

Hamilton Renal Dialysis Unit

Quality Report

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

Ratings

Overall rating for this location

Are services safe?

Are services effective?

Are services caring?

Are services responsive?

Are services well-led?

Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Summary of findings

Letter from the Chief Inspector of Hospitals

Hamilton Renal Dialysis Unit is operated by Fresenius Medical Care Renal Services Limited. Fresenius Medical Care Renal Services Ltd. is a subsidiary of Fresenius Medical Care SE and is responsible for the operation and management of dialysis centers in the UK and Ireland, in partnership with NHS trusts and purchaser groups.

The building is situated in a business park in Leicester, which was converted and opened in July 2010 as an independent unit providing haemodialysis.

The main referring unit is University Hospitals of Leicester NHS Trust. The unit primarily serves the communities of Leicester and Leicestershire. It also accepts patient referrals from outside this area.

The hospital has had a registered manager in post since January 2016.

The service was last inspected in June 2015 as a pilot inspection using the new methodology.

Summary of findings

Our judgements about each of the main services

Service

Dialysis Services

Rating Summary of each main service

Hamilton Renal Dialysis Unit is operated by Fresenius Medical Care Renal Services Limited. The clinic has 19 dialysis stations divided between three side rooms and four bays. Facilities also include a consulting room, isolation room, meeting room and patient kitchen. 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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Hamilton Renal Dialysis Unit

Services we looked at

Dialysis Services

Summary of this inspection

Background to Hamilton Renal Dialysis Unit

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The service was last inspected in June 2015 as a pilot inspection using the new methodology.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, Sarah Cooper.

The team included one other CQC inspector, a specialist advisor with expertise in renal dialysis, and an expert by

experience. An expert by experience is someone who has developed expertise in relation to health services by using them or through contact with those using them – for example as a carer.

Information about Hamilton Renal Dialysis Unit

Hamilton Renal Dialysis Unit is a nurse led unit and patient care follows a team nursing approach. The unit has one ward and is open from 6.15am to 11.45pm. Each session provides dialysis for 19 patients with chronic renal failure.

Hamilton Renal Dialysis Unit is registered to provide the following regulated activities:

- Treatment of disease, disorder or injury.

During the inspection we spoke with 13 staff including; registered nurses, dialysis assistants, reception staff, drivers and housekeeping staff. We spoke with 16 patients. We received one letter and 25 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed 12 sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12

months before this inspection. The service has been inspected once before in June 2015, which found that the service was meeting all standards of quality and safety it was inspected against at the time.

Activity (June 2016 to May 2017)

- The service delivered 16,416 haemodialysis sessions. These were all to NHS funded patients.
- At the time of inspection the service had 114 patients receiving care on a regular basis. All patients treated were over the age of 18. Of the 114 patients, approximately 50% were between 18 and 65 and 50% were over 65 years.

The unit employed 26 staff, including nine dialysis nurses, three dialysis assistants, one receptionist, a housekeeper and 12 drivers. If necessary the unit had access to the Fresenius bank of staff or a local agency.

Summary of this inspection

NHS consultants supported patients with their dialysis regime, and staff at the unit were able to contact renal doctors at their commissioning NHS trust any time of the day or week.

Track record on safety (June 2016 to May 2017)

- No never events were reported.
- Four clinical incidents were reported.
- No serious injuries were reported.
- One incident of healthcare acquired Meticillin-resistant Staphylococcus aureus (MRSA) was reported.
- Four incidences of hospital acquired Meticillin-sensitive Staphylococcus aureus (MSSA) were reported.
- Zero incidences of hospital acquired Clostridium difficile (C.diff).
- Two incidences of another bacteraemia
- The service received two formal complaints.

- A dietician visited weekly, a Fresenius dietician assistant visited twice a week and a consultant nephrologist also attended weekly.

Services accredited by a national body:

The provider had 'ISO 9001 quality management system' and 'OHSAS 18001 H&S' accreditation.

- The ISO 9001 quality management system is a standard based on a number of quality management principles including a customer focus and continual improvement.
- OHSAS 18001 is an Occupational Health and Safety assessment. It is an internationally applied British Standard for occupational health and safety management systems.

Services provided at the hospital under service level agreement:

- Cleaning service
- Dietician support
- Interpreting services
- Pathology and histology

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 renal dialysis services.

We found the following areas of good practice:

- Staff understood and fulfilled their responsibilities in relation to incident reporting and learning from incidents. We saw evidence of sharing of incidents throughout Fresenius.
- Staff training was monitored through a training matrix. Staff were supported by the clinical manager to attend training.
- Staff had an understanding of their responsibilities in regard to safeguarding and a knowledge of historic and current safeguarding concerns.
- The unit appeared visibly clean and demonstrated good compliance in aseptic non touch technique, hand hygiene and infection prevention control.
- Patient identification was performed before dialysis and administration of medicines.
- The environment was in accordance with building regulations.
- Records were contemporaneous and stored securely when not in use.
- Patient risk assessments were completed for all patients, however we did not see additional risk assessments if a patient had a unique risk.
- Plans were in place to respond to emergencies and major situations.

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

- A member of staff who had responsibility for mentoring others did not follow acceptable asepsis and needle safety procedures.
- During the announced inspection we identified that staff were not using the reporting documentation for emergency transfers via 999 calls appropriately.
- During the announced inspection staff were not completing dialysis summary patient assessment forms consistently.
- We found that all staff were out of date with their information governance training.

Are services effective?

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

We found the following areas of good practice:

Summary of this inspection

- Patients care and treatment was planned and delivered in line with current evidence based guidance, standards and best practice legislation.
- Patients had assessments of their needs including clinical needs, physical health, and wellbeing and nutritional needs.
- Care and treatment was regularly reviewed and updated.
- Information about people's care and treatment, and their outcomes, was routinely collected and monitored. This information was used to improve care. Outcomes for people who use services were positive, consistent and met expectations.
- Staff were qualified and had the skills to carry out their roles effectively and in line with best practice.
- Staff received appraisals and new staff completed appropriate induction periods.
- Care between professionals was co-ordinated with all teams involved in assessing, planning and delivering people's care and treatment.
- Staff had access to information from the service and the referring NHS trust.
- Consent to care and treatment was obtained in line with legislation and guidance. We saw evidence of staff gaining consent prior to care and treatment.

Are services caring?

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

We found the following areas of good practice:

- Feedback from people who use the service and stakeholders was positive about the way staff treated people. People were treated with dignity, respect and kindness during all interactions and relationships with staff were positive.
- People told us they felt supported and that staff cared about them.
- People were communicated with and received information in a way that they could understand.
- The allocation of a named nurse ensured patients were involved in their care.
- Staff responded compassionately when patients needed help and support.
- Patient's confidentiality and privacy was respected at all times.
- Staff had an awareness of the emotional impact of receiving care within the satellite unit.

Are services responsive?

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

Summary of this inspection

We found the following areas of good practice:

- Services were planned and delivered in a way that met the needs of the local population, a driver service and extended opening hours maximised patient access.
- Patients were supported to dialyse away from base if they wished.
- Facilities and premises were appropriate for the services being delivered.
- Where possible, dialysis sessions were organised to suit the patients.
- Waiting time was kept to the minimum.
- Link staff supervised vascular access and liaised with the NHS trust.
- Patients knew how to raise a concern or complain. Complaints and concerns were always taken seriously, responded to in a timely way and listened to.

Are services well-led?

