

West Byfleet Dialysis Unit

Quality Report

Tavistock House, Unit 11 Camphill Road, West
Byfleet, Surrey KT14 6EW

Tel:01623 445100

Website:www.freseniusmedicalcare.co.uk

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

Summary of findings

Letter from the Chief Inspector of Hospitals

West Byfleet Dialysis Unit is operated by Fresenius Medical Care Renal Services Limited. The service has 25 dialysis stations which includes four isolation rooms. The unit is built on two levels and is a purpose built facility for the treatment of chronic kidney failure. The unit has the capacity to dialyse 120 patients.

Dialysis units offer services which replicate the functions of the kidneys for patients with advanced chronic kidney disease. Haemodialysis is used to provide artificial replacement for lost kidney function.

The main referring renal unit is St Helier Hospital Renal Department, which is part of the Epsom and St Helier University Hospitals NHS Trust. The trust's consultant nephrologists visit the dialysis unit four times per month. The wider multi-disciplinary team include: a dietician, transplant nurse, blood transfusion nurse and the vascular access team also visit at varying times.

The unit operates from Monday to Saturday. Treatment is delivered across five treatment sessions. On Monday, Wednesday and Friday they operate between 6.30am and 23.30 pm (three treatment sessions) and on Tuesday, Thursday and Saturday between 6.30am and 18:30pm (two treatment sessions).

Staff within the clinic have direct access to St Helier's renal unit data base allowing for ease of access to all relevant patient information and referrals. The Fresenius data base links information with the trust's database.

The arrangements for emergency patient care, for example cardiac events are directed via 999, and all Fresenius staff complete the appropriate basic life support training.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 26th June 2017, along with an unannounced visit to the centre on 10th July 2017.

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

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.

Services we do not rate

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

We found the following areas of good practice:

- There were effective systems in place to keep patients safe. This included appropriate management and reporting of incidents, effective cleaning schedules and maintenance programmes. All staff were aware of their roles and responsibilities in ensuring patient safety.
- Staff completed competencies according to the Fresenius medicine management policy.
- Patients' medical and nursing records were secure. Staff had access to all relevant records ensuring patients' care was as planned and not delayed.
- Staff worked collaboratively with the trust to monitor and assess patients regularly. Patients and their GP's were provided with written updates on their condition and treatment plans.

Summary of findings

- Staffing levels were maintained in line with the trusts contract arrangements. Nursing staff had direct access to a consultant nephrologist who was responsible for patient care. In emergencies, patients were referred directly to the local acute NHS trust or the local commissioning trusts renal unit.
- Staff were aware of their roles and responsibilities to maintain the service in the event of a major incident. Patients were able to continue their treatment at alternative centres.
- All policies and procedures were based on national guidance and compliance was monitored through an effective audit programme.
- Patient's pain and nutrition were assessed regularly and patients were referred to appropriate specialists for additional support as necessary.
- There was a comprehensive training and induction programme in place to ensure staff competency.
- There were processes in place to ensure effective multidisciplinary team working, with specialist support provided by the referring trust.
- There were effective processes in place for gaining patient consent for treatment.
- Patients were treated with respect and compassion. Staff took care to maintain patient dignity and confidentiality when delivering care and treatment.
- Staff were familiar with and worked towards the organisational vision of providing the best possible care for renal patients.
- There were effective processes in place to monitor risks associated with the service and individual patients.
- Quality assurance meetings occurred regularly and included the wider multi-disciplinary team.
- All staff and patients were positive about the service.

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

- Best practice guidelines advise two registered nurses check at the point of administration of intravenous medicines. We saw the sodium chloride (0.9%) ampules were not checked by two nurses at the point of administration.
- The unit was in poor decorative repair. We saw cracks on walls and parts of the flooring covered by tape. This could harbour dirt and dust and make cleaning difficult.
- Outside the unit the grounds were in poor repair which made it difficult for people disabled or in wheelchairs to safely move from the car park to the unit.
- Chairs in the clinic out patients department were not made of wipe clean material to prevent the spread of infections.
- On the inspection day, the outside waste disposal area was not locked; we also found three bulk storage bins in the disposal area to be unlocked.
- Not all waste bins were labelled to indicate the type of waste to be disposed in accordance with HTM07-01. This meant there was potential for waste not to be segregated properly.
- The unit did not review the personal emergency evacuation plans to ensure information about the patient was up to date in the event of an emergency.
- The number of patient records audited each month was inconsistent and did not constitute 10% of records being audited.

Summary of findings

- The unit did not have an up to pathway or tool kit for managing suspected infections, and sepsis.
- The competency assessment document for dialysis assistants, who were able to administer anticoagulants (a medicine that thins the blood), were not fit for purpose. The competencies referred to a medicine which was no longer in use on the unit.

Professor Ted Baker
Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

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

Summary of findings

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West Byfleet Dialysis Unit

Services we looked at

Dialysis Services

Summary of this inspection

Background to West Byfleet Dialysis Unit

West Byfleet Dialysis Unit is operated by Fresenius Medical Care Renal Services Limited. Fresenius Medical Care was awarded the contract as part of a partnership agreement with Epsom and St Helier's University Hospital NHS Trust. The service initially commenced in 2000 and was known as Woking Dialysis Unit with 11 stations until

moving site and becoming West Byfleet Dialysis Unit in July 2007. It is a private medical dialysis unit in West Byfleet, Surrey. The unit primarily serves the community of West Byfleet

The unit had a registered manager in post since July 2008.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector, and two other CQC inspectors. The inspection team was overseen by an Inspection Manager and Alan Thorne head of hospital inspections.

Information about West Byfleet Dialysis Unit

The Fresenius Dialysis Unit at West Byfleet is a 25 station 'standalone' dialysis unit.

There are three 'treatment sessions' of patients dialysed on Monday, Wednesday and Friday, usually, with 24 patients dialysed in the morning, 24 in the afternoon and 24 patients in the evening. There are two 'treatment sessions' of patients dialysed on Tuesday, Thursday and Saturday, with 24 patients dialysed in the morning and 20 patients dialysed in the afternoon. There are on average 1350 treatments sessions delivered a month.

The usual times for dialysing patients was between 06.45 am and 23.30 pm (Monday, Wednesday, Friday). The dialysis unit opens from 06.30 am and closes at its latest at 23.45 pm.

Fresenius renal care is contracted to complete dialysis for local patients with close links with the local commissioning trust who provided medical cover, pharmacy support, transport coordination, and regular contact with the multidisciplinary team. The clinical teams attend the centre regularly and assess patients in preparation for monthly quality assurance meetings.

The centre is registered to provide the following regulated activities:

- Treatment of disease, disorder, or injury.

During the inspection, we visited the treatment areas where dialysis took place, and the other non-clinical areas of the unit, such as the maintenance room and water storage area. We spoke with 10 staff including; registered nurses, dialysis assistants, health care assistants, reception staff, and a nephrologist. During our inspection, we reviewed 10 sets of patient records and medicine prescription charts.

There were no special reviews or investigations of the centre ongoing by the CQC at any time during the 12 months before this inspection.

In the 12 months before our inspection, there were 5,073 dialysis sessions carried out for 18 to 65 year olds and 12,008 sessions for people over 65 years of age. Thirty two patients were aged between 18 and 65 years and 81 patients over 65 years of age. All patients were NHS funded. An average of 368 treatments was delivered each week.

Summary of this inspection

The dialysis unit provided services for people who were on holiday. No service was provided for patients under 18 years of age. Both male and female patients are treated in the same areas at the same times.

The dialysis unit did not employ any doctors. The centre employed 10 whole time equivalent (WTE) registered nurses, six WTE dialysis assistants and nine WTE health care assistants.

Access to the facility was by established routes with bus stops in close proximity. Most patients used hospital arranged transport to and from the centre. Ambulance access was available and a designated drop off base was available at the entrance. A small number of patients used private transport and designated parking was available.

Track record on safety in 12 months before inspection:

- No never events.
- No incidences of healthcare associated MRSA.
- No incidents of Methicillin – sensitive staphylococcus aureus (MSSA).

- No incidences of healthcare associated Clostridium difficile.
- No incidences of healthcare associated infection caused by other bacteraemia.
- No incidences of pressure ulcers
- Four incidences of patient falls.
- Six complaints received.

Services provided under service level agreement:

- Clinical and or non-clinical waste removal.
- Pathology and histology.
- Water treatment system maintenance.
- Laundry services and provision.

Other services were carried at the location and included pre-dialysis consultations, education sessions and phlebotomy services. These clinics were run by St Helier's renal unit. Fresenius offered administrative support and phlebotomy upon request.

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:

- There were effective systems in place for recording and escalating incidents. There was a positive safety culture, which was inclusive of all staff.
- Staff were compliant with mandatory training and there were systems in place to alert staff when training was due.
- Staff were aware of their roles and responsibilities in the escalation of safeguarding concerns.
- The equipment used were visibly clean, with evidence of effective cleaning regimes and schedules in place. Staff followed infection prevention and control procedures across the dialysis pathway.
- Audits were completed to ensure compliance with local policy and procedure.
- All equipment was maintained according to the manufacturer's guidance.
- There were systems and process in place to manage medicines.
- Patients medical and nursing records were held securely, with direct access to all relevant records at each area where treatment was provided.
- Staff worked collaboratively with the referring commissioning trust to monitor and assess patients regularly.
- Medical advice was available, with direct access to the appropriate consultant or renal team at the commissioning trust.
- Nursing staffing levels were maintained in line with contract arrangements.

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

- We saw the sodium chloride (0.9%) ampules were not checked by a second nurse at the point of administration. Best practice guidelines advise two registered nurses check at the point of administration of intravenous medicines.
- We found the outside waste storage area was not locked and three bulk containers were not locked inside the area.
- Poor décor of the unit resulting in cracks on the wall and tape on the floor were sites for dust and dirt to harbour. This could make cleaning difficult.

Summary of this inspection

- Outside the unit the grounds were in poor repair which made it difficult for people disabled or in wheelchairs to safely move from the car park to the unit.
- Chairs in the clinic area were not of a wipe clean material to prevent the spread of infection.
- Not all waste bins were labelled to indicate the type of waste to be disposed off. This had the potential for waste not to be segregated properly.
- The unit did not have a pathway and toolkit for managing suspected infections, and sepsis.
- Personal emergency evacuation plans for patients were not regularly reviewed, which meant information about the patient was not up to date.

Are services effective?

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

We found the following areas of good practice:

- All policies and procedures were based on national guidance.
- The unit had a ISO(9001) accredited quality management system .
- Patients' pain and nutrition were assessed regularly and patients referred to appropriate specialists for additional support as necessary.
- The unit had a comprehensive annual audit schedule to ensure national and local policy were being followed.
- The service monitored key performance indicators to monitor against Renal Association standards.
- Staff completed a competency pack on commencement of their post.
- Staff had the skills, knowledge and experience to ensure safe patient care.
- There were processes in place to ensure effective multidisciplinary team working, with specialist support provided by the referring commissioning trust.
- All staff had access to electronic management systems where details of patients consultations, investigations, care and treatment were stored.
- Consent processes were in place for gaining patient consent for treatment.

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

- In the nursing documentation audit, inconsistent numbers of nursing records were audited each month.

Summary of this inspection

- Dialysis assistants, competency assessments did not contain the correct medicine,
- Nursing competencies were not regularly reviewed.

Are services caring?

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

We found the following areas of good practice:

- Patients were treated with respect and compassion.
- Nursing staff gave patients adequate time to ask questions and provided written information regarding patients' conditions, treatment plans and support networks.
- A patient guide was given to patients when arriving at the unit to answer areas of concerns for patients and give them an overview of the dialysis process.

