Renal Services (UK) Limited- Havant

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

Overall summary

Renal Services (UK) Havant is operated by Renal Services (UK) Limited. It provides dialysis services and is commissioned by Portsmouth Hospitals NHS Trust, as part of their renal service.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 20 June 2017 along with an unannounced visit on 29 June 2017.

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

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

Services we do not rate

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

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

- Patient group directions were not being used correctly in line with current legislation.
- There was a lack of formal patient identification checks, which had the potential for patients to be placed at risk. Neither did this practice comply with the organisational medicines management policy or the Nursing and Midwifery Standards for Medicine Management, Standard 2 and 8.
- Although patient risk assessments were completed regularly to help ensure patient safety, there was a lack of individualised patient care plans to lessen risks identified by these assessments. There were no personal evacuation plans in place for most of the patients; these were a new initiative recently implemented.
- The documentation audit tool was not reflective of current practice so could not be used to effectively identify areas for improvement.
- The policy and procedures for incident management were not clear, detailed and comprehensive, to provide consistent guidance for staff, and few staff

Summary of findings

had read them. For example, the organisational risk management and incident reporting policy (2017) had insufficient guidance on when and how to apply the duty of candour requirements.

- There was no local risk register; risks were not identified and owned locally but were corporate and high level.
- There was no patients transport group despite the negative responses in the patients experience survey.
- The staff were not aware of a formal tool for the recognition and treatment of sepsis.

- < > provider had not reported on their compliance to the Workforce Race Equality Standard.
  There were generally good standards of infection prevention and control processes observed.
- There was an effective process for obtaining patient consent for treatment; there was good access to the on call renal team, dietitian, pharmacy and specialist nurses. Counselling support was available. Care was based on Renal Association guidance and other evidence based practice.
- We witnessed a friendly atmosphere within the unit, with staff treating patients with kindness. There had been over 100 written compliments but no written complaints in the past twelve months.
- Most patients we spoke with were happy with their care and treatment. There was a dedicated holiday coordinator, who arranged patient's holiday dialysis. Patients had individual televisions and access to Wi Fi whilst having dialysis.
- There had been no reported incidents of patients cancelled for non-clinical reasons over the past twelve months. There was no waiting list and there was capacity to assist the trust with demand.
- The organisation had a planned replacement programme for the dialysis machines.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve.

We also issued the provider with three requirement notices that affected Renal Service (UK) Limited – Havant. Details are at the end of the report.

Professor Edward Baker

Chief Inspector of Hospitals

Summary of findings

Contents

Renal Services (UK) Limited- Havant

Services we looked at
Dialysis Services

Summary of this inspection

Background to Renal Services (UK) Limited- Havant

Renal Services (UK) Havant is operated by Renal Services (UK) Limited. The service opened in 2008. It is a private dialysis unit in Havant, Hampshire providing dialysis to NHS patients referred from the local NHS trust. The unit primarily serves the communities of the surrounding area.

The unit's registered manager had been in post since 2008. The nominated individual had been registered with the CQC since 2012.

NHS consultant nephrologists, from the local NHS trust renal centre who are the service commissioners, held the responsibility for patients' clinical care. They ran clinics on site and referred appropriate patients for dialysis.

An announced inspection was carried out on the 20 June 2017, 7.30am until 7pm and followed up by an unannounced inspection on the 29th June 2017 11.30am until 4pm.

Our inspection team

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

Tim Cooper, Head of Hospital Inspection, oversaw the inspection team.

Information about Renal Services (UK) Limited- Havant

The Renal Services (UK) Limited-Havant occupied two floors in an office block close to a large commercial centre. The service comprised 28 dialysis stations including two side rooms on the lower floor for the segregation of high-risk patients. It was open for three sessions per day, Monday to Saturday from 7am until 11.30pm. It was accessible via a ramp through a secure entry door system.

There was a training service for patients who wanted home dialysis at the location, which the local NHS trust staffed and organised. This was not inspected.

The service was registered with the CQC to provide the following regulated activities for adults over 18 years old:

- Treatment of disease, disorder or injury

Renal Services (UK) Limited- Havant did not offer a service for patients requiring peritoneal dialysis. It supported patients for holiday dialysis subject to there being available space.

There was an unmanned patient waiting area with wheel chair scales, located on the ground floor. There were dialysis stations on the ground and first floor. There was lift access to the second floor.

The access to the kitchens, storerooms, clean and dirty utility rooms, the first floor water treatment plant and staff rooms was by security keypad entry.

During both inspections, we visited both floors of the unit. We spoke with18 staff including; registered nurses, dialysis assistants, health care assistants and senior managers. We spoke with 17 patients. We also received five 'tell us about your care' comment cards, which patients had completed prior to our inspection. During the inspection, we reviewed 24 sets of patient records.

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

The unit was previously inspected in August 2013, which found that the service was meeting all standards of quality and safety it was inspected against.

The accountable officer for medicine safety was the registered manager.

Activity

Summary of this inspection

- At the time of the inspection, there were 138 NHS patients registered at Havant for dialysis, 52 were between18 to 65 years and 86 were above 65 years. The unit provided 432 dialysis sessions per week
- From 1 March 2016 to 31 March 2017 there were 19,492 haemodialysis sessions provided.
- Outpatient clinics also take place on site including NHS consultant clinics, pre dialysis nurse specialist clinics, dieticians clinics and vascular nurse specialist clinics.

Track record on safety

- Zero never events had taken place.
- Zero serious incidents had taken place.
- Twelve clinical incidents had taken place and been investigated.
- 27 patient deaths over the past two years, none had occurred on site but at home or in hospital.
- Zero incidents of healthcare acquired Methicillin-resistant Staphylococcus aureus (MRSA).
- Zero incidents of healthcare acquired Methicillin-sensitive Staphylococcus aureus (MSSA).
- Zero incidents of healthcare acquired Clostridium difficile (c.diff).
- Zero incidents of healthcare acquired E-Coli.
- Zero incidents of bacteraemia (blood infections).
- Zero formal complaints.

Services accredited by a national body:

Whilst there were no services accredited by a national body, the provider had ISO 9001 quality management certification.

Services provided at the unit under service level agreement:

- Clinical and non-clinical waste removal supplied through an external contract.
- Water treatment plan and dialysis equipment supplied through an external contract.
- Environmental cleaning supplied through an external contract.
- Medical equipment supplied through an external contract.
- Training and development provided through an external contract.
- Pathology provided through the local NHS trust.
- Transport contracted through the local NHS trust.
- Interpreting services provided through the local NHS trust.

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?

Are services safe?

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

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

- Patient group directions were not being used safely and in line with current legislation.
- The organisational risk management and incident reporting policy had insufficient guidance on when and how to apply the Duty of Candour requirements. While staff were clear about the importance of being open and honest, they did not understand the term 'duty of candour'. Staff were not informed about when the Duty of Candour would apply or the requirements. Not all staff were up to date with their mandatory training.
- During the unannounced inspection the unit was not secure; all the security key pads were fixed as 'open', there was no attempt made to rectify this by staff. This meant that unauthorised visitors could access the unit and associated medicines and equipment stores.
- The patient identification process did not comply with the organisational medicines management policy (2017) or the Nursing and Midwifery Standards for Medicine Management, Standards 2 and 8.
- There had been no specific organisational audits for medicines or documentation. The tools used were trust designed and therefore did not follow all unit processes, therefore areas of noncompliance, had not been identified.
- There was a lack of individualised patient care plans to lessen risk identified by risk assessments.
- There were no personal evacuation plans in place for most of the patients, as this was in the process of being implemented.
- There was no formal tool for the recognition and treatment of sepsis, although senior nurse leaders told us it was being developed.

However, we also found the following areas of good practice

- There were generally good standards of infection prevention and control processes observed.
- Patients were regularly risk assessed for safety risks.

Are services effective?

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

Summary of this inspection

We found the following areas of good practice:

- Care was based on Renal Association guidance and other evidence based practice.
- Staff were competent or undergoing training to achieve competency to deliver the patients' care.
- Patient consent for treatment was obtained prior to any dialysis commencing on the patients initial visit.
- The unit's patient outcome data was inputted to the renal registry through the commissioning NHS trust.
- There was good communication with the commissioning trust who provided access to the on call renal team, dietitian, pharmacy and specialist nurses.