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

We found the following areas of good practice:

- There was a clear understanding of the vision and values, driven by quality and safety.
- Staff felt supported by colleagues and described managers as visible.
- Clinical governance was managed at corporate level with information supplied by clinic managers.
- Risk registers and risk planning was under development at the time of our inspection.
- Working relationships with the referring NHS trust and the unit were good.
- There was a monthly review of the clinical dashboard to assess the unit's performance.
- The unit was proactive in addressing staff concerns raised.
- Fresenius supplied information to staff on the impact of the United Kingdom leaving the European Union on the staff's right to work. This explained that Fresenius would financially support the application of residency by staff.

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

- Risk registers and governance had not been a regular item on the clinic team meetings.
- Some policies contained out of date guidance or were due for review

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Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

- The organisation had a clinical incident reporting policy effective from June 2016 that provided a framework for reporting and managing all incidents and near misses, to improve the quality and safety of its service. The policy was in date and set out the accountability, responsibility and reporting arrangements for all staff in relation to incidents. The policy and procedure provided clear guidance for staff on the processes and expectations in relation to incident reporting and learning and included; the process for reporting incidents, the process for investigating incidents, open and honest communication including duty of candour requirements and the process for shared learning.
- Staff reported incidents via several forums. Clinical incidents were reported via an electronic reporting system. Between January 2016, and December 2016, there were four incidents reported and two notifications to the CQC. We saw evidence of investigations and recommendations following two incidents relating to patients testing positive to a bacterial infection. The recommendations were developed in collaboration with the commissioning NHS trust.
- Incidents relating to treatment were reported as treatment variance reports, and recently unexpected transfers to hospital were reported via a third incident reporting system. Clinic managers held the responsibility of identifying the appropriate reporting system.
- Staff reported emergency transfers via 999 calls on a separate reporting template. Between January 2016

and December 2016, six emergency 999 calls were made and all six patients were transferred to hospital. These were investigated by the clinical incident team. The chief nurse told us that documentation had been implemented as a result of 999 transfers, to assist earlier detection of an unwell patient. During the announced inspection we identified that staff were not using the documentation appropriately. Email reminders were sent to all staff by the chief nurse, to explain the relevance of the documentation, and an audit of the chart included in the new notes audit.

- Learning from incidents nationally was circulated to all staff via a clinical awareness update. Staff within the unit read and signed the document to confirm they had read it. We reviewed minutes of staff meetings, previously there was no incident learning on the agenda. A new agenda format in June 2017 included learning from incidents as a regular item.
- We saw patient safety alerts sent to all areas as learning bulletins and colleague updates. These included concerns such as cracking of connection caps and the practice of dry needling (inserting an unprimed needle to perform dialysis). This process had evolved over the past three years, from just when a serious incident occurred, to a chance to share learning.
- Incident and complaint investigations were discussed at the monthly multidisciplinary meeting with the commissioning NHS trust.
- In addition to the clinical incident reporting, in the event of a minor clinical or patient safety incident pre, during or post dialysis treatment, staff completed a treatment variance report (TVR) or unit variance report (UVR) within the electronic patient record. The data

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within the system was reported on a monthly basis to both the area head nurse and the renal nurse at the referring NHS trust. In 2016, the unit reported 2455 TVRs within the electronic system.

- There had been no incidence of a 'never event' in the last 12 months prior to this inspection. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- There were no notifiable safety incidents that met the requirements of the duty of candour regulation in the 12 months preceding this inspection. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain notifiable safety incidents and provide reasonable support to that person. All staff had received or were timetabled to receive duty of candour training. We spoke with four staff, they had an understanding of being open and honest, but could not describe the process followed.

Mandatory training

- Fresenius Medical Care had an detailed 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.
- Staff training files included a contemporaneous training record. This included details of training undertaken, including induction, fundamental skills, advancing and management training.
- We reviewed a copy of the organisation's training and education matrix, which gave details of induction, mandatory and optional training modules. Modules were allocated by staff group. Training was delivered by a mixture of classroom, same time (virtual classroom), e-learning and video learning.
- Mandatory training for all staff groups included basic life support, anaphylaxis, moving and handling, safeguarding, infection prevention and control

including hand hygiene, fire safety, information governance, Mental Capacity Act and Deprivation of Liberty Safeguards, dementia awareness and ethics and business conduct.

- In addition to theoretical and practical basic life support training staff received unannounced basic life support simulation training. The simulated basic life support sessions included feedback forms and a quiz for all staff. In the event of a lack of understanding, the head nurse and training lead developed a programme of support for the individual member of staff.
- At the time of inspection, most staff were up to date with their mandatory training apart from the information governance training. In the data provided, all staff were out of date with their information governance training. Time had been allocated for staff members with elements missing to complete the training.
- Clinic managers ran monthly checks of the electronic training records to monitor staff compliance with the 100% training target, and informed staff of any training due for renewal. Staff were supported to complete training during work. In the event of staying later to complete training staff were paid for those hours.

Safeguarding

- The clinic manager was the safeguarding co-ordinator for this location, with responsibilities for monitoring and recording safeguarding concerns, making referrals to and liaising with other agencies and arranging the training for staff. They had a link to the NHS trust level four lead for safeguarding for onward referral of all safeguarding concerns.
- Fresenius had a safeguarding adults and children's policy (May 2015) which was available to all staff members. Although the clinic only treated adults, and patients were discouraged from bringing children to the unit, it was acknowledged in the policy even though a health professional may not be working directly with a child, "they may be seeing their parent, carer or other significant adult and have knowledge which is relevant to a child's safety and welfare."
- Staff were trained to recognise adults at risk and were supported with an effective safeguarding policy in

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place. All four staff we spoke with could give examples of raising safeguarding concerns with the local authority. Safeguarding contact numbers and a flow chart were visible in the waiting area.

- At the time of inspection, 12 out of 14 staff (86%) had received safeguarding adults, level two, and children's level one training. Plans were in place to train the other two members of staff. The unit had access to the NHS trust level four safeguarding lead.
- During the visit staff were able to relate situations where the safeguarding of vulnerable adults had been an issue. They demonstrated an awareness of patients who would be at risk of physical, emotional and financial abuse. One safeguarding investigation was underway with the support of the referring NHS trust.

Cleanliness, infection control and hygiene

- Fresenius services had a companywide hygiene and infection prevention and control (IPC) policy dated February 2016, which aimed to establish and maintain a common approach to safe hygiene practices in dialysis clinics.
- The provider's policy on hand hygiene, the Nephrocare Hygiene Plan (July 2016), described in detail how, when and why staff should carry out hand hygiene. The guidance described how staff should carry out clean or aseptic tasks. Staff also referred to the provider's Hygiene and Infection control policy (February 2016). The protocols for infection control were based on the Renal Association Blood Borne Virus Infection guidelines.
- Sinks and hand gels were accessible throughout the unit in accordance with Health Building Note 00-30 infection control in the built environment. We saw staff performing thorough hand washing at appropriate times throughout care and treatment.
- Between January 2017 and May 2017, staff monthly hand hygiene audits demonstrated 100% compliance. Staff were reminded in staff meetings to use gloves appropriately and not infect hands post hand washing. The monthly environmental audit demonstrated 95% to 97% compliance. Staff were reminded to clear all debris off the floor and ensure housekeeping staff wore appropriate personal protective equipment (PPE) such as gloves and aprons.
- The service reported all infections to both the commissioning authority and centrally to Fresenius. Between January 2017 and May 2017, no cases of methicillin resistant *Staphylococcus aureus* (MRSA) bacteraemia were reported, although, there were three cases of methicillin sensitive *Staphylococcus aureus* (MSSA) bacteraemia. MRSA is a bacterium responsible for several difficult-to-treat infections. MSSA differs from MRSA due to antibiotic resistance. All cases were reported as clinical incidents and investigations completed. No connection was made between each of these cases.
- Annual commissioning trust IPC audits made recommendations for areas of improvement. Results for the June 2017 audit were largely positive with no major or critical breaches of IPC standards identified. Where the unit had failed to meet trust IPC standards we saw an action plan had been created and all actions had been addressed within the required time frame.
- Staff performed disinfection of dialysis machines between each patient and at the end of each day. These followed manufacturer's and IPC guidance for routine disinfection. We saw documentation of the cleaning of dialysis machines previously used for infected patients. This was in accordance with Fresenius guidelines. Spare dialysis machine were stored clean and ready for use. Spare dialysis machines were stored cleaned, labelled and identifiable for their designated use.
- The IPC policy included recommendations for the cleaning of critical (items that enter sterile tissue, body cavities or the vascular system), semi-critical (contact with mucous membranes) and non-critical (skin contact) items. Where possible, single use items were in use in the unit. Predominantly, we saw staff following the IPC policy using an aseptic non touch technique when connecting and disconnecting dialysis lines.
- During the inspection we saw one out of five staff not adhering to good asepsis practice. This member of