Are services responsive?

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

We found the following areas of good practice:

- The dialysis unit had been built to provide local dialysis patients with a treatment centre nearer to their home.
- The needs of different people were taken into account when planning and delivering services.
- Staff were supportive of patients wishing to change dialysis sessions due to personal circumstances.

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 felt valued and there was a positive culture. We observed team working and staff respecting each other.
- Staff were aware of the company desire to be open and honest whilst achieving good results.
- Local leadership was strong and staff felt well supported.
- Staff reported the clinic manager was supportive.
- The unit worked closely with the local commissioning trust .
- The dialysis unit had effective systems in place to monitor risk and quality, using a dashboard to evidence performance and identify trends or areas of improvements.

Dialysis Services

Safe

Effective

Caring

Responsive

Well-led

Are dialysis services safe?

Incidents

- Fresenius had a clinical incident reporting policy that provided a framework for reporting and managing all incidents and near misses, to improve the quality and safety of its service. Incidents were identified, reported, investigated, and learned from to prevent recurrence.
- Staff had a good understanding of the processes to report incidents. Staff reported incidents using an electronic reporting system. Incidents were reviewed by the clinic manager and investigations and outcomes were shared with staff through staff handovers and staff meetings. We saw in the June 2017 staff meeting, incidents were discussed.
- The unit had reported no never events in the period June 2016 to May 2017. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- The unit had reported three deaths over the 24 month period prior to the inspection of which two were unexpected. We reviewed the CQC data base and saw the unit had informed the CQC of the deaths through the statutory notification system. We found no evidence that mortality and morbidity meeting took place to discuss whether clinical care delivered had contributed to the deaths.
- We reviewed the clinical incident log between August 2016 and February 2017, and saw six incidents had been reported. Clinical Incidents included needle dislodgements, cardiac arrests and issues with

medical devices. Clinical incident reports were completed and sent to the Fresenius clinical incident review team who reviewed the incident and put an action plan in place. We reviewed the incidents with the clinic manager who was able to describe the actions following the incidents. The six incidents were classified as four low harm, one moderate harm and one severe harm. We saw the severe harm clinical incident was in the process of being investigated by Fresenius and had been reported to the CQC.

- As well as the clinical incident reporting, in the event of a minor clinical or patient safety incident before, during or after dialysis treatment, staff completed a treatment variance report (TVR) or unit variance report (UVR) within the electronic patient record. The data within the system was reported on a monthly basis to both the area head nurse and the renal nurse at the local commissioning trust.
- TVR's included patients who do not attend (DNA's), shorter treatment times, hypotension, blood clotting, poor blood flow and any patient slips . In the six months up to March 2017, 226 TVR were raised. During that period the top five reports included patients shorter treatment times, DNA's, hypotension, hypertension and treatment procedure variances. We saw TVR's relevant to particular patients were discussed with the consultant at the monthly review meetings.
- In the same reporting period, four incidents of patient falls were reported. The clinic manager told us a accident form was completed and sent to the Fresenius Health and safety officers. Further risk assessments would be completed and measures introduced to prevent further incidents.
- The unit kept a log of the 999 calls made by the unit prior to a clinical incident report being completed.

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Between January and March 2017, three 999 calls were registered. We reviewed the log and saw the patients received medical care at the local acute NHS trust and then returned back to West Byfleet to continue their treatment.

- Lessons learnt from incidents were regularly communicated through handovers and staff meetings. Staff confirmed they received feedback following incidents. We saw evidence of the minutes of staff meetings and learning bulletins sent round by Fresenius. Staff showed us a learning bulletin about 'dry needling' cannulation technique. Staff told us they had seen the bulletin and were no longer using the technique.
- Fresenius had a duty of candour policy which was aligned with National Patient Safety Agency (NPSA) 2009 guidance. 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 (other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person. We reviewed the moderate and severe clinical incidents and saw that they had activated the duty of candour process.
- Staff we spoke with had a good understanding of the duty of candour requirement and were able to explain how it applied to their specific roles. Staff told us what constituted the duty of candour and what steps to follow when a trigger had been reached.
- The clinic manager described that following any serious incident (SI), patient safety was secured, and a root cause analysis was carried out. An action plan would be implemented to ensure prompt and appropriate clinical care that prevented further harm occurring. A letter of apology would be issued to the patient and family and this included the progress of the investigation and outcomes. We saw evidence of the correspondence sent to the family following a recent clinical incident. This ensured the family were kept up to date of the the event and the investigation.

Mandatory training

- Fresenius Medical Care had an extensive training and educational manual. This outlined the expectations of all staff on mandatory training, additional training, accessing training and the use of the electronic

systems. Annual mandatory training included fire, life support, infection control, and medicine management. Training to be completed every two years included safeguarding, moving and handling and fire risk assessments.

- We reviewed the 2017 training and monitoring tool. Staff training files included a contemporaneous training record which contained details of training undertaken, induction, fundamental skills, advancing and management training.
- Records demonstrated clinical staff were up to date with essential (fundamental) training. This included basic life support, automated external defibrillation, anaphylaxis, safeguarding, moving and handling and infection prevention and control.
- The clinic manager completed monthly checks of the electronic training records and informed staff of any training due. Staff told us the Fresenius education coordinator would also remind them when training was due.
- Staff completed their mandatory training though the online system and attended face-to-face training which took place at Fresenius head offices. This allowed staff to meet staff from other units. Staff told us time was made available during the working week to complete the mandatory training.

Safeguarding

- Fresenius had systems in place to safeguard adults and children who may be identified as at risk of abuse. No safeguarding concerns were reported to CQC in the period between June 2016 and May 2017.
- Staff we spoke with were aware of their responsibilities in relation to safeguarding vulnerable adults and children and could locate and describe the Fresenius safeguarding policy. Fresenius confirmed that staff were trained to level 2 for both adults and children's safeguarding training. Training took place every three years and was due in July 2017.
- The clinic manager was the safeguarding lead for the unit. The unit had access to the training and education manager who was trained to level 3. The lead for adults was the training facilitator. We saw safeguarding contact numbers and a flow chart were available in the staff room for staff to refer to.

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- People under the age of 18 were not treated within the clinic. Visitors were not permitted to bring children into the clinical area due to the unsuitability of the environment. Staff completed children's safeguarding e-learning training every three years which gave staff a level of awareness around what they would do if they were told any worrying information about a child. Staff received level 2 training which was in line with national guidance. The intercollegiate guidance document "Safeguarding Children and Young People" (2014) states, all non-clinical and clinical staff that have any contact with children, young people and/or parents and/or carers should undertake safeguarding children level two training.
- Staff told us they would escalate any safeguarding concerns to their clinic manager who was responsible for reporting safeguarding concerns to the local safeguarding board. We were unable to establish the level of training the clinic manager had undertaken.
- Staff demonstrated an awareness of their patients and would raise any concerns of physical, emotional, and financial abuse during the nursing handovers.

Cleanliness, infection control and hygiene

- All areas we visited within the unit were visibly clean and tidy. We saw there were good infection control practices in place. For example, all staff in the treatment area were 'bare below the elbow'. This was in line with national guidance, National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England' (epic3), which states healthcare workers, should ensure their hands are cleaned effectively by removing all wrist and hand jewellery.
- There were sufficient hand washbasins (HWB) available, in line with the Department of Health's Health Building Note (HBN) 07-01: Satellite Dialysis Unit. This included HWB's that were accessible by wheelchair patients, as patients needed to wash their fistula arms before treatment. Soap cartridges and disposable hand towels were available next to the sinks. We also saw alcohol based hand gel was available throughout the unit.
- Information about the World Health Organisation (WHO) 'five moments for hand hygiene' was displayed near the HWBs. This helped remind staff of the importance of when and how to clean their hands, before and after key activities such as before and after patient contact.
- We saw staff cleaning their hands either at the HWB or using the alcohol-based gel, in line with the WHO 'five moments of hand hygiene' and National Institute for Health and Social Care Excellence (NICE) quality standard (QS) 61, statement three. This standard states people should receive healthcare from healthcare workers who decontaminate their hands immediately before and after every episode of care.
- We reviewed the hand hygiene data supplied to us by the unit. It showed between January and June 2017, compliance was 93% in January, 92% in February, April and June and 91% in March and May. The audit checked compliance with WHO 'five moments of hand hygiene'. We saw the 'moment' staff were most non-compliant was 'after contact with patient surroundings'. Where there were episodes of non-compliance we saw members of staff were spoken with immediately. This meant the unit could be confident staff were cleaning their hands in line with policy, and staff were willing to challenge non-compliant behaviour.
- We saw the infection control audit for the unit undertaken in June 2017. The audit included, but was not limited to, cleanliness of the environment and equipment, staff adherence to 'bare below the elbow', management of sharps, and hand hygiene. The unit was compliant in 72 standards, with seven recommendations and 15 minor non-compliances. These included, non-adherence to uniform policy (staff members wearing necklaces and inappropriate earrings) and a thermometer found not to be clean. No major or critical non-compliances were identified as none were found.
- Mattresses (chair and bed) were included in the June 2017 audit. This found the mattresses used by the unit were fit for purpose and provided protection from infection and pressure damage.

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- Personal protective equipment (PPE) was widely available and in sufficient quantities on the unit. PPE is aprons, gloves, visors and masks or other garments or equipment designed to protect the wearer's body from injury or infection.
- During our inspection we saw staff wearing PPE appropriately. For example, we saw visors and masks were worn when removing patients from dialysis machines, where there was potential for blood to be splashed in the staff members eyes, nose or mouth. We also saw gloves and aprons were only worn during patient contact. In addition, we saw visors were cleaned between patients.
- If patients were identified as being at risk with a potential or actual infectious condition, four side rooms were available, to reduce the risk of cross infection. For example, patients with a blood borne virus (BBV), such as hepatitis B (HBV) or hepatitis C virus (HCV), or other infections such as Meticillin resistant Staphylococcus aureus (MRSA), or Meticillin sensitive Staphylococcus aureus (MSSA). MRSA is a type of bacterial infection, is resistant to many antibiotics, and has the capability of causing harm to patients. MSSA is the type of bacterial infection, but is more easily treated with antibiotics.
- All patients were routinely screened on admission to the unit, and then for MRSA and MSSA. If any patients were identified as having MRSA, they were treated and then re-swabbed to see if they were clear of the bacteria. In addition, they would be isolated during their dialysis treatment. At the time of inspection, we were told the unit currently had no patients with MRSA or MSSA.
- Admission and routine monitoring for BBV was in place on the unit. Patients were screened for HBV, HCV, and human immunodeficiency virus (HIV). If patient were found to be positive for a BBV, they would be placed in isolation for their treatment. For patients who were found to be carrying HBV, they would have a dedicated machine that was used for them alone. This was in line with the Renal Association Guidelines: blood borne virus infection. At the time of our inspection, the unit told us there were no patients with HBV infection.
- Patients were placed in isolation if they returned from a holiday that required dialysis away from base, in an intermediate or high-risk country. Intermediate risk countries included, but were not limited to, South East Asia and South America. High-risk countries included, but were not limited to, Indian sub-continent and parts of Africa.
- The Department of Health (DoH) advises there is an increased risk of getting a BBV infection associated with dialysis abroad. Countries have been separated into low, intermediate, and high risk, and have made recommendations for action on returning following dialysis away from base. Patients, who had been abroad to an intermediate or high risk country and had dialysis away from base, were routinely placed in isolation. This is in line with best practice guidance 'Good Practice Guidelines for Renal Dialysis/ Transplantation Units', which suggests patients returning from high risk countries are placed in isolation for at least two months. In addition, the unit made sure the patient had used a dedicated machine during this period. We saw there were two dedicated machines for patients returning from dialysis away from base, who fulfilled these criteria, we saw there, were signs in place, indicating the machine could only be used on this group of patients.
- The unit did not have their own holiday coordinator, but had a link nurse who would manage both patients wanting to come to the unit and those that required dialysis away from base. The unit worked with the local commissioning trusts holiday coordinator. The holiday coordinator would make sure the correct tests (including BBV and MRSA) were in date, prior to the patient arriving at the unit.
- Machines were automatically put through a 'heat' disinfection sterilisation process between patients, as part of the dialysis machine cycle. We saw this was recorded on records kept at the machine. In addition, once a week the machines would be put through a 'chemical' disinfection sterilisation cycle.
- We saw the outside of the machines were routinely cleaned with a disinfection-based product following use on a patient.
- There were sharps bins available throughout the unit and we noted the majority of the bins were assembled

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correctly, labelled, and dated. None of the bins were more than half-full, which reduced the risk of needle-stick injury. This is in line with Health Technical Memorandum (HTM) 07-01: Safe management of health care waste.