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

- There were variations observed in clinical expertise between permanent staff.
- The Renal Services (UK) Limited-Havant staff used a large patient diary, which held patient details in addition to the patient record. The diary therefore had to be retained for eight years.'

Are services caring?

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

We found the following areas of good practice:

- Most patients we spoke with (94%) gave positive feedback about their care in the unit.
- We witnessed a friendly atmosphere within the unit, with staff treating patients with kindness.
- Patients were encouraged to be involved with their care as much as they were able.
- Patients in need of counselling or psychology support could access this through the trust.

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

- There were no fitted privacy screens, only mobile screens stored in a cupboard. We did not hear staff asking patients if they would like them when their chest lines were being accessed for set up.
- The organisation stated there was a named nurse concept, however, none of the patients we spoke with knew this or who their named nurse was.

Summary of this inspection

Are services responsive?

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

We found the following areas of good practice:

- There had been no reported incidents of patients cancelled for non-clinical reasons over the past thirteen months.
- There was a dedicated holiday coordinator who arranged patients holiday dialysis.
- Patients who indicated a desire to start home dialysis could be referred into the home dialysis team who were based on site and organised by the trust.
- There had been over 100 written compliments but no written complaints in the past thirteen months.
- Patients had individual televisions and access to Wi Fi whilst having dialysis.
- There was no waiting list and there was capacity to assist the trust with demand.

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

- There was no patients transport group despite the negative responses in the patients experience survey. We were told that patients did not want to form an official transport group.

Are services well-led?

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

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

- The staff had access to policies and procedures which although recently reviewed did not always provide comprehensive clear guidance to the reader. Few staff had read them.
- The auditing tools did not reflect current local practice so could not identify areas for improvement.
- There was no local risk register; risks were not identified and owned locally but were corporate and high level.
- There had been no recent staff survey.
- There was no written strategy for the service provided by Renal Services (UK) Limited, Havant.
- The staffing roster gave staff only two weeks' notice of their shifts, so permanent staff felt they were being rostered around temporary staff.
- There was no organisational Workforce Race Equality Standard report.

However, we found the following areas of good practice:

Summary of this inspection

- The organisational aim of the service was supported by seven values and was on display. Staff were familiar with them and worked to maintain them.
- The organisation had a planned replacement programme for the dialysis machines.

Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are dialysis services safe?

Incidents

- Renal Services (UK) Limited had a risk management and incident reporting policy (2017), which detailed the incident reporting process for all types of clinical and non-clinical incidents. They were graded in five categories between the lowest 'no harm' and the highest of 'death'. The policy explained staff's responsibilities in reporting incidents and risks.
- Renal Services (UK) Limited – Havant reported no never events for the previous twelve months. 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 harm or death but neither need have happened for an incident to be a never event.
- Whilst 27 patients had died over the past two years, none had occurred in the unit but in their homes or in hospital. None was unexpected or attributed to their renal dialysis. The coroner had not investigated any of the deaths.
- Staff had been encouraged to increase the number of incident reported, as it was felt by Renal Services (UK) Limited that they were low reporters. Between 1 January 2017 and 31 May 2017 there had been 11 incidents reported out of 12,000 dialysis sessions. The highest numbers (three in each) were in emergency transfers and access issues. There had been 16 incidents reported in the previous year.
- Staff we spoke with confirmed they understood the process for reporting incidents and could describe incidents, which they would report using the online reporting system. The senior nurses could describe changes because of incidents, but the junior nurses we spoke with had not been in post very long and did not have this knowledge.
- We saw the reporting documents relating to the 11 reported incidents and could see where improvements had been identified as a result. One example was a patient who was a dedicated sports supporter, and missed many of his sessions due to fixtures. The staff reported the missed sessions as incidents. They had taken action by rescheduling the patient's sessions around the fixtures.
- The head of nursing reviewed the incidents for the whole organisation every quarter and identified any themes. One example was patient falls, 15 had occurred during the past year within the whole Renal Services (UK) Limited organisation, many in the patient weighing areas. This had prompted the development of a falls risk assessment and a clinical pathway to help prevent future patient falls by appropriate interventions. In addition, the organisation installed grab rails in the weighing area and a call bell close to the weighing machine. However, when we looked at the weighing area in Havant we identified that the position of the wall-mounted bell may cause a patient to lean forward dangerously to access it; as it was located on the far side of the machine.
- The 'Duty of Candour' is a regulatory duty that relates to openness and transparency and requires providers of health and social care service to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- The Renal Services (UK) Limited risk management and incident reporting policy (2017) explained the

responsibility of staff to uphold the requirements of the Duty of Candour, within the organisation's 'being open' policy. However, there was no guidance on how and when the Duty of Candour should be applied. Staff knew about being open and honest when things went wrong although not all were familiar with the term or principles of the Duty of Candour requirements and when it should be applied.

Mandatory training

- Renal Services (UK) Limited commissioned the delivery of fourteen mandatory training topics during an annual training day which both permanent and bank staff were required to attend. These included for example, basic and intermediate life support, health and safety, fire safety, safeguarding level 2 for both adults and children and infection control.
- Of the 19 members of permanent staff working in RSH, three (16%) were non-compliant and had not completed their annual mandatory training day.

Safeguarding

- Renal Services (UK) Limited had updated policies for the protection of vulnerable children and vulnerable adults. The service lead for safeguarding was the head of nursing supported by the unit manager. The safeguarding lead had received level 3 training in safeguarding children and training in adult safeguarding to equip them for the role.
- Staff we spoke with were aware of the safeguarding policies and their responsibilities within them. They told us they knew whom the safeguarding lead was and who to contact for help.
- Although no young person under the age of 18 years was dialysed in the unit, the organisation acknowledged the role that staff could play in the reporting of suspected concerns. The vulnerable children policy stated individual and corporate responsibilities relating to this. Staff received level 2 safeguarding children training, organisational data showed the compliance for this training was 84%.

Cleanliness, infection control and hygiene

- When we inspected on the initial announced inspection, the unit was visibly clean, free from dust and clutter. However, when we returned on the unannounced inspection, we saw some floors, such as in the waiting area, were visibly dirty and the unit appeared more untidy and cluttered.
- We saw staff using personal protective equipment (PPE), including face visors to protect them against splashes when initiating and completing dialysis. Staff were seen to adhere to the uniform policy, were bare below the elbows with minimal jewellery and wore clean uniforms.
- We witnessed staff actively cleaning equipment after each patient's use; this included the chairs, tables, patient call bell and TV handsets, the dialysis machines including blood pressure cuffs. Staff changed the pillow's disposable covers between patients. We saw staff using appropriate PPE when cleaning.
- There were alcohol sanitiser gels situated at sinks and at some door entrances to encourage staff, visitors and patients to use them. Each patient dialysis station had a pump sanitiser gel dispenser on the table, which staff and patients could access. Staff asked patients to wash their arms before their cannulation, and there were posters encouraging this process.
- Nurses had training in aseptic non-touch technique as part of their induction, this was to minimise the risk of cross infection to the patients. Staff we observed had differing levels of competency in their techniques. For example, of five different staff members caring for ten patients, one staff member was observed contaminating the sterile field and incorrectly opening sterile packs.
- Staff signed daily cleaning checklists on completion of the cleaning tasks and we saw most were completed. Staff were assigned dialysis stations to undertake an additional weekly clean to ensure that the stations were clean for patients to use.
- Renal Services (UK) Limited had an infection control policy (2017) which outlined the processes for staff to use when patients were positive to blood borne viruses. The policy contained guidance about patient immunisation, methicillin resistant staphylococcus aureus (MRSA) and hepatitis screening, the segregation of patients and machines for positive or post-holiday patients.

