The Gamma Knife Centre at The National Hospital for Neurology and Neurosurgery

Quality Report

The Gamma Knife Centre at QSRC
National Hospital For Neurology and Neurosurgery
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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	Requires improvement
Are services safe?	Requires improvement
Are services effective?	Requires improvement
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Inadequate

Overall summary

The Gamma Knife Centre at The National Hospital for Neurology and Neurosurgery is operated by QSRC Limited. QSRC Limited is an independent health care

Summary of findings

service and a wholly owned subsidiary of Medical Equipment Solutions Ltd (MESL). The Gamma Knife service is delivered by the centre working in partnership with University College London Hospitals NHS Foundation Trust (UCLH) as the host trust.

This service provides outpatient and day case treatment to both NHS and private patients using stereotactic radiosurgery (SRS) to treat tumours or lesions within the brain. This can include secondary brain tumours (metastases), other tumours (malignant and benign), as well as vascular and functional conditions.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 22 and 23 November 2016 and returned on 1 December 2016. We inspected this service under the medical care core service.

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

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

Services we rate

We rated this service as requires improvement overall because:

- We were not assured that clinical governance and risk management processes were robust. We found that whilst plans for the centre's governance structure had been developed, in practice governance structures were not yet fully embedded and the reporting structure and responsibilities within the service and the partnership with the host trust were not clear.
- We found a failure to implement recruitment procedures to provide assurance that employees and consultants working under practising privileges complied with the Health and Social Care Act 2008, to employ fit and proper persons. Managers lacked oversight of the practising privileges process. The centre did not have its own policy for granting and reviewing practising privileges and could not provide evidence that all appropriate recruitment checks had been carried out. This meant there was a lack of oversight of the recruitment process for consultants applying for practising privileges.
- There was no formal process to ensure staff working under practising privileges had an appropriate level of valid professional indemnity insurance in place. We found insurance documents for two consultants were out of date and that there was no formal system in place to review this.
- The centre's risk register did not reflect all corporate and clinical risks and did not record any controls or actions to mitigate the risks that were identified. Regular management review of the risk register was not evident and plans to introduce a new risk register had not yet been actioned.
- There was no clear strategy for the development of the service following the award of the NHS England (NHSE) contract. We were unable to see a strategic plan setting out how the service would expand to meet the contract requirements. The leadership team could articulate their plans for the future but did not have this written down as a strategy agreed by the host trust. The business plan for 2017 did not include any plans to meet delivery of an expanded service.
- The service did not fully meet the NHS England service specification for stereotactic radiosurgery. There was no oncology input during the planning and treatment stage of the patient pathway. There was no oncology representation at the specific gamma knife multidisciplinary team (MDT) meetings and the oncologist had not received specific gamma knife training. After the inspection, the provider told us that they had introduced a further planning meeting involving all members of the MDT, including the clinical oncologist.
- There were inconsistencies in staff understanding of how incidents were reported and investigated. We heard several different versions of the incident reporting system and how this operated in practice from the staff. Learning from incidents was not always consistently shared with all staff.
- Although there were clearly defined service level agreements for medical physics input the capacity of this service was limited. The service level agreement

Summary of findings

for continuity of treatment should the machine break down had expired. There were no contingency plans in place if the equipment broke down or if a medical physicist was unavailable at short notice.
- The service collected patient comments and complaints but we did not see any evidence of changes following feedback.

However:

- We observed staff delivering excellent patient care and they clearly responded to individual patient needs.
- Feedback we received from patients and relatives about the service was consistently positive.
- Staff told us they enjoyed their work and felt well supported by the leadership team.
- We saw record keeping was of a good standard and processes had improved to ensure all notes were available during treatment.
- The multi-disciplinary team meetings were well attended and clearly documented to ensure a robust referral process
- Equipment was well maintained and the environment was clean. Internal infection control audits indicated compliance with national guidance standards.
- The arrangements and systems to ensure patient safety before the gamma knife surgery took place were used consistently.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with a Warning Notice for breach of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 19 (1)(a)(b)(2)(a)(3)(a) to employ fit and proper persons. Details are at the end of the report. After the inspection we carried out a return visit to the provider on 31 January 2017 and found that the provider had made significant improvements towards meeting the requirements of the Warning Notice.

