

# Gloucester Royal Hospital Renal Units

## 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

Gloucester Royal Hospital Renal Units is operated by B. Braun Avitum UK Limited. The service has a total of 50 stations across three units providing haemodialysis treatment for adults (those aged 18 years and above). Two of the locations; Cotswold and the Severn units operate on an outpatient basis and are open six days a week. On three days a week the outpatient units remain open until midnight. Ward T7B provides five beds for patients with more complex needs who require 24 hour treatment and care. A holiday haemodialysis service was available to patients living out of the county and a home haemodialysis service was available to patients who were deemed suitable for this by their treating consultant.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 23 and 24 May 2017 along with an unannounced visit to the service on 1 June 2017.

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

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

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

We found the following area of outstanding practice:

- Patients were supported to actively engage with their disease and treatment plans as much as they wanted to in order to achieve good outcomes and maintain quality of life. This was supported through continuous discussion, and shared care planning with staff. For example: patients were enabled to access their blood test results remotely and to complete clinical procedures related to haemodialysis treatment. Also, if deemed suitable by their consultant, patients were provided with training and specialist equipment to be able to independently have haemodialysis treatments at home.

We found the following areas of good practice:

- Effective systems were in place to ensure all haemodialysis equipment was regularly serviced and maintained in accordance with the organisations policies and manufacturers recommendations.
- The water plant treatment systems were checked twice a day and consistently exceeded safety standards recommended for haemodialysis treatments.
- Adequate stocks of consumable equipment were available to meet service needs. Stock rotation processes were followed to ensure consumables used in the delivery of treatment and care were in date.
- Staff had the right skills and experience and were supported with professional development. This included accessing specialist renal training with university level accreditation.
- The majority of staff were supported to have annual appraisals and complete both the organisations and local trust mandatory training. There were a range of in date policies and procedures which staff knew how to access.
- Positive and collaborative working practices were established between NHS consultants and dietitians and B. Braun clinical staff. This partnership working enabled the promotion of coordinated patient treatment and care.
- Detailed patient records were maintained and regularly reviewed. A combination of electronic and written patient records were completed. These included a descriptive documentation of the treatment and care provided to patients.

# Summary of findings

- Positive patient outcomes were well established. Gloucester Royal Renal services monitored key performance indicators (patient outcomes). Senior staff attended meetings every two months to report these back to commissioners. These consistently demonstrated the service performed as well as other similar haemodialysis services.
- Patients' were overwhelmingly positive regarding how they were provided support by staff. Patients' told us they felt involved with their treatment and care and that staff demonstrated compassion, dignity and respect at all times.
- The service was responsive to the needs of local people. There were no waiting lists for haemodialysis treatment and if patients were deemed suitable by their treating consultant, there was the option of a home dialysis service.
- Patients were supported with access to holiday haemodialysis. This included support to organise this in other haemodialysis services nationwide or worldwide, and also to provide haemodialysis to patients not local to the Gloucestershire area.
- Patients' records were clear and organised and stored safely. Regular audits were completed and actions taken to maintain good record keeping standards.
- Clinical care was consultant led and regularly reviewed. There were effective processes in place to respond to patients who unexpectedly deteriorated. All staff had in date resuscitation training and the service promptly transferred patients to the local NHS trust when required.
- There was a positive working culture and staff told us they were proud of the patient care provided and enjoyed working for the organisation.

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

- The registered person must ensure the proper and safe management and use of all medicines. Gloucestershire Royal Renal units did not have a relevant policy or patient group direction (PGD) or use prescriptions for all fluids. This was not in line with national guidance (Standards for Medicines Management, Nursing and Midwifery Council, 2007, National Institute for Health and Care Excellence, CG 174, 2013).
- There was no policy, standard operating procedure or specific staff training to promote the early identification of sepsis (infection) in line with national guidance (NHS England, 2015).
- The registered manager should ensure they have knowledge of and evidence compliance with the Workforce Race Equality Standard (WRES) and Equality Delivery System (EDS2) which became mandatory in April 2015.
- Improvements were required to show how incidents were interrogated for safety and quality improvements. How actions were completed and learning shared was not always evident.
- The processes to fully share and learn from serious incidents required improvement. Meetings between B. Braun and NHS staff had been facilitated to explore learning without all the relevant staff being invited to meetings.
- Most of the clinical staff we spoke with did not know which patients had a Do Not Attempt Cardio Pulmonary Resuscitation (DNACPR) in place. This included acute patients admitted from other wards within the local NHS trust to ward T7B.
- Improvements were required to governance processes. There was a lack of documentation to show how quality and performance information had been scrutinised for trends and learning. Meeting minutes lacked action plans and timescales and staff did not routinely receive feedback from management meetings or from those meetings held with the local NHS trust.
- Whilst senior staff demonstrated they escalated any identified issues to other relevant organisations, this was not always done in a timely manner. This included notifying the Care Quality Commission (CQC) and the local NHS trust.
- Staff lacked understanding regarding best practice for end of life care, when this might be appropriate to discuss with medical staff and how staff could best support patients.

**Professor Edward Baker**  
**Chief Inspector of Hospitals**

# Summary of findings

## Our judgements about each of the main services

### Service

### Dialysis Services

### Rating

### Summary of each main service

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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# Gloucester Royal Hospital Renal Units

**Services we looked at**

Dialysis Services;

# Summary of this inspection

## Background to Gloucester Royal Hospital Renal Units

Gloucester Royal Hospital Renal Units is in the city of Gloucester, within the county of Gloucestershire. The haemodialysis service started during 1992 and was provided by alternative providers until 2012 when B. Braun Avitum UK Limited took over the contract.

Gloucester Royal Hospital Renal Units is a nurse led service providing haemodialysis treatment on behalf of Gloucestershire Hospitals NHS Foundation Trust. The service is for adults (aged 18 and above) who live within the Gloucestershire area. A home haemodialysis service is provided for patients assessed as suitable for this and a holiday service is also provided for patients who live in other counties.

Gloucester Royal Hospital Renal Units provides haemodialysis from three sites within a local NHS trust site. Included in the contract for dialysis services is the provision for home haemodialysis. We inspected Gloucester Royal Hospital Renal Units on the 23 and 24 May 2017 and 1 June 2017. At the time of the inspection there were 206 patients using the service.

Gloucester Royal Hospital Renal Units is registered to provide the following regulated activities:

- Diagnostic and screening procedures.
- Treatment of disease, disorder or injury.

The service has had a registered manager in post since 2 April 2012 and the current manager was registered with the CQC since that time.

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, and the most recent inspection prior to this one took place in January 2013. At this time the service was meeting all standards of quality and safety it was inspected against.

We inspected Gloucester Royal Hospital Renal Units (Cotswold and Severn Units and T7B ward) using our comprehensive inspection methodology.

## Our inspection team

The team that inspected the service comprised a CQC lead inspector, Katharine Lewis, one other CQC inspector, and a specialist advisor with expertise in renal dialysis. The inspection team was overseen by Catherine Campbell, Inspection Manager.

## Information about Gloucester Royal Hospital Renal Units

During the inspection, we visited all three haemodialysis sites provided by Gloucester Royal Renal services. Two of the locations; Cotswold and the Severn units operate on an outpatient basis and are open six days a week. Cotswold is the main outpatient service with 29 patient stations, including four side rooms. The Severn Unit has 16 stations including two side rooms for low dependency patients.

On three days a week the outpatient units remain open until midnight. Ward T7B provides five beds for patients

with complex needs who require 24 hour treatment and care on an inpatient basis. Haemodialysis on ward T7B was provided during out of hours on an on call basis by senior B. Braun staff.

A home dialysis service was provided for patients deemed suitable by their treating renal consultant. Patients using this service were provided training and

# Summary of this inspection

reviewed at their home every month by a designated team. All dialysis equipment is provided by B. Braun Avitum UK Limited and the installation of the equipment is provided by an external company.

During this inspection we spoke with 10 patients and one relative. We also received 83 'Tell us about your care' comment cards which patients had completed prior to our inspection. We spoke with 39 staff including: 29 registered nurses and health care assistants, one reception staff and three senior managers. At the local NHS trust we spoke with four renal consultants, one ward sister and one dietitian. During our inspection, we reviewed 15 sets of patient records and six staff human resources files.

Gloucester Hospital Royal Renal Units could provide a maximum of 888 haemodialysis sessions across the three locations every week. The number of sessions actually provided on a weekly basis differed in response to each patient's individual needs. Most patients attended clinics three times per week. Between January 2016 to December 2016, 23,311 haemodialysis sessions had been provided to 206 patients'. In addition, four patients were supported with home haemodialysis. Of these patients, 68 (33%) were aged between 18 and 65 years old and 138 (67%) of the patients were aged above 65 years old. All patients were NHS-funded.