- The policy referred to the Renal Association guidelines (2007), and although the guidance stated an update was due in 2011, this was not available. The Department of Health 'Good Practice Guidance for Renal Dialysis' (2002) was referenced. However, there was no reference to the Health and Social Care Act (2008), code of practice in the prevention and control of infection and related guidance (2015). This sets out clear systems and criteria for good infection prevention and control practices.
- Staff assessed patients for infection risk on referral to the unit and confirmed their current Hepatitis B status. This was retested following any condition change or post-holiday. The unit had two segregated side rooms for the use of high-risk patients such as those with Hepatitis B or other blood borne viruses. Patients who were classed as high risk for cross infection would have segregated and labelled dialysis machines for their use only.
- The local trust infection prevention and control team undertook spot check audits to the unit, these included hand hygiene results and observation of infection prevention and control practice. The latest results from June 2017 were 96% compliant. There had been no reported patients' infections over the past year.
- Renal Services UK had guidelines for water testing and disinfecting water plant and dialysis machines (2017). We saw dialysis machines running disinfection programmes, and staff cleaning them thoroughly and appropriately between patients.

Environment and equipment

- The unit had a doorbell entry, patients weighed themselves and waited in the lower unmanned reception area for staff to greet them and take them for dialysis. The security of the inner door to the lower dialysis stations was by keypad access; the first floor door to the unit was not secure.
- The unit stored resuscitation equipment appropriate to the needs of the unit in non-tamper evident trolleys. There was a daily check of the resuscitation equipment, which was fully completed. Oxygen was stored appropriately in mobile trolleys, with masks and tubing available on the trolleys for quick access in any emergencies.
- Renal Services (UK) Limited carried out a planned preventative maintenance programme. Daily, weekly, and monthly records of equipment checks, maintenance and servicing and any faults were monitored internally. The local NHS trust, which commissioned the service, also used a monthly monitoring matrix system.
- There were three different machines in use, staff were trained to use all three. There were six spare dialysis machines; the company had a 20% spare policy to allow for replacement if there was a machine failure. One was segregated for an isolated 'high risk' patient. A patient at high risk of infection was having dialysis in one of the two side rooms so not to be a risk to other patients. There was a machine 'refresh' programme; for machines that were nearing the end of life. All machines were in date for servicing and electrical safety checks.
- An external company was contracted to respond within 12 or 24 hrs of a fault reported, in and out of hours depending on the type of equipment failure. Renal Services (UK) Limited monitored the average response times, which showed an average dialysis repair, took six hours to rectify.
- There was a small technician's room for any maintenance or small repairs of the dialysis equipment. Visiting engineers were able to use this room.
- An external company maintained medical equipment for example, patient weighing scales and pulse oximeters; they issued certificates of compliance. However, despite re-calibration earlier in the year, all three sets of patient weighing scales were weighing differently; there was no plan for recalibration. Staff told us they were aware and made sure patients were weighed on the same scales before and after dialysis for consistency. Some patients told us they felt anxious about the discrepancy. All medical equipment was in date for safety checks.
- Staff checked the first floor water treatment plant twice daily for flooding; it had a central floor drain system and a large door threshold to prevent any flooding. Competent staff tested water quality daily.

There was a monthly laboratory test for microorganisms, bacteria and endotoxins. The results showed no incidents of water contamination this year, between January 2017 and May 2017.

- The air conditioning on both floors had broken down; portable units were hired for patient comfort. The storage area was registering very high temperatures during this time and the inspection team checked stock for safety in the extreme heat. All was found to be within safe parameters, although the alcohol gel was moved to a cooler area.
- We saw that the alarms were set on the machines; they alerted staff of any problems such as variations in blood pressure outside of safe parameters. They were answered promptly, with staff actively covering other colleagues' alarms.
- The dialysis chairs all had a nurse call bell attached to the armrest. Staff responded to the nurse call bells promptly.
- Each patient station had a dialysis electric reclining chair, with armrests and footplate for comfort. Patients had access to a ceiling mounted TV for use with their own earphones. The spaces between stations appeared to be quite close but we were assured by the senior nurse leaders who had measured the compliance with the Health Building Note 07-01 and its predecessor Health Building Note 53 with the required 900mm between each station.
- Each patient dialysis station had a patient bed table, which staff used as a dressing trolley, with an attached sharps bin. We saw that the sharps were sometimes difficult to introduce to the bin through the small lid opening.
- Staff transferred the clinical waste and full sharps bins from the unit dirty utility room to a secure waste compound on a trolley, the compound had locked large waste bins. There was a risk assessment for the safe transfer of waste.
- We found on the unannounced inspection that all the keypad locked doors were left open. These included the main unit doors, clean and dirty utility rooms where medicines and waste were stored, and the main stock storage cupboard on the first floor.
- There were no dialysis 'beds' as patients needed to use the reclining chairs for admission acceptance. Staff were able to access pressure relieving 'seat' cushions for patients at risk of pressure ulcers; however, these would not provide relief to sore heels or spinal pressure points. There were no pressure relieving mattresses available. There were no blankets provided, patients supplied their own.

Medicine Management

- Staff used a combination of patient group directions (PGDs) and patient specific directions (PSDs) designed to support the safe administration of medicines; these were provided by the commissioning NHS trust. A PGD is a document which, when appropriately authorised allows for the administration of medicines to a group of patients for the treatment of specific conditions by named, authorised registered health professionals. A PSD is an instruction, generally written and signed by a doctor allowing for medicines to be administered to a named patient after the prescriber has assessed the patient on an individual basis.
- The trust supplied a pre-printed PSD booklet for the unit patients' with agreed named medicines and their specific directions for use in line with clinical guidelines. They included for example, intravenous fluids for use when the patient had a low blood pressure or oxygen therapy when required in emergencies.
- The PSD booklet did not contain instructions for Enoxaparin sodium injection; this was an anticoagulant medicine given for the prevention of blood clots whilst having dialysis. Instead, there was a historic PGD supplied by the trust for staff to use for the administration of this medicine.
- The Renal Services (UK) Limited senior team had identified the PGD's review date was November 2016 and had contacted the acute trust for a revised version. At this time, the trust acknowledged that the new PSD document due in March 2017 did not include Enoxaparin sodium, and the unit was instructed to continue to use the PGD. This information had been shared with the staff.
- On the announced inspection, staff were unable to locate the PGD for the prescription and use of Enoxaparin sodium when it was requested by the

inspection team. The senior team told us that they thought the PGD had been archived during a recent 'tidy' and this would have been a mistake, and it had not been realised it was missing until requested by CQC. We were told by senior staff that an electronic version was available, however staff were unable to access the system the time of our visit. Any electronic version while a source of reference would not have included the staff authorisation process. The Renal Services (UK) Limited senior team obtained a replacement PGD for staff to sign immediately.

- On the unannounced follow up inspection, we were informed the Enoxaparin sodium PGD had been incorrectly archived on the 16 June 2017; this had been retrieved on the 21 June 2017.
- Two non-registered healthcare staff had signed the Trust Enoxaparin sodium PGD in accordance with the acceptable staff characteristics deemed as competent within the same document. The senior nurse leaders said these staff did not administer this medicine; however, this was the opposite of what one of the staff reported. They told us they had received training and had administered the medicine on five occasions. The administration of an injectable medicine via a PGD by a person who is not a member of the registered professions stated in the legislation was in contravention of the Human Medicines Regulations 2012 governing the use of PGDs. These state that only registered health care professionals can administer medicines from a PGD and they cannot delegate to non-registered health care professionals.
- The terms of the PGD listed at the top of the PGD document stated that all authorised staff should receive a copy of the PGD, this had not happened since 2011 when it was initially set up. No staff had been given copies of the PGD; the senior nurse leaders were advised of this after feedback at the unannounced inspection.
- Any staff using a PGD should sign the PGD to indicate they have read and understood the document. This signature should be signed by a person authorising their use of the PGD. This process should be repeated for each version used. Authorising signatures for each individual registered professional's signature had not been added appropriately to the PGD. One member of staff for example had not been authorised since 2011 on version 1 and were now using version 3.1. Senior nurse leaders were advised of this omission on the unannounced inspection.
- There had been no specific staff training in the use of PGDs or PSDs. The intravenous competency training for staff included the administration of some medicines such as iron or vancomycin but not in using PGDs and PSDs. Following the CQC inspection, the Renal Services (UK) Limited senior team issued training via a draft policy with a knowledge check. However, the new policy was not compliant with the Human Medicines Regulations 2012, as it included non-registered staff in the use of PGDs.
- The Renal Services (UK) Limited's medicine management policy (2017) stated that staff must confirm the patient's name, date of birth (DOB) and postcode before administering medicines. We observed eight different patients receiving intravenous medicines; nurses asked patients for their DOB but not their postcode when administering medicines. We confirmed with senior nurse leaders and patients that this was normal practice. The staff assured us that with holiday patients they were more careful.
- The senior nurse leaders told us that due to the 'high risk of error' they retrieved Enoxaparin sodium or other injections for their individual patients from the clinical room. The registered manager told us Enoxaparin sodium 'was always' given at the start of dialysis so there was no need for a time to be recorded on the dialysis prescription, however they should always be initialled as given. We saw this process was not consistent, as although staff always affixed product stickers with batch numbers to the notes; they had not initialled 27 of 64 dialysis prescriptions (42%) which were reviewed.
- There had been no regular medicine administration audits. A trust monthly audit included some components of medicine administration, but did not cover the specific local process. This meant that the audit process might omit to identify areas for improvement. Since the initial inspection, the Renal Services (UK) Limited senior team had designed a broad medicine audit tool.