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staff was responsible for supporting and mentoring junior staff. We observed the staff member re-sheathing needles and the contamination of sterile areas. This was highlighted to the clinic manager who addressed the issue. On the unannounced visit we saw improved practice.

- Staff were bare below the elbow and wore protective personal equipment (PPE). We observed they changed protective aprons and gloves in line with their infection prevention and control guidelines, to minimise the risk of any spread of infection. They also wore visors and ensured both they and patients wore face-masks when connecting or disconnecting central venous catheters. They used the correct colour coded PPE when caring for people with an infection risk in the isolation rooms.
- Staff at Hamilton Renal Dialysis Unit attended infection control meetings and study days at the local NHS trust. This gave opportunity to discuss concerns and issues surrounding infection control practices. We saw minutes of meetings highlighting feedback on latest infection control guidance.
- During the inspection we observed all areas of the unit to be visibly clean. Cleaners and housekeepers were present throughout the day and overnight to perform cleaning duties. We observed staff cleaning equipment and machines during this inspection.
- All patients we spoke with were positive about the cleanliness of the unit. A patient commented that the scales were often dirty in the evening. This was raised at the unannounced visit to the clinic staff as the unit appeared cluttered.
- Guidelines for water testing and the disinfection of water plant and dialysis machines were readily available to all staff. These outlined the process in the event of an out of range measurement. Daily water quality tests were performed by staff trained to do so. Between January 2016 and December 2016 no samples were outside the acceptable range. In addition, Fresenius and the local NHS trust monitored the bacteriological testing of the water surveillance system monthly.

- All water testing for the unit was carried out in line with the recommendations by the UK Renal Association and European standards for the maintenance of water quality for haemodialysis and haemodiafiltration.
- Procedures were in place to assess patients as carriers of blood born viruses (BBV) such as Hepatitis B and C. This included routine testing of susceptible patients in line with best practice guidelines and using a nominated machine after a patient returned from holiday dialysis in another unit. Policies gave staff clear guidelines in regard to appropriate infection practice, for example MRSA and MSSA screening, BBV, no-touch aseptic technique and the use of isolation rooms.
- There were guidelines for staff in the event of a patient testing positive for a BBV such as Hepatitis B and C. These included the use of a separate room for dialysis and appropriate protective equipment for staff.

Environment and equipment

- Hamilton dialysis unit was situated in a single storey building within a business park. The layout of the dialysis unit was compatible with health and building notification (HBN07-01) guidance. Access was good for both able bodied and disabled patients, parking plentiful with a secure entry point. A nurse's station allowed visibility of all patients during dialysis although portable privacy screens were available when required. Security screens permitted staff to monitor patients nursed in side rooms. Patients could, if they wished, speak with each other during dialysis in line with HBN recommendations. There were nurse call bells accessible at each station.
- The Fresenius facilities management team were responsible for both reactive and preventative maintenance work of dialysis and the water treatment plant. This included monitoring and organising work requested by the dialysis unit. This work included annual service testing of all equipment. All equipment checked during the inspection was service tested and in date. In the event of faulty equipment, staff completed a fault report and decontamination certificate and stored the equipment away from the clinical area in a non-conformance area.

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- We reviewed the equipment and environment maintenance and servicing plan for April 2017 to March 2018. This plan included calibration and maintenance of the fire extinguishing and detecting system, dialysis machines, electric chairs and beds, and other types of equipment such as infusion pumps, and patient hoists. This plan also included planned maintenance and treatment of the water tanks and systems.
- Dialysis hours log on dialysis machines monitored dialysis hours. All machines had been used for less than 40,000 hours with a replacement programme in place when these hours were reached.
- Dialysis sets were single use, CE marked (demonstrating European conformance) and disposed of within clinical waste. The lot number of the sets in stock was held within the stores department in the unit. Some blood bottles on the equipment trolley had passed their expiry date. We notified the manager and these were removed immediately. On the return unannounced visit, all consumables were in date.
- Patient weigh scales were available on the unit and had been appropriately service tested. Staff told us, in the event the weigh scales developed a fault or were unfit for use, a replacement set was available on the unit and the fault would be reported to an external company for repair.
- In the event there was a failure of a dialysis machine whilst a patient was receiving treatment two 'back up' dialysis machines were available. We reviewed the replacement machines, saw they had been appropriately safety tested, and were clean and ready to use.
- Staff had access to standard operating procedures for all equipment. This included storage instructions, use, cleaning and maintenance advice.
- Emergency equipment was easily accessible, checked consistently, with items appropriately packaged, stored and ready for use.
- We observed all staff to have regard for alarm guards on the dialysis machines. Alarms were addressed appropriately and not overridden. This meant

significant risks such as the detection of dislodged needles could be identified at the earliest opportunity thus avoiding the risk of significant blood loss or cardiac arrest.

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 shift leader was responsible for the drug cupboard keys.
- The organisation had a companywide medicines management policy, effective June 2016, which we reviewed.
- Medicines, including intravenous fluids, were stored in cabinets within a locked clean utility room. We saw records of receipt and monitoring of medicines. No controlled drugs were stored at the unit. Medicines were ordered via the local commissioning NHS trust or a private pharmaceutical company.
- Medicines requiring refrigerated storage were stored at the correct temperatures to ensure they would be fit for use. We reviewed the fridge temperature records for March 2017 to June 2017 and saw where staff had signed daily to indicate temperatures had been checked and were within the required range. We spoke with staff who told us that where temperatures were not within the required range this would be escalated to the nurse in charge. We saw a recent learning bulletin (June 2017), highlighting the actions to take in the event of a thermometer that was out of range.
- Portable oxygen for emergency use was stored appropriately with correct signage.
- Staff had access to pharmacy support from the local NHS trust pharmacy for additional advice relating to dialysis drugs. Fresenius head office had pharmacy support for staff to access.
- Staff received annual medicine management training. A virtual classroom session was provided around preventing medication errors. All clinical staff had completed this training.
- We saw staff performing positive patient identification prior to the administration of medicines. Medicines were checked by two members of staff, one of whom

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(the registered nurse) then administered it, not leaving medicines unattended and confirming all prescriptions were administered during dialysis. This was in line with Nursing and Midwifery Council code, best practice and patients confirmed that this was normal practice.