Whilst there were established, close working relationships with the renal consultants at the local NHS trust, no medical staff were employed by B. Braun. Across all three locations (Cotswold, Severn and T7B) there were a total of 32.3 whole time equivalent (WTE) registered nurses employed. In addition there were 8.1 WTE health care assistants and 3.1 WTE dialysis assistants. A clinic administrator worked part time across both the Cotswold and Severn Units. Staff tended to be based on one of the three locations but worked where required to fill service gaps. Priority was given to ensuring there were sufficient experienced staff on Ward T7B where the most complex patients were admitted. If required, the service had access to a list of bank staff who had been subject to fitness to practice checks. No controlled drugs were held or used by B. Braun staff on any of the three haemodialysis services.

## Track record on safety

- From January 2016 to January 2017 no never events had been reported. These are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers. During the same period no serious injuries had been reported.
- During 2016 there had been two unexpected patient deaths which had occurred during haemodialysis treatment on ward T7B. The clinical care of both of these patients had since been reviewed through a multidisciplinary meeting within the local NHS trust and additional actions plans put in place. It was confirmed both patients had complex health needs and died of natural causes.
- From September 2016 to March 2017, a total of 550 clinical incidents had been reported for the three locations. The reasons for these included issues such as clotted lines, hypotension (low blood pressure), patient falls, missed haemodialysis sessions and insufficient patient weight loss following treatment.
- From January 2016 to January 2017 no incidents of hospital acquired methicillin-resistant *Staphylococcus aureus* (MRSA) or hospital acquired methicillin-sensitive *Staphylococcus aureus* (MSSA) had been reported.
- From January 2016 to December 2016 there had been no written complaints. However there were regular verbal complaints regarding issues with transport via an external provider.

## Services accredited by a national body

- Investors in People accreditation (2016).
- ISO 9001:2008 (accreditation given to organisations, which fulfil a set of quality management standards).

## Services provided under service level agreement

- The buildings used for haemodialysis are owned by a local NHS trust and leased to B. Braun.
- The local NHS trust maintains the building and is responsible for:
- The removal and disposal of all clinical and non-clinical waste.
- Maintenance of the grounds associated with the leased buildings
- Maintenance of medical equipment.



# Summary of this inspection

- The provision of pathology and histology services.
- Cleaning of the buildings and communal areas.
- Maintenance of water treatment systems.

# 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 haemodialysis where these services are provided as an independent healthcare single speciality service.

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

- The registered person must ensure the proper and safe management of all medicines. Gloucestershire Royal Renal units did not have a relevant policy or PGD or use prescriptions for all fluids. This was not in line with national guidance (Nursing and Midwifery Council, 2007, National Institute for Health and Care Excellence, CG 174, 2013).
- There was no policy, standard operating procedure or specific staff training to promote the early identification of sepsis (infection) in line with national guidance (NHS England, 2015).
- There was a lack of evidence regarding both detailed analysis of incidents and how learning is shared with all staff.
- Improved coordination was required regarding how B. Braun and the local NHS trust investigate, review and complete actions as a result of serious incidents.
- The environment provided by a local NHS trust at all three locations did not fully meet national recommendations for haemodialysis services. There were no long term action plans in place to address this.

However, we also found the following areas of good practice:

- The majority of staff had in date mandatory training.
- All areas appeared visibly clean and staff followed B. Braun policy and procedures to prevent the spread of infections.
- The water treatment plant area and checks showed 100% compliance with required standards.
- Patient records were clear and organised and stored safely. Regular audits were completed and actions taken to maintain good record keeping standards.
- There were effective processes in place to respond to patients who unexpectedly deteriorated. All staff had in date resuscitation training.

### Are services effective?

We do not currently have a legal duty to rate dialysis where these services are provided as an independent healthcare single speciality service.

We found the following area of outstanding practice:

# Summary of this inspection

- Patients were supported to actively engage with their disease and treatment plans as much as they wanted to in order to achieve good outcomes and maintain quality of life. This was supported through continuous discussion, and shared care planning with staff.

We found the following areas of good practice:

- Care plans followed national best practice guidance before and during treatments. Clinical outcomes were monitored, reviewed and regularly reported to commissioners.
- Data was collected and submitted, to the UK Renal Registry by the local NHS trust. Performance indicators for Gloucestershire Royal Renal units were similar to the country average.
- Processes were in place and followed to ensure patients had access to dietetic services and nutrition was regularly reviewed.
- Staff had suitable skills, knowledge and experience to care for patients. Staff were supported with continuing professional development and had access to a range of policies and procedures.
- There was effective multidisciplinary working across the service and with the local NHS trust.

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

- The service did not follow national guidance and recommendations for patients with chronic kidney disease approaching end of life (DH, 2009).

## Are services caring?

We do not currently have a legal duty to rate dialysis where these services are provided as an independent healthcare single speciality service.

We found the following areas of good practice:

- Patients told us staff were kind, caring and compassionate.
- Patient satisfaction surveys were completed in order to look for ways to improve how treatment and care was provided. There was evidence actions were taken in response to patient feedback.
- Processes were in place to support and encourage patients to become as involved with their treatment as they wished
- Staff were sensitive to the emotional impact of haemodialysis treatment and nurtured positive and supportive relationships with patients.

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

# Summary of this inspection

- Improvements were required in how staff recognised and supported patients potentially approaching the last year of life.

## Are services responsive?

We do not currently have a legal duty to rate dialysis where these services are provided as an independent healthcare single speciality service.

We found the following areas of good practice:

- Regular contract reviews were held with commissioners who reported the service to be good and responsive to the needs of patients.
- Processes were in place to introduce new patients to the service and enable individual concerns and needs to be addressed.
- Systems were in place to support the provision of holiday haemodialysis, supporting patients to attend other services and enabling others to attend Gloucestershire Royal Renal units.
- A home haemodialysis service was available to patients deemed suitable for this by their treating renal consultant.
- Processes were in place to maintain access and flow through the haemodialysis service and there were no patient waiting lists.

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

- There were no easy read resources available for people with learning disabilities.
- There was no specific training for staff to improve understanding about patients with memory loss or learning disabilities.
- Action plans to address transport issues (with an external provider) had not proved effective.

## Are services well-led?

We do not currently have a legal duty to rate dialysis where these services are provided as an independent healthcare single speciality service.

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

- There was a lack of documentation to show how a range of safety, risk and quality service information had been interrogated for learning.

# Summary of this inspection

- There were no governance audit trails to show how safety, risk and quality improvement action plans had been completed, in what timescale and by whom.
- Processes to share with staff learning from incidents and other risk and quality information were not fully effective.
- Improvements were required to demonstrate how local risks had been identified and action plans put in place to mitigate against these risks

However, we also found the following areas of good practice:

- Senior staff had the knowledge, skills and experience to lead effectively.
- Staff felt valued and supported in their roles and reported a positive working culture.

# Dialysis Services

Safe	
Effective	
Caring	
Responsive	
Well-led	

## Are dialysis services safe?

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.

### Incidents

- There had been no reported Never Events at Gloucester Royal Renal Units. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- We had concerns regarding the processes to investigate and take action following serious incidents. There had been two unexpected patient deaths reported during 2016. We saw records which showed the registered manager had produced a chronology of events and reviewed the treatment and care provided. Whilst the registered manager demonstrated understanding of the issues, emphasis had been on what had been provided. There was a lack of written information highlighting how incidents had been analysed for learning. Actions had been recommended but it was unclear how these had been evidenced as completed.
- Senior staff confirmed all incidents were discussed with the local NHS trust as part of the contract review every two months. However, these reviews took the form of presentations and whilst we were assured by both B. Braun and the NHS trust that supplementary discussions took place, these were not documented.
- The two unexpected patient deaths had also been reviewed as part of the local NHS trust processes during consultant led mortality and morbidity (M&M) meetings. Senior B. Braun staff told us the registered manager would attend relevant M&M meetings but this had not

happened for these two unexpected deaths. This meant there had been potential for some detail and/or context relating to these patient deaths to have been overlooked. Action plans had been identified from the M&M meeting. It was not clear if these actions had been fully completed, when and by whom as we were provided with inconsistent feedback.