- Medicines were seen appropriately stored within locked cupboards within a locked room on the announced inspection. Some dialysis medicines, which were dependant on strict temperature storage, were located in a locked refrigerator. The lock on the refrigerator was not working properly which meant that drugs could be accessed easily. This was reported to the senior nurse leaders at the time of the inspection for repair. On the unannounced inspection the door lock was not secured and the refrigerator lock was still not working.
- All refrigerators used for medicine storage should have their temperatures monitored regularly to ensure that medicines requiring refrigeration were kept within their recommended temperature ranges. This should be by a thermometer with a minimum and maximum temperature set (between 2-8 °Centigrade). On inspection, we were told that all of the unit's refrigerator thermometers had broken. We saw the records showed how the temperatures were not recorded regularly, and had no actions being taken when temperatures were outside of the acceptable limits. Inappropriate domestic kitchen thermometers had replaced the clinical thermometers. The unit senior nurse leaders were informed of the need to replace with accurate clinical thermometers and this was seen to have been completed on the unannounced inspection.
- The monitoring of the room temperatures used for storing medicines not requiring refrigeration should also be carried out regularly, the service could not provide assurance that the rooms were kept within the recommended temperature range.
- When the unit was closed, the medicine keys were stored securely in a key safe.

Records

- The unit used a combination of paper and electronic forms of documentation. The patient record in operational use was paper based and contained a segregated record for daily use. An electronic system was used daily to submit any clinical 'variances', however these were not copied into the patient folders. A variance was any variation in the dialysis prescription or untoward incident that had occurred whilst the patient was having dialysis.
- Records were kept securely in a keypad locked room when not in use. The records were held centrally on the nurse's desk for staff to update before staff returned them to the locked store.
- The unit staff used secure passwords to access the trusts electronic record system; the team leaders entered the patients' outcomes and their weights. They printed out the dialysis prescriptions following any amendments by the trust staff. The unit staff told us that trust medical staff including consultant nephrologists regularly accessed and viewed the system for any updates and recent blood results.
- The unit staff also had access to electronic copies of any recent patients' NHS clinic letters, the majority of patients attended clinics on site, supported by the senior nurse leaders. Staff were therefore updated immediately of any treatment changes; copies of any letters to the patients' GPs were available electronically.
- The patient paper records included for example, patient consent to dialyse, their admission details, and infection screening results. There was also the PSD and the monthly blood results sheet. There were no daily evaluations of care except for the occasional brief one line on the dialysis prescription. The records showed that when a patient was assessed as a high risk of falls for example, there was no individualised care plan outlining interventions to prevent a fall and any subsequent evaluations of these plans.
- Nurses did not consistently sign their initials for set up and completion on the daily dialysis prescriptions. A review of 64 dialysis prescriptions found 18 or 28% without any nurse initials for set up or completion of dialysis.
- There was a monthly performance audit undertaken on behalf of the trust, which covered compliance with treatment documentation, however the unit had documentation such as new risk assessments that were not checked by the audit tool. Therefore, the results did not give a complete picture of the standard of record keeping. The past four months audits had scored between 96.4% and 98.5% compliance of those areas of documentation audited.
- There was a process of recording patient updates and details of changes in two large unit paper diaries;

these were secured in a locked room out of hours. Patient names were listed with any updates on care or treatment written beside. The senior nurse leaders were asked about information governance and data protection using this system, which held accessible patient details for longer than was necessary, for example up to the twelve months whilst the diary was in use.

Assessing and responding to patient risk

- The provider received a signed patient referral document from the referring consultant, which included for example details of the patient's medical and infection screening history. On the patients' first visit to the unit, their individual safety risks were assessed and their results recorded.
- The patients were weighed prior to each dialysis session. An agreement of how much fluid would be removed during the session was reached with the patient, taking in to account the patients well-being and their starting weight.
- The patient's temperature, pulse and blood pressure were checked at the start of and then throughout the session. This was part of the close monitoring of the patient to ensure that their condition remained stable throughout their dialysis session.
- Whilst the staff did not use the national early warning system for monitoring the patient's observations, if the staff had any concerns about a patient's condition, they would immediately contact the on call renal team at the local NHS trust.
- There was no formal tool for the recognition and treatment of sepsis, however the close monitoring meant that patients were escalated appropriately when patients' observations indicated any raised risks. Staff we spoke with could describe clearly their actions for the escalation of these patients. The senior nurse leaders told us the organisation was rolling out training in sepsis and a recognition tool was being designed to comply with National Institute for Health and Care Excellence (NICE) NG51.
- Staff told us that there had been some new risk assessment sheets designed by the head of nursing, for example, the assessment for pressure ulcer prevention; falls risk assessment and fluid evaluation. Staff completed them with some variability as they were new and had yet to be embedded.
- Over the two inspection visits, we reviewed 24 sets of patient records; we saw that patients had initial risk assessments, which were reassessed regularly. Staff told us of their practice if a patient was at high risk of developing a pressure ulcer they would obtain a pressure relieving seat cushion. If a patient developed a pressure ulcer, they would be transferred back to the acute hospital to have dialysis on a bed. However, there were no individualised care plans seen to minimise high risks, and therefore no evaluations of the any specific interventions to minimise the risks.
- There were no personal evacuation plans seen for any of the patients on our inspection, despite many patients being immobile and in wheelchairs. Senior staff told us these were new and only recently requested, therefore they were in the process of implementing them.

Staffing

- The unit employed 13.64 whole time equivalent (WTE) registered nurses (RNs), including the clinical manager and senior sister, and five WTE health care assistants (HCAs) of which two were dialysis assistants.
- At the time of the inspection there were seven WTE dialysis nurses posts vacant, in the past twelve months six had joined and three had left the service. There were no vacant HCA posts but in the previous twelve months, three had left and four had joined the service.
- Senior nurse leaders told us that active recruitment was taking place and some applicants had been accepted for the unit and were arranging start dates.
- The commissioning NHS trust determined the staffing ratio, and the skill mix by the British Renal Workforce Strategy Group. The unit worked on a rota based on one RN to every four patients, with a ratio of 70% RNs and 30% non-registered staff. Staffing levels and skill mix were monitored monthly as part of the performance matrix from the local trust. We saw the movement of staff from other units to ensure numbers were sufficient for the patient to staff ratios at Havant.