- We saw waste was separated and in different coloured bags to signify the different categories of waste. This was in accordance with the Health Technical Memorandum (HTM) 07-01: Safe Management of health care waste and control of substance hazardous to health (COSHH), health, and safety at work regulations. However, not all waste bins were labelled to indicate the type of waste to be disposed, in accordance with HTM 07-01, which says 'labelled colour coded waste receptacles should be supplied for each waste stream'.
- We saw there were no domestic waste bins in the dirty utility for items such as paper towels used following hand hygiene; this meant there was the potential for waste not to be segregated correctly.
- All waste was kept appropriately in bulk storage bins, in a designated area on the unit premises until collected. However, we saw the bulk storage area was located by the car park at the back of the unit which we found it to be unlocked. In addition we checked three bulk storage bins in the compound and found them to be unlocked. One bin containing closed sharps bins, and two containing clinical waste bags. This is not in line with HTM 07-01 5.98, which states bulk storage areas should be away from routes used by the public, be totally enclosed and secure, and kept locked when not in use. We highlighted this to the manager during the inspection and during the unannounced inspection we found the storage area to be locked.
- We inspected the beverage room on the unit, and found it to be visibly clean and tidy. There were facilities for staff to make patients hot and cold drinks. We saw there were individually packed biscuits for patients if they wished. All opened food was stored in pest proof containers. We saw records, which showed daily temperature checks for the fridge were undertaken. This provided assurance food stored in the unit refrigerator was within recommended temperature range to maintain food safety.
- We looked at the dirty utility on the unit, which had a separate dedicated hand hygiene sink, a slop hopper for disposal of body fluids and a separate deep sink for cleaning of equipment. This was in line with HBN 00-09: infection control in the built environment. However, the dirty utility contained other items such as unused blood collection bottles, spare blood pressure cuffs and sphygmomanometer's (an instrument for measuring blood pressure). Clean items should not be stored in the dirty utilities, as it poses a risk to cross infection.
- We found equipment on the unit was visibly clean, and staff had a good understanding of their responsibilities in relation to cleaning equipment. The unit had a daily workload rota which included the cleaning of equipment, such as patient scales and wheel chairs. Each item on the daily workload rota was allocated a task, which was assigned to a member of staff. We saw the daily workload rota was completed and up to date.
- Cleaning equipment was stored in a designated room, which was locked. The room was visibly clean and tidy, with a slop hopper to dispose of dirty water, and a small hand washing basin available. Cleaning staff used a colour coding system based on the national guidance for colour coding to prevent the spread of infection.
- The unit had a large water treatment room on site. Drinking water standards are inadequate for haemodialysis since patients are exposed to many thousands of litres of dialysis fluid yearly. Water used for dialysis needs to be treated appropriately to remove impurities. An outside contractor managed the water treatment room, and would respond to a concern on site within four hours.
- On a daily basis specific nursing staff who had been trained, would undertake routine testing of the water, such as testing for water hardness, or changing of filters. If a problem was found, they were able to contact the outside contractor for advice. We saw records were kept of these daily checks, which were up to date and fully completed.
- Water quality testing was also undertaken to test for micro-bacterial and endotoxin levels (bacteria that can be dangerous for patients on dialysis). We saw the

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testing was undertaken monthly in line with national guidance. Records were kept of the results of these tests and we found these were up to date and fully completed.

- Water supplies were maintained at safe temperatures and there was regular testing and operation of systems to minimise the risk of pseudomonas and Legionella bacteria. During our inspection, we saw copies of the records for flushing of water outlets. This is in line with requirement of Health and Safety Executive (HSE) L8; and Health Technical memorandum HTM04-01 A and B: guidance on the control of legionella.
- There was a dedicated infection control link nurse for the unit. Link nurses are members of the department, with an expressed interest in a specialty; they act as link between their own clinical area and the infection control team. Their role is to increase awareness of infection control issues in their department and to motivate staff to improve practice. We saw there was yearly update training for link nurses, most recently in May 2017. We saw items such as hand hygiene audit tool, BBV update, overview of their role and sepsis were discussed.
- We saw on the stairs leading to the first floor and in side room three, the walls had cracks or holes. The DoH HBN 00-09 states, walls should be 'Smooth cleanable impervious surfaces are recommended in clinical areas.' Damage to walls can harbour dirt and dust and make the cleaning difficult. Therefore, the unit did not meet this standard. The clinic manager told us Fresenius were aware and a refurbishment programme had been agreed but we were not told the start date.
- Some areas of the unit, had flooring that had tape present. Department of Health's (DoH) Health Building Note (HBN) 00-09: infection control in the built environment, states, 'Flooring should be seamless and smooth, easily cleaned and appropriately wear-resistant.'. Flooring that has tape in place or is damaged can harbour dirt and dust and make cleaning difficult. Therefore, the unit was not meeting national guidance. However, we were told the unit had recently secured funding to replace all the flooring in the unit.

- We saw chairs in the first floor waiting area were intact, but not made of wipe-clean materials. HBN 00-09 recommends soft furnishing (including chairs), 'should be covered in a material that is impermeable, preferably seam-free or heat-sealed.' Therefore, the unit was not meeting national guidance.

Environment and equipment

- The unit provided 21 dialysis stations, and four side rooms. This is compliant with HBN 07-01 5.34, which states 'there should be an allocation of one to two isolation rooms per 12 stations'. The dialysis stations were separated into four areas in the unit. Each area had a small nurse's station attached. These meant nurses were able to see their patients easily.
- Each area had a minimum of two HWB available for hand washing. This is compliant with HBN 07-01 5.22 which states 'there should be at least one wash-hand basin between two stations'. There was a HWB located opposite the entrance to the unit, where patients could wash their fistula arm before treatment.
- There was a central nurse's station, which was located by the end bay and the side rooms. The side rooms were observable from the main nurse's station and the main unit.
- Each of the dialysis stations had a reclining chair or a bed, a dialysis machine, table, television, and a nurse call bell. All stations were numbered. This meant equipment remained in the same locations and patients were assigned to specific stations. There was one station that was not routinely assigned to a patient; this was to allow any emergency or extra dialysis sessions to take place.
- There were four trollies in the dialysis treatment area, which contained sterile disposable items, such as syringes, needles, and gauze swabs. All items we looked at on the trollies were in date and the packaging was intact.
- The unit had enough dialysis machines for each of the 25 stations, and the two machines designated for dialysing patients returning from holiday. In addition, the unit had three spare machines. This meant if a machine broke down nursing staff could use the spare machine while the technical engineer repaired the broken machine and not affect patient care.

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- There was a rolling programme of maintaining of equipment to ensure equipment was safe and ready for use. Maintenance of equipment was generally undertaken using one of two methods. Planned preventative maintenance (PPM) or reactive maintenance. PPM was undertaken on a regular programme to meet statutory requirement, legislation, manufacturer's guidelines and industry best practice. At the unit, PPM for equipment was undertaken every two years, with an interim service yearly. Reactive maintenance was undertaken on an 'as required' basis to address damage, breakdown, or failure. Staff were aware of the process for reporting faulty equipment.
- Renal Association guidance suggests dialysis machines should be replaced between seven and ten years or when they have completed 25,000 to 40,000 hours of dialysis. We saw during routine services this information was logged and all machines were within national guidance. A replacement programme was in place to ensure machines would be replaced when they came to the end of their working life.
- Emergency equipment was located on the unit. The resuscitation trolley contained all the required emergency equipment including, an automated external defibrillator (AED) and medication to manage a medical emergency, such as a cardiac arrest. An AED is a portable device that checks the heart rhythm and can send an electric shock to the heart to try to restore a normal rhythm. Medicines were stored in a sealed tamper evident box. This is in line with the Resuscitation Council Guidelines (November 2016), which states 'all resuscitation drugs must be stored in tamper-proof boxes'.
- Records showed the trolley was checked daily, whilst the unit was open. All drawers had the correct items in accordance with the checklist. The resuscitation trolley was not locked, and easily accessible in the event of an emergency. This is in line with the Resuscitation Council Guidelines (November 2016).
- We looked at various pieces of equipment for example, patient walk on weighing scales and blood pressure machines. An extra set of weighing scales were available as a back up. We saw electrical testing stickers on equipment, which indicated the equipment was safe to use.
- We inspected the main storage area for the unit which stored single use items used during the dialysis process. The area was found to be visibly clean and tidy. There was enough shelving for equipment to be stored off the floor. Larger items were stored on wooden pallets. The equipment store was located on the first floor in a secure part of the unit and there was a lift designated to transport supplies.
- The water treatment plant had a sloped floor to a drain, and a cement raised band in place to prevent water seeping to the rest of the unit in the event of a large water leak. This was in line with HBN 07-01.

Medicine Management

- The clinic manager had lead responsibility for the safe and secure handling and control of medicines. On a day to day basis the nurse in charge was responsible for the drug cupboard keys. We saw 11 keys were on a chain with only one key being identified. This made the task of finding the correct key time consuming.
- There was no nominated pharmacist aligned to the unit. However, staff could contact the pharmacy department at the local commissioning trust for guidance. There was no pharmacy input at the multidisciplinary team meeting nor did a pharmacist visit the unit.
- Fresenius had a medicines management policy. The unit were using the newest version of the policy that being version 6. All staff had signed and dated when they had read the policy. The purpose of the policy was to ensure the safe management of medicines in line with national guidance. This included suitable arrangements for the recording, safe-keeping, handling, and disposal of medicines. We saw staff administering medicines following the policy; this included patient identification, checking medicines by two staff members; one of whom (the registered nurse) then administered the medicine.
- The nursing documentation audit, which took place monthly, covered medicine management. We reviewed four nursing documentation audits which took place between April and June 2017. We saw the June 2017 audit picked up that in four out of nine medicine charts, not all relevant detail was completed on the charts this included the patients name, NHS number and the drug therapy prescriptions required

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up dating. Actions from the audit would be monitored by the deputy clinic manager and the team leaders, with the deputy having the responsibility to ensure nursing action plans were completed. In the charts we reviewed during the inspection we saw the above actions had been completed.