- Improvements were required to how learning from incidents was shared. Staff told us feedback took place during monthly staff meetings. When we asked staff to provide examples of feedback or learning from incidents, most staff were unable to do this. We looked at the staff meeting minutes for the Severn and Cotswold units dated January, February and March 2017. These did not document any discussion of learning from incidents.
- Staff demonstrated they understood their responsibilities and processes to report incidents. This was completed through two systems. The NHS system (Datix) for incidents related to service level agreements and a B. Braun system for clinical incidents. A summary of clinical incidents was presented to the NHS trust as part of the contract review meetings, held every two months. Between September 2016 and April 2017, 550 clinical incidents had been reported. We looked at the records during these dates and saw most of these related to missed or shortened haemodialysis treatments (due to illness or patient choice) and hypotension (low blood pressure).
- Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, is a new regulation which was introduced in November 2014. This Regulation requires the trust to be open and transparent with a patient when things go wrong in relation to their care and the patient suffers harm or

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could suffer harm which falls into defined thresholds. Senior staff demonstrated understanding of duty of candour by explaining what type of situations it had been used previously.

## Mandatory training

- The registered manager confirmed 100% of staff were compliant with mandatory training. Training included both B. Braun and mandatory training required also by the local NHS trust. This included: basic and intermediate life support (dependent on role), management of medicines, infection prevention and control, fire safety, manual handling, safeguarding vulnerable adults and child protection, Mental Capacity Act 2005 training and health and safety. We saw reminders for staff mandatory training was documented in team staff meetings (January, February and March 2017).
- The manager confirmed bank or agency staff also completed mandatory training and before commencing any work a general health and safety induction was completed. This included: emergency procedures, use of fire equipment, layout of the building, access to basic renal information, policies and procedures, haemodialysis prescription and operation of essential equipment such as the haemodialysis chair.

## Safeguarding

- There was good compliance with mandatory safeguarding training. Three levels of safeguarding training were available. B. Braun staff attended level two training which was appropriate for their role and level of interaction with patients. The registered manager confirmed all staff had attended or were booked onto mandatory safeguarding vulnerable adults and safeguarding children's training level two refresher courses. These were accessed through the local NHS trust. Records were on display to which confirmed this.
- Staff demonstrated an understanding of their safeguarding responsibilities and processes to follow. This included how to escalate and report safeguarding concerns and who to liaise with for additional advice or support.
- The staff we spoke with about safeguarding were able to demonstrate an understanding of what kind of issues might alert them to consider possible safeguarding issues, and what they could do to respond to the patient in a safe and supportive manner.

## Cleanliness, infection control and hygiene

- The three locations all appeared visibly clean. The NHS trust provided cleaners for the general and communal areas such as the waiting and consultation rooms and toilets. Any issues with the standard of cleaning were promptly reported to the cleaning supervisor and NHS trust infection control lead who took any required actions. Clinical areas such as the sluice and stock rooms were all observed to be visibly clean and organised.
- The haemodialysis chairs were cleaned in-between each patient by B. Braun staff and were deep cleaned every week. However, we observed some of the chairs on the Cotswold and Severn units had tears on the headrests and seats which had been covered with tape. This meant decontamination processes may not have been as effective as they should have been. The seat manufacturers were contacted regularly regarding repairs and were visiting during our inspection. Arrangements were being made for replacements.
- The haemodialysis machines were programmed to decontaminate after each use and once a week to follow an extended cleaning and decontamination process. Connection tubes were single use only. Each patient station was cleaned by B. Braun staff using an antibacterial solution after each treatment. We saw these procedures followed during our inspection.
- On the Cotswold and Severn units there were a total of seven side rooms and on ward T7B there were two side rooms. These were used as required as isolation rooms to provide haemodialysis to patients assessed as presenting potential increased infection risks. These rooms had en suite toilets and additional basins for handwashing.
- Staff followed B. Braun policy and procedures to prevent the spread of infections when patients went on holiday. We spoke with one patient who had recently returned from holiday in a high risk area. This patient explained that because of the increased infection risks upon return they had received treatment in an isolation room, using a machine that had been reserved solely for their use. Regular blood screening tests had been completed over a number of weeks, the last of which has been sent to an external service for independent verification.
- The service had effective water testing procedures in the water treatment plant area. Staff carried out checks in the morning and afternoon before treatment sessions started. We looked at records dated June 2016 to

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January 2017. These showed of the measures monitored, standards were met or exceeded national or European guidance. For example: the water treatments plant sampling for ultra-pure water. The European standards for bacteriology were 0.1 (CFU/ml, Renal Association, 2009 and European Best Practice Guidelines for Water Treatment, 2016). The standards at Gloucester Royal Renal units was set and achieved at a higher level of purity; 0.03 (CF/ml). Senior staff confirmed there were always staff trained to complete the water testing on duty.

- Systems and processes were in place to survey patients for blood borne viral infections. This included screening for methicillin-resistant *Staphylococcus aureus* (MRSA), methicillin-sensitive *Staphylococcus Aureus* (MSSA), Hepatitis B and C and for human immunodeficiency virus (HIV). All patients were routinely screened every three months. We reviewed records dated June 2016 to January 2017, one patient had been identified as a MRSA carrier but no new patient infections related to blood borne viruses had been identified.
- We observed staff followed aseptic techniques to attach patients to the haemodialysis machines. This meant using sterile equipment and following a defined process which was designed to minimise the risks of patient contamination and infection. The risk of a patient contracting an infection as a result attachment or detachment was very low. There were 197 patients using the service (on average three times per week). From June 2016 to January 2017 one patient had been identified as having a central venous catheter infection.
- The maintenance of the environment on the Cotswold and Severn units and ward T7B was the responsibility of the local NHS trust. On ward T7B material curtains hung in- between patient beds. Whilst these did not look unclean, they had not been dated to identify when they should be replaced.
- Screening procedures completed by the NHS trust had detected potential patient infection risks during March 2017. This was connected to some of the routine water supply provided through the local NHS trust (separate and not related to the haemodialysis machines). The registered manager assured us that B.Braun staff had been vigilant in taking precautionary actions to mitigate against the risks identified and the NHS trust had put in place an action plan to address the issues.
- Staff hand hygiene audits had been completed every month. We reviewed records dated June 2016 to

January 2017 for the Cotswold and Severn units. These showed between 85% and 95% compliance with hand hygiene policy. Actions documented as put in place included raising staff awareness and liaising with the NHS trusts infection control lead nurse. We observed staff were bare below the elbow in order to be able to effectively complete hand hygiene and minimise infection risks. The results of audits and infection prevention policy updates were documented as discussed as standing agenda items within monthly team meeting minutes (January 2017 to March 2017).

- Each patient was provided with their own blood pressure monitoring cuff which was stored in a plastic wallet in their care records. Staff told us this was done in recognition of the frequency of use and to reduce the chances of spreading infection between patients. The cuffs were replaced approximately every three months for new ones or sooner if required.
- The service had standard operating procedure (SOP) for infection control to provide additional staff guidance. We observed all staff wore personal protective equipment such as aprons, gloves and visors before commencing any treatment or care. Patients confirmed that staff always wore protection and used antibacterial hand gel before and after any clinical procedures. We observed staff used sharps boxes appropriately. These were kept closed between use to avoid accidental needle stick injuries.
- Relatives of patients were asked to leave the dialysis station before the patient was attached and disconnected from the haemodialysis machine. Patients and relatives understood this was to reduce the risk of accidental contact with fluids.

## Environment and equipment

- The Cotswold and Severn outpatient environments were not purpose built for haemodialysis treatments and had been previously used by the local NHS trust as inpatient wards. They did therefore not fully comply with national guidance (Health Building Note: 07-02, 2013) for the delivery of a haemodialysis service. Staff worked around any issues to minimise potential impacts on patient care.
- Ward T7B was a specific bay off the main renal ward at the local NHS trust. B.Braun was contracted by the local NHS trust to accommodate up to five patients on T7B and the environment was seen to be cramped, with little space between or around patients. There was a lack of



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storage for everyday equipment on T7B and we observed some was stored on the floor and on shelves, partially blocking emergency call bells. We spoke with staff who confirmed they were able to safely provide patient care but this could be awkward due to the limited space. Staff told us they occasionally bumped equipment and there was limited sitting space for patients' visitors. Senior staff told us they could not remove a bed as this would then impact on patient needs and flow (admissions/discharges).

- Two additional side rooms were also available to the haemodialysis service which was near to T7B. When patients were in a side room staff used a baby monitor to listen for any haemodialysis warning alarms in-between direct observations. We spoke with the trust consultants and B.Braun staff who told us both side rooms were infrequently occupied at the same time. The trust was aware of all the environmental issues for all three locations but did not have any plans in place to address them due to a lack of available funds.
- Emergency equipment was available in each of the three locations. Each area had a resuscitation trolley which included a portable suction unit and automated defibrillators that staff had been trained to use. It was not clear on ward T7B what processes were in place for B. Braun staff to be assured that NHS staff had completed the resuscitation trolley checks. Emergency medicines for anaphylaxis (a severe and potential life threatening allergic reaction) were stored within a tamper evident box on the resuscitation trolleys.
- Gloucestershire Royal Renal units followed an equipment replacement programme in line with national guidelines. All the haemodialysis machines were replaced every 10 years as recommended by the Renal Association (Guideline 2). Processes were in place to ensure faulty haemodialysis machines were repaired promptly and spare machines were kept at all three locations. The haemodialysis machines were equipped to run off an emergency battery pack which gave sufficient time for a patient to be safely disconnected from the machine.
- The service had effective systems in place to ensure all medical equipment was regularly serviced and maintained in accordance with the manufactures guidelines. Records were maintained to show what equipment was due a service when this had been arranged. The records were regularly reviewed by the registered manager and administrator.