- To maintain safe staffing levels bank staff were often utilised, agency staff were not routinely used. Many of the organisations and the trust's permanent staff also worked as bank staff, which provided better continuity and care to the patients. We recognised some senior staff that were based in other Renal Services (UK) Limited units were also bank staff at Havant, working on their 'days off'. There had been 249 bank RN shifts used in the previous three months to our inspection, and 103 HCA shifts. The staff worked flexibly covering a variety of different shifts between 7am and 11.30pm.
- During a new bank nurse's first shift, the shift or clinic manager gave them an induction and signed off a competency assessment. This included for example, medicine calculations, intravenous competency with haemodialysis and vascular access.
- Staff had handovers regularly, they ensured that information was shared relating to changes in patient plans or clinic appointments.
- The local trust's consultant nephrologists, who commissioned the service, supplied the medical support for the unit. They provided remote review of patients' bloods, direct contact for advice, onsite clinic visits and direct referrals. The renal on call team were available for patient escalations and advice in and out of core working hours. Patients we spoke with confirmed they saw their consultants a minimum of every three months.
- The trust also provided support to the unit by phone with a renal pharmacist, dieticians and anaemia teams, and a close link to the senior renal team.
- There were no directly employed technical staff; these were requested via the central team for support with any equipment issues.

Major incident awareness and training

- The RSH unit was on the critical or priority list of the local water and electrical suppliers. There were location specific business continuity plans in place, to use in the event of any failure. These also included inclement weather and transport failure.
- There was a minimum of 20% machines not in use in the unit. The water plant alerted staff if there was a break in water supply, there was a 'break' tank, which contained 20 minutes further water to discontinue patients' dialysis safely. If there was an electricity failure, the dialysis machines had reserve batteries, which allowed time for the staff to discontinue patients' dialysis safely.
- The new dialysis-training framework contained links to understanding and management of dialysis patients in the event of any systems failures.
- The unit as part of the building neighbourhood had regular building fire alarm tests. There were in date fire extinguishers at fire alarm points close to the exit doors.

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

Evidence-based care and treatment

- NHS consultant nephrologists led the patients care, and in accordance with the latest national guidance. Renal Services (UK) Limited- Havant monitored and aimed for compliance with the Renal Association Standards. The unit offered patients Haemodiafiltration, which is dialysis that promotes the efficient removal of large as well as small molecular weight solutes from blood. Clinical evidence indicated that Haemodiafiltration achieves better outcomes for patients.
- The service offered all patients dialysis three times a week, which was in line with the Renal Association Guidelines; however, there was some flexibility within the patient group where some had declined three sessions. As part of the patients' referral assessment, the NHS trust assessed their suitability for inclusion on the kidney transplant list.
- The unit staff assessed patients' vascular access in line with National Institute for Health and Care Excellence (NICE) Quality Standard 72 statement 8. They took consented photographs to help assess any changes or access problems, such as poor blood flow and infections. The staff recorded their notes within the trusts electronic system, for review by the patient's consultant nephrologist.
- The nurses monitored patients' blood results and submitted monthly samples for analysis. Blood results were monitored for urea removal, as recommended in

the Renal Association Standards, to measure how effective the dialysis treatment had been in removing waste products. The unit also measured dialysis adequacy and urea reduction. The named nurses shared and discussed the monthly blood results with their patients.

- A trust dietician visited every month and reviewed patients' nutritional status as frequently as was needed, at a minimum every quarter. This complied with the Renal Association guidelines that state four to six monthly dietician reviews should be carried out for stable patients on haemodialysis.
- The head of nursing had developed some specific patient risk assessments based upon the latest national guidance; these included for example the Braden score for pressure ulcer risk, and a falls risk assessment. These had yet to be fully embedded in practice, as there was variability seen in their completion.
- Renal Services (UK) Limited had created competency frameworks and policies based on the Renal Association standards, NICE standards and guidelines set out by the commissioning NHS trust.

Pain relief

- The head of nursing had developed a new pain assessment-scoring tool, this was still being embedded in practice and in most records it was not completed.
- There was no provision for pain relief medicines in the unit, patients were asked to bring their own medicines for self-administration when having dialysis.

Nutrition and hydration

- Patients were offered and enjoyed a hot drink and toast whilst having dialysis, and most brought additional snacks.
- There was a nutritional link nurse, who could access the trust dieticians by telephone for advice or guidance. The dieticians were regular visitors to the unit when they spent alternating whole days every month seeing the patients having dialysis during the three sessions.
- Fluids were carefully monitored and recorded whilst the patients were having dialysis and details of weight and the agreed target fluid removal entered into the dialysis machine and onto the patient dialysis prescription. The nurse and patient discussed and agreed the target fluid loss prior to dialysis starting.

Patient outcomes

- The unit reported patients 'clinical variances' to treatment outcomes every day to the senior team. These included incidents from 1 February until 30 April 2017 for example, 1.2% or 60 patients being over target weight, 0.9% or 45 suffering hypotension and 0.32% or 16 with poor line flow. 0.24% or 12 patients had shorter dialysis sessions than were planned.
- All Renal Services (UK) Limited units were required to report monthly on patient clinical outcomes, these included patients' monthly blood results, dialysis adequacy, vital signs, target weights and nutritional status.
- The local NHS trust also monitored the performance of the unit using a set performance matrix, this was divided into facilities and nursing. Facilities oversaw the availability of equipment, water quality and environment. The average score for the unit for both nursing and facilities was 97.5% compliance.
- The dialysis patients were part of the NHS trusts activity and their outcome data was entered into the Renal Registry by the trust rather than by the individual unit. Therefore, specific unit details from the Renal Registry were not available to the unit or patients. The trust data showed all patient outcomes were within the expected range.
- Patient bloods were taken monthly for analysis, results were then reviewed electronically by their NHS consultant nephrologists and any changes to treatment recorded on the trust system. The unit's team leaders discussed the blood results and any implications with their patients. Particular interest was in the blood urea levels as this indicated effective dialysis was taking place as per Renal Association (RA) Guidelines. From 1 January until 31 May 2017 the RA standard urea reduction ratio was achieved in 90% of patients. 60% of patients' haemoglobin, over 65% patients' calcium and over 65% patients' blood phosphate levels were achieving the RA standards.

- The unit collated the waiting times for patient transport, and fed them back to the trust. The patient satisfaction survey showed 50% of patients were dropped off between 30 and 60 minutes before their appointments and 50% up to 30 minutes after dialysis. 16% patients waited up to an hour to be collected. 75% of patients stated their treatment always started on time.

Competent staff

- An external company provided staff training, including all annual mandatory, health and safety and incident reporting training.
- Staff were supported by an annual performance review in which an appraisal and personal development plan was agreed between the staff member and line manager. We saw that one member of staff was out of date for an appraisal but the rest were completed.
- The unit manager was responsible for staff supervision, management and clinical leadership. Each new staff member was assigned a mentor who oversaw their induction and ensured their clinical competencies were completed.
- The head of nursing implemented a new training framework in January 2017, known as 'Novice to Competent Dialysis Nurse Practitioner Programme'. This was a six months framework, which contained core dialysis knowledge and practice components with associated competencies for completion by the trainee renal nurses. Mentors signed off these competencies when trainees completed their training.
- On inspection, we saw seven staff who had been recently appointed were working on their competency frameworks.
- The clinical nurse specialist was implementing reflective practice and action learning sets to support the staff. All senior staff nurses had mentorship courses offered, to enable them to support their mentees.
- Renal Services (UK) Limited, seconded nurses to the Advanced Renal Course with three different universities located across England. Seven unit staff had completed this training.
- An external company provided recruitment and support with human resource issues; they screened potential new employees for suitability and performed the appropriate background checks. The senior nurse leaders carried out the interviews for both permanent and bank or temporary staff.
- New employees were given an induction period, when they were not counted in the staffing numbers, this enabled them to receive the organisational induction. This time also allowed staff to learn the work processes, policies and procedures for the unit.
- There were no reassessments of competency regularly undertaken, we observed a variety of different staff grades attaching and taking patients off dialysis, two members out of the five permanent staff witnessed, had poor clinical techniques.