- No controlled drugs (prescriptions controlled under the Misuse of Drugs legislation) or patient group directions (PGDs) were used during dialysis treatment or stored within Hamilton Renal Dialysis Unit. PGDs allow some registered health professionals (such as nurses) to give specified medicines (such as painkillers) to a predetermined group of patients without them seeing a doctor.
- Prescriptions were completed by the NHS consultant. Medication for additional long term conditions were prescribed and monitored by the doctor responsible for the patient's care (hospital or GP). Staff communicated changes in medicines made by the renal consultant to GPs via electronic records. Staff within the unit did not prescribe medicines, however urgent prescriptions were supported by the commissioning NHS Trust renal team.
- All paper prescription charts originated from the commissioning NHS trust. These included as standard, appropriate medicines in event of an emergency situation, such as anaphylactic reaction, hypoglycaemic (low blood sugar) or breathlessness.

Records

- Fresenius had a national Clinical record keeping policy, effective from June 2016, which we reviewed. This policy detailed the expectations of the quality of clinical records and also the documents that should be included within a patient's medical records. A list of approved abbreviations was included within this policy which meant that anyone reading the records should be able to understand what was written.
- Hamilton Renal Dialysis Unit used a combination of Fresenius electronic and paper records. In addition the staff had access to the local NHS trust's electronic records. Data was automatically shared between the electronic databases. This ensured that consultant nephrologists had access to the patient records at all times. We saw blood results discussed with the renal registrar on call.

- In all records reviewed, we saw evidence of review of care plans. In addition, the named nurse monthly checklist included prompts for updating care plans and assessments. Monthly notes audits monitored the completion and updating of care plans. A process was in place for actions taken after a few care plans lacked patient identification labels.
- All patients had a named personal information card which facilitated access to treatment records. These were collected by patients from the nurse on entry into the unit.
- When not in use record and cards were stored securely in locked cabinets.
- During dialysis the electronic patient care plan was updated, including an audit trail of treatment. We reviewed 12 sets of paper and electronic records. All records viewed were legible, included amongst other details, care plans, consent, three monthly blood results, routine observations, intravenous line checks, a named nurse, named nurse checklist, evidence of multidisciplinary review, prescription and screening results.
- All new patients had a comprehensive patient referral/admission document completed. This included information from the referring unit and the dialysing unit. A data quality confirmation check was also included on the form to ensure the data provided by the referring NHS trust reflected accurate patient information. Any discrepancies were documented on the records.

Assessing and responding to patient risk

- Patient records included risk assessment of pain, using a numerical score, a waterlow score which identifies an individual's risk of developing a pressure ulcer and an assessment to identify those at risk of a fall. One patient with a high risk dialysis access port had not had a risk assessment performed, however, when we escalated this, staff were aware of the risks of this type of catheter.
- Only patients deemed as stable and low risk were dialysed at Hamilton Renal Dialysis Unit. Staff assessed each patient's suitability for care at a satellite

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dialysis unit. In the event of a change in condition staff liaised with the NHS consultant to discuss a plan of care. Staff maintained records of high risk patients for closer monitoring.

- Two renal consultants visited the unit weekly to perform monthly patient quality reviews. We reviewed 12 patient records that included documentation of reviews of blood results and treatment.
- Staff performed observations on all patients before, during and post dialysis. The electronic monitoring system alerted staff to a deterioration in a patient's blood pressure or heart rate. If a patient appeared unwell or showed signs of deterioration staff monitored them more closely and would either continue monitoring, or return the circulating fluid and discontinue the dialysis as per guidelines. They would assess whether the patient required transfer to an acute hospital via emergency services. We saw staff performing more frequent observations in the event of a patient not feeling well. Appropriate actions were taken to prevent further deterioration in the patient's physical health.
- Patient observations were documented on dialysis summary patient assessment and evaluation charts. These were used to give a view of observations over several dialysis sessions. We reviewed ten charts and none had been completed accurately or consistently. We raised this with the Fresenius chief nurse who resent the reminder to all staff to complete the documentation. This aspect of records had not previously been audited. When we returned for the unannounced visit, we looked at ten forms. All the forms had been completed for the three dialysis sessions that had occurred since our previous visit.
- The unit did not use a nationally recognised early warning scoring system to monitor deterioration in the patient's condition. Observations, including temperature, blood pressure and heart rate were recorded on the patient's daily dialysis record sheet and within the electronic records at the start, during and at the end of dialysis.
- Guidelines were not in place on the process to follow in the event of a patient showing signs of sepsis. However, staff had access to the referring NHS trust's guidance, which included the process to follow.
- Electronic systems included a three monthly assessment of the screening status of all patients for potentially infectious blood born viruses such as Hepatitis B.
- Staff told us and we saw patient identification performed by a name and date of birth confirmation prior to commencing treatment and on administration of medicines. This was in line with Nursing and Midwifery Council guidance that, staff 'must be certain of the identity of the patient to whom the medicine is to be administered.' The service did not have a documented patient identification policy in place. Some staff told us that they knew the patients so well that they did not feel formal identifications were necessary.
- Staff reported any non-urgent patient concerns to the clinic manager who either escalated these to the consultant nephrologist or kept notes on a recently implemented patient concerns record until the next consultant visit. In the event of an urgent concern staff could access the on call nephrologist registrar or consultant at one of the two referring NHS trusts.
- Patients did not receive blood transfusions at this unit. Where a blood transfusion was required this would be carried out at the referring NHS trust.
- Fresenius had a patient transfer policy in place. Emergency transfers of care were undertaken via local emergency ambulance services using a 999 call. Any non-urgent transfers were performed in consultation with the nephrology consultants. Between January 2016 and December 2016, six emergency transfers of care occurred.
- The organisation had a companywide complications, reactions and other clinical events pathways document, effective November 2016, which we reviewed. This documented some possible medical complications or reactions that could occur during dialysis and used flowcharts to outline actions that staff should take in these circumstances. In addition the service had a cardiopulmonary resuscitation policy which included guidance on the treatment of collapse or cardiac arrest and the use and daily checking of the defibrillator.
- A link nurse was responsible for vascular access. Patient vascular access was discussed with the

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referring NHS trust. A protocol was in place for the monitoring of vascular access via digital images, this was supported by the NHS trust. The process was monitored closely to improve the access to appropriate care for patients.

Staffing

- Hamilton Renal Dialysis Unit worked to a predetermined staff to patient ratio and skill mix of one qualified staff member to every four patients, as defined initially by the referring NHS trust. Which they managed to achieve for all dialysis sessions. At the time of inspection, this included ten registered nurses and three dialysis assistants.
- Three nurses held a dialysis qualification. During the focus groups other nurses expressed an interest in completing the course.
- The unit currently had one registered nursing vacancy with interview dates booked for staff.
- 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. For the reporting period March 2017 to May 2017, 32 shifts had been filled with agency staff.
- The dialysis unit was a nurse led unit. Staff described and we saw access to medical staff to be good. Staff in the unit contacted local NHS trust renal registrars and consultants for advice.
- A detailed handover was completed in the middle of the day. Staff asked colleagues to monitor patients whilst not present, for example when retrieving medicines or during breaks.
- There were no medical staff employed at the unit. Every week a dedicated renal consultant employed by the commissioning NHS trust attended the clinic for renal outpatient appointments. These appointments were organised by the commissioning trust.

Major incident awareness and training

- The service had an Emergency Preparedness Plan, effective from February 2015. This highlighted the actions taken in event of an emergency. These were defined as; a situation which poses or has already

caused a serious risk to health, life, property or environment. Hard copies of the plan were kept in four places at the location, so that staff could have access to the information in the event of an emergency (reception, manager's office, staff kitchen, within the emergency bag). This plan gave staff clear guidance and contact numbers for key personnel within the organisation and externally, for example the local authority or Environment Agency. All staff we spoke with were aware of the plan for each patient.