- We observed on both the Severn and Cotswold units that hazardous and flammable liquids had been stored in accessible cupboards in the utility rooms. These liquids had been placed in unlocked cupboards with the keys left in the doors. We discussed this with staff at the time of our inspection.
- The local NHS trust was responsible for, and completed weekly fire alarm testing, emergency lighting checks, smoke alarm tests. Senior staff confirmed these were completed.

## Medicine Management

- Gloucestershire Royal Renal units did not have a relevant policy or PGD or use prescriptions for all fluids used. Although it is a common practice to give additional fluids in dialysis unit, there should be a policy for staff to refer to, or a patient group direction (PGD). Otherwise the fluids should be prescribed as fluids are classed as medicines. Therefore, the registered nurse did not have the required permissions to administer additional fluids during haemodialysis. This was not in line with national guidance (Standards for Medicines Management, Nursing and Midwifery Council, 2007, National Institute for Health and Care Excellence, CG 174, 2013).
- Processes were in place and followed to ensure patients' medicines were regularly reviewed. The consultant nephrologists reviewed and prescribed each patients treatment plan for one month at the time. B.Braun staff discussed and documented each patient's treatment during a monthly quality assurance meeting with the renal consultant.
- Gloucestershire Royal Renal units had access to pharmacy support at all times through the local NHS trust. A designated pharmacist (employed by the local NHS Trust) was available from Monday to Friday from 9am to 5pm. During all other out of hours an on-call pharmacist could be contacted for advice.
- Staff did not formally check patients identification before administering intravenous medicines. Staff told us this was not done as they knew all patients very well. This did not follow guidance from the Nursing and Midwifery Council (NMC, 2015). The substantive staff confirmed they checked patients identity when there were new patients and when bank or agency staff were

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administering medication. There was a 'general medicines guideline' which provided information about medicines management for staff, including bank and agency staff.

- Medicines were stored safely. On the Cotswold and Severn units we observed clean utility rooms where medicines were stored in locked cupboards. On T7B medicines were kept in a locked cupboard. We checked some of the medicines and found that all were in date. There were fridges for medicines, which required cool storage. The fridges were locked and a registered nurse carried the keys. Staff monitored and documented the fridge temperatures daily and knew what actions to take if temperatures were not within an acceptable range. We reviewed records for April and May 2017. These documented checks had been completed and signed to confirm they were within an acceptable range. during April and May 2017.
- The registered manager told us that all staff complete e-learning on medicine management as well drug calculation tests which was part of mandatory training. Records showed all staff had completed this.
- We looked at 15 patient records and saw prescriptions had been fully completed and the information was clear, dated and signed.
- The storage of oxygen cylinders complied with The Department of Health: Medical gases. Health Technical Memorandum 02-01 (2006) recommendations. Racking systems were used to store cylinders in designated areas. This helped to prevent accidental damage or cylinders being knocked over.

## Records

- Information was shared between the B.Braun electronic database and the local NHS hospital. A combination of paper and electronic patient records was used. This meant the consultants and dietitians working within the NHS trust and B.Braun staff had access to the current patient records at all times.
- We reviewed 15 patient records and found them to be organised, clear, and factual with written entries dated and signed. We observed patients' records had been stored securely in locked cupboards.
- Processes were in place to regularly audit the quality of patient records. Records reviews took place every three months by senior staff who checked all information was up to date and fully completed. We reviewed the results from audits carried out from January 2017 to April 2017.

These showed compliance with standards of between 91% to 95%. Actions were noted in the front of files for the patients named nurse who signed and dated to confirm when these had been completed.

- We observed two haemodialysis patient stations had been placed behind one of the nurses desks on the Cotswold unit. The stations were not far from and facing the computer monitors and staff telephone, both of which were used with regard to patient information. This meant patients' may have had access to other patient confidential information.

## Assessing and responding to patient risk

- The clinical care of patients was consultant led. There were five renal consultants who completed patient quality reviews by visiting the services service every month or more frequently if required. We looked at review minutes dated January and February 2017. These listed reviews to clinical care and changes to treatment plans. These were initialled and dated by B.Braun nurses when and required actions had been completed.
- Processes were in place to access medical support in the event of patient deterioration. The renal consultants could be contacted by fast bleep, email or telephoned between 9am and 5pm, Monday to Friday. During all other times an on call renal consultant or medical service could be accessed through the local NHS trust switchboard. Staff understood the policy and procedures to safely transfer a patient to the local NHS trust.
- Processes were followed by staff to review and monitor the health of patients before during and after haemodialysis treatment. A range of clinical checks were completed and recorded before treatment started. These included: general health, weight and blood pressure. Throughout treatment each patients' blood pressure, pulse and temperature were recorded and again at the end of treatment. When new patients started treatment, their identification was checked and staff told us if possible an experienced or senior nurse was allocated as their key worker.
- B.Braun nurses were all trained in basic life support and four senior staff had been trained in intermediate life support. We saw records documenting all staff had in date resuscitation training. We reviewed records related to a patient who had experienced a cardiac arrest.

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These documented that the patient had been successfully stabilised by B.Braun staff prior to the local NHS trust resuscitation team arriving to provide additional support

- Staff were sensitive to subtle changes in the health of patients. Staff told us that because they saw the same patients three times per week, often for months or years, they got to know individuals very well and recognised when people did not present in their usual way.
- One patient told us: “I am so grateful for the attention and kindness of all the management and staff. I was taken ill during 2016 and was given immediate attention by the staff on duty that day, who called 999. It turns out I have angina. The staff are so friendly and cheerful which keeps me going”. Another patient said: “I suffered a cardiac arrest, the responsible staff looked after me with much skill and all my needs were dealt with immediately”.
- Individual patient risks were assessed and regularly reviewed. Each patient referred for haemodialysis was placed on a 90 day care pathway. This pathway included assessment and actions related to: infection screening, patient education programme, tissue viability, diet and venous needle dislodgement. Where required action plans were documented as put in place to mitigate against any identified risks.
- Patients were allocated a specific (named) nurse who took responsibility for a continuing care pathway after the 90 day care pathway had been completed. We looked at 15 patient records and saw risk and other clinical assessments had been re-evaluated every three months. Where necessary action plans were documented and signed when completed.
- Processes were in place to alert staff to potential treatment issues. The nurses pre-set alarms on the haemodialysis machines which had were set to respond to pre-defined parameters related to each patient's treatment plan. We observed when an alarm went off, staff responded quickly and reviewing both the cause and checking how the patient was feeling.
- However, there was no policy, standard operating procedure or specific staff training to promote the early identification of sepsis (infection) in line with national guidance (NHS England, 2015). Senior staff told us they

contacted the patient's consultant if there were signs of infection. Antibiotics could be prescribed and provided or the patient could be transferred to the local NHS trust for further assessment and treatment.

- Each patient who was considered for the home haemodialysis service had their individual risks and safely assessed by their renal consultant. Eligible patients were provided with training on the Severn Unit in an area specifically designed for home dialysis training. A competency document was completed and a checklist signed off by staff before each patient was deemed safe to go home.
- Processes were in place to continually assess and monitor potential risks for patients who had home dialysis. Patients were able to telephone Gloucester Hospital Royal Renal Units at any time for advice and support and could return to the outpatient units for treatment in the event further training or support was required. In addition, home visits were undertaken every month by a member of the home haemodialysis team during which blood and water samples are obtained and sent for screening for infection.
- How to effectively respond to clinical risks were discussed as a standing agenda item within team meetings. We looked at staff meeting minutes dated January 2017 to March 2017. The records documented discussions on what actions to take in the event of a clinical emergency. For example: in response to a patient having a heart attack or if found unresponsive.

## Staffing

- The staffing ratio was determined by the contract between Gloucester Royal Hospital Renal units and the local commissioning NHS Trust. Across all three locations (Cotswold, Severn and T7B) there were a total of 32.3 whole time equivalent (WTE) registered nurses employed. This met the ratios recommended in the Renal Workforce Planning Group (2002) and the Renal Association (2009). Staff told us they felt there were sufficient staff to meet patients' needs.
- On the Cotswold Unit which provided the main outpatient service, the nurse ratio was established for one nurse for every three and a half patient's. The Severn Unit took low dependency patients and the ratio was established at one nurse for every four patients.