Multidisciplinary working

- The consultant nephrologists from the commissioning NHS trust had overall responsibility for the patients' care. Staff used the trusts electronic system for communicating monthly blood results and any changes in the patient's condition to their consultants. Nurses from the unit supported the patients having their reviews.
- The consultants held review clinics on the site, this enabled patients to be reviewed whilst they were on site for dialysis and prevented them having a further visit to the hospital. Patients were scheduled for appointments at a minimum every three months whilst they were attending the unit for dialysis.
- The dieticians and specialist nurses also held clinics twice a month on site, the dietician covered the whole of the three-session day to maximise their access to patients.
- Staff escalated any patient concerns to the on call renal registrar at the local trust; this was via the trust switchboard and a bleep. Staff used this for example when there was any indication of infection or sepsis in a patient. Staff recorded any interventions electronically for access by the whole trust team.
- Patients could access counselling and psychology support if the staff felt it would benefit them. The trust consultants made referrals when appropriate.

- We observed good interaction between the unit and the trust with a patient due for an elective operation, with staff calling the trust to ensure that dialysis was booked for the patient during their planned stay.
- Pharmacy support was provided remotely by the trust and there was a named renal pharmacist who could be called by telephone. They had not visited the unit.

Access to information

- Staff recorded any outcomes or variations in the patients planned care in the Renal Services (UK) Limited electronic system, this was accessible to Renal Services (UK) Limited- Havant staff only. The trust's electronic system was accessible to staff at Renal Services (UK) Limited- Havant.
- We saw in some of the patients records we reviewed there had been sharing of information between the NHS, dialysis service and GP, with copies of letters printed out for information. Staff were able to easily access clinic letters through the trust's electronic system.
- Staff accessed blood results via the trust electronic system; senior nurse leaders told us that the patients' named nurses informed the patients of their results and discussed any diet or lifestyle adjustments.
- The unit used a large diary system to record changes or adjustments to patients care; this was used in staff handovers and was accessible to all staff. There was a list of all patients every day, with any prompts or care adjustments detailed beside the names. The diary was locked away at night; but there was no system for removing past patient names or details of care for the whole year. This is a concern regarding compliance with the Data Protection Act (1998), which requires data to be held for no longer than is necessary. The Records Management Code of Practice for Health and Social Care (2016) states that clinical diaries must be written up and transferred to the main patient file, if not they must be retained for eight years. As we were not assured that information was fully transferred to the main patient folder, an eight year retention rate would apply.'

Consent, Mental Capacity Act and Deprivation of Liberty

- Each patient had a 'consent to treatment' signed document in their paper records, this covered consent to dialysis treatment, the sharing of their information such as blood results and the use of photographs in fistula management. The patient signed this at their initial visit prior to commencing treatment. Staff did not ask for verbal consent at each dialysis session. They respected their patient's decisions if they wished to miss or shorten a session, and tried to ensure that the patients were fully aware of the risks and then recorded this as a variance.
- Staff we spoke with were aware of the Mental Capacity Act 2005; they understood the rights of a patient to decline treatment. Staff we spoke with told us that patients with declining capacity or understanding such as those living with dementia would not normally be considered suitable for dialysis in this unit. They were either not accepted or referred back to the trust for dialysis if their capacity or understanding deteriorated.

Are dialysis services caring?

Compassionate care

- The Renal Services (UK) Limited described their approach as delivering 'inspired patient care'. They collected patient feedback using several different methods, a local suggestion box, directly to the trust and in the patient satisfaction survey annually in December. The last survey in December 2016 indicated 79% patient satisfaction for the environment, 80% satisfaction for staff treating them with respect and dignity and 91% for helpful staff.
- We witnessed staff interacting with patients in a friendly and welcoming way; patients did not have an assigned station so waited in the reception area to be escorted to their dialysis station. There was a jovial friendly feeling to the various conversations which were overheard.
- We saw that there was individual consideration for the patients' personal and cultural needs for example a patient awaiting transfer to the trust was cared for in one of the side rooms. This allowed the staff to monitor them more closely whilst resting rather than

be sent to the trust and have to wait for a bed to become available. Another patient was in conversation about moving his or her regular time slot because of attending a family occasion.

- Staff respected patients' privacy and held quiet conversations with them when discussing their dialysis plans.
- We spoke with 17 patients across the two site visits. The feedback was almost all positive with comments referring to a 'good service', 'good care' 'staff are a nice bunch' 'staff always ask how I am'. One patient negatively described their experience of 'having to wait a long time' in the waiting area to be set up for their dialysis. The five CQC feedback cards contained all positive comments including 'staff are marvellous', 'staff all very professional' ' staff do fantastic job' ' cannot praise staff enough for dedication and care', 'always listened to.. an exceptional unit'.
- There were no fitted privacy curtains around the stations, although there were portable solid screens for use these were stored in a locked cupboard. We did not hear any of the patients being asked if they would like to be screened when their chest lines were being set up. This lack of privacy could negatively impact the dignified care and experience of some patients.

Understanding and involvement of patients and those close to them

- Patients we spoke with appeared fully informed and involved with their care, they knew about their latest blood results and were reassured that they could see someone from the trust renal team if they needed to.
- Patients were involved as much as they were able with their care; they weighed themselves if they were able to and shared the information with their assigned nurse.
- The organisation supported the holding of patient and relatives social events at Easter and Christmas; these helped to develop their relationships and provided social opportunities for patients.
- The staff spoke about using a 'named nurse' approach, however, the patients we spoke with did not know who their named nurse was and there was no patient information displayed to indicate who their named nurses were. The patients confirmed that they had regular information about their blood results but this was with a number of nurses.

Emotional support

- The patients received prompt responses to their call bells or machine alarms. Staff cross-covered each other, which meant that patients received prompt attention at all times, which prevented the escalation of any anxiety.
- Patients did not have a set dialysis station but moved around from day to day. Most patients seem to know the staff and each other very well, greeted them by their first names, and exchanged friendly banter. They appeared at ease and there was a convivial atmosphere in the unit.
- Patients could access the support of counsellors or psychology support if needed. Nurses identified the need and accessed support for the patient through the trust's consultants. Patients told us they appreciated the ability to see their consultants and dieticians on site.
- We witnessed that the staff provided calm reassurance to patients and fully explained the care processes as they were undertaken. A CQC patient feedback card spoke about the unit being 'one big family'.

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

Service planning and delivery to meet the needs of local people

- Renal Services (UK) Limited-Havant was not purpose built but commissioned within an office block in 2008; internally there were clearly defined patient and staff only areas. The unit was compliant with the NHS Estates guidance (Health Building Note 07-01). However, there was only one patient toilet on each floor, which catered for able, disabled and mixed sex patients' access. The DOH guidance (2007) requires toilet facilities to be gender specific in health care facilities.

- The demographics of the patients attending the unit were 15% under 54 years, 47% over 55 years and 38% over 75 years. There were slightly more men attending than women.
- The unit had increased regularly in size, in direct response to the trust's growing demand for more capacity. From ten stations with a two-session day initially, up to the 28 stations with three session days six days per week in 2017.
- The building location had adequate designated parking spaces for those patients who chose to drive themselves to the unit; there was wheelchair ramp access to the secured front door and a lift for access to the first floor.
- Outpatient clinics took place on site weekly, the consultant nephrologistswould see patients in a confidential clinic room or whilst they were dialysing if that was the patient's choice. Patients confirmed they saw their consultants at least every three months.
- There was no transport user group for their patients; the local NHS trust commissioned patient transport. The staff provided feedback regarding any transport timing issues that caused delays in the dialysis and put pressure on the unit. Patients we spoke with were mostly happy with their transport although a few coming from the west of the location spoke of problems with excessive traffic and long journey times. One patient was personally paying to travel by taxi due to thisMost patients stated they were within a 30-minute journey time. Comments from patients include 'transport organisation is very poor', 'new drivers do not know which order … to pick up, leading to redirection and lateness of drop offs'.
- Within the patient satisfaction survey 2016, there were four specific questions relating to transport issues. The results showed that of all the questions, the transport issues had the most negative responses; the unit's action plan created in February 2017 however did not reflect any of the transport issues.
- Staff could request interpreters via the NHS trust if there was a need to provide patient information in alternative formats or languages.
- Many of the patients attending the unit were frail and reliant on mobility aids such as frames or wheelchairs. Personal evacuation plans were not seen in any of the records that were reviewed as Renal Services (UK) Limited had only just had requested them for patients. This meant that in the event of fire, patients who would need additional help for evacuation had not been identified and a plan agreed. The Renal Services (UK) Limited senior team was exploring further potential capacity by moving some of the offices and clinical rooms out into an adjacent area and converting these to patient areas.