- The unit did not use or store any controlled drugs (CD's), medicines that are liable for misuse and have additional legal requirements regarding their storage, prescription and administration. We checked three nursing trolleys in the treatment bays and found prescribed medicines were stored appropriately.
- Medicines were reviewed at the quality assurance meetings for each patient. The consultant prescribed medicines administered during dialysis. This included anti-coagulant (medicines that help prevent blood clots), iron infusions, intravenous (IV) antibiotics for suspected and actual dialysis line sepsis. We saw prescription charts were clearly written, showed no gaps or omissions and were reviewed regularly. Staff told us if a prescription has not been signed by the consultant the medicine would not be administered and a clinical incident form would be raised.
- We reviewed nine medicine administration charts. Allergies were clearly documented on each chart and we saw the allergies were confirmed on the electronic prescription chart.
- The medicine room was entered through a controlled key pad. In the room, medicines were stored in locked cupboards although we found one of the cupboards unlocked. We saw sodium chloride (0.9%) 100ml and 1,000ml were kept in cardboard boxes on the counter. This is not in line with national guidance.
- A registered nurse (RN) told us medicines were ordered weekly and would arrive at the unit by a courier in a locked medicine container. A RN would check delivery and place the stock in the cupboards. The storage system of medicines allowed the 'expire first' medicines to be used first. The delivery note for new medicines was placed in the despatch folder which we reviewed and saw all recent dispatch notes were in place.
- Medicines which were temperature sensitive were monitored closely. The medicines management policy gave guidelines for staff for action to take in the event temperatures were outside the required ranges. During the inspection the temperature in the medicines room was outside the required range. We saw staff reported the out of range temperatures to the clinic manager and the appropriate actions were taken.
- Fridge temperatures were recorded daily in line with best practice. We saw between May and June 2017 a total of 61 entries were completed and all temperatures were within range. Staff were able to explain what to do in the event the temperature was outside the expected range.
- The unit had three oxygen cylinders. We saw two oxygen cylinders, were chained to the wall with one free standing. All three cylinders were due to expire in May 2020.
- We saw medicines that were given 'as needed', which are known as "PRN" medicines were prescribed in all the prescription charts we reviewed. This included medicines such as paracetamol (a pain reliever and a fever reducer) and oxygen. In the nine charts we reviewed we saw all patients had PRN's prescribed. This allowed the RN to administer the medicines in a timely manner when the patients required them.
- During haemodialysis, sodium chloride (0.9%) solution is used in a variety of situations including the treatment of hypotension (low blood pressure), priming, and wash back of the machines and as a flush when heparin free dialysis is recommended (no anti-coagulant is given at the beginning of treatment). We saw in five charts sodium chloride(0.9%) had been prescribed to support these situations up to a 1,000ml. In the charts we reviewed the amount of sodium chloride (0.9%) administered was documented, for example in one chart we reviewed, we saw 26 entries for the flushing of needles and in a second chart we saw four entries. All entries had two signatures, one of which was a RN, which is in line with national guidance.
- We observed the appropriate checking of medicines prior to it being administered to the patient. Before administration of the anti-coagulant, the dialysis assistant checked the preparation, strength and expiry date both verbally and visually with a RN. This followed the Fresenius policy where it stated two

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persons check anti-coagulants before administration, one of whom must be a registered nurse. Before administering medication staff would ask for the patient's date of birth. We reviewed nine medicine prescription charts and saw the anti-coagulant had been signed by two members of staff. One RN told us they use the 'five rights' (including the right route, patient, drug, dose, time before administering medicines).

- We observed ampules of sodium chloride for flushes were checked by two members of staff, with one member of staff signing the drug chart at the end of the check. However the solution was not administered following the check and would be left on an open table until it was needed at the end of the dialysis session. The second nurse would sign the chart at the point of administration. This practice is against national guidance which states wherever possible, two registrants should check medication to be administered intravenously, one of whom should also be the registrant who then administers the intravenous (IV) medication.

Records

- The unit used a combination of Fresenius paper and electronic based record systems to record all aspects of patients' care. In addition, the staff had access to the local commissioning trust's electronic records. Data was automatically shared between the electronic databases. This ensured consultant nephrologists had access to the patient records at all times.
- Paper records consisted of all patient risk assessments, consent forms, and dialysis and medicine prescriptions. All paper records we reviewed were legible. Electronic records including records from the local commissioning trust and blood test results were accessible to all staff attending the unit.
- We looked at three patient records and found they were well maintained and completed with clear dates, times and designation of person completing the documentation. The patient records included information such as the patients past medical history, what type of access for dialysis was used, and patient observations including weight. In addition, we saw staff had completed patient risk assessments. These included risk assessments for falls, malnutrition and moving and handling. All risk assessments were completed followed national guidance.
- Patient medical records were paper based. At the time of inspection, we saw patient personal information and medical records were managed safely and securely, in line with the Data Protection Act. When not in use patients notes were kept in a locked cupboard. During their treatment, patient's records were moved to a folder on top of the dialysis machine beside the patient's chair or bed. This provided access to them for the nurse during dialysis. These notes included clear printed treatment charts and detailed care plans.
- We saw patients had care planning documents in place. These were general pre-printed care plans into which the patients name was added. For example, we saw care plans for anaemia and nutritional status. A care plan provides direction on the type of nursing care a patient may need. It can include a set of actions the nurse needs to carry out to resolve a condition or support a patient as identified by the nursing assessment. However, we saw care plans remained generic, there was room for individualising these care plans, by the addition of extra information unique to the person, but most of the care plans we looked at had not been adapted to the individual person.
- We found the records to be comprehensive and included completed risk assessments, consent to treatment forms, dialysis prescription chart, nursing notes of the treatment delivered, AVF/AVG (arteriovenous fistula/ arteriovenous graft) assessment records, care plan and medicine prescription charts. This meant there were clear records around the care being delivered.
- All patients had a named personal information card which facilitated access to treatment records. These were collected by patients and cross checked by staff against the planning book at the start of treatment. In the event of a missing card staff could create a new card for access to the data.
- We saw the electronic records detailed dialysis sessions by date and time. This meant any changes in treatment, any problems occurring during the session

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and any treatment changes could be easily identified. Staff told us if a patient required treatment at the local commissioning trust for a period, they could continue to track their care, and provide the appropriate treatment on their return to the unit.

- The RNs told us they had access to the local commissioning trust's patient management system. This allowed the RNs to view clinic assessments, investigations, test results, multidisciplinary team meeting notes and treatment and care provided.
- We observed information around the traceability of single use items were recorded in the patient's electronic notes. This ensured the clear identification and traceability should any issues develop in the future.
- All new patients had a comprehensive patient referral/admission document completed. This included information from the referring unit. A data quality confirmation check was also included on the form to ensure the data provided by the referring trust reflected accurate patient information.

Assessing and responding to patient risk

- Patient referral letters and admission documents included documentation that the patient had been assessed by the consultant nephrologist as in a stable condition, and suitable for care within a satellite dialysis unit.
- At the time of our inspection, the unit had no reported incidents of sepsis. Sepsis is a potentially life threatening complication of an infection. We were told staff followed the complications policy, but a sepsis policy was currently being written. We saw at the most recent Inflectional control link practitioner meeting (ICLP) meeting sepsis and a sepsis pathway were discussed.
- Staff were able to tell us the steps they would follow in the event they suspected a patient had sepsis. This included, but not limited to, contacting the senior doctors at the local commissioning trust for advice, taking a blood culture (a test that looks for infections in the blood stream) and where applicable transferring the patient for review.
- The unit had access to services provided by the local commissioning trust, such as the vascular access,

sepsis and the blood transfusion teams. Staff followed the local commissioning trust's policy for sepsis (a potentially life threatening complication of an infection) any patient the staff thought to be unwell would be able to access the local commissioning trust for urgent medical review. Nursing staff told us they would not commence dialysis if they suspected sepsis.

- We saw there were well structured handovers between the nursing staff, which made sure important information was passed onto each other. This included, but not limited to, all known risks, any incidents that may have occurred, patients attending for dialysis that day, and other news such as patient from the unit who had received a kidney transplant. We also saw there was a central communication diary which was used to pass on important messages for that day.
- The unit did not use any early warning system to recognise deteriorating patients however, staff told us they would escalate when a patient felt unwell. An assessment would be completed which included blood pressure (BP), temperature, pulse, respiration and oxygen saturation levels. Any issues raised would be referred to the renal team at the local commissioning trust and the patient would be transferred for medical support.
- During our inspection, we saw alarms on the dialysis machines were answered quickly. Alarms would sound for a variety of reasons, including sensitivity to patient's movement, blood flow changes, and any leaks in the filters. Nursing staff did not override alarms.
- Comprehensive risk assessments were carried out for patients and risk management plans were developed in line with national guidance. Risks were managed positively. We reviewed three set of electronic patient records and saw risk assessments included pressure ulcer assessments, manual handling, iron deficiency, renal bone disease, and fluid management assessments. These risk assessments ensured whether staff had taken enough precautions or should do more to prevent harm.

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- All patients had their blood pressure (BP) monitored before, midway through treatment and after treatment. Staff told us if a patient felt unwell their BP would be reviewed hourly.
- Fresenius had a patient transfer policy in place. When a patient was identified as deteriorating by nursing staff their concerns were immediately escalated to the clinic manager who would contact the consultant or renal registrar at the local commissioning trust followed by dialling 999 to get the patient transferred for medical treatment. Over the reporting period (June 2016 to May 2017) 15 patients were transferred from the service to another provider.
- Nursing staff reviewed the patients' vascular access on each session. This included reviewing the arterial and venous pressure, looking for any redness and any possible site of infection. Any concerns would be raised with the access team at the local commissioning trust. A visiting nurse from the local commissioning trust would visit the unit to perform transonic ultrasounds on the AVF's to monitor the flow rate of the fistula. High flow rates would require a review by a vascular surgeon.
- At the time of the inspection, we saw personal emergency evacuation plans (PEEPs) for people who used the service were in place. PEEPs provide important information for staff and other services in the event of an emergency. The plans included a moving and handling assessment for each patient in the event of an emergency evacuation. For example, 'mobile, walks with the aid of a walking stick'. We saw the patient signed each plan. However, there were no review dates on the PEEPs, which meant patients mobility status could change, and the plan may not be up-to-date.
- We saw an emergency supply of single use items, for example gauze, giving sets, and space blankets were available following the any evacuation. The kit was positioned in the outpatient's clinic.
- Patients were required to confirm identity prior to treatment and administration of medicines. This was completed by staff asking patients to confirm their date of birth, which was checked against the patient record, the dialysis or medicine prescription or dialysis card. We saw staff checked patients as they commenced treatment.
- Patient identification (ID) bracelets were attached during the administration of blood transfusions. Patients were required to wear an ID bracelet for the duration of the treatment, following the confirmation of their name and date of birth. Two nurses checked this prior to the administration of the blood transfusion, in line with best practice.
- Emergency antibiotics were administered for suspected infections following a discussion with the medical team. A framework was used to identify any patients with a potential infection; this included the review of any wounds and dialysis catheter exit sites for signs of infection prior to commencing treatment.
- If following monthly bloods it was identified a patient had low potassium levels, portable dialysate fluid (a solution used during dialysis to pull toxins from the blood) would be used, instead of dialysate from the central supply. This would help to raise the patient's potassium levels following dialysis and prevent the patient from risk of too low levels of potassium in the blood.
- We saw a first aid and eye wash kits were available at the nurse's station to be used in an emergency.