- Folders containing emergency numbers were easily accessible at the nurses' station.
- The unit had a contract with the local water authority to prioritise the service in the event of water failure.
- In the event of power failure, all dialysis machines had a battery backup system allow time to permit patient's blood to be returned to them.
- Each patient's notes included patient personal emergency evacuation plans. These were patient specific summaries on the individual needs of each patient in the event of an emergency evacuation. Ambulant level, weight, height and days of the week attended were all documented.

Are dialysis services effective?

Evidence-based care and treatment

- Staff within the unit used a Fresenius own 'Good Dialysis Care' policy and procedure document, which was compliant with European Renal Best Practice (ERBP) and the Kidney Disease Outcome Quality Initiative (KDOQI) guidelines. It contained instructions for staff in how to use the specific dialysis equipment and there was clear referencing to other policies and best practices. The Good Dialysis Care policy excluded medicines for units in the UK, as Fresenius had created a separate UK medicines policy in accordance with the UK Nursing and Midwifery Council Standards for medicine management.
- Within the policy guidance, staff followed current evidence based guidance, including National Institute of Health and Care Excellence (NICE) and The National Service Framework for Renal Services in providing care for patients. For example, the Standards of good

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Dialysis care guideline 2016. This guidance was incorporated into the local NHS and Fresenius (Nephrocare) guidelines. We looked at five policies, these were all version controlled and in date.

- Policies and procedures were reviewed yearly via the certified international organisation for standardisation integrated management system (ISO). The 2016 quality management system audit demonstrated compliance in monitoring of out of date policies.
- Renal Association guidelines were followed for the management of 'life-threatening' haemorrhage from arteriovenous fistula (AV) and AV grafts. An AV fistula is an artificial connection or passageway (using a synthetic tube implant) between an artery and a vein providing needle placement access for dialysis.
- Fistulas and grafts were assessed pre-dialysis and following treatment. We saw evidence of this in all the patient records we reviewed. This met NICE Quality standard [QS72]: Renal replacement therapy services for adults. If a concern was identified staff could digitally photograph the fistula or graft and forward to the referring consultant nephrologist.
- Staff monitored and recorded patients' vascular access in line with NICE Quality Statement (QS72) statements 8 (2015): 'Haemodialysis access – monitoring and maintaining vascular access'. The vascular access lead was responsible for contact with the renal consultant at the local NHS trust. Timely creation of fistula access was the responsibility of the NHS consultants. At the time of inspection, 58% (67) of patients had an arteriovenous fistula (AVF). This was worse than the UK Renal Association guidance of 80%. Monthly vascular access monitoring was discussed with the NHS vascular access nurse to develop plans for the patients requiring the surgical creation of an AV fistula or graft.
- All patients had their weight, temperature, pulse and blood pressure checked at the beginning and end of dialysis. This was documented within the electronic record.
- The unit did not offer peritoneal dialysis. Peritoneal dialysis (PD) is a type of dialysis that uses the peritoneum in a person's abdomen as the membrane through which fluid and dissolved substances are

exchanged with the blood. It is used to remove excess fluid, correct electrolyte problems and remove toxins in those with kidney failure. Home dialysis was not supported from the unit.

- The review of patient records demonstrated to us staff had considered individual patient needs for example, age, disability, race and religion or belief. This meant discrimination was avoided when making care and treatment decisions.

Pain relief

- Paracetamol was provided via patient specific directives from the NHS trust. This meant that patients could receive analgesia if required.
- The unit used pictorial and numbered pain assessment tools to monitor patient's pain levels.
- Patients we spoke with told us staff monitored their comfort and pain levels throughout treatment.

Nutrition and hydration

- Patients had access to food and hydration while undergoing treatment.
- A service level agreement (SLA) was in place for dietetic support, which was provided by a nearby NHS trust. Following a review of a patient's blood results, the dietician provided support remotely through telephone advice and during regular visits. Where indicated a referral would be made to outpatient dietetic services. In addition to the SLA, Fresenius provided a dietetics assistant to support and advise patients on dietary choice. The dietetic assistant was available on the unit every week. This meant that when patients requested support, it was provided within a couple of days.
- Large pictorial boards in the waiting room provided information for patients on special diets including what to eat at a BBQ and leaflets on eating healthily.
- We saw that patients were provided with written information and guidance relating to their diet and fluid management.
- Patients were weighed on arrival to the unit at each visit. This was to identify the additional fluid weight

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that needed to be removed during the dialysis session. This varied from patient to patient. Some patients were observed weighing themselves prior to dialysis, and inputting this into the dialysis machine.

Patient outcomes

- The unit participated in the UK Renal Registry through the referring NHS trust. The UK Renal Registry is a resource for the development of patient care in renal disease. It provides a focus for the collection and analysis of standardised data relating to the incidence, clinical management and outcome of renal disease. Due to the inclusion of data with other units, the unit was not able to benchmark the effectiveness of the service against other providers.
- The Fresenius Medical Care electronic record system did however provide a 'management' system to give reports and trends on patient outcomes. This enabled the unit to compare their service to other Fresenius units, and if necessary, make improvements in order to meet the national standards. A report was shared with the NHS consultants on the unit's achievement of the quality standards.
- Clinical outcomes for renal patients on dialysis can be measured via blood test results. The blood results were monitored before and after dialysis treatment on a monthly basis as directed by the commissioning NHS trust and in accordance with the Renal Association Standards. Results were collated on the unit electronic database. The data was reviewed by the clinic manager and consultant to monitor individual patient outcomes.
- The results showed the unit performance in the achievement of quality standards based on UK Renal Association guidelines. We reviewed results of blood tests from February 2017 to April 2017. These comprised of a number of outcomes;
- Two standards we looked at show how much waste products are removed from the patient and how effective the dialysis is;
 - the rate blood passes through the dialyzer over time, related to the volume of water in the patient's body (Kt/V).
 - and the Urea Reduction Ratio (URR).
- On average just over 73% of patients had effective dialysis based on the Kt/V
- Renal Association guidelines indicate a target of 65% for URR. From February 2017 to April 2017, 91% of patients at Hamilton Renal Dialysis Unit had an acceptable URR level, which was better than the guideline target.
- We also looked at the standards indicating patients' haemoglobin (Hb) was at safe levels. Haemoglobin is the oxygen carrying cell within the blood. Anaemia can be a complication of renal failure and dialysis associated with increased risks complications. From February 2017 to April 2017, the average number of patients with the NICE recommended target of Hb 100-120 g/l was 62%. Where patients had low Hb levels they were given injections of a hormone-stimulating agent to help their body produce more red blood cells, iron injections and blood transfusions.
- Potassium levels in the blood are monitored as part of the Renal Association standard. From February 2017 to April 2017, 95% of patients had potassium levels within acceptable ranges.
- From February 2017 to April 2017, we saw 100% of patients who attended three times a week were dialysed for the prescribed four hours treatment time. This is better than the minimum standard of 70%.
- In the 12 months leading up to our inspection, 100% of patients received high flux dialysis. High flux dialysis is a form of more effective clearance of the waste products and fluid. High flux dialysis delays long-term complications of haemodialysis therapy.
- The unit monitored treatment variances such as cannulation problems, clotting, high and low blood pressure, changes in procedure, machine malfunctions and patients who did not arrive for dialysis. There were 2455 variations in 2016, these results were used to assess issues and make improvements where possible.

Competent staff

- All members of nursing staff had completed a 'Standard of good dialysis' training session and annual reassessment.