Access and flow

- There was a clear referral pathway for new patients, there were no patients on the waiting list and the utilisation of the unit capacity for the months of January until March 2017 was an average of 82%.
- There had been 19,492 patient dialysis sessions provided between 1 March 2016 and 31 March 2017. There had been no patients cancelled or delayed for their dialysis sessions for a non-clinical reason over this period.
- All patients were offered three sessions per week, each for a minimum of four hours, although this was flexible according to the consultants' wishes. The unit could accommodate twice weekly or additional dialysis hours for patients if required.
- Patients were able to dialyse in the time slots which they preferred to suit their personal commitments and lifestyle. Patients told us that there was also flexibility to change the occasional session for a special event or appointment. Staff would plan the patients session times around consultant or dietician appointments.
- Senior nurse leaders told us there was capacity on the twilight and some daytime sessions to respond and assist the trust with emergency capacity issues. Lower risk patients would be accepted when this occurred.
- Any patients who did not attend for dialysis were reported as incidents and followed up by staff.

Meeting people's individual needs

- Patients were able to visit the toilet before dialysis commenced, as it was located in the waiting area. Staff helped patients who needed assistance before taking them into the unit and starting their dialysis session.

- There was a water fountain, a wall mounted television and accessible mixed sex toilet facilities provided in the reception area. There were a large number of patient wheelchairs stored in this area whilst their owners received dialysis.
- Patients had access to an individual TV set, personal lighting and there were DVD players on request. Wi-Fi was available for those patients wanting to access the internet or their treatment information within 'Patient View' on laptops or tablets.
- The Renal Services (UK) Limited employed a dedicated holiday dialysis coordinator who provided help in arranging holiday dialysis. They liaised with patients, trusts consultants and units to book sessions for patients wanting to take a holiday. Although there was no set holiday availability, the unit was usually able to accommodate holiday patients.
- There was a strict criterion for acceptance, to prevent cross infection to other patients and to ensure that the patients' needs could be safely cared for in a standalone unit. Specific information was requested four weeks prior to the holiday dates and checked by the unit staff prior to the patient being accepted. The information included for example, their fitness status, infection status and require only low dependency nursing care.
- Patients who wished to participate in their own care were supported to do so. On their initial visit they would be asked about the level of involvement they wanted. We did not see many patients actively involved in self-care.
- There was a home dialysis teaching facility on site, which was managed by the trust, for teaching patients about home dialysis. Patients were referred into this if they so wished and met agreed criteria.

Learning from complaints and concerns

- Whilst there had been over 100 compliments to the service in the twelve months betweenthere had been no written complaints. Patients told us if they had any problems they would speak to the senior staff and they would sort it out.
- The organisational complaints procedure was included in the patient's guide which was given to patient's on their first visit. The complaints procedure was a four staged escalation approach with clear timescales and named individuals for responses, similar to that used in the NHS.
- Renal Services (UK) Limited reviewed all units' complaints and responses at the organisation's monthly clinical governance meetings; the minutes were circulated to all units' staff for learning.

Are dialysis services well-led?

Leadership and culture of service

- There was an organisational structure, described by the senior team as flat and 'nurse led', which showed how the unit fitted into the organisation. This illustrated how the two senior nurse leaders reported into the regional clinical manager and then into the head of nursing. The head of nursing and the head of contracts (quality and regulatory) reported to the chief operating officer. At the top of the organisation, there was a partnership of medical director, chief executive officer and the board of directors.
- The Renal Service (UK) Limited-Havant two local senior nurse leaders, both had extensive renal clinical experience and formal renal qualifications. A regional clinical manager supported them. The two senior nurse leaders were clear about their individual roles and responsibilities. Staff we spoke with understood how they could access the organisation's senior team members if they needed to.
- Staff we spoke with felt supported by the two senior nurse leaders and we saw them actively practising their clinical roles and providing guidance and advice to more junior staff.
- The senior nurse leaders had approachable and accessible leadership styles; the staff and patients knew them by name and obviously felt comfortable sharing conversation.
- The two senior nurse leaders spoke of recent changes within the organisation; they understood and supported the changes to their practice. They spoke of good support from the organisation's senior team with daily calls and prompt responses to any of their queries.

- The senior nurse leaders acknowledged difficulties in writing the staffing rota in time for staff to plan their lives; usually it was with only one to two weeks' notice. This meant that the unit staff were often unhappy about the late allocated shifts; we were told the main issue was trying to find cover for all the shifts before publishing the rota.
- The Workforce Race Equality Standard (WRES) is a requirement for organisations, which provide care to NHS patients. This is to ensure employees from a black and minority ethnic (BME) backgrounds have equal access to career opportunities and receive fair treatment in the workplace. WRES had been part of the NHS standard contract since 2015. NHS England indicates independent healthcare locations whose annual income for the year is at least £200,000 should produce and publish WRES reports.
- When we inspected Renal Services (UK) Limited did not have or maintain a WRES report although the external provider of recruitment services, monitored diversity in order to ensure staff equality. We saw on inspection that the workforce throughout the organisation was a diverse cultural mix of staff.
- There was an equal opportunities policy within the staff handbook, which outlined the processes to prevent discrimination related to age, gender, marriage or civil partnership, pregnancy or maternity, religion or beliefs, sex or sexual orientation.

Vision and strategy for this core service

- Renal Services (UK) Limited stated their organisational aim was to provide 'Inspired Patient Care'. The organisation had identified seven values, which supported this aim. These were stated as :-
- < >
  Service Excellence
- < >< >
  Communication
- < >< >The unit displayed the organisational aim and values in the patients waiting area in and within the patient guide. Staff we spoke with showed a general understanding of them.
  - Renal Services (UK) Limited had developed a service development strategy, which was for growth linked to a response in demand.
  - The unit senior nurse leaders attended organisational away days and conferences, to support and develop them in their roles.

Governance, risk management and quality measurement

- Renal Services (UK) Limited described their governance framework as two streams, clinical governance and corporate governance. There was a named organisational lead for both streams. The clinical governance lead was responsible for compliance with Renal Association Guidelines, clinical risks, incidents, patient satisfaction, clinical audits, infection control, information governance, and policies and procedures. The corporate governance lead was responsible for quality management for example covering health and safety, non-clinical risks, business continuity, environmental, human resource and financial management.
- We observed, that the organisational governance processes had not been effective for identifying when practice was not in line with the organisational policies, procedures and expectations or current legislation and national guidance. The local trust visited regularly and fed back any clinical or organisational issues. The last visit from the trust's senior nurse was in April 2017, and the trust infection control team had visited for an unannounced spot check audit in June 2017.
- Renal Services (UK) Limited clinical governance strategy was dated 2017, and outlined their aims as
  - Demonstrating outcomes of patient care
  - Continually monitor and improve practice and services against National and European standards
  - Ensuring staff are skilled and trained
  - A commitment to sharing information and having supervision from NHS trusts
  - Auditing clinical outcomes for patients'
- The organisation held a quarterly clinical governance meeting; chaired by the chief operating officer and attended by the medical director, head of nursing and regional clinical manager. Although

the minutes showed that, they discussed local incidents and unit clinical variances, complaints, audits and operational issues. Any actions agreed did not appear to be monitored for local unit completion.