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Ward T7B provided five beds for patients with complex needs who required 24 hour treatment and care. On T7B the ratio was one nurse for every two and a half patients.

- In addition on the Cotswold Unit there were 5.8 WTE health care assistants and 2.6 WTE dialysis assistants. On the Severn Unit there were 2.3 WTE health care assistant and 0.6 WTE dialysis support worker. A clinic administrator worked part time across both the Cotswold and Severn Units.
- Gloucester Royal Hospital Renal Units was a nurse led service, no medical staff were employed. The renal consultants from a local NHS trust were responsible for each patient's treatment and care plan. The consultants confirmed they worked closely with B.Braun staff.
- The service manager told us no bank or agency staff had been used between November 2016 and May 2017. The organisation had a list of bank staff who had been subject to fitness to practice checks. This included compliance with: professional registration, occupational health, mandatory training and Disclosure and Barring Service (DBS). The organisation also used an agency for which the same fitness to practice checks had been applied.
- The staff rota was completed in a way which ensured there was always senior staff on duty, to support junior, new staff or bank and agency staff. When senior staff were on holiday or absent, other senior staff were redeployed to cover from other local B.Braun services.

## Major incident awareness and training

- The service had contingency plans for use in the event of emergencies. This included actions to follow and the relevant personnel to contact in the event of: fire, electricity failure and multiple machine failure. Records were available listing alternative haemodialysis services with the potential to support Gloucester Royal Renal Units patients if treatment was urgently required.
- Safe fire evacuation procedures were discussed individually with each patient. In the 15 patient records we reviewed, the processes and procedure to follow in the event of a fire was signed by both the patient and nurse to confirm instructions had been discussed and understood.

- We saw procedures to follow in the event of a fire had been documented as discussed within staff team meeting minutes (dated March 2017). This included that all staff had signed to confirm they were aware of the most current processes and actions to follow.

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

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.

## Evidence-based care and treatment

- Treatment plans took account of national best practice guidance. Clinical care was consultant led and delivered on nurse led services. On referral patients commenced on a 90-day treatment plan followed by a continuing treatment care pathway. These were based on the Renal Association Haemodialysis guidelines (2009) and the National Institute for Health and Care Excellence (NICE, Quality standard QS72, 2015).
- The Renal Association (2009) recommends haemodialysis treatment for most patients should total 12 hours week, which are typically three treatments per week. This was met on average 92% of the time. Reduction in treatment times were recorded as due to patient choice.
- The service completed a number of monthly quality checks which showed compliance with national standards. We looked at records dated June 2016 to January 2017. These showed all standards had been met. For example: The Renal Association (2015) recommends 80% of patients should have a fistula (surgically created vein) or graft vascular access created for haemodialysis treatment. This was met with 84% of patients during 2016 and 81% of patients in January 2017.
- NICE Quality Statement (QS72, 2015) was followed with regard to how staff monitored and maintained each patient's vascular access. Most patients attending B. Braun had an arteriovenous fistula; a surgical created vein used to remove and return blood during haemodialysis. We saw individual care plans for those patients with arteriovenous fistulas that were difficult to cannulate (insert a tube into). These care plans included

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detailed drawings and written guidance from the vascular consultant who had completed the procedure. Experienced staff took responsibility for cannulating difficult to access fistulas.

- Staff followed evidence-based guidance regarding clinical observations and checks before the start of treatment (Renal Association, 2005) This included checking vital signs such as blood pressure, pulse and temperature. We observed how staff discussed results with patients and adjusted treatments accordingly and within the parameters set by the patient's consultant. This promoted optimum haemodialysis treatments.
- At the start and end of treatment patients' were weighed. The assessment and continuous review of each patients weight helped staff assess the effectiveness of each dialysis session and followed best practice within national guidance (Renal Association, 2005).
- The service was not familiar with national guidance for end of life care such as the End of Life Care in Advanced Kidney Disease (DH, 2016). Taking account of end of life care needs was included in B. Brauns patient care plan and was part of the National Service Framework for Renal Services (Part 2, 2005). We asked staff what end of life care tools were used with patients. Senior staff did not have a full understanding of how they might contribute to end of life support. Therefore patients identified as potentially approaching the last year of life may not have had the full range of their needs supported by B. Braun staff.

## Patient Outcomes

- Performance indicators for Gloucestershire Royal Renal units were similar to the country average. Combined NHS and B. Braun data was collected and submitted to the UK Renal Registry via the local NHS trust. This included information about: frequency of treatment, number of treatment sessions, blood pressure recordings. Performance indicators were similar to the country average.
- The service completed a number of monthly quality checks, which showed compliance with national standards. These checks included monitoring of treatment time for each patient. For most people this totals 12 hours week, typically provided through three weekly treatments. Records dated June 2016 to January

2017 showed this was achieved for between 91% and 94% of patients. This exceeded the B. Braun target of 87%. When treatment times were reduced, this was recorded as due to patients' choice.

- Our specialist advisor reviewed patient test results for a range of clinical information collated by B. Braun every month. This included rates and measures related to: haemoglobin, ferritin (iron), phosphate, calcium and albumin. The results indicated whether haemodialysis treatment plans were effective and where adjustments to care plans might be indicated. Our specialist advisor confirmed the patient test results were within the normal ranges identified within national guidance such as the Renal Association (2009) and National Institute for Health and Care Excellence (NICE) guidance (NG8, 2015).
- The commissioners of Gloucester Royal Renal Units were highly satisfied with the service provided, stating patient care was consistently delivered to high standards and key performance indicators set as part of the contract had been met or exceeded.
- We looked at B. Braun records dated November 2016, January 2017 and March 2017. These included a range of performance metrics, audits and issues related to service delivery. For example: there had been no delays to the start of treatment on both the outpatients units apart from those due to the late arrival of transport.

## Pain relief

- Gloucestershire Royal Renal units did not stock or routinely administer pain relief medication. Staff took care to ensure patients were comfortable whilst receiving dialysis and regularly checked how people were feeling. Prior to connecting patients to the dialysis machine, staff offered the use of a local anaesthetic cream.
- Patients attended for haemodialysis on an 'outpatient' basis and took their own medication as prescribed. If patients complained about pain during treatment, nurses assessed possible reasons and checked with the renal consultant if required. Patients could be provided with paracetamol when required if this had been prescribed.

## Nutrition and hydration

- Dietitians from the local NHS trust reviewed patients' nutritional needs. The dietitians met with patients every three months and reviewed their treatment plans with



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them. During the months in-between patient appointments, test results and action plans were reviewed by the dietitians via the IT system. We observed any changes to treatment and care plans were communicated to Gloucester Royal Renal Units staff by email or telephone and written up in patient records promptly.

- Patients were weighed on arrival to the centre at each visit to identify the additional fluid weight that needed to be removed during each dialysis session. This varied from patient to patient. Some patients were observed weighing themselves prior to dialysis, and inputting this into the dialysis machine. Nursing staff told us that all patients were encouraged to participate in their treatment to different levels.
- Staff offered hot or cold drinks, sandwiches and snacks during treatments which were provided by the local NHS trust. Many patients brought in their own lunch or snacks to eat during their treatment.

## Competent staff

- Staff were employed on the basis that they could demonstrate suitable qualifications, skills and experience relevant to the post applied for. The organisations human resources department completed checks upon appointment. These included: confirmation of registration (which was rechecked every year), Disclosure and Barring Service (DBS) checks, review of references and an occupational health assessment.
- New staff completed a six month probationary period during which new employees were expected to understand, and follow the organisations policies, procedures, processes and complete all mandatory training. New staff were assigned a mentor and were supernumerary during the probation period. Before being allowed to work independently, new staff were required to demonstrate a range of competencies which were signed off by their mentor. These included: medical devices training for the dialysis machines and infusion pumps used, understanding of the principles of drugs used, such as anticoagulants.
- Nurses received training and competence assessment for a technique referred to as wet needling (needle primed with Normal Saline). This was used when connecting patients to the dialysis machines. When nurses took a blood sample from the fistula (an

expanded vein), they used a technique they had been trained to use referred to as 'dry' needling (needle remains unprimed). This was done to ensure the blood sample was not diluted.