Action the provider MUST take to meet the regulations:

- The provider must ensure that there is a robust process for ensuring that consultants and all other staff have the skills, competency, professional registration and good character to practise in the centre, including evidence of current professional registration, indemnity insurance, up-to-date appraisal and training and Disclosure and Barring Service checks (DBS) and that practising privileges are reviewed in-line with the relevant policy.
- The provider must ensure that there are effective governance, reporting and assurance mechanisms that provide timely information so that performance and outcomes are monitored effectively and in line with hospital policy and risks can be identified, assessed and managed. Reporting structures and responsibilities should be clearly set out and adhered to.
- The provider must ensure that the risk register is up to date and fit for purpose and reflects current clinical and corporate risks. There should be clear controls and review timescales identified for each risk.
- The provider must ensure that incidents are reported in-line with the relevant incident reporting policy. The provider must ensure that the incident reporting process is clear and consistently applied and understood by staff. Learning and feedback from incidents should be shared with staff.
- The provider must ensure that the service meets the NHS England service specification for stereotactic radiosurgery including the additional standards for tier 3 and 4 conditions requiring a gamma knife trained clinical oncologist to be part of the planning and treatment team.

Action the provider SHOULD take to improve

- The provider should review contingency plans to address the risk of equipment break down or if a medical physicist or other key staff were unavailable at short notice. The provider should ensure there is a business continuity plan to minimise the impact of events that stop or reduce the service to patients' care and treatment.
- The provider should ensure staff are aware of the duty of candour policy and their obligations.
- The provider should ensure that patient outcome data is collected and that benchmarking with equivalent sites is carried out.
- The provider should review patient feedback and take appropriate action to identify areas for improvement

Summary of findings

- The provider should ensure there is a clearly documented strategy for the development and expansion of the service to meet the requirements of the NHS England (NHSE) contract.

Professor Edward Baker

Deputy Chief Inspector of Hospitals- London

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Medical care	Requires improvement 	We rated medical services at The Gamma Knife Centre as requires improvement overall. The service was rated as inadequate for the well-led domain and requires improvement in the safe and effective domains. We rated caring and responsive domains as good.

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The Gamma Knife Centre at The National Hospital for Neurology and Neurosurgery

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Background to The Gamma Knife Centre at The National Hospital for Neurology and Neurosurgery

The Gamma Knife Centre at The National Hospital for Neurology and Neurosurgery is operated by QSRC Limited. QSRC Limited is itself a wholly owned subsidiary of Medical Equipment Solutions Ltd (MESL).The Gamma Knife Centre is located on the lower ground floor of The National Hospital for Neurology and Neurosurgery.

This service treats NHS and private patients using stereotactic radiosurgery (SRS) to treat brain tumours and other intracranial indications. The centre is operated as a partnership with the National Hospital for Neurology and Neurosciences (NHNN), part of University College London Hospital NHS Foundation Trust (UCLH). The partnership provides treatment for NHS patients from all over the UK and offers a service for private patients across the world.

The centre opened in 2012 and registered with CQC to provide the regulated activities of surgery and the treatment of disease, disorder or injury (TDDI) and, at the time of our inspection, had treated over 600 patients. In June 2016, QSRC, in partnership with UCLH, was awarded the NHS England contract to become a Supra-network SRS/SRT centre for the South of England, the North and North Central London region. This means that the centre can now treat tiers 3 and 4 patients, who generally have more complex or rarer conditions. The centre was also recently awarded the NHSE contract for paediatrics and, working in partnership with Great Ormond Street Hospital, will now provide treatment to children aged four to 12. In October 2016, the centre treated its first paediatric patient.

The provider's nominated individual for this service is Lynne Brooks who was managing director of QSRC and its parent company MESL. The registered manager for the service is Alexander Polonsky who is also the lead therapeutic radiographer for the centre. He joined the organisation in July 2016 and his application for registered manager had just been approved by CQC during the week of our inspection. The previous registered manager had left the organisation approximately 12 months previously and the service had not had an interim manager during this time.

We carried out the announced part of the inspection on 22 and 23 November 2016 and returned on 1 December 2016.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector, two other CQC inspectors both with radiotherapy experience, a CQC assistant inspector and a specialist advisor with expertise in clinical oncology. The inspection team was overseen by a CQC inspection manager.

Information about The Gamma Knife Centre at The National Hospital for Neurology and Neurosurgery

The Gamma Knife Centre is located on the lower ground floor of The National Hospital for Neurology and Neurosurgery (NHNN). The centre had one treatment room, one head-frame fitting room and two small individual patient waiting rooms. There was also a separate room where the admin staff were based and treatment planning was carried out. During the inspection, we visited all these areas and also visited the day-case ward in NHNN where patients were cared for before starting their treatment.