- The unit's senior nurse leaders reported the units' clinical performance to the clinical governance committee; this included any variances to patient care and subsequent actions to support the patients. Any incidents and variances were shared for learning. There was a monthly manager's team call used for updates on operational issues such as recruitment, appraisals, and rosters.
- The local senior nurse leaders held regular staff meetings for exchange of information and updates; these had minutes so that all staff could read the updates.
- Staff from the unit attended the commissioning trust's monthly renal update; minutes showed that items discussed included quality improvements, vascular access, transport and infection controlThe trust' lead nurses made regular quality monitoring visits and reported any issues.
- Renal Services (UK) Limited had an organisation wide risk register, which was located in the business continuity policy; there was no local Renal Services (UK) Limited- Havant risk register. This meant that local staff might not recognise, raise and own their local risks. There were no risks identified that were specific to the Havant location.
- Local health and safety and environmental risk assessments had been undertaken and paper copies filed in a folder for review. Senior nurse leaders showed us for example, an in date local risk assessment for the transport of clinical waste to the external waste compound. This had assessed the manual handling and transportation risks with actions.
- The Renal Service (UK) Limited had reviewed and updated most operating policies in the previous six months to our inspection. However, we found polices did not always provide comprehensive clear guidance to the reader. For example, the risk management and incident reporting policy (2017) and the summary incident-reporting flowchart outlined responsibilities and actions to take when incidents occurred. The flow chart showed which incidents needed to be reported to external bodies such as the CQC and when to contact the NHS trust. This level of detail was not in the policy. There was no clear description of clinical and non-clinical incidents or near misses. This meant that staff might miss opportunities for learning from incidents to prevent recurrences. We were told that the flow chart and the policy were meant to used together.
- The unit had a file of printed operational policies for staff reference, most dated March 2017 as they had recently been reviewed. There was a signature list in place for staff to sign when they had read each policy. However, on inspection we found that only a limited number of policies were signed as read. We saw that out of 22 policies, the majority had just the same two signatures signed as read from the list of 19 staff. For example, the medicine management policy (2017) had just five staff out of 19 indicating that they had read it.
- The infection control policy (2017) did not refer to the Health and Social Care Act, 2008, code of practice on the prevention and control of infection and related guidance (2015) which sets out the systems and criteria for good infection control and prevention practices. The medicines management policy (2017) did not include details relating to the storage of dialysis medicines on site or any medicine audits. A new draft policy 'Use of PGD/ PSD Policy' that was created following the initial inspection, did not comply with the Human Medicines Regulations 2012.

Public and staff engagement

- We witnessed that patients and staff were actively engaged in decision making about the treatment plan before starting dialysis, recording any decisions on the dialysis prescription.
- The organisation actively sought patient views before selecting new equipment, for example there was a trial of exercise bikes at the unit prior to two bicycles being purchased.
- There was an annual patient satisfaction survey undertaken, the latest in December 2016 showed

that between 63 % and 91% of patients were 'always' satisfied with aspects of their care. There were three areas of concern identified (excluding transport issues); the cleanliness of the patient toilet, level of noise, and contact details for patients after leaving the unit. All of these issues were detailed in an action plan with actions completed. The transport issues were not addressed although a live spreadsheet was maintained for the trust to discuss key performance indicators at the transport contract team meetings.

- Patients participated in local and national patient surveys, the senior nurse leaders told us that it was difficult to get patients to respond.
- Only 6% of patients belonged to the local Kidney Patients Association, 12% knew who the local representative was and 62% did not view it as a useful resource.
- The patient' guide had been recently updated and contained information about unit and manager contact details, including emergency out of hours numbers and details of how to make a complaint. There was also a patient comments box for patients to raise or comment anonymously on their care.
- There had not been a recent staff survey and the Renal Service (UK) Limited described this being a priority for later this year. There were details within the staff handbook relating to staff whistleblowing and raising concerns.
- < > Renal Service (UK) Limited senior team stated they provided opportunities for staff feedback via the daily phone calls to the senior nurse leaders. However, this was not routinely accessible to more junior staff that only had access to their mentors and the local senior nurse leaders.

  The Renal Service (UK) Limited ensured that improvement was sustained by close working with the local trust, organisational learning from any incidents or complaints and links with the British Renal Society Clinical Practice Committee.
- The unit had been involved in local fundraising initiatives. There had been open days for health care professionalswho worked in care homes to increase awareness of kidney disease.
- The Renal Service (UK) Limited technicians monitored the usage of the dialysis machines, when each had completed 35,000 hours there was a planned schedule for replacement. The asset register was held by the head office for all the machine nationally so there was an organisation approach to replacement.
- There was a new programme for the recycling of dialysis concentrate containers via an external company; all cardboard packaging was also recycled.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must take prompt action to address a number of significant concerns identified during the inspection in relation the governance of the service, with particular reference to the use of the patient group directions.
- The provider must ensure that staff are aware of the requirements of the Duty of Candour and when it should be applied.
- The provider must ensure that the system of door keypads for patient security is utilised.
- The provider must ensure the audit programme is designed to improve quality standards. For example, to audit medicines management, and records reflect agreed processes and practices.
- The provider must ensure that patients have individualised care plans for lessening any identified safety risks.
- The provider must ensure that all staff have completed education in the recognition and treatment of sepsis.

The provider must review its process for patient identification, to comply with its own policy and the Nursing and Midwifery Standards for Medicine Management, Standards 2 and 8.

Action the provider SHOULD take to improve

- The provider should complete the personal evacuation plans for all patients to enable their safe evacuation in case of emergency.
- The provider should develop a clear, accurate policy and procedure for incident management.
- The provider should check that patients are formally identified at the start of each session and before administration of medicines, in line with their policy.
- The provider should carry out a survey of staff views to identify areas for improvement.
- The provider should create a service strategy for the unit, so staff and patients understand and can participate in forward planning.
- The provider should check policies and procedures are aligned to best practice and are sufficiently comprehensive to guide staff. For example, the risk management and incident policy (2017), the medicines management policy (2017) and the infection control policy (2017). The draft PSD and PGD policy should reflect the Human Medication Regulations (2012).
- The provider should ensure that staff have read the reviewed policies.
- The provider should ensure that all staff complete annual reassessment of competencies.
- The provider should undertake a risk assessment of the location of the patient call bell near the wheelchair weighing scales.
- The provider should consider setting up a patient transport group to reflect the negative experiences of some patients.
- The provider should review the use of the patient diary, with reference to keeping patients details accessible for longer than is required.
- The provider should ensure compliance to the Workforce Race Equality Standard.
- The provider should review the maintenance of the patients' privacy and dignity, for example , lack of fitted privacy screens, mixed sex facilities such as toilets.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **How the regulation was not being met** The patients who had identified safety risks did not have individualised care plans to lessen the risks. Staff were not compliant with the providers medicines policy and with the NMC Standards 2 and 8 for Medicine Management. Patients did not have personal evacuation plans in place. The use of door security keypads was not consistently used to keep patients safe.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **How the regulation was not being met** Staff were not aware of the protocol to assist in the recognition and treatment of sepsis. Audit tools did not fully monitor processes to improve the quality and safety of the service.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 20 HSCA (RA) Regulations 2014 Duty of candour Staff were not familiar with the requirements of Duty of Candour and when it should be applied.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **How the regulation was not being met** • Failure to ensure that good governance processes are in place and facilitate effective operating systems to comply with these regulated activities. Systems and processes such as regular audits were not being effectively used to assess, monitor and improve the quality and safety of the service. • There was a lack of understanding of the correct process for the use of a patient group direction (PGD), for the administration of Enoxaparin sodium. To minimise the likelihood of risks and to minimise the impact of risks on people who use services. • The PGD for the administration of Enoxaparin sodium had been removed from the premises and staff continued to administer the medicine without any other form of legal prescription. • The PGD was noted to have a review date of 16 November 2016. This meant there was no current PGD reflective of the legal requirements of the Human Medicines Regulations 2012 for staff to follow to ensure the safe administration of Enoxaparin sodium. • The staff's individual signatures had not been authorised correctly with only one authorising signatory on a page. • The PGD in use referred to the following staff characteristics being able to administer from the PGD, this included registered nurses, trained health care support workers, dialysis assistants and senior administrative technicians. The Human Medicines

This section is primarily information for the provider

Enforcement actions

Regulations 2012, Schedule 16 Part 4, the legal framework by which PGD's can be used, specifies that PGDs must be undertaken by a registered health professional only.

- There has been no audit of medicine administration practice.
- While risk assessments were being completed they were not consistently followed up with individualised plans of care to reduce any risk
- When 64 individual dialysis prescriptions were reviewed, 27 were not initialled to confirm the administration of the Enoxaparin sodium.

Regulation 17, (1) (2) (a) (b) (c) (f)