- Processes were followed to enable staff to have access to policies and good practice guidance. The registered manager and other senior staff shared responsibility for ensuring all policies were in date. Staff accessed policies via the organisations intranet. If these were required to be printed, all policies stated they were valid for a 24 hour period only. This promoted the use of the most current best practice standards by prompting staff to recheck the intranet for updates.
- Staff were supported with continuing professional development. This included access to a specialist post registration renal course. The registered manager and two senior dialysis nurses had completed this course. Whilst the specialist course was not compulsory, other registered nurses were attending or were booked to go on the course.
- The health care support workers were encouraged and supported to complete national vocational qualifications (NVQs). A senior support worker role was being developed by the organisations national clinical lead. Part of the aim of this role would be to provide additional development opportunities for staff.
- Staff completed a range of mandatory training through B.Braun and the local NHS trust. We reviewed the training records and saw all staff (not on long term leave) were compliant with mandatory training.
- Those staff responsible for water plant safety checks had completed additional training and competency assessment in bacterial water sampling and the use of Endosafe (a rapid microorganism test). Staff carried out water plant checks twice a day to ensure patient safety during the two haemodialysis sessions provided. We looked at records from January 2017 to April 2017 which recorded the tests were 100% compliant with standards.
- Staff were supported in their roles with an annual appraisal. This was a review of performance and objective setting for each staff. Records showed all staff had an in date annual appraisal.

## Multidisciplinary working

- There were established and effective multidisciplinary working between staff at B.Braun and with other professionals. The renal consultants and dietitians from the local NHS trust visited Gloucestershire Royal Renal

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units when required but at a minimum on a monthly basis. B.Braun and the NHS staff told us the working relationships between the services were good. Other professionals involved with the treatment and care of patients, such as GP, pharmacist and psychologist were liaised with as required. We saw this documented where required in records.

- Records held by B.Braun showed patients had been asked for consent to share information. In the 15 records we reviewed, patients had signed to confirm consent for the release of personal and confidential information. This included test results which were shared with: consultants, GPs and dietitians.
- We observed effective communication between unit staff and saw the senior dialysis nurse maintained an overview of patient needs at all times. Although senior staff provided clinical patient care, they had capacity to support more junior or less experienced staff.
- Monthly multidisciplinary quality assurance meetings were held with B.Braun staff and NHS renal consultants and dietitians. These meetings were used to review patients' treatment and care plans. We looked at records dated January 2017 and February 2017. These had been initialled and dated by B.Braun nurses to confirm when actions had been completed.

## Access to information

- Systems were in place to share clinical information with relevant professionals in a timely way. Gloucestershire Royal Renal units had processes in place to submit information electronically to the local NHS trust. At the beginning, throughout and at the end of each patient's treatment, clinical information was recorded (written) by nurses. At the end of treatment sessions details of each patient's clinical information was added onto an electronic system. This enabled the patients treating consultant and dietitian to have access to up to date clinical information in a timely way.
- All treatment and patient clinical observations could be accessed on the IT system remotely by the patient's consultant and dietitian at any time. We saw consultants were contacted on the phone during and after treatments by nurses who wished to discuss clinical issues. Any necessary adjustments to treatment plans were recorded promptly.
- Patients were supported to actively engage with their disease and treatment plans as much as they wanted to in order to achieve good outcomes and maintain quality

of life. This was supported through continuous discussion, and shared care planning with staff. For example: patients were enabled to access their blood test results remotely and to complete clinical procedures related to haemodialysis treatment. Also, if deemed suitable by their consultant, patients were provided with training and specialist equipment to be able to independently have haemodialysis treatments at home.

- We observed all aspects of each patient's care was discussed with them before, during and after treatments. In the 15 care records we reviewed we saw patients GPs and other relevant health professionals had been contacted and relevant patient information had been shared.

## Equality and human rights

- The Equality Act 2010 places a legal duty on all services to 'make reasonable adjustments' in order to avoid putting a person with disabilities at a substantial disadvantage when compared to a non-disabled person. Staff obtained information about patients' communication needs in line with the Accessible Standards (2016). This was done as part of each patient's initial assessment.
- Staff ensured patients' needs were met wherever possible. For example: facilities on the outpatient units (Severn and Cotswold) were accessible by patients using wheelchairs or walking aides, an interpreting service was available and staff were respectful of cultural beliefs. This was evident in by how staff explained and understood each patient's personal preferences and was documented in care records.

## Consent, Mental Capacity Act and Deprivation of Liberty

- Patients were supported to be able to give informed consent. Information booklets were provided to patients at referral and the start of treatments. Patients told us these resource had been helpful in enabling understanding about renal disease and treatment options. Patients confirmed staff discussed information and encouraged questions.
- Processes were followed to gain patients' consent before starting any treatment and care. We observed staff checked with patients that they had permission to proceed prior to beginning any clinical procedure.

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Consent to treatment and tests was also documented in all of the 15 care records we reviewed. Consent records had been signed by patients to confirm the parameters of what they agreed to.

- Staff understood what processes to follow if a patient's ability to provide informed consent to care and treatment was in doubt. This included raising issues with senior staff and the patient's consultant prior to starting. One of the renal consultants explained what processes they had followed with a patient who had a learning disability. This involved an assessment of the patients' mental capacity and a multidisciplinary best interests meeting. This complied with the recommendations in the Mental Capacity Act (2005).

## Are dialysis services caring?

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.

### Compassionate care

- We spoke with 10 patients and one relative of a patient during the inspection and received 83 completed comment cards from patients who wrote about the care they had received. The majority of these were overwhelmingly positive regarding staff being kind, caring and compassionate. Patients told us "All staff are caring and treat me with dignity and respect", "The staff are great, caring and thoughtful" and "I have been having treatment for many years. The staff have always been caring and treated me with dignity and respect". The few negative comments related to delays waiting for transport and damaged chairs.
- We observed staff had professional but friendly and kind interactions with patients and those people close to patients. Staff were seen to treat patients with dignity and respect. We observed staff interact with patients in a compassionate manner. The atmosphere in all treatment areas appeared calm.
- The service carried out annual patient satisfaction survey in order to look for ways to improve how treatment and care was provided. We reviewed the

results from the last survey completed during 2016. On the outpatients units the response rate was 51% for Cotswold and 40% for Severn. Of those patients who responded, 90% were satisfied with the care provided.

- There was evidence staff took actions from patient feedback. Some patients had reported the temperature in the unit did not suit them. The temperature had to be kept within a range that enabled effective clinical treatments to be completed. In response, each patient was provided with a personal blanket. Other patients had reported dissatisfaction with the comfort of the treatment chairs (which had originally been chosen by patients). The registered manager told us they were in the process of reviewing potential alternatives.

### Understanding and involvement of patients and those close to them

- The majority of patient feedback we received was positive about being supported to understand and be involved in treatment and care. Patients told us: "Treatments have been explained to me using words I can understand", "The nursing staff are efficient, helpful and friendly, always prepared to listen" and "staff listened when I asked questions relating to dialysis. The staff also listened to my comments and took account of these" and "I have an allocated nurse but all the nursing staff are unfailingly polite, patient and quick to respond to the occasional 'emergencies'".
- Records documented treatment plans had been discussed with patients. These included: treatment plans, the need for regular blood tests and additional procedures that might be necessary as a consequence of treatment. For example: blood transfusion and intravenous medicines. There was a secondary part to the patient consent form which was completed by B.Braun staff. This was a signed declaration by a nurse confirming the following had been explained and discussed with the patient: the intended benefits of haemodialysis, common side effects of treatment, risks of infection, risks associated with missed treatments and potential reactions to medicines prescribed. All 15 of the care records had signed consent and signed secondary declaration forms completed.
- Processes were in place to support and encourage patients to become as involved with their treatment as they wished. Part of each patients care plan was an education programme. This included discussions



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through the use of information booklets on a range of topics such as: vascular access, understanding blood results and fluid restriction. This was provided not only to educate patients regarding their conditions but also to promote confidence to actively engage and take ownership of treatment. Each patient was asked what they might like to be responsible for and provided the necessary support to do this. For example; some patients took responsibility for weighing themselves before and after treatment, and taking routine infection control swabs. Other patients took responsibility for inserting and removing the needles required for haemodialysis treatment.

- Processes were followed to work collaboratively with patients. Patients' told us they knew who their allocated nurse was and what this person's role was in relation to their care. In the patient survey (2016) 90% of those who responded felt they had sufficient information regarding their medication, treatment and about how to maintain general health,
- Patients said if they had any questions about their treatment and care they would not hesitate to raise these with staff. However, there were no specific resources such as easy read to aid understanding and involvement for people with learning disabilities. Staff said if required they would work with carer's or would contact the local NHS trust to access the learning disability lead nurse.
- The majority of the haemodialysis stations were in an open area. However, we observed staff took care to speak with patients quietly to maintain confidentiality. The unit had consultation rooms where patients could speak with staff in private if they wished. The patients we spoke with told us they preferred to be in the company of other patients during all of their treatment. We did receive some patient feedback noting that despite the availability of consultation rooms these were rarely used as consultants and dietitians tended to visit during haemodialysis treatments.