Staffing

- The unit was a nurse led unit. There was no medical staff based on site, medical cover was provided by the local commissioning trust. The unit had an establishment of substantive RN's, dialysis assistants, health care assistants (HCA) and a receptionist to support the 113 patients having treatment at the unit. The unit had the capacity to treat more patients and was therefore undertaking a recruitment programme at the time of the inspection to support increased patient numbers.
- The unit had two dedicated consultants from the local commissioning trust, who managed the medical care of the patients. The consultants would run a clinic twice a month and every first Thursday of each month. During the visits, the consultant would see a planned

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list of patients in the consulting rooms, and anyone identified by the staff as requiring a review. Any urgent advice and/or referrals would involve the renal registrar at the local commissioning trust.

- The unit worked to a predetermined patient to staff ratio and skill mix, one qualified staff member to every four patients, as defined by the local commissioning trust. At the time of inspection this included 10 whole time equivalent (WTE) RN, six WTE dialysis assistants, and nine WTE HCA's. The skill mix ratio was 70% qualified staff to 30% unqualified staff. These ratios were defined in the contract with the local NHS trust.
- Compliance with staffing ratios was maintained using an electronic rostering system. Unfilled shifts were filled with re-rostering permanent staff, requesting staff from the Fresenius medical services flexi bank or using an approved external nursing agency.
- At the time of the inspection the deputy clinic manager told us they had two RN vacancies (one full time and one part time). One full time dialysis assistant and one full time house keeper. A recruitment programme was under way.
- The clinic manager was supernumerary, working predominantly Monday to Friday, undertaking management duties as well as being a source of specialist knowledge for operational staff. The clinic manager attended nursing handovers and had knowledge of all patients undergoing treatment at the unit.
- A suitably experienced and qualified renal nurse, who had the relevant knowledge and skills to support the staff and patients, led each shift.
- We observed the nursing handover and found it to be a structured and effective communication tool, which promoted continuity of good care. All patients were mentioned at handover. Relevant information such as the patient's present condition, blood results and any associated appointments or changes in their dialysis prescription were discussed between the staff about to come on duty from the morning or afternoon staff.
- Link nursing roles were in place within the unit. These included infection control, health and safety, integrated management system, infection control,

anaemia and hepatitis B. The roles of the link nurse were to attend yearly updates and bring changes in practice. All updates were given to staff at staff meetings and handovers.

- Access to the renal team at the local commissioning trust for additional support or advice was available to all staff. This included in the event of an emergency the on-call renal registrar or consultant. Access was also available to the renal dietician and vascular access team. The clinic manager told us the renal matron was also at hand for support and guidance. Good lines of communication were in place.

Anticipation and planning for potential risks

- All staff received fire safety training as part of their mandatory training programme; staff told us they had the opportunity to rehearse scenarios and we saw evacuation equipment was available at the unit. Fire alarms were tested weekly on a Friday morning. The majority of staff had completed mandatory fire training. Recent scenario training in May 2017 covered cardiac arrest and Cardio Pulmonary Resuscitation (CPR) simulations.
- An emergency preparedness plan was in place covering various scenarios that may affect the day-to-day running of the unit such as loss of electricity, loss of water system, information technology (IT) infrastructure failure, and major staff shortages. We saw procedures in and out of hours were in place along with the contact details of all relevant persons and emergency response numbers. A copy of the plan was displayed in reception and the staff room.
- The clinic manager told us the renal unit at the local commissioning trust would be notified of any events that stopped the running of the unit. After any emergency situation had been resolved, an investigation into the cause of the event was undertaken along with an improvement plan. Debriefing and learning outcomes were completed after the event to inform staff of what did and did not go well.
- In the event of power failure, all dialysis machines had a battery backup system to permit patient's blood to be returned to them before being disconnected from the machine.

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

Evidence-based care and treatment

- Fresenius policies and procedures, used within the unit, followed evidence based practice. The clinic manager told us if required, local standard operating procedures were developed to fill in any local gaps in policy. The Fresenius policies we reviewed had version control and were in date, all were referenced to current best practice from a combination of national and professional guidance including the National Institute for Health and Care Excellence (NICE) and The National Service Framework for Renal Services in providing care for patients.
- West Byfleet Dialysis Unit had an audit programme in place which supported the care provided against its own policies, work instructions, and standard operating procedures. Audits undertaken included monthly nursing documentation and announced infection prevention and control (IPC) hand hygiene audits. All were audited in line with national guidelines.
- Fresenius operated an ISO accredited Integrated Quality Management System (9001). This ensured all policies and procedures supported best practice evidence, and with an annual review requirement this provided assurance the evidence base was current. Documents held in the quality management system were available for staff to access. Documents were password protected and version controlled. We reviewed the policy, 'Complications, Reactions and other Clinical Event Pathways' version 11 and saw staff had read and signed to say they had read this version of the policy in November 2016.
- We reviewed the March 2017 ISO 9001 quality management report and saw eight recommendations were made, six of which had actions. The recommendations made included updating a job description, lack of dates related to training and discrepancies in records from the local commissioning trust renal unit and the unit. All recommendations made had been implemented by the unit.
- Dialysis access is an important marker of clinical care. Functioning arteriovenous fistulas (AVF - surgically created vein used to remove and return blood during dialysis) are regarded as the best form of vascular access for adults receiving haemodialysis. Staff monitored and recorded patients' vascular access which included AV fistulas/grafts and tunnelled catheters on a vascular access monitoring chart. Staff completed the chart weekly following a review of the patients' vascular site. Any concerns would be raised with the local commissioning trusts access team where the patient would receive an appointment to be assessed. This was in line with the NICE Quality Statement (QS72) statement 8 (2015). 'Haemodialysis access-monitoring and maintaining vascular accesses and the renal association guideline 6.3.
- Timely creation of arteriovenous fistula (AVF) and arteriovenous graft (AVG) was the responsibility of the consultants. We reviewed data and saw in April 2017, 77%, May 80% and June 82% of patients had an AVF and in April 6.7%, May 7.6 %, June 8.7% had an AVG in place. The UK Renal Association guidance is that 85% should have AVF/AVG in place. The commissioning trust would decide who was suitable for AVF/AVG so it was difficult for Fresenius to influence these figures.
- Treatment delivered was managed in accordance with professional guidance, for example, NICE, Renal Association, and the National Services Framework for Renal Services. The clinic manager was able to demonstrate the compliance of the unit to the Renal Association standards. For example in line with the Renal Association guideline 6.1, 'recommend that the rope-ladder and buttonhole techniques should be used for cannulation of AVF and rope-ladder for AVG'. We observed during the inspection the nursing staff were using the rope ladder technique to cannulate AVF's.
- Prior to patients receiving dialysis, during and post dialysis all patients were reviewed by the nursing staff. This included documenting the patients' weight, temperature, pulse, and blood pressure along with any other medical issues raised by the patient. Nursing review notes were completed by the nursing staff which was then put into the Fresenius electronic

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management system and the local commissioning trusts management system. This allowed staff at the local commissioning trust to review the patients nursing reviews. This followed best practice guidance.

- The unit did not directly contribute data to the UK Renal Registry, as the unit's data was uploaded to the national database from the local commissioning trust. The data was not identified per location.
- Medical advanced planning and end of life care decisions were made in conjunction with the consultant who would then refer the patient to the advanced care specialist nurse at the specialist renal unit at the commissioning trust.
- We reviewed the results of the nursing documentation audit completed monthly between March and June 2017. Ten per cent of patient prescriptions were due to be checked at random each month, however we found the number of patient records fluctuated from month to month. For example, in April 2017 only two records were checked and in May only one record was checked. This was not in line with Fresenius policy.
- Areas covered in the audits included the documentation of the patients' care pathway, consent forms, medicine charts, and personal emergency evacuation plans. The June 2017 audit highlighted manual handling and drug therapy charts needed updating and medicine prescriptions charts did not have patients name and NHS number. All actions were passed on to the named nurse to complete. During the inspection we saw the actions were completed.

Pain relief

- Any issues identified with pain were discussed initially with the nursing staff that escalated concerns to the consultant. Patients who required an urgent review for pain management were referred to their General Practitioner (GP) or the consultant depending on the severity of the pain.
- If patients required a short term local anaesthetic to support the insertion of the dialysis needles, a prescription would be required. None of the registered nurses (RN's) were trained in non-medical prescribing at the unit. Therefore, the RN would contact the renal

registrar at the NHS renal unit where a prescription would be faxed, scanned, or emailed to the unit. This would be followed up by a written prescription the following day.

- Any patient requiring long term local anaesthetic for the insertion of the dialysis needles would attend their GP and get a local anaesthetic cream prescribed that helps to numb the skin. This would be administered by the patient prior to coming to the unit.
- We saw paracetamol was prescribed as an 'as required' medicine in prescription charts to support patients who may develop a headache or pain at the site of the needles during dialysis. By prescribing paracetamol, pain management could be delivered in a timely manner by the nursing staff.
- Staff told us no pain management tool was in use within the unit to access any patient's pain levels.

Nutrition and hydration

- Patients who have renal failure require a strict diet and fluid restriction to maintain a healthy lifestyle. We were told patients were reviewed by the dietitian every three months. Advice would be given regarding any changes needed in their diet. This was followed up with written patient information. Staff told us the dietitian would be informed if patients had any dietary preferences, religious requirement, or renal bone disease (a disease which occurs when kidneys fail to maintain proper levels of calcium and phosphorus in the blood).
- Staff screened all patients for malnutrition and the risk of malnutrition on admission, using the Malnutrition Universal Screening Tool (MUST). MUST was documented within the integrated care pathway records. We reviewed three sets of medical records, which showed these had been completed correctly. This is in line with NICE QS 24, statement one. This standard states 'People in care settings are screened for the risk of malnutrition using a validated screening tool.'
- Patients were provided with hot drinks and biscuits during their dialysis treatment.

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- Patients were encouraged to bring in their own appropriate food to their dialysis treatment sessions if they preferred. Diabetic patients were closely monitored throughout treatment and encouraged to bring food along to support them during treatment.
- Patients weighed themselves before treatment each day. This was compared with the patient's dry weight which was used as a base line. Weight above the dry weight was removed during treatment. We observed staff talking to patients about the amount of fluid that would be removed during the treatment and asking patients if they were happy with the amount. Too much fluid removed can cause the patient to drop their blood pressure during treatment.
- The staff told us they encouraged patients to regularly measure their fluid output balances. This was to support patients on the amount of fluid intake per day in order to prevent fluid overload.

Patient outcomes

- Clinical outcomes for renal patients on dialysis can be measured by the results of their blood tests. Quality assurance meetings took place monthly to review all patients' blood results, progress, and general condition with the consultant and clinic manager. All changes to treatment parameters or referrals to other services were coordinated by the clinic manager and reported to the clinical staff for further action. Outcomes and changes were discussed with all patients by their named nurse and dietician. Results were collated on the NHS trust and Fresenius computer database used at the unit. They provided customised reports and trend analysis so changes could be made to patient's treatments to meet national standards.
 - Key performance indicators had been developed from the Renal Association module 2: clinical practice guidelines for haemodialysis. Fresenius had set targets relating to optimising patient conditions and experience, which included the effective daily treatment times being equal to or greater than 240 minutes. In April 2017, 62.07% of patients achieved these daily treatment times, in May 62.7%, June 63.72% and in July it rose to 67.59%. The target set for this quality standard was set at 70% ,data shows the unit was slightly below this standard. Treatment times are one of the variants that contribute to dialysis adequacy.
- Patients' pre dialysis haemoglobin concentration should be maintained between 10 and 12g/dl. The target set by Fresenius was 70% of the patients should sit within the range. In April 2017, 78.10% was achieved, in May 77.78%, June 77% and July 75.68%. All of which were better than the target set. It was difficult for the unit to influence these figures as these were prescribing decisions which were made at the NHS trust.
 - Dialysis is necessary to remove waste products such as urea from the blood. To see whether dialysis is removing enough urea, the patients' blood was tested to measure dialysis adequacy. This is called the urea reduction ratio (URR) meaning the reduction in urea as a result of dialysis. Renal Association Standards recommend all patients should achieve above 65%. In April 2017 the unit achieved 100%, May 95.33%, June 91.2% and July 94.4%. This demonstrated the unit was performing better than the standard and patients were achieving good dialysis to improve the health of the patient.
 - The unit also measured the Kt/V (indicates the amount of blood cleared of urea) which is another way of measuring the effectiveness of dialysis. The UK Renal Association guidelines state for patients who receive haemodialysis three times a week, each treatment should achieve an Kt/V equal to or greater than 1.2. We reviewed the data submitted and saw that in April 17, 95.79% of patients achieved the required value. In May 17, 93.55% and in June 17, 95.79% of patients achieved the required value.
 - The pre dialysis serum phosphate level in the blood should be between 1.1 and 1.8 mol/l. The target set by Fresenius was 75% of patients should sit within this range. We reviewed the data and saw in April 2017 (54.3%), May (51.8%), June (52%) and July (40.54%) patients sat within this range with the majority of patients slightly above or below this range. This had resulted in discussions between the consultant and dietician around talking to patients about their diet and prescribing medicines as this level can be influenced by the patient diet.

