract with the NHS trust had been extended three times, and was effective until March 2019.
- The unit offered two sessions per day. It did not offer twilight or evening sessions, which might suit patients who prefer to dialyse after the normal working day. This option was offered at other 'spoke' clinics, however, and the clinic manager said this had not been raised as an issue and patients had not requested later sessions. One patient told us they had made arrangements with their employer to work at the unit during their dialysis session and they would not prefer a twilight shift.
- Approximately 80% of patients accessed the clinic using patient transport. There was no transport user group, but the clinic manager commented that patient feedback consistently highlighted transport as an area of concern. Patients told us delays in patient transport where their main issue of concern. The service monitored and reported on transport delays to the commissioning NHS trust, who commissioned the patient transport services.

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- Patients who used their own transport appreciated the good access to free parking at the unit, in contrast to the parking arrangements at the hospital.
- The unit had been designed for the delivery of dialysis services and the facilities and premises were appropriate for the needs of patients requiring dialysis.

Access and flow

- Patients could only access services at the clinic with a referral from the commissioning NHS trust. There was an admission criterion that the hospital would only make referrals to this unit if patients were stable on dialysis. In line with the policy for patient referral and acceptance for treatment (December 2015), the clinic manager, or deputy, was responsible for accepting new referrals. The service was for people living locally in the Basingstoke and north Hampshire area.
- There was no waiting list at the clinic. The clinic could accommodate additional patients if they met the admission criteria and the hospital made the required referral.
- As far as possible, the clinic tried to accommodate patients' specific wishes for dialysis regimes. For example, they supported people who worked by allocating times to suit their work commitments and changed sessions to fit in with patients' social lives.
- The clinic had a batched appointment system so that patients knew the start and finish times for their dialysis. The start times were staggered by 15 minutes, to enable staff to connect and disconnect patients in groups, with the aim of minimising their waiting times. In practice, patients sometimes had to wait for transport but the appointment time helped create a more systematic treatment process.
- Staff monitored when patients dialysis was delayed due to patient transport issues, and when patient transport brought patients early (more than 30 minutes) to the clinic. They shared the results with the patient transport provider and commissioner.

Meeting people's individual needs

- Staff said they were made aware of patients with any specific, individual needs on admission. For example, staff knew how to book interpreters if patients required this support. There were no patients on who required interpreters at the time of the inspection.
- The unit was accessible to patients who used wheelchairs. There was a hoist, as well as other moving and handling equipment for those patients needing manual handling assistance to access the dialysis chairs. The policy for patient referral and acceptance for treatment outlined the requirements for new referrals, to help the unit plan for new patients, such as making provision for patients with bariatric needs.
- The NHS hospital rarely referred patients to the service who they assessed as needing additional support, for example because they lived with dementia or a learning disability.
- The clinic did not offer home dialysis. The NHS hospital managed the training and support for patients on home dialysis, assisting patients with training from an alternative spoke unit. The Basingstoke clinic was not a training centre for home dialysis but it worked with the NHS trust to assess patients who might be suitable for home dialysis.
- Staff encouraged patients to carry out some aspects of their dialysis care, such as checking their own weight pre and post dialysis, and where possible, checking their own blood pressure and temperature. Staff also promoted 'Patient View', where patients could check their blood results online, using their own allocated log in.
- New patients were invited to visit the clinic prior to starting their dialysis programme at this location. This enabled them to familiarise themselves with the environment, and the staff. Staff said they were also able to talk them through the dialysis processes and highlight any differences from the procedures at the hospital.
- The clinic had produced a patient guide (September 2016) as a welcome pack for new patients. Each person's patient guide included important information about their specific appointment time, their allocated named nurse and the clinic's contact details. It also

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included information on patient transport, what to bring and options for holiday dialysis. The guide also explained different blood results and how to interpret them.

- Patients had named nurses to take overall responsibility for their individual care. The named nurses had monthly discussions with patients and built relationships through regular reviews of their care and wellbeing. Due to shift changes, the named nurse did not have day-to-day responsibility for a patient's care, but aim of offering named nurses was to develop a more personalised approach to care.
- Staff supported patients with their individual holiday dialysis plans. One person said they were particularly grateful for this support and the process worked well. The patient guide included information on how to set up holiday dialysis and what to expect on return from their holiday.
- There was a range of useful patient information in the waiting room, relating both to the haemodialysis process and to the clinic's performance. There were photos of the staff and information on who was on duty that day, so patients and visitors knew what to expect. Patients could access toilets from the waiting room and could weigh themselves on the walk-on scales.

Are dialysis services well-led?

Leadership and culture of service

- Staff said they were supported by the manager, deputy manager and the two team leaders and there was a culture of mutual support and teamwork. Staff said the manager was approachable, and they enjoyed working at the unit.
- Staff also said the consultants and dietitian from the NHS hospital worked collaboratively with the clinic staff and were available to answer questions and provide advice.
- The clinic manager's time was split between management and nursing roles. The deputy manager supported the clinic manager by carrying out specific duties including audits and different leadership roles.