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Between July 2015 and June 2016, there were 120 day case episodes of care recorded at the service; of these 70% were NHS-funded and 30% other funded. No patients stayed overnight at the hospital during the same reporting period although 12 patients were admitted as inpatients to the National Hospital for Neurology and Neurosurgery (NHNN) following their procedure at the service.

During our inspection we spoke with 11 members of staff including, one consultant oncologist, the registered manager, the deputy medical director (neurosurgeon), the managing director of QSRC, the medical physics lead, a radiologist and other staff including therapeutic radiographers , as well as nursing and administrative personnel. We spoke with three patients in the unit who were receiving treatment and two of their relatives.

We also received 39 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed five sets of patient records.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. There had been one previous inspection since the service was registered with CQC this took place in January 2014 which found that the service was meeting all standards of quality and safety it was inspected against.

There were 13 consultants (eight neurosurgeons, one clinical fellow and four neuro-radiologists) who worked at the Gamma knife Centre under practising privileges. All were employed by UCLH. Medical physics services were provided by Medical Physics Limited and there were three members of the medical physics team. There was six staff employed directly by the service, including the registered manager (who was also the lead therapeutic radiographer), two other therapeutic radiographers, two admin staff and one nurse. One therapeutic radiographer and one of the admin team were on maternity leave during our inspection.

Between July 2015 and June 2016, the service reported no never events, clinical incidents, complaints or incidences of hospital acquired infections.

A number of services including cleaning, portering and radiology diagnostics and reporting were provided under a service level agreement by UCLH through the National Hospital for Neurology and Neurosurgery.

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?

Requires improvement

We rated safe as requires improvement because:

- There were inconsistencies in staff understanding of how incidents were reported and investigated. We heard several different versions of the incident reporting system and how this operated in practice from the staff. Learning from incidents was not always consistently shared with all staff.
- Not all staff we spoke with were aware of the duty of candour policy and their obligations.
- The centre did not keep a specific record of healthcare acquired infections or surgical site infections.
- There were no contingency plans in place if the equipment broke down or if a medical physicist was unavailable at short notice.
- The risk register lacked any controls to record how the service was mitigating the risks identified.
- Recruitment checks for staff and consultants working under practising privileges were not consistently carried out. The centre could not provide copies of DBS certificates for all staff and consultants.
- There was no policy for granting and reviewing practising privileges. This meant the service did not have oversight of the recruitment process and patients were at risk of being exposed to individuals who were not appropriately qualified nor fit to carry out their role

However:

- Medicines were prescribed by medical staff and clear records were kept.
- We saw record keeping was of a good standard and processes had improved to ensure all notes were available during treatment.
- Equipment was well maintained and the environment was clean. Internal infection control audits indicated compliance with national guidance standards.

Are services effective?

Requires improvement

We rated effective as requires improvement because:

- The service did not fully meet the NHS England service specification for stereotactic radiosurgery (SRS). There was no

Summary of this inspection

oncology input during the planning and treatment stage of the patient pathway. There was no oncology representation at the specific gamma knife multi-disciplinary team meetings and the oncologist had not received gamma knife training.
- There was limited outcome data collected since the service started. A retrospective audit was in place. However, staff told us the outcome data would be available to meet the new service specification. We could not verify this at the time of the inspection.
- There was limited comparison of outcome data with of other SRS centres including the sister site in Sheffield.
- The information held within the staff and consultant files was incomplete and did not demonstrate a robust recruitment process to ensure staff competency.

However:

- Staff working in the service on a regular basis undertook specific training supported by competency frameworks and assessments.
- Medical staff obtained full consent from patients prior to the gamma knife procedure starting.

Are services caring?

Good

We rated caring as good because:

- We observed staff delivering excellent patient care and they clearly responded to individual patient needs. We observed a supportive team approach to patient care.
- Feedback we received from patients and relatives about the service was consistently positive.
- We saw that patients' privacy and dignity was maintained and respected by staff.
- We observed staff providing patients with information on the procedure they were undergoing. Patients were given the opportunity to ask questions and staff responded to provide further explanations where needed.

Are services responsive?

Good

We rated responsive as good because:

- The service performed well against the patient waiting time standards. Reasons were documented for any breaches and all were due to patient choice. Staff confirmed that the centre routinely met a two-week target for patients with cerebral metastases.
- The service had reported no complaints between July 2015 and the time of our inspection.

Summary of this inspection

- Staff told us that patients who needed to travel long distances were given the options of visiting the centre on the most convenient day to reduce several visits. Patients with certain conditions were offered the option of an overnight stay in the NHNN.
- The centre had cancelled no patient procedures for non-clinical reasons in the 12 months prior to our inspection.