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- Ferritin (blood cell protein that contains iron) levels in the blood must sit between 200-800ng/ml. Data confirmed in April 2017 (76.2%), May (73.15%), June (78%) and July (72.97%) of patients sat within this range improving patient outcomes. Patients outside this range would have their levels re-evaluated at the monthly quality meetings.
- A high level of potassium in the blood (called hyperkalaemia) is unpredictable and can be life-threatening. It can cause serious heart problems and therefore needed to be monitored to ensure patients do not have acute rises in potassium levels. Potassium levels in the blood must therefore sit between 4.0-6.0 mmol/l. We reviewed data and saw in April 2017 (89.5%), May (87.9%), June (84%) and July (86.4%) of patients sat within this range. Patients outside this range had a discussion with their named nurse to discuss ways to reduce the level, for example an additional dialysis session to remove the high levels of potassium.
- On a weekly basis patients' vascular access site was monitored and maintained to minimise failure. This was in line with national guidance. We saw data that confirmed in April 2017, vascular access management achieved 73.8%, this was slightly below the target set of 76%. An escalation policy was in place to address any vascular access issues. All staff we spoke to were aware of the procedures to follow.

Competent staff

- Staff in the unit had the relevant qualifications and memberships appropriate to their position. We saw data that confirmed all registered nurses had their Nursing and Midwifery Council registration. There were systems which alerted managers when staff's professional registrations were due and to ensure they were renewed. We reviewed the records which confirmed all professional registrations were up to date.
 - All staff were supported by the Fresenius regional head nurse and the clinic manager to ensure the maintenance of standards and competence.
 - All new staff completed an induction programme. We saw there was a structured programme in place.
- During our inspection we looked at four induction records and they were completed. This demonstrated the unit made sure new staff had all the information and competencies needed to do their jobs.
- All staff on the unit completed competency assessments to ensure they had the skills and knowledge to carry out the roles they were employed to do. For example, staff involved in the dialysis of patients had to complete various additional competencies such as 'demonstrating venous access' and 'competency document for registered nurses experienced in the field of haemodialysis'. Staff were encouraged to undertake continuous professional development (CPD), and were given opportunities to develop their clinical skills and knowledge through training relevant to their role. We saw evidence of this in staff appraisal records, such as applying for a mentorship or renal course, or attending study days.
 - During our inspection we looked at four CPD folders for staff on the unit. We saw the folders were tidy and well organised with a standard approach. This meant staff and managers could easily find certificates or competencies. We saw mandatory training was up to date and each staff member had an individual training matrix.
 - However, we saw the competency assessment document for dialysis assistants, who were able to administer anticoagulants (a medicine that thins the blood), were not fit for purpose. The competencies referred to a medicine which was no longer in use on the unit. Although this had been crossed through on some and the correct medicine written, this was not present on all competency assessments. This meant the unit could not provide assurance all dialysis assistants had been trained as competent at giving the correct anticoagulant. We told the manager, who told us they would review the document and ensure the correct medicine, or space to write the correct medicine was in place.
 - The unit had systems for supporting staff with learning and development. Data provided by the unit showed 100% of staff had an appraisal within the last 12 months. Yearly appraisals identified areas for development and an agreed timescale for completion. For example, these included future learning such as attending internal or external study days, or future

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career aspirations. This meant the service was able to address any potential staff performance issues. During our inspection we looked at six appraisals records for staff at the unit and found they were up to date and completed. In addition, where appropriate there was a six-month review to assess performance.

- All registered nurses (RN) had recorded validation of professional registration. This meant the unit conducted annual checks to ensure all the nurses were registered with the Nursing and Midwifery Council (NMC).
- The clinic manager told us that two RN's had attended an external renal course with one RN in the process of applying for the course. This meant that two members of staff had developed specialist knowledge in the care of renal patients. Two other RN's had attended the Fresenius three month renal course.
- One RN told us Fresenius supported attendance at a mentorship course and extra modules on the renal course to learn about peritoneal dialysis and transplantation.

Multidisciplinary working

- The local commissioning trust provided all the specialist support for patients. This included the consultant, dietician, and vascular access team. Staff told us there were good lines of communication between the unit staff and the local commissioning trust.
- Monthly multidisciplinary team (MDT) meetings took place at the unit. The trust consultant and clinic manager attended these. During the MDT patients' most recent blood results and medicines were discussed and recorded in the electronic patient record along with any current care needs. We reviewed three sets of electronic records and saw all care records had been updated following the MDT.
- The dietician visited the unit every three months following the monthly bloods. This allowed discussions to take place around the patient's diet if necessary. Any verbal guidance given by the dietician would be followed up by written information which allowed the patient to read and refer to the information at their leisure.

- We observed within the unit, all staff worked collaboratively and well together to promote the health and well-being of the patients.
- The clinic manager told us no physiotherapist visited the unit. Exercise during dialysis can improve the wellbeing of the patient.

Access to information

- All information needed to deliver effective care and treatment was available to staff through either electronic or paper records. Fresenius had an electronic system which staff used to enter all the patient information related to the care and treatment delivered. The dialysis machine information would be automatically sent to the electronic system via a patient identifiable card placed in the dialysis machine at the beginning and end of the treatment.
- We were shown the Fresenius electronic system and saw information recorded included the nursing update notes of the daily review of the patient including any health issues, assessment of the vascular access and treatment parameters including pump speeds, arterial and venous pressures. This ensured up to date care and treatment parameters were recorded.
- All staff at the unit had access to the local commissioning trusts electronic system. There was a confidentiality agreement between Fresenius and the local commissioning trust allowing Fresenius authorised staff access to their system. All patient information was visible to the multi-disciplinary team. All registered staff involved in delivery of patient care could access blood results, view clinic records, and monitor progress of the patient.
- On the nursing station, staff held a daily diary. This was a form of reference for all staff and held patient individualised treatment requirements for the sessions. For example, information on changed sessions, if bloods were required and why and any other relevant information. Staff could read the diary prior to their shift to update themselves prior to handover as well as add to the diary. One staff member told us they would read the diary and ask the nurse in charge if they had any queries.

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Consent, Mental Capacity Act and Deprivation of Liberty

- Fresenius had a consent policy in place. Consent to treatment means a person must give their permission before they receive any kind of treatment or care. An explanation about the treatment must be given first. The principle of consent is an important part of medical ethics and human rights law. Consent can be given verbally or in writing.
- In the six patient records we reviewed, all patients had been consented for their dialysis treatment when they started treatment. We saw Fresenius consent forms. Written consent was a one off process and covered dialysis treatment along with the risks and benefits associated with the treatment.
- Staff we spoke with, on the unit were aware of the consent policy and the correct procedures to ensure patients gave valid verbal consent prior to treatment. We observed a RN placing the patient on treatment; we observed the RN checked the patient's identification asking for their date of birth. During all the observation, we heard nursing staff ask patients if they were ready to be prepared for treatment. This was taken as verbal consent.
- All staff received training in the requirements of the Mental Capacity Act (MCA) 2005 as part of their mandatory training. MCA training was 100% compliant. However, we saw no routine mental capacity assessments on the patient records we reviewed.
- On the electronic patients records we saw on the opening screen on the top right hand side it stated whether a patient had an active do not attempt cardio-pulmonary resuscitation (DNA CPR) order in place, this alerted staff that a DNA CPR was active. Staff told us DNA CPR's were discussed at handover and this was confirmed when we observed the nursing handover during the inspection.
- We saw patients signed their care records. This included, but not limited to, consent to treatment, data protection information (including what we hold, how we use patient data and disclosing to a third party), and a section for advanced directives and do not attempt CPR orders (DNACPR). We saw these were completed in the three patient records we reviewed.

- We found In one further patient record, a DNA CPR order that was completed on a St Helier's DNA CPR order. On reviewing the Fresenius, Do not attempt cardio-pulmonary resuscitation (DNACPR) policy number UK-CL-09-43, a universal order should be used at satellite dialysis unit, and not the trusts DNA CPR order.

Are dialysis services caring?

Compassionate care

- We observed the staff on the unit being kind, caring, and compassionate towards their patients. All patients we spoke with told us staff always introduced themselves, were polite. We observed staff escorting patients into the treatment area, helping patients on to the treatment chairs and communicating with the patients as they went.
- During the inspection one patient told us "they received good care and all staff were kind," this was confirmed by another patient who told us "the care was excellent and staff were very kind and would solve any issues they raised with them."
- Patients felt pleased and respected as they were involved, supported, and encouraged to be partners in their care and decision making. This commenced at the consultation meeting with the consultant and continued through to treatment. Support was available across the renal pathway.
- Staff understood patients' personal, cultural, social, and religious needs. We saw these were taken into account when planning treatment. For example, patient's dialysis sessions were planned around their work, social events, and hobbies.
- Patients received treatment in shared areas; however curtains were in place if a patient wanted privacy such as being connected to the machine.
- We reviewed 'tell us about your care' comment cards we had sent to the unit to be filled in by patients before our inspection. Out of 17 cards, 13 were positive (76%), and four cards (24%) had negative

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comments. The negative comments related to transport, the air conditioning system, and an inadequate waiting area where patients wait on their arrival and departure following treatment.

- The positive comments included, “the staff are very good, they are always friendly and happy”, “staff are very polite, and they listen to you with respect and give the right advice” and, “I have only had good experiences on a weekly basis.”
- Nursing staff maintained patients comfort using additional pillows, pressure relieving aids and if necessary a hospital bed. We saw when patients felt cold during treatment a blanket was offered.
- We saw in the National Patient survey 2016, 80 patients took part in the survey with a response rate of 65%. Data showed 83% of patients had confidence in the nurses with 79% saying they would recommend this dialysis unit to their friends and family in need of dialysis. In addition, 96% of patients felt the atmosphere in this dialysis unit was friendly and happy.

Understanding and involvement of patients and those close to them

- Each dialysis patients had a named nurse who fed back patients treatment plans and clinical results including the blood test result and MDT outcomes. It meant patients had a consistent point of contact and would help staff to deliver consistent care. We saw staff speaking with patients about their treatment and blood results.
- When patients were initially referred to the unit they could visit the unit with a family member or friend for a look around. Fresenius had developed a ‘Patient guide’ which included information regarding blood tests, living with haemodialysis, vascular access, hygiene and infection control, diet and health and safety. Patients were given the guide at the beginning of treatment; this allowed them to read the information in their own time.
- Nursing staff told us they saw their patients frequently and they were familiar with how they were feeling on

the day and were able to identify when patients were having a bad day or were feeling unwell. This allowed staff to give the necessary support or make a referral to the appropriate healthcare professional.