- The clinic manager reported to the area head nurse. The clinic leaders had a good understanding of the needs of the unit and its staff. The manager had completed appraisal training and all staff had participated in annual appraisals. Although there were some specific training courses for managers, the clinic manager here had not yet completed all those relating to human resources.
- Although staff were aware of the duty of candour, they had not completed classroom training in the subject, and this was booked for later in the year. 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 that person. The manager had received awareness training on this topic. The staff we spoke with recognised the need to be open and transparent with patients in relation to incidents, but were not aware of the legal requirements. The manager and area manager said there had been no incidents that would have invoked the duty of candour. The Fresenius process for reviewing incidents meant an assessment of whether an incident should invoke the duty of candour was taken after the incident had been reported to the chief nurse.

Vision and strategy for this core service

- Fresenius had a corporate code of ethics and business conduct based on its core values of quality, honesty and integrity, respect and dignity and innovation and improvement. Staff also had the company handbook, which provided an overview of Fresenius Medical Care and its values, aims and objectives. Staff said their focus was patient care and ensuring a good patient experience. They told us they liked working at the units because they enjoyed supporting the patients.
- The clinic's 2016 corporate strategy objectives were divided into those for patients, employees, community and shareholders. At Basingstoke, we saw the progress report for these objectives. These included completing the patient satisfaction survey in March 2016, ensuring 90% for new patients achieved their prescribed treatment times and submitted 95% clinical incident reports within three days. Employee objectives

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included introducing an awareness campaign to reduce slips trips and falls, which was completed in February 2016. In April 2016, the clinic reported it had responded to all audit recommendations or actions.

- When the service was first commissioned, it had expected to expand and provide additional capacity. There had not been demand for this and the unit was operating with a maximum of 19 stations. It had operated at about 85% capacity (based on staffing for 19 stations) between November 2016 and January 2017.

Governance, risk management and quality measurement

- Senior staff acknowledged that individual clinics had not set up systems for identifying and managing their key risks. This was an area that was being addressed corporately at the time of the inspection, with the appointment of a new quality and risk manager and the piloting of local risk registers at some clinics. Clinic staff had not developed a robust awareness and recognition of risks, for example in relation to medicine management and infection control. For example, staff did not always formally identify patients and their prescriptions before starting treatment and administering medicines.
- The Fresenius systems, processes and practices were ISO 9001 quality management accredited. As a multinational organisation, policies reflected national guidance where appropriate, such as the medicine management policy. This was as UK policy reflecting the Nursing and Midwifery Council Code of professional standards. However, the clinical risk policy and clinical governance strategy we were given were last updated in 2009 and 2010 respectively. The safeguarding policy (2015) did not make reference to the most current guidance.
- Fresenius's clinical governance policy described the clinical governance framework. The medical director chaired the clinical governance committee (CGC), which was a subcommittee of the Fresenius board. The CGC was responsible for establishing effective quality improvement practices, such as audit, updating practices and policies in line with best practice guidelines and developing the workforce. The strategy required clinics to report to the CGC each

month, with their clinical governance meeting minutes, clinical variance reports, audit outcomes and reports on serious incidents, accidents and near misses.

- In practice, we found the clinical review report was required quarterly not monthly. This meant the CGC did not scrutinise performance as frequently as specified in their policy. We also found clinic meetings were held less frequently than monthly.
- The CGC was made of the medical director, representative regional managers (on a rotational basis) and the director of clinic services. This was therefore a small team responsible for the clinical quality of the organisation. The regional business manager did not have a clinical role, but they monitored the clinic's compliance against the commissioning trust's contract.
- The clinic collated performance clinical review reports, which included patient outcome data and showed month on month trends, targets, action plans and who was responsible. The patient data was colour coded (red, amber and green), with red for outside the expected range and green for within. The reports also included staffing information. Reports for February and March 2017 showed that the results were not reviewed and signed off by a senior manager and that actions were not allocated to specific staff to address. Some indicators showed a trend of non-compliance, such as hydration status and hepatitis B vaccination, yet there was no explanation or action noted. The manager submitted these clinical review reports to the clinical governance committee each quarter. The manager said they only received feedback if there were queries with the results submitted. This indicated a lack of overall clinical governance.
- Clinic managers attended quarterly meetings, two nationally and two regionally, which included training and discussion forums. Managers informally supported each other and shared learning on an ad hoc basis.
- Fresenius had carried out three corporate level audits of the clinic. These were audits of; the integrated management system (February 2016), health and safety (October 2016) and infection prevention and control, including hand hygiene (November 2016). The

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clinic manager said they had performed well in these audits and had completed in any outstanding actions. The clinics were not compared against each other based on these national audit performances. In addition, clinic staff carried out monthly hand hygiene and patient records audits and team leaders supported staff individually where they needed to improve practices.