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- All new staff completed an induction which included mandatory training in safety systems, processes and practices linked to the care and management of dialysis patients. Preceptors trained new recruits and recorded training in their integrated competence document.
- We reviewed four staff records. All contained completed competency assessments in the use of dialysis equipment and completed induction period.
- Three members of staff held an external renal qualification and a further member of staff was registered to commence the training.
- Mandatory training records were monitored by the chief nurse and clinic manager, staff were notified four weeks prior to mandatory training becoming out of date.
- The files included details of up to date Nursing and Midwifery Council registration and revalidation.
- The Training and Education Progression Plan included a comprehensive induction and preceptorship programme for all new staff. This included a wide range of essential training. Following the supernumerary period staff commenced a probationary and supervised period. Staff were not to perform dialysis alone until they had achieved all relevant competencies, such as supervision in catheter dressing, vascular accessing techniques, safe injection practices, management of intravenous cannula, tunnelled and temporary central lines, AV fistulas and grafts and transfusion of blood.
- During the inspection, we saw new staff observing techniques and working alongside experienced staff members.
- Staff received medical device training as part of their induction / supernumerary process. This was managed locally and we saw documentation confirming that all staff had received medical device training.
- Basic life support training was a mandatory training requirement that all staff were required to undertake on an annual basis. All staff had completed this training and were competent to use all items of emergency equipment. For example, the automated external defibrillator (AED). The area chief nurse completed ad hoc basic life support simulation sessions to assess staff competency.
- Training was made up of face to face, online electronic learning or virtual classroom sessions. Staff also received simulation training within the clinic environment.
- Staff performed annual self-assessments of competence prior to their annual appraisal. This followed company guidance and highlighted training and development needs. Staff told us and we saw evidence of annual aseptic non touch technique training.
- At the time of our inspection, all staff had received annual appraisals in the last 12 months.
- Staff held lead roles for vascular access link nurse, electronic records, water treatment, health and safety, diabetes link nurse, away from base (holiday) link nurse and infection prevention control.
- In the event of poor performance staff received performance improvement plans (PIP) designed to help employee's performance. These followed a structured process laid out in the employer's handbook.
- Fresenius employed drivers who received training in managing patients post dialysis. This included basic life support training and guidance on whether a patient should be conveyed. In the event of an emergency staff were aware of how to manage the patient and who to report to. All taxis contained first aid kits supplied by Fresenius medical care.
- The Fresenius staff handbook (April 2016) stated that employees must notify their manager if they are convicted of a criminal offence or receive a caution. All new staff undertook criminal records checks at recruitment.
- A local NHS trust sepsis management training was given to all unit staff. The unit sepsis folder included signatures from staff to confirm reading and understanding the recognition and management of sepsis.

Multidisciplinary working

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- There were processes to ensure effective multidisciplinary working. The consultant nephrologists from the commissioning NHS trust had overall responsibility for the patients' care. The unit staff recorded any communications to the consultants in the electronic system, which the trust could access. For example, the regular monthly blood results spreadsheet, allowed for a 'virtual patient' review by consultants, dieticians, specialist nurses and the dialysis unit staff.
- Staff had effective working relationships with the commissioning NHS trust. This was confirmed by feedback from the renal nurse specialist. Staff were friendly, knowledgeable and experienced and had processes to support safe delivery of care.
- The consultant nephrologist from the local NHS trust reviewed patients every three months. New patients were seen within a month of commencing treatment. We saw evidence of this within the records reviewed.
- Patients had access to a visiting dietician who also attended the multidisciplinary discussions. They reviewed patients each month and patients could make contact in between appointments if required. In addition, a Fresenius dietician assistant attended the unit twice a week to support patients with dietary advice.
- The consultant nephrologist, dietician and unit clinic manager attended monthly clinic reviews. This ensured that care was delivered in a co-ordinated way, with all teams involved.
- Communication with GPs was the responsibility of the referring consultant, although if the staff reported good working relationships with many patients' GPs. Copies of GP letters were kept in the patients notes.
- Staff escalated any concerns to the NHS nephrologist at the referring trust. During our unannounced inspection, we saw prompt escalation of blood results and good communication with the on-call renal registrar.
- The unit had recently implemented a correspondence log for staff to maintain. This included patient concerns to discuss non-urgent cases with the

consultant. This was in addition to the multidisciplinary review meetings. The process had proved useful at another unit and rolled out across the service.

Access to information

- Staff at the unit had access to the patients Fresenius and NHS records, including blood results.
- The Fresenius patient treatment database automatically transferred patient data into the commissioning NHS trust's clinical database.
- Electronic policies and procedures were accessible throughout the unit. These included both Fresenius policies and those of the commissioning NHS trust. Staff training folders included a signature sheet confirming staff had read updated policies.
- Patients could request access to 'Patient View', which showed the latest test results, letters and medicines, plus information about diagnosis and treatment electronically. The clinical manager was available to assist patients in getting set up and logging in.
- The unit had face-to-face handovers twice a day, this ensured that information was shared relating to changes to patients' plans or clinic appointments.
- The unit provided patients with an individual information card that held their personal data, for example, their weight and daily dialysis plan. These were collected and used by the patient to record self-weigh prior to and after their dialysis. During dialysis these cards were updated with the latest information.
- For patients receiving away from base (holiday) dialysis the unit completed 'incoming holiday patient forms.' This ensured all relevant information was gathered relating to the incoming patient.

Equality and human rights

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

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- Patient records reviewed demonstrated staff had considered individual patient needs for example, age, disability, race and religion or belief.
- Equality and human rights and Mental Capacity Act (2005) training was included in the company mandatory training. All staff in Hamilton Renal Dialysis Unit had completed this training.

Consent, Mental Capacity Act and Deprivation of Liberty

- The organisation had a companywide policy for consent to examination or treatment, effective October 2014, which we reviewed. This policy made reference to the Mental Health Act (2007) and the Mental Capacity Act (2005) and gave staff clear guidance about their responsibilities to obtain and document consent for, or refusal of, treatment.
- All patient records included a consent to treatment record. Staff obtained verbal consent from the patients. These were audited in the unit monthly record audit with 100% compliance.
- The staff demonstrated a clear understanding of the right of a patient to decline treatment and the impact of someone with mental health conditions. Staff would discuss concerns around mental health with the GP and had supported referrals in the past.
- During the time of our inspection, no patients were receiving care who lacked capacity to make decisions in relation to consenting to treatment. Staff informed us that in the event of a patient lacking capacity they would be referred to the NHS nephrologist with family or carer support.
- A family member or carer for support accompanied patients whose understanding was limited either due to a language barrier or due to learning disabilities. If required the unit had access to the local NHS trust language line for interpreting purposes.
- Training was provided to enhance the nursing team's awareness of dementia care, the Mental Capacity Act 2005, consent and deprivation of liberty standards in order to promote the specialist care needed by the patients referred to the unit.

Compassionate care

- During our inspection, we spoke with 16 patients who received regular treatment at Hamilton Renal Dialysis Unit. All patients were positive and satisfied with care they received at the unit.
- Staff demonstrated an understanding and awareness of caring for individuals with respect to people's personal, cultural, social and religious needs. Patient birthday and special days were recognised and celebrated by staff.
- Patients told us staff treated them with courtesy and provided them with honest explanations into their care. The patients we spoke with knew they had a named nurse, but were happy to discuss care with all staff.
- Patients told us and we saw patients treated with dignity and respect. Screens were used to provide privacy when staff accessed lines situated in private areas.
- Confidential discussions were held in a quiet room. Some patients told us this was helpful if they wanted to speak in private. This was supported by the scores in the patient's survey, where 98% of patients who responded (53 patients responded) said they felt their confidentiality was respected.
- Patient satisfaction was formally measured through an annual patient satisfaction survey. Results from the 2016 survey were displayed in the waiting room. These indicated that 82% of patients would recommend the unit to a friend and 96% of patients said there was a happy and friendly atmosphere. Displayed in the waiting room were actions taken in response to a patient complaint. It reminded staff to discuss the relevance of blood results with patients so they knew they were receiving enough dialysis.
- Staff monitored patients throughout their dialysis session. This meant staff were able to respond in a compassionate, timely and appropriate way when patients experienced physical pain, discomfort or emotional distress. We saw staff responded promptly to calls for help, alarms on dialysis machines and any non-verbal signs of distress.