- Staff encouraged patients to take responsibility for parts of their treatment, such as weighing themselves prior to dialysis, undertaking blood pressure, measuring their temperature, and preparing the machine. Staff told us one patient was on the self-caring programme which allowed the patient to line and prime the machine prior to treatment. Patients on the self-care programme were taught by the specialist nurse at St Helier’s. Nursing staff told us patients liked to have some control over treatment and it gave them a sense of independence.
- All patients were reviewed by the consultant and dietitian who enabled discussions of any concerns, medicines, treatment changes, and plans for different dialysis. Patients told us they saw the dietitian regularly and were given advice on diet and fluid allowances. The information given allowed them to plan their diets and take responsibility to ensure they remained well while on dialysis.
- Patients told us they received consultant reviews. These would take place either in clinic upstairs or whilst having dialysis. However, two patients felt the consultant reviews were infrequent and would prefer more frequent reviews.
- Patients we spoke with told us staff discussed their treatment and any changes with them. Patients felt comfortable to approach staff and ask questions.

Emotional support

- Patients were supported by the nursing staff to access support and additional services as necessary. Patients had access to a social worker and psychologist. Staff told us if they identified any person with an emotional issue, they referred them to the consultant, who then referred patients to the psychologist. Patients with financial or social issues were referred to the renal social worker for support.

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- Staff were aware of the impact dialysis had on a patient's wellbeing, and staff supported patients to maintain as normal life as possible. Staff encouraged patients to continue to go on holiday, and participate in the management of their treatment.
- We saw the 'Patient Guide' provided details of national and local support networks for patients and their loved ones. This included organisations such as the British Kidney Patients Association and the National Kidney Federation who undertake social events, and support networks for patients and their loved ones.

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

Service planning and delivery to meet the needs of local people

- Dialysis services were commissioned by NHS England. The service specification for the unit was defined by the local commissioning trust and commissioners. Patients were referred to the unit by St Helier's Hospital renal team. Monthly contract meetings took place between the hospital renal team and Fresenius to discuss and monitor the service delivered against the defined specifications. In addition, through the collection of key performance indicators and quality outcomes.
- Patients who required dialysis in the West Byfleet area were assessed by St Helier's renal team where the suitability to dialysis in a satellite unit was decided. Patients who were stable and fitted the referral criteria were then referred to the unit. The unit had capacity to expand the number of patients attending and the times of session available if necessary following the necessary recruitment programme.
- The unit consisted of three main areas on two levels. The reception and waiting area, dialysis treatment room and services corridor were on the ground floor with the clinic rooms on the first floor. Each area was secure with electronic pass access. Patients arriving in the reception were required to be buzzed in through a secure door into the waiting area and then through another buzzed door into the treatment area. The service corridor contained all treatment storage, water room, maintenance room, kitchen, and dirty utility room.
- The unit offered a holiday dialysis programme. The local commissioning trusts holiday co-ordinator would assist patients to find a clinic near their holiday lodgings with patients contacting the holiday clinics to arrange possible dates. Locally the clinic manager and the holiday co coordinator would make arrangements with the receiving holiday clinic around the treatment parameters, bloods, and medicine delivered to ensure treatment remained consistent and the receiving clinic had all the necessary information.
- Nursing staff were aware of the process for receiving patients on holiday and told us there was a process in place to ensure their safety. This included treatment in a side room, the taking of regular bloods. In addition patients were placed on the electronic management systems so if a patient review was required by the consultant this could be undertaken in a timely manner with all the up to date patient information and treatment data.
- Facilities were available at the unit to treat bariatric patients. This included beds and chairs which could support the patients and larger blood pressure cuffs. The couches were suitable up to 220 kilograms, which meant that patients over this weight would be treated at the local commissioning trusts renal unit.
- The clinic manager told us that no interpreters were available at the unit however; access to an interpreter could be made via the local commissioning trust. Staff described using family members if necessary, although this is not considered good practice within the healthcare setting. One staff member told us if the patients first language was not English they usually just managed by the patient understanding simple questions and some staff could support by speaking other languages.
- Patients who were admitted to hospital for more than three weeks were discharged from the dialysis unit. When the patient was well enough to be referred back to the unit the patient would be referred back.

Access and flow

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- Patients were assessed for their appropriateness to attend the unit by the local commissioning trusts renal team. Patients with acute kidney disease were treated at the local commissioning trust and only chronic, long-term dialysis patients were referred to the unit for treatment. The referral to the unit was completed by the renal matron who contacted the clinic manager informing them of the patient. The clinic manager would conduct a review of the patient prior to attending the unit and would allow one week between a referral to admission to ensure all systems were in place to support the safe care of the patient.
- The unit's present capacity was 120 patients. At the time of the inspection 113 patients were receiving treatment at the unit. We reviewed data submitted and saw that in the last 12 months 16,236 treatments were delivered.
- The unit reported no cancelled dialysis sessions in the preceding 12 months. The total number of planned dialysis sessions delayed for a non-clinical reason was zero. This meant no patients had to have their treatment re arranged at another unit
- The majority of patients attended the unit for treatment on a morning, afternoon and evening shift on set days, for example every Tuesday, Thursday, and Saturday mornings. Patients we spoke with told us that they had some choice in when they attended and could get their appointment slot re scheduled if they had an appointment or family occasion.
- Staff told us patients daily waiting time was kept to the minimum; however, this was not audited and we did not see any evidence to support this. Appointment start times were staggered to reduce waiting times. No patient's we spoke with complained they had to wait long for treatment.
- The majority of appointments with the consultant or dietitian were scheduled for the same day as patient's dialysis sessions to prevent multiple attendances at the unit. However, in some circumstances appointments would occur on non treatment days which is a concern for patients having to attend the unit over four days.
- If capacity allowed the unit would accept patients for dialysis who came to the area while on holiday. The unit would request information and tests, such as testing for HBV, to be done prior to the patient being accepted at the unit. When patients were referred to the unit, the consultant and multidisciplinary team would review the shared information to identify whether the patient was suitable to be treated at the satellite unit.
- Although the unit did not have their own holiday coordinator, staff were able to describe the process for organising patient to have dialysis away from base . All requested information and tests, such as testing for Hepatitis B virus (HBV) would be sent or be performed prior to the patient leaving for their first dialysis session.
- The unit provided information in formats which supported and reflected cultural diversity with the patient guide available in a number of language options.
- The unit was open from 6.30am to 23.30 pm Monday, Wednesday, and Friday. On a Tuesday, Thursday and Saturday the unit closed at 6.30pm. There was three 'treatment sessions' of patients dialysed on Monday, Wednesday and Friday, with 24 patients dialysed in the morning, afternoon and twilight shifts. There were two 'treatment sessions' of patients dialysed on Tuesday, Thursday and Saturday, with about 24 patients dialysed in the morning and 20 patients dialysed in the afternoon. Twilight sessions allowed many patients to continue to work while receiving treatment.
- All clinic letters were sent to patient's General Practitioner (GP) by the consultant. Any urgent advice and referrals made between clinic appointments would be made to the Renal Registrar at St Helier. Fresenius provided clerical support and phlebotomy at these clinics. By having these clinics in the unit, patients were able to access care close to home. It also allowed patients to start to develop a relationship with the unit prior to starting treatment.
- The unit provided disabled access, wheelchair accessible toilets inside and outside the clinical area

Meeting people's individual needs

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and a selection of mobility aids. We saw hoists were available for patients who could not transfer and wheelchairs were used to assist patients to and from their transport.

- Patients had access to a personal television and Wi-Fi during their dialysis sessions. We observed some patients slept during their treatment where as some were using computers and tablets to pass the time during their treatment.
- The unit was able to support patients who needed to rearrange their treatment days in order to attend appointments or family events. Alternative appointments were arranged following a review of the available sessions and staffing numbers.
- At the back of the unit parking slots were reserved for patients attending the unit. This allowed patients to park close to the unit with minimum distance to walk. We saw the ground was uneven and in poor repair. This would make wheelchair access difficult. No CCTV was available at the back of the building. This meant if the patient fell or needed help staff may not be aware.
- NICE quality standards (QS72- standard 6) indicate adults using transport services to attend for dialysis are collected from home within 30 minutes of the allotted time and collected to return home within 30 minutes of finishing dialysis. The quality standard indicates dialysis providers should collect evidence at unit level to ensure the standard is being met. We were unable to view this data at the inspection as transport was the responsibility of local commissioning trust. Any problems with transport would be reported by the unit secretary to the transport manager. The nursing staff would complete a non clinical incident report.
- Nursing staff would ask patients to attend their GPs if they identified any medical or social needs to ensure patients kept a healthy life style.
- Staff told us adjustments could be made for someone living with learning disabilities or dementia; this could result in a carer being in attendance during treatment.
- Nursing staff told us patients could attend the toilet during their dialysis sessions if they requested. This

would require the patient to be disconnected from the dialysis machine briefly and then be reconnected. However, this was uncommon as the majority of patients had reduced urine output.

- No 'hearing loop' was available if patients were hard of hearing. These meant systems were not in place to support the hard of hearing which could result in poor communication between staff and patients.
- Patients receiving treatment in the open area could request the closing of the curtains should they wish privacy from the other patients. For example, when accessing central lines in private areas of the body and in case of an emergency.
- Staff told us patients would sit on the same chair within the same bay, for the majority of the time. These meant patients could build friendship groups with the people they sat with.
- A link nurse was responsible for the monitoring of patients vascular access sites. Any issues were discussed with the vascular access team at the local commissioning trust. A protocol was in place for the monitoring of vascular access.

Learning from complaints and concerns

- People we spoke with told us they felt happy to complain to the nurse in charge or the nurse caring for them. Staff told us verbal complaints would be discussed at handovers.
- We saw Fresenius Medical Care Renal Services Ltd had a 'Feedback policy' which set out how compliments, comments, concerns, and complaints were dealt with. The clinic manager was responsible for the management of complaints within the unit. The Clinic Services Director ensured all complaints were discussed at the Clinical Governance meetings to identify where service improvements were required across the services.
- In the last 12 months data showed six complaints had been received through the formal complaints system. Five complaints had been upheld. All complaints received were categorised into topics, these included transport, quality of care, staff attitude, unit management and others. We reviewed the data and saw solutions were put in place to solve the issues.