- The clinic manager submitted monthly blood reviews to the trust renal clinical governance committee, with patient specific concerns and action plans. These were also recorded in the patient notes, with any recommended actions.
- The commissioning trust did not carry out formal regular contract reviews. The clinic manager attended monthly clinical meetings at the trust; the renal subgroup meetings. The trust's haemodialysis lead chaired these meetings, which were set up to communicate trust quality initiatives and developments. In addition, there was a clinic managers meetings following these renal subgroup meeting, to enable managers to share ideas and learning.
- Staff understood the procedures for reporting, reviewing and reflecting on incidents. They completed actions following audits and surveys in a timely way. The clinic manager escalated issues in line with guidance and to progress solutions. The 2016 staff survey showed all staff understood their work responsibilities and were trust to do their job.
- The service aimed to support improvements in patient transport. The clinic monitored when patient transport was early or late in delivering patients to the clinic for dialysis, and collecting them to return home. The log showed there had been 12 delayed starts and three early drop-offs logged between 2 December 2016 and 6 February 2017. The log showed that patients had still received their prescribed dialysis treatment. Transport was discussed at the monthly renal meetings and patients were given details on how to make complaints to patient transport services.
- Staff on the unit were not aware of the Workforce Race Equality Standard (WRES) requirements. This is a requirement for organisations which provide care to NHS patients to ensure employees from black and

minority ethnic (BME) backgrounds have equal access to career opportunities and receive fair treatment in the workplace. Organisations are required to assess their progress against the WRES indicators and publish the data. Since 2015, WRES is part of the NHS standard contract, and also applies to independent healthcare locations whose annual income for the year is at least £200,000.

Public and staff engagement

- The clinic sought patient views through the annual patient surveys. There was a response rate of 69% in the last survey in 2016 which indicated a good level of engagement. The clinic displayed the results and the actions taken in response to the survey, to keep patients informed.
- The patient group had a patient representative to raise issues with the clinic manager. Not all patients knew this. Most patients however said if they had any concerns they would raise them with the manager directly, and they described the manager as having an 'open door' approach.
- We spoke with the clinic's patient representative during our inspection. They said they met with the clinic manager every couple of weeks and if patients had any issues or concerns they sometimes preferred to raise them through the representative. They said the only issues related to transport. Staff monitored the transport issues and shared the results with the trust each quarter.
- All staff engaged in the annual staff survey, undertaken in November 2016. Results showed 92% of staff would recommend the unit to friends and family if they needed dialysis. The same percentage of said their training and learning was effective. The percentage of staff who looked forward to coming to work had increased year on year, to 77% in 2016. The full results of the survey were displayed in the staff room, with the completed action plan. The actions included improving the scores for; the proportion of staff who felt the job was good for the health, and the proportion of staff who felt they were able to meet the conflicting demands of their time.
- Staff had access to the Fresenius company handbook, which included advice on raising concerns, and the company's whistleblowing policy and process.

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Innovation, improvement and sustainability

- Two patients told us that staff went the extra mile in providing support and care and there was a culture of providing high standards of care. The staff were proud to have introduced a patient welcome pack and guide, and felt this had improved the patient experience and their understanding of procedures within the clinic.
- Consultant staff said staff at the clinic had set up improved processes for managing blood samples and this worked efficiently.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure that risks to patients are identified, assessed and monitored consistently, and that staff use individualised, updated care plans and action plans to enable them to support patients safely.
- The provider must ensure the system for reporting on clinical performance is robust, with regular review and planned actions for improvement.
- The provider must ensure that risks associated with systems are managed effectively. This includes the system for identifying patients when they present for treatment and the system for recording patient information in different places.
- The provider must ensure care and treatment is provided in a safe way for patients, by using safe infection control techniques

- The provider must ensure that staff administer medicines safely.

Action the provider **SHOULD** take to improve

- The provider should ensure notifications to CQC are submitted without delay, and within the timescales laid out in the Fresenius policies.
- The provider should ensure that patients are positively identified before they start treatment.
- The provider should ensure clinic managers, as registered managers are fully informed of the usage levels and projected replacement dates of the dialysis machines.
- The provider should support staff to complete all training, including duty of candour.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity

Regulation

Treatment of disease, disorder or injury

Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment

How the regulation was not being met

Staff did not carry out formal identification checks of the patient prior to dialysis or administering medicines.

There were inconsistent practices in applying aseptic or clean techniques when connecting patients with AV fistulas for dialysis.

Regulation 12 (1)(2)(a)(b)(g)(h)

Regulated activity

Regulation

Treatment of disease, disorder or injury

Regulation 17 HSCA (RA) Regulations 2014 Good governance

How the regulation was not being met

Staff did not have a good understanding of risk management and challenging practices to improve care and safety.

Regulation 17(1)(2)(b)