Are dialysis services caring?

Understanding and involvement of patients and those close to them

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- Staff communicated with patients so that they understood their care, treatment and condition. In order to prepare and familiarise patients with what they could expect whilst receiving treatment at the unit, staff discussed this with them as part of their consent to treatment.
- A process was in place to support patients during initial appointments; this included giving the patient time to discuss their care and to ensure they had understood the information. Second and third sessions were also tailored to suit the needs of the patient, both physically and emotionally. A patient confirmed that this was the case and they had received appropriate information.
- Patients were reviewed a minimum of every three months by the consultant nephrologist and monthly by a dietician. This allowed the opportunity for the patient to discuss any concerns they may have. Additional visits by either health care professional could be arranged as required. One patient saw the consultant every six weeks.
- Patients and their relatives were encouraged to participate in their treatment. Staff encouraged patients to take responsibility for parts of their treatment, such as weighing themselves prior to dialysis.
- The unit used a named nurse approach. However, patients told us they knew all the staff and could approach any one of them regarding their care and treatment. Staff at the referring NHS trust told us the Hamilton unit staff were advocates for their patients.

Emotional support

- Staff we spoke with understood the impact that a person's care and treatment had on their wellbeing and the impact on the family both physically and emotionally.
- Patients told us they were given time to discuss their care and emotional health.
- Patients at Hamilton Renal Dialysis Unit had access to the referring NHS trust's psychology support although this was limited due to availability. Staff told us if they were concerned about a patient, they would contact the patient's GP for extra support.

- Both patients and staff described to inspectors the emotional impact of losing patients. They said this almost brought them closer together.

Are dialysis services responsive to people's needs?

Meeting the needs of local people

- A number of information leaflets were available for patients offering information and support around renal disease and dialysis. Many of these leaflets were available in other languages if required. The unit provided information in formats that supported and reflected cultural diversity with the patient guide available in a number of language options.
- The unit provided a service to patients dialysing 'away from base' for example, on holiday. Patients we spoke with had received support from the staff at Hamilton Renal Dialysis Unit to organise away from base dialysis. One patient explained that a month's worth of supplies were sent to India to enable them to receive dialysis there. They felt that the service at Hamilton was "second to none," despite having received treatment in several units.
- Staff described supporting a patient to contact social services due to their vulnerable situation and lack of clean clothing. This meant that the patient could attend the unit feeling dignified by their appearance.
- We saw evidence of the clinic manager monitoring and supporting patients who requested different dialysis sessions. Staff described accommodating patient's wishes to attend family occasions and holidays.

Service planning and delivery to meet the needs of individual people

- The clinic manager liaised regularly with the referring NHS trust to ensure local people who met the criteria for care at Hamilton Renal Dialysis Unit received care there.
- Fresenius ran a transport service specifically for the patients of Hamilton Dialysis Unit. Drivers were located on site, which prevented patients waiting for the transport to arrive.

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- During the monthly named nurse discussion and matron's two monthly clinical rounds, staff asked patients about the transport facilities and were given the chance to discuss issues and concerns. We saw evidence of drivers responding well to the groups of patients they transported.
- Toilet facilities were available for patients to use before dialysis commenced. Toilets were not gender specific and were spacious enough to provide access for a wheelchair and assistant. Staff and patients told us it was rare they needed to use this facility during dialysis as this would interrupt or prolong the treatment. However, this could be accommodated if necessary.
- Staff could access interpreting services via the referring NHS trust. Patients told us that they had been offered this when organising their treatment.
- Dialysis away from Base (holiday) patient requests came via head office to the dialysis unit. If capacity existed the clinic manager allocated sessions on the required dates.

Access and flow

- Due to the nature of referrals from the NHS trust, the unit did not have a waiting list.
- Referrals for admission were controlled by the referring NHS trust who contacted the unit to inform them of potential patients. The patient numbers were reviewed weekly in multi-disciplinary team meetings, held with the NHS trust's consultant nephrologist and renal team, where patient capacity at the unit was discussed.
- Between January 2017 and March 2017 utilisation was between 89% and 95%. Throughout 2016, no sessions were cancelled or delayed for non-clinical reasons. Hamilton Renal Dialysis Unit did not have a waiting list.
- Allocation of dialysis sessions was initially organised according to availability with the patient's wishes in mind. If the patient requested a different time every effort was made to accommodate this.
- The referring NHS trust had responsibility for organising clinic appointments held at the unit. Staff told us they tried to support patients when attending these appointments; however, they could not always guarantee they were on dialysis days.
- Patient waiting time was kept to a minimum and dialysis start times staggered to reduce waiting times. Of the 16 patients we spoke with, all were complimentary of the transport system and did not complain of delays. The service did not perform an arrival or waiting time audit.
- Patients told us that the lack of reception staff in the evening caused a delay in entry into the unit via the doorbell system. On our unannounced evening visit, there was no sign of a delay.

Learning from complaints and concerns

- The organisation had a companywide feedback policy, effective June 2016, which we reviewed. The policy covered compliments, comments, concerns and complaints and gave staff guidance for the handling of complaints and concerns.
- The service created an action plan as a result of the 2016 Patient Satisfaction Survey in the form of a "you said, we did" document. One issue raised by patients was that they did not have enough information about how to raise a concern. The service response was for all named nurses to inform patients individually about how to raise a complaint or concern.
- At the time of our inspection, all patients we spoke with knew how to complain. We saw signs in the waiting room explaining, to patients how to complain, and actions taken in response to a patient concern. This involved reminding staff to discuss blood results carefully with patients and explain how staff monitored that dialysis was effective.
- The service had received two complaints during 2016; the manager monitored the theme to these complaints. We saw evidence of an apology to the patients and reminders to staff around attitude and behaviour. All complaints were dealt with within a week of the complaint occurring in accordance with the unit policy.
- We did not see evidence in staff meetings of sharing of, or learning from complaints, however, this may have

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been due to no complaints in the last three months before our inspection. The clinic manager told us this would be the forum in which learning would be shared.

Are dialysis services well-led?

Leadership and culture of service

- Hamilton Renal Dialysis Unit was part of Fresenius Medical Care. The national organisation was led by the Clinic Services Director who reported to the Managing Director. Clinics were divided into three regions, each led by a Regional Business Manager. Each region was further divided into three teams, led by a regional head nurse. The regional head nurse had close contact with the unit and attended regularly. The regional 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.
- The clinic leader had been in post for the past two years and described receiving support and role development from the area head nurse. Over the two year period, the unit demonstrated an improvement in both audit completion and audit results.
- The unit performance was monitored by the area head nurse through clinical performance reports. The clinic manager had a good knowledge of the current performance and the improvements that were required. These included closing the gap between prescribed and delivered dialysis times and improving patient feedback.
- Staff described the manager as visible and approachable and we saw an obvious open door policy. Patients who dialysed in the evening session felt that they did not have the contact with the clinic manager, but described the deputy manager as supportive and proactive.
- The working relationship between the referring NHS trust and the clinic manager was a close and

supportive one. The NHS matron told us that managing a busy satellite unit was a challenge and the clinic manager would benefit from the continued support of Fresenius senior leaders.