## Emotional support

- Patients and staff spent a considerable amount of time together (typically 12 hours per week) which enabled positive and supportive relationships to be developed. Patients told us they felt safe and supported. Feedback included: "I'm always listened to", "The staff are caring and concerned about your condition whilst being

friendly and instilling confidence" and "The staff will always listen to me if I want to talk". In the patient survey (2016) 90% of those who responded rated the friendliness of staff as excellent or good.

- Staff were sensitive to the emotional impact of haemodialysis treatment. Staff asked patients about their emotional wellbeing part of the continuing care pathway. This was documented in care records as reviewed every three months. If required, referrals could be made for specialist emotional support via a clinical psychologist based at the local NHS trust.
- Improvements were required to how patients potentially approaching the last year of life were recognised and supported by staff. Patients ongoing care plans included a section on end of life care needs. Staff also had access to the local NHS trust's end of life care pathway. However, all of the staff we spoke with felt end of life conversations were the role and responsibility of the consultants. When we asked how patients could be supported in between consultant visits, staff were not able to give examples. In addition, there was no evidence to demonstrate care had been planned in accordance with national frameworks such as 'End of life care in Advanced Kidney Disease' (DH, 2008).

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

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.

## Meeting the needs of local people

- Regular contract reviews were held to ensure the service was meeting the needs of local people. These meetings were held every other month with the commissioning local NHS trust during which all aspects of the contract were discussed. We spoke with senior staff from the local NHS trust who told us they felt B.Braun provided a good service which adequately met the needs of local people. For example, new patient referrals for haemodialysis were offered appointments in line with each renal consultant's recommendations.
- The two outpatient services at the Cotswold and Severn units were open six days a week. On three days a week

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the outpatient services were open until midnight. Staff said this enabled more patient choice for appointment times and reduced the impact on patients with jobs or other commitments.

- A home dialysis service was provided for patients deemed suitable by their treating renal consultant. Patients using this service were provided training and reviewed at their home every month by a designated team.
- The unit did not have a transport user group as patients did not want this. However, the manager told us individual patients raised issues with them regarding transport as they occurred. The registered manager met regularly with the transport service to discuss the issues raised.
- We obtained other transport feedback from surveys carried out by the local Clinical Commissioning Group and Health Watch and from the renal consultants. Issues were frequently reported regarding the effectiveness and responsiveness of the transport service and how this impacted on patients' treatment. Action plans to date had not improved on the issues.

## Access and flow

- The local clinical commissioner (CCG) determined how and where the haemodialysis services were provided based on the needs of people living within the Gloucestershire area. The provision of the service was kept under two monthly review to ensure adequate patient access to the haemodialysis service.
- Gloucestershire Royal Renal units had the capacity to provide up to 888 haemodialysis sessions per month. However, the number actually varied every week dependent upon the needs and demands of patients. There were 206 patients who attended the service. Between October 2016 and December 2016 the service operated between 75% and 76% of total capacity.
- Different haemodialysis sessions were available for patients to attend in order to support and provide flexibility to meet individual preferences and circumstances. Cotswold and the Severn units provided 45 stations for outpatient appointments six days a week from 7am. On three days each week the outpatient clinics remained open until midnight to provide increased flexibility and choice with appointment times. Ward T7B provided five beds for patients with more complex needs who required 24 hour treatment and care.

- Processes were in place to maintain access and flow through the haemodialysis service. When a new patient was referred the clinic manager was notified in writing by the patients renal consultant with a start date. The patient was then contacted by the unit and additional information was obtained including transport requirements. An appointment was then offered on the basis of availability and patient's preference and choice. The service manager confirmed there was no patient waiting list.
- Patient transport to and from the units was reported to be poorly organised. Transport to and from the haemodialysis units was facilitated by an external service. During January 2016 the Healthwatch Gloucestershire team spoke with: 19 patients who attended the Cotswold and Severn units, the registered manager, two other staff and a transport driver. The transport delays caused treatments to be delayed and some patients opted for shortened treatments (against medical advice) in order to be ready for transport.

## Service planning and delivery to meet the needs of individual people

- Processes were in place to introduce new patients to the service and enable individual concerns and needs to be addressed. The renal consultants instigated new referrals. The registered manager invited new patients to visit the unit before starting their treatment. Other staff told us they would approach patients who had already been attending long term to see if they would be willing to discuss processes and procedures with newly referred patients. Staff told us all patients had reported these were important and valuable experiences.
- Staff at the Cotswold and Severn units worked in partnership with patients in order to accommodate preferred time slots for haemodialysis wherever possible. One patient explained how staff had altered their treatment times in order for them to attend a family wedding.
- The facilities provided at the Cotswold and Severn units were planned in order to support patient comfort and choice during the four hour treatment sessions. Each patient station was equipped with a television; patients were provided with their own individual headset and had access to free Wi-Fi. Stations also had tables and staff offered hot and cold drinks, sandwiches and snacks during treatments. Toilets were accessible to patients with both right and left sided disabilities.

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- Staff recognised the impact of attending clinics three times per week on patients' lifestyle. Patients gave examples of how B.Braun staff had liaised with other services to arrange other appointments to take on the same day as haemodialysis treatment was booked. Patients told us this reduced the need of having to attend health appointments on additional days of the week.
- Systems were in place for the provision of holiday haemodialysis treatments to external (non- Gloucester) patients. The stations were not block booked for these sessions but allocated on demand and availability. Records showed between January 2016 and December 2016 holiday sessions had been provided to 34 external patients. Staff also supported Gloucester Royal Renal unit patients to attend other haemodialysis services nationwide and worldwide during holidays. This included ensuring other services had the correct prescription and treatment plan and relevant test results.
- A home haemodialysis service was available to patients deemed suitable for this by their treating renal consultant. Patient training and support was provided by staff on a designated area of the Severn Unit which had been specially designed for this purpose. A competency document was completed and signed off by staff before the patient was deemed safe for home haemodialysis. The home installation was provided by a third party company but all dialysis equipment and consumables were provided by B.Braun. Between January 2016 and December 2016 four patients were supported to have home haemodialysis.
- A range of information was available to patients. For example we saw booklets related to diet and fluid management. There was a range of haemodialysis and other health information available through the organisations website. This included written and video information on kidney disease, medicines, diabetes and transplantation. Staff confirmed they had access to an interpreter service. However, there were no specific easy read resources for patients with learning disabilities. Staff told us they would provide support through the person's main carer or access a specialist nurse at the local NHS trust.
- Staff were respectful of different cultural and spiritual needs and how this could impact on treatment and care

plans. For example; the registered manager told us they gave a small Christmas present to patients but checked with individual patients for whom celebrating Christmas was not part of their culture and beliefs.

- An interpreting service was available and staff said they could access information in alternative languages. Staff told us they regularly had patients with learning disabilities and memory issues. Staff accessed training about memory loss and learning disabilities via the local NHS trust every three years. However, the staff we spoke with about these patient groups did not reference any training or resources they used to promote best practice.

## Learning from complaints and concerns

- All the patients we spoke with about complaints told us they understood what processes to follow and would not hesitate to raise issues with staff. From January 2016 to December 2016 there had been 12 written complaints, the majority of these related to issues with transport via an external provider. The registered manager of Gloucester Royal Renal units had been having monthly meetings to attempt to address issues but no long term solutions had been found. The local clinical commissioning group (CCG) had also completed their own investigation and concluded the majority of patient transport was achieved within an acceptable time range.
- Patients had received feedback on the results of a patient satisfaction survey completed during 2016. Staff also discussed potential solutions to issues raised. For example; the temperature of the units did not suit all patients, some of whom had complained of feeling cold. Staff explained that the temperature was controlled to enable treatments and nursing procedures to be managed effectively. In addition, B.Braun funded the purchase of a blanket which was provided to each patient for their personal use.
- If patients had complaints or concerns about their care staff followed a standard operating procedure. Staff also told us complaints were rare but any patient concerns were discussed during staff handovers and during team meetings.

# Dialysis Services

## Are dialysis services well-led?

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.

### Leadership and culture of service

- Senior staff had the relevant skills, knowledge and experience to manage the service. The registered manager was also supported by two senior dialysis nurses. The nurses and registered manager all had renal and managerial experience and had completed a post-registration renal qualification. The registered manager was also supported by an operations manager, clinical quality manager and a practice development nurse.
- The registered manager rotated working between the three locations at Gloucestershire Royal Renal units and a fourth service nearby. The registered manager demonstrated a good understanding of the day to day pressures of the units and of broader health care challenges.
- The registered manager was reported to be visible and approachable. All the staff we spoke with confirmed that they saw the registered manager regularly and that they were responsive when based in an alternative unit. There was an 'open door' policy and staff told us they felt they could raise any issues of concern with senior staff without fear of reprisals.
- Staff told us they felt valued and respected and were proud of the patient care they provided. Many of the staff had been working at Gloucestershire Royal Renal units for five years or more, stating it was a nice, friendly and supportive environment to work.
- The registered manager did not have any knowledge of the Workforce Race Equality Standard (WRES) and Equality Delivery System (EDS2). This became mandatory in April 2015 for services that deliver £200,000 or more of NHS-funded care. WRES looks at the extent to which black and minority ethnic (BME) background employees have equal access to career opportunities and receive fair treatment in the workplace. Services are required to collect, report,

monitor and publish their WRES data and take any required action to improve workforce race equality. Whilst corporate reports could be written, information should have been collected and reported at local level.