However:

- Although patient comments and feedback was collected by the service via the patient experience survey, we did not see any evidence of changes following feedback.
- There had been a previous agreement in place with another SRS centre to allow patients to continue their treatment if there were any contingency plans required. This agreement had lapsed.

Are services well-led?

Inadequate

Are services well-led?

We rated well-led as inadequate because:

- We were not assured that clinical governance and risk management processes were robust. We found that whilst plans for the centre's governance structure had been developed, in practice governance structures were not yet fully embedded and the reporting structure and responsibilities within the service were not clear.
- Managers lacked oversight of the practising privileges process. The centre did not have its own policy for granting and reviewing practising privileges and could not provide evidence that all appropriate checks had been carried out. This meant there was a lack oversight of the recruitment process for consultants applying for practising privileges.
- There was no formal process to ensure staff working under practising privileges had an appropriate level of valid professional indemnity insurance in place.
- The centre's risk register did not reflect all corporate and clinical risks and did not record any controls or actions for the risks that were identified. Regular management review of the risk register was not evident and plans to introduce a new risk register had not yet been actioned.
- As part of their contract with NHS England (NHSE) to treat tiers 3 and 4 patients, the centre was required to meet the standards of the NHSE's new service specification for stereotactic radiosurgery (SRS). We found that not all of these standards were being met.

Summary of this inspection

- There was no clear strategy for the development of the service following the award of the NHS England (NHSE) contract. We were unable to see a strategic plan setting out how the service would expand to meet the contract requirements.

However:

- Although recent changes in key staff meant the leadership team was fairly new, staff told us the team was effective and promoted a positive culture within the service.
- There was evidence of both staff and patient engagement within the service.
- The service demonstrated many areas of good practice. For example, the team used comprehensive checklists before starting any treatment.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Medical care	Requires improvement	Requires improvement	Good	Good	Inadequate	Requires improvement
Overall	Requires improvement	Requires improvement	Good	Good	Inadequate	Requires improvement

Requires improvement

Medical care

Safe	Requires improvement
Effective	Requires improvement
Caring	Good
Responsive	Good
Well-led	Inadequate

Are medical care services safe?

Requires improvement

We rated safe as requires improvement.

Incidents

- The centre reported no clinical or non-clinical incidents between June 2015 and July 2016.
- The centre also reported no deaths or serious injuries for patients in its care between June 2015 and July 2016.
- The centre reported no never events between June 2015 and July 2016. Never events (NEs) are serious incidents that are wholly preventable as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.
- Staff and managers told us there had been some incidents reported in recent months. However, the staff feedback differed and we were not clear from the documentation available what these incidents were. Some staff told us of events that had occurred that should have been reported as incidents but had not been. Not all staff were clear of the reporting process.
- Staff gave an example of how practice had changed as a result of an incident such as the removal of cannulas would only now take place in the preparation room following an incident involving a cannula left in a patient waiting area. However, learning from incidents was not formally recorded or shared across the wider MESL organisation.
- We noted that incidents were not discussed at the MESL board meeting held in June 2016 or at the sub-contractor meetings held with the host trust, University College London Hospitals NHS Foundation Trust (UCLH) in July and September 2016.
- Staff we spoke with, including the registered manager were unclear who was responsible for the oversight of the incident reporting and investigation process.
- Therapeutic radiographers were aware of Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) requirements and the need to report radiation incidents to CQC. They did this through their Radiation Protection Supervisor (RPS), who was one of the therapeutic radiographers and the Radiation Protection Advisor who was available to them as part of the service level agreement (SLA) with UCLH.
- There had been no reportable radiation incidents in the reporting period prior to the inspection.
- Not all staff we spoke with were aware of the duty of candour policy and their obligations.

Safety thermometer or equivalent (how does the service monitor safety and use results)

- The centre did not keep a specific record of healthcare acquired infections or surgical site infections. However, patients were seen for day case treatment in the majority of cases and we were told there had been no reported injuries, healthcare acquired infections or surgical site infections in the centre.

Cleanliness, infection control and hygiene

- The centre was visibly clean. We saw that up to date green “I am clean” stickers were used to denote when an item of equipment had been cleaned and was ready for use.