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- In the last 12 months the unit had received nine formal written compliments. The majority were thanking staff for their care and compassion when caring for a relative at the unit.
 - Staff were able to explain clear processes were in place for the management of complaints this included informal complaints made verbally by patients and formal written complaints. When a patient raised a verbal concern and before the process was formalised, methods would be employed to try and resolve the situation and quickly as possible. This included meeting with key people to discuss the concerns. FMC also monitored the number of complaints centrally. Each dialysis unit that had a risk profile and the number of complaints was one of the indicators.
 - We were unable to determine if the unit responded to complaints in line with the FMC complaint policy. We reviewed the complaints log and found the date the unit responded to the complaint was not always recorded or was unclear
 - We saw 'Tell Us What You Think' leaflets were available in the patient waiting area to encourage patient comments, concerns, or compliments. We saw in the 'Patients Guide' a section described what the patients could do if they wanted to complain. As all patients were NHS patients they were also signposted to the local commissioning trust's Patient Advice Liaison Service (PALS) and complaints management system to raise any issues around the care and treatment they had received. This meant patients had the information available to them to raise a concern.
- services, financial and human resource directors, as well as a medical adviser. At a local level, West Byfleet Dialysis unit had a regional business manager and area head nurse who supported the unit. The area head nurse attended unit meetings, supported new staff, provided training such as simulation training and worked closely with the clinic manager.
- The clinic manager welcomed the support of the head nurse and described a good working relationship.
 - There was a clear management structure which staff were aware of at the unit. This meant leadership and management responsibilities and accountabilities were explicit and clearly understood. The clinic manager had support from the deputy clinic manager, nursing staff, dialysis assistants, healthcare assistants and a receptionist. All staff had the skills, knowledge, and training to deliver specialist care and treatment.
 - All staff we spoke with thought their line managers and regional business manager were approachable and supportive. Staff told us the senior management team (SMT) would visit the unit, at least once per month, to deliver training and could be approached with any concerns or queries. Staff were confident managers had the skills; knowledge, experience, and integrity they needed to lead the service.
 - The clinic and regional business manager appeared knowledgeable about the service users' needs, as well as their staff needs. One staff member told us the regional business manager visited the unit and felt they could raise issues with them if necessary. Managers, we saw were committed to their roles and responsibilities.
 - Staff told us the unit was a good place to work, everyone was friendly, they had sufficient time to spend with their patients, and they were proud of the work they did. One staff member told us they felt very supported by the line manager as they were very helpful.
 - Staff told us they could contact the consultant, renal registrar on call and lead renal nurse at St Helier's renal unit via email or telephone. All were responsive to requests and provided support when required.

Are dialysis services well-led?

Leadership and culture of service

- Fresenius Medical Care Renal services leadership priority was to ensure the delivery of safe, high quality care for patients with each dialysis unit operating within a defined management structure from a local, regional, and national perspective. This structure was designed with leadership, governance and culture at its heart in order to maximise the delivery of high quality person-centred care.
- The national organisational structure included a managing director, director of nursing, clinical

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- The unit had two vacancies for dialysis RNs at the time of inspection. One dialysis RN had left the service and one had joined the service in the previous 12 months.
- There were no vacancies for dialysis assistants and two vacancies for health care assistants (HCA's) at the time of the inspection. Five HCA's had joined the service in the previous 12 months increasing the establishment of HCA's.
- The average of sickness absence over the three months before inspection was five percent for dialysis nurses and zero percent for dialysis assistants, and HCA's. The national average sickness is between 3 and 4% so the unit was performing well against the national average for dialysis and HCA's and not so well for dialysis nurses.

Vision and strategy for this core service

- The Fresenius corporate vision was to create a future worth living for dialysis patient's world-wide every day. Fresenius's values were stated as: quality, honesty and integrity, innovation and improvement, and respect and dignity. Staff we spoke with were aware of the organisation values.
- Staff we spoke with were aware that achieving high standards and ensuring patients' treatment was effective, was a key strategy for the unit.
- Fresenius had set objectives for the organisation and units to achieve. We reviewed the 2016 template and saw objectives around the patient; employee, the community, and the stakeholder were set along with evidence of progress and a completion date. We saw all objectives had been meet.
- An information board highlighting the company commitment to patients, staff, shareholders, and community was on the wall in the patient waiting area.

Governance, risk management and quality measurement (medical care level only)

- Fresenius Medical Care had a governance framework which ensured an effective organisational structure that supported the delivery of services and minimised the risks across all areas of business. We saw a clinical governance committee met every month and the attendees included the clinic manager. Their role was to monitor and lead on the delivery of an effective governance and quality process in the unit.
- The staff within the unit were supported locally by an area head nurse whose key responsibility was to monitor the performance of the unit. Clinic reviews formed a critical part of the monitoring process and were based on key performance indicators. These clinic reviews provided the forum for discussions culminating in actions plans for continuous improvement which fed into local clinic staff meetings and quality assurance meetings with the consultant nephrologist.
- The service used a corporate and clinical governance framework and had plans in place to move to an integrated governance framework. The incident reporting fed into the clinical governance framework and clinical review process. Clinical incidents were monitored centrally with clinical update. Learning bulletins were sent by the chief nurse to ensure learning was shared with staff across the organisation.
- Fresenius had a quality management system in place, ISO 9001. The quality policy puts the patient at the core of what they do, which links to their four key objectives, patients, shareholders, the community and employees. All internal policies, procedures, and processes were reviewed on a regular basis. Staff were trained on the procedures, local audits were performed, and that corrective and preventative measures were taken when incidents, accidents, errors, or concerns were identified with clear instruction on escalation and reporting principles. We reviewed the objectives action plan for West Byfleet and found the majority of objectives had been implemented by the unit within the set time scale.
- Fresenius had a risk management system in place. All risks contained a risk rating and subsequent mitigating actions. Risk Assessments for service users, staff, facilities, and equipment were undertaken. The risk assessments were developed in line with national guidelines, updated and relevant training provided. We saw evidence the risks were reviewed regularly by management and they were working towards mitigating the risks. The clinic manager told us there was nothing on the risk register that was very worrying. Most risks were controlled except for staffing.
- We saw there was a local risk register in place for West Byfleet dialysis unit. The loss of water and staffing

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were two items on the risk register at the time of the inspection. All risks were discussed every three months with the regional business manager. Staff we spoke with had a good understanding of what a risk was. They were clear who they would raise this with, that it would be acknowledged and action taken.

- The clinic manager told us regular meetings took place with the renal matron and lead consultant at the local commissioning trust and the Fresenius area manager. The meeting took place every three months and areas discussed were key performance indicators such as the number of patients on treatment, number of missed treatments, shortened treatments, and number of slots available. This kept the local commissioning trust up to date on the care of their patients and whether the contract in place was being met.
- A contract review meeting was in place to discuss the contract and any governance issues. We reviewed the minutes of the December 2016, January and February 2017 meetings and saw areas discussed included audit results, safeguarding, case reviews, and patients who had recently died. We did not see that risks, incidents or complaints were discussed which would give the attendees an overview of the safety of the services being provided.
- Patients' data and outcomes were submitted to the renal registry by St Helier's renal team. The data was not individualised per unit.
- The clinic manager had regular contact with the renal matron and the consultants around the care and treatment of the patients. A clinical dashboard measured a range of key performance indicators. Staff we spoke with were aware of key performance indicators and the importance of them.
- A structured audit programme supported the unit to ensure patient quality and safety was at the forefront of service provision. These took place monthly. These included standards and delivery of patient care through nursing records, infection control, patient experience which were in line with national guidelines and the National Service Framework. Where there was a need to improve processes an action plan was put in place. Actions were monitored locally. These ensured lessons could be learnt and actions would be

completed. We saw audits were discussed at the clinical governance meeting to ensure all senior renal staff at Fresenius and the local commissioning trust were updated.

- The clinic manager told us standard operating procedures and policies were a combination of Fresenius and local commissioning trusts policies and procedures. For example Fresenius policies included the medicines management policy (effective 2013) and complications, reactions and other clinical event pathway. For blood transfusions, the educational nurse from the trust would undertake face to face training and complete the competencies. The unit would follow the trusts policy. One registered nurse told us two blood transfusions had taken place on the unit since January 2017. The educational nurse supervised the first transfusion with a team leader supervising the second infusion. This showed that staff managed the risk effectively through collaborative working.

Public and staff engagement

- The aim of Fresenius was to learn from user and staff feedback to improve their service. Annual patient and employee satisfaction surveys were undertaken and the results were implemented in order to continuously improve. We saw in the patient handbook patients were encouraged to make comments about the service. In the waiting area we saw a complaints and concerns suggestion box where patients could place comments.
- A patient's newsletter was available to keep patients updated on what was happening on the unit. We saw a copy of the newsletter in the waiting area. It answered patient queries which included asking patients to talk to their named nurse should they have a query, remember to wash their fistula arm before treatment and to put their shoes on to walk about. These ensured patients were kept up to date on what was happening on the unit and direct patients around safe care.
- In November 2016, a Patient Satisfaction Survey was completed with a response rate of 65%. Areas to review and improve upon included: increasing patient knowledge of haemodialysis and haemodiafiltration,

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dialysis adequacy, dialysis access care and patient awareness of who to contact in case of questions and concerns. We reviewed the 2016 action plan and saw the unit were addressing the issues raised.

- Prior to patients starting dialysis treatment at the unit, patients were invited to come to the unit with family members to look round and ask any questions they may have to alleviate any fears. This would help patients to come to terms to this life changing procedure they were about to go through.
- Fresenius completed annual staff surveys and staff could raise issues at staff meetings which took place monthly. In the November 2016 annual employee satisfaction survey, there was a response rate of 94%.The following items were listed as some of the areas to review and improve upon: initiating improvements in our dialysis unit, staff satisfaction with the level of pay, experience of discrimination,

harassment, bullying or abuse at work from patients and involvement of staff in important decisions. The areas for improvement and review had been implemented in an action plan.

- Staff told us there were no staff awards or any Fresenius conferences to attend. However some training was face to face at head office which allowed staff to meet other staff from other units.

Innovation, improvement and sustainability

- The service promoted recycling and minimising waste. The clinic manager collected monthly figures of waste reduction and electricity and water savings. This highlighted the need to ensure leaks were reported promptly and unused lights and computers turned off.
- The unit had an ISO accredited Integrated Management System (9001) which ensured all policies and procedures supported best practice evidence. This was reviewed annually to provide assurance the evidence base was current.

Outstanding practice and areas for improvement

Outstanding practice

We saw a good working relationship between all staff and an inclusive partnership with patients.

Areas for improvement

Action the provider **MUST** take to improve

The provider must ensure two members of staff check ampules of sodium chloride (0.9%) and are both available at the point of administration.

The provider must ensure competency assessments for the administration of anticoagulant medication, by dialysis assistants contains the correct medication.

The provider must ensure the unit has a sepsis pathway and tool kit for managing suspected infections, and sepsis.

The provider must deliver level 2 children's safeguarding training to all staff and level 3 to the unit manager.

Action the provider **SHOULD** take to improve

The provider should ensure personal emergency evacuation plans are regularly reviewed, to ensure information about the patient is accurate in the event of an emergency.

The provider should ensure the nursing documentation audit is completed consistently and the standard 10% of records are checked monthly.

The provider should improve the internal décor of the building to prevent the storage of dust and dirt and allow good cleaning practices.

The provider should ensure the chairs in the first floor waiting area are made of wipe-clean materials.

The provider should ensure that the bulk storage area is kept locked and the bulk storage bins within the area are locked at all times.

The provider should ensure waste bins are labelled correctly to prevent the potential for waste not to be properly segregated.

The provider should complete Mental Capacity assessments on admission or when required.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>12 (2) (g) the provider must ensure the proper and safe management of medicines.</p> <p>How this regulation was not met:</p> <p>We saw evidence of intravenous drug administration was not in line with Nursing and Midwifery Council (NMC) Standards for Medicines Management. This was because two members of staff were not available at the point of administration of the ampules of sodium chloride (0.9%) solution.</p>
Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>12(2) (c) ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely;</p> <p>How this regulation was not met:</p> <p>We saw some dialysis assistant's competency assessments for the administration of anticoagulant medication, did not contain the correct medication</p>
Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Treatment of disease, disorder or injury

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

12(2) (a) assessing the risks to the health and safety of service users of receiving the care or treatment;

How this regulation was not met:

The unit has no pathway or toolkit to manage suspected infections, and sepsis