### Vision and strategy for this core service

- B.Braun had a corporate strategy which was to provide safe patient care and to engage with local communities. Staff we spoke with told us they believed the vision to be focused on the provision of good, safe patient care.

### Governance, risk management and quality measurement

- There was an organisational governance framework in place to support how risks and quality issues were monitored and managed. The registered manager completed an operational report management plan every month which was sent to B.Braun head office. This recorded information about, key performance indicators, reported incidents and staffing. The registered manager told us any identified issues were discussed with the clinical or organisational lead. No records were maintained relating to this or subsequent actions put in place.
- The service also contributed to a regular audit programme. This included the rates of: patient falls, safety incidents, infection rates, staff hand hygiene and water system management. The audits were monitored at corporate level and any necessary actions passed back to the registered manager and discussed during the contract review meetings held with the local NHS trust every two months.
- Improvements were required to some governance processes. There were quarterly operational management meetings during which the operational reports were discussed. However, there was a lack of documentation and audit trail to show how quality, risk and performance information had been scrutinised for trends and learning. We looked at meeting minutes dated: 30 June and 1 July 2016, 12 and 13 January 2017 and 17 and 19 April 2017. The majority of the minutes for the meetings took the form of lists. There was no documentation to identify how issues had been interrogated for risks and learning. Where actions had been made there were no start or completed dates, and not all actions had recorded who was responsible for their completion.

# Dialysis Services

- Improvements were required to how learning from incidents was effectively cascaded. We spoke to 28 staff during our inspection and asked about feedback and learning from incidents. Whilst some staff told us this was done during team meetings, most staff were unable to provide examples. There had been two unexpected patient deaths during 2016 and most of the staff we spoke with about this told us they did not know of actions put in place as a consequence of the reviews. Some staff were unaware there had been unexpected patient deaths the previous year. In addition staff were not aware of the outcomes of governance, corporate and commissioning meetings. This meant staff were not fully aware of their accountability in supporting service improvements.
- The B. Braun operations manager and the registered manager met with the local commissioning NHS trust to report on key performance indicators every two months. We reviewed the last three contract review meeting minutes dated: November 2016, January 2017 and March 2017. These had been attended by senior clinical and organisation staff from the trust. The presentations included a review of governance risk and quality information such as incidents and complaints. However, no records had been maintained of associated discussions, debate or actions plans. We spoke with four of the five renal consultants who regularly attended the commissioning review meetings. They confirmed the presentations were discussed and where necessary actions put in place. The renal consultants told us they were very happy with the standards of care and services provided at Gloucestershire Royal Renal units.
- Improvements were required to how risks were evidenced and managed. The registered manager had a list of completed local risk assessments and there was a corporate health and safety risk register. However, both of these documents related to general risks. For example: actions to take in the event of a power failure and risks associated with taking blood samples.
- The registered manager demonstrated they had a good understanding of specific local risks. For example: impacts on patient treatment resulting from transport delays (external provider), and a recent spike in staffing vacancies on one of the units. The registered manager was able to explain what actions they had taken to mitigate against the identified risks. However, there was no documentation to evidence this and maintain an audit trail and time line of any actions taken.

## Public and staff engagement

- We saw staff had friendly and professional relationships with patients, most of whom they had known for years. We heard staff checking how patients were feeling and any information related to the service delivery was shared during staff handovers and escalated where required. Patients told us they would not hesitate to discuss issues with staff.
- Processes were in place to gather information from patients and there was evidence this had been positively responded to. We observed there were confidential comment boxes within the units, which staff told us they checked.
- A patient forum had taken place during February 2017 and patient views were more formally requested as part of an annual survey. Recent changes in response to patient feedback had included: the provision of individual headphones to reduce the noise of televisions (one by each station), dimming of lights in designated areas to enable rest, and rotating the order sandwiches were provided to enable varied choice for all patients.
- Systems were in place to gather staff feedback. Monthly team meetings were held and the staff we spoke with told us they felt confident to be able to raise issues and contribute to solutions. Staff were encouraged to attend or contribute to quarterly employee forum meetings and the B. Braun chief executive facilitated roadshows to both inform staff about company updates and to gather staff feedback.

## Innovation, improvement and sustainability

- B. Braun was in the process of developing a senior haemodialysis support worker role. Part of the outcome for this related to providing increased development opportunities for support workers. This work was being led by the clinical quality manager.
- There were no official sustainability plans in place to cover in the event that the registered manager or other senior staff left the service. The operations and registered managers told us the two senior nurses in post had extended managerial tasks as part of their roles. We were told these nurses or other staff from alternative services could step in during staff absences or vacancies.

# Dialysis Services

- B.Braun staff worked closely with the local NHS trust and were involved national projects. The local NHS trust provided information confirming B.Braun were involved and supporting with two national research projects.



# Outstanding practice and areas for improvement

## Outstanding practice

- Patients were supported to actively engage with their disease and treatment plans through continuous discussion, and shared care planning with staff. For example: patients were enabled (if they wished) to access electronic systems to view their blood test results remotely. This supported patients to more fully understand and participate with their treatment and care, also at a time and place that suited them.

Patients were supported (if they wished) to complete clinical procedures for haemodialysis, such as cannulation (inserting needles and tubes to connect for treatment). If deemed suitable by their consultant, patients were given training and specialist equipment to be able to independently have haemodialysis treatments within their own home.

## Areas for improvement

### Action the provider **MUST** take to improve

- The provider must ensure the proper and safe management of all patient medicines which includes the use of fluids during haemodialysis.
- The provider must ensure there is a policy in line with best practice and specific staff training for the early identification of sepsis (infection) in line with national guidance (NHS England, 2015).
- The provider must improve governance processes to ensure it is clear how issues related to safety and quality are scrutinised. These should include clear documentation evidencing how action plans have been completed.
- The provider must review their risk management processes to include evidence of how local service risks are identified and acted upon.
- The provider must ensure there are effective processes in place to ensure learning from all safety, risk and quality issues are disseminated to all staff.

### Action the provider **SHOULD** take to improve

- The provider should review the processes in place with the local NHS trust to more effectively fully share and learn from serious incidents.

- The provider should review processes to ensure all staff know which patients had a Do Not Attempt Cardio Pulmonary Resuscitation (DNACPR) in place.
- The providers should review processes to demonstrate how all relevant risks are escalated to others in a timely manner.
- The provider should review staff understanding regarding end of life care and take action to ensure treatment and care given is in line with best practice.
- The provider should have easy read and other resources available for patients with learning disabilities. Staff should have access to training regarding supporting patients with memory loss or learning disabilities to promote best practice.
- The registered manager should ensure they have knowledge of and evidence compliance with the Workforce Race Equality Standard (WRES) and Equality Delivery System (EDS2) which became mandatory in April 2015.

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
Diagnostic and screening procedures Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>Care and treatment must be provided in a safe way for service users. The registered person must ensure the risks to the health and safety of service users receiving care and treatment are assessed.</p> <p>The registered person must ensure the proper and safe management of medicines.</p> <p>Gloucestershire Royal Renal units did not have a policy or use a patient group direction or use prescriptions for additional fluids given to patients during treatment. This was not in line with national guidance (Standards for Medicines Management, Nursing and Midwifery Council, 2007, National Institute for Health and Care Excellence, CG 174, 2013).</p> <p>There was no policy, standard operating procedure or specific staff training to promote the early identification of sepsis (infection) in line with national guidance (NHS England, 2015).</p> <p>Regulation 12 (1)(2)(g)</p>

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>Systems or processes must be established and operated effectively to ensure compliance with requirements of this Part.</p>



This section is primarily information for the provider

## Requirement notices

Governance processes related to safety and quality lacked evidence of scrutiny for learning and service improvement. Improvements were required to processes for reviewing incidents with the local NHS trust.

There was no documentation related to the identification of local risks

There was no evidence to show how action plans had been put in place to mitigate against risks and make quality improvements.

There was a lack of effective processes in place to share safety and quality actions and learning with all staff.

Regulation 17 (1)(2)(b)