- One member of staff spoke of working shifts that suited life outside of work. These were addressed on a case by case basis.
- The organisation has a companywide Code of Ethics and Business Conduct, which we reviewed. This policy stated the company does not permit workplace discrimination of any kind.
- Fresenius Medical Care stated in the company handbook that they 'are an equal opportunities employer and do not discriminate on the grounds of gender, sexual orientation, pregnancy or maternity, marital or civil partner status, gender reassignment, race, colour, nationality, ethnic or national origin, religion or belief, disability or age.' We saw on inspection that the workforce was a diverse cultural mix of staff.
- A memorandum was displayed in the staff room explaining to staff the impact of the United Kingdom leaving the European Union on the staff's right to work. This explained that Fresenius would financially support the application of residency by staff.

Vision and strategy for this core service

- Fresenius services core values were to put patients and partners first, consistently striving to deliver an exceptional service. The service's vision was to always do the right thing with honesty and integrity, whilst never compromising safety and health of their patients. The other two service visions were for staff to work together in teams to accomplish more together than what is possible individually and the service promised to be results orientated, and execute care urgently and consistently using best practice.
- Their mission was to deliver superior care that improved the quality of life of every patient, every day, setting the standard by which others in the health care industry are judged. The core values were 'quality, honesty and integrity; innovation and improvement; respect and dignity.' Staff we spoke to were aware of these core values and described them in their own words.

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- Twice yearly conferences for managerial staff were centred around the values, with breakout sessions that focused on sharing the values with the clinic staff.

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

- Fresenius had a clear governance structure within the managers in the organisation. The recent employment of a national quality and risk manager was in support of the process.
- The clinical governance strategy highlighted the strategic aims of clinical governance within a supportive environment. The clinical governance committee monitored performance of the organisation and was overseen by the medical director. The monitoring of performance was supported by five objectives; to identify and manage expectations, provide clinically effective services; develop and empower staff; engage patients and provide open management.
- The clinic manager collated performance clinical review reports, which included patient outcome data and showed month on month trends, targets, action plans and who was responsible. The patient data was colour coded (red, amber and green), with red for outside the expected range and green for within. These were reported to the corporate governance team.
- The clinic manager had six monthly one to one meetings with the area nurse and director. These were in addition to a yearly appraisal that involved the development of a plan for formal training.
- The involvement of the individual staff in governance in the clinical areas was minimal. Within the clinics, the management of blood results and the dialysis treatment was the governance focus for staff. There was a limited understanding of risk assessments and clinical incident management due to these being the responsibility of the clinic manager.
- A new clinic review process further captured overall month on month clinical effectiveness and improvement areas. As part of the Fresenius clinical governance review and reporting, a report defining the clinic achievement of the Renal Association standards was sent to the respective NHS trust clinicians.
- Risk registers and governance had not been a regular item on the clinic team meetings. A new agenda to team meetings, implemented in June 2017, had incidents as a regular item.
- At the time of our inspection, a clinic risk register was under development.
- Hamilton Renal Dialysis Unit worked closely with the local NHS commissioning trust. Monthly meetings included senior staff from both the NHS trust and Hamilton Renal Dialysis Unit. We saw evidence of a duty of care audit performed by the NHS trust and an action plan in place. Many of the actions were around the cleanliness of the building in 2016. A new housekeeper had been appointed recently and hygiene standards had improved. This was demonstrated by a recent re-audit.
- Fresenius Medical Care reviewed policies and procedures yearly, in compliance with the requirements of the ISO quality management system 9001. However, clinical risk policy and clinical governance strategy had not been updated since 2009 and 2010. We also found some policies did not reference to the most current guidance such as the safeguarding policy (2015).
- We reviewed details of a contract for Hamilton Renal Dialysis Unit to provide services on behalf of a local NHS acute trust which specified the responsibilities of the provider, for example frequency of specific blood tests for patients.
- We saw evidence of learning from learning bulletins and colleague updates. This process had evolved over the past three years, from when a serious incident occurred, to a chance to share learning. In 2016, 17 colleague updates were sent, and between January 2017 and May 2017, five colleague updates and two learning bulletins had been sent.
- The Workforce Race Equality Standard (WRES) is a requirement for organisations, which provide care to NHS patients. This is to ensure employees from black and minority ethnic (BME) backgrounds have equal access to career opportunities and receive fair treatment in the workplace.
- WRES has been part of the NHS standard contract, since 2015. NHS England indicates independent

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healthcare locations whose annual income for the year is at least £200,000 should produce and publish WRES report. Fresenius did not currently have or maintain a WRES report or action plan to monitor staff equality.

Public and staff engagement

- The service gathered patients and staff views through surveys. It undertook a patient satisfaction survey in November 2016. We reviewed the action plan created as a result of this survey, which was in the form of “you said, we did.” For example, patients commented that they wanted to know if they were getting sufficient dialysis treatment to which the service reminded staff to make sure they had discussions with individual patients about their blood results.
- The annual employee satisfaction survey in October 2016, had a response rate of 87%. Staff highlighted concerns of feeling under pressure due to agency staff not performing adequately, inadequate supplies and equipment to do their job, and feeling undermined by patients.
- The organisation responded to all these areas, by emailing the agency provider highlighting the staff performing well and using those as a preferred choice. A discussion was held, and reminder given to all staff on dealing with difficult behaviour and not tolerating bullying and harassment. The unit made the monitoring of stocks a greater focus, with a nominated staff member in charge.

- Patients we spoke with were confident they could raise concerns with the clinic manager. However, one patient told us they had requested an evening receptionist several times, but the service had not supported this. The patient was concerned the clinic manager was not on duty during the evening, although could name the manager and described them as a caring and compassionate nurse.
- The British Renal Association patient advocate had links with the unit and paid occasional visits. Feedback from their visits was presented at the NHS engagement meetings. The patient advocate also commented on the lack of reception staff at the time of their visit.

Innovation, improvement and sustainability

- The unit ensured all available dialysis sessions were filled in close liaison with the referring NHS trust.
- Staff members spoke of a ‘grow your own’ mentality having moved from driver to support staff and then dialysis assistant with support and training. The unit had actively encouraged members of staff to train towards other roles and apply for other positions within the organisation.
- The unit had a Fresenius environment statement poster in the waiting room explaining energy savings and sustainability. The service promoted recycling and minimising waste. The unit manager collected monthly figures of waste reduction and electricity and water savings.

Outstanding practice and areas for improvement

Outstanding practice

- Staff were supported to train towards other roles within Fresenius. We saw an example of a staff member who became a dialysis assistant and commence a career in healthcare with the support of the staff within the unit.

Areas for improvement

Action the provider SHOULD take to improve

Action the provider SHOULD take to improve

- The provider should ensure all staff adhere to correct infection control procedures and maintain a sterile environment throughout connecting patients to the dialysis machines.
- The provider should ensure that all staff have completed their information governance training.
- The provider should ensure that changes to documentation are audited and followed up to monitor compliance and assess effectiveness of information.
- The provider should ensure that equipment within trolleys is checked regularly and no equipment has passed the expiry date.
- The provider should consider how patients access the unit on an evening and how they access the unit manager should they need to
- The provider should ensure that policies and guidance contains the most up to date information available at time of review.
- The provider should ensure they have knowledge of and evidence compliance with the Workforce Race Equality Standard (WRES) which became mandatory in April 2015.