- We observed staff washing their hands before attending to each patient. Internal infection control audits were undertaken on a monthly basis and demonstrated compliance with latest guidance.
- Adequate supplies of personal protective equipment (PPE) including disposable gloves and aprons were available in the centre. We observed staff using these when delivering care. We saw that staff adhered to the 'bare below the elbow' policy.
- We observed a consultant wearing gloves when fitting head frames on patients prior to radiosurgery.
- The frame fitting procedure was undertaken using sterile instruments and appropriate aseptic (no touch) technique.
- We observed that sharps management complied with Health and Safety Regulations 2013. Bins were locked, were not overfull and were dated and signed.
- All patient areas at the centre including the patient waiting bays, preparation and treatment rooms were clean and tidy.
- There was a contract in place with the host hospital, the National Hospital for Neurology and Neurosurgery (NHNN) to keep the premises clean.
- We observed staff sending the frame fitting kits to the decontamination service within NHNN. Staff told us they had a service level agreement in place and sufficient equipment was available to rotate through the decontamination service.
- Safe disposal of clinical waste was managed by NHNN.
- Radiotherapy staff received their infection prevention and control training through the UCLH mandatory training system. We saw evidence that this was up to date.
- The centre did not have its own toilet facilities but staff, patients and visitors used those provided by the NHNN which were single, disabled access toilets. This toilet was a short way along the corridor for ease of use. It was visibly clean and cleaning schedules were in place and complete.

Environment and equipment

- The rooms in use to provide this service were suited to their purpose and comprised of a dedicated stereotactic radiosurgery (SRS) centre within the basement corridor of the NHNN. The consulting and preparation areas, treatment room and administration areas were well equipped with everything staff needed to provide the service. Staff we spoke with had some concerns over the effectiveness of the air conditioning unit in the planning room which got very hot due to the number of monitors and people present in the room. We did not see any evidence this had been formally escalated as an incident nor was it recorded on the risk register.
- The patient waiting bays were free from any hazards and the areas were comfortable and well decorated.
- There were no obvious radiological environmental hazards observed within the centre at the time of our inspection. Staff wore personal radiation dose monitors which were monitored in accordance with the relevant legislation.
- All radiation areas had secure access. There were safety notices on the doors into the treatment room which stipulated safety measures. Radiation warning lights were in place and we observed they were in working order.
- There was an appropriate clinical preparation room suitable for the head frame fitting, storage of equipment and storage and preparation of medicines.
- The resuscitation trolley was available a short distance along the corridor outside the MRI unit. We saw evidence the trolley was checked and maintained appropriately. This was the responsibility of the NHNN MRI service.
- Staff ensured equipment throughout the centre was calibrated and maintained with appropriate maintenance contracts and service level agreements for specialist equipment including the Gamma Knife. We reviewed the emergency procedures policy in the event of an equipment failure. This was last updated in August 2016. Staff we spoke with could tell us what they needed to do in the event of an emergency.
- Patient dose records were recorded on the electronic system.
- Staff carried out the quality assurance checks for all radiotherapy equipment. We observed the recording of these checks and they were all within the tolerance limits to operate the equipment safely. These were mandatory (must do) checks based on the Ionising Radiation Regulations 1999 and (IR(ME)R) 2000. These protected patients and staff against unnecessary exposure to harmful radiation.
- We reviewed the IR(ME)R documentation and saw that consultant neurosurgeons were registered IR(ME)R practitioners and the therapeutic radiographers and physicists were operators. This complied with the IR(ME)R regulations.

- One of the lead therapeutic radiographers was the radiation protection supervisor (RPS) and they had carried out the appropriate training.
- Radiation safety risk assessments were in place and accessible on the shared drive for all staff to access.
- The risk register included a risk around quality assurance failure and equipment downtime but with no recorded mitigations or actions plans in place.
- The radiation source was four years old and due for replacement. This increased treatment times by 18%.
- Staff told us the annual radiation safety audit was due in December 2016. We reviewed a copy of the previous radiation safety audit carried out by the radiation protection advisor (RPA) in October 2015. The audit concluded that the centre was complying with legislation relating to the use of ionising radiations. There were also three recommendations made by the RPA, one of which was that QSRC should confirm that the Health and Safety Executive (HSE) had been notified of the use of ionising radiations. Following our inspection we were provided with a copy of an updated audit carried out on 29 November 2016. In this report it was noted by the RPA that evidence of notification to HSE was still not available. This audit also confirmed that the centre was compliant with ionising radiations legislation.

Medicines

- There were arrangements in place for managing medicines. This included obtaining, prescribing, recording, handling, storage and security, dispensing, safe administration and disposal.
- Staff told us, and records showed that the nurse checked drugs regularly and rotated stock appropriately.
- Consultant neurosurgeons prescribed and administered local anaesthetic when fitting head frames. They prescribed and administered the drug for each individual patient.
- The anaesthetic was stored in a lockable cupboard in the preparation room.
- There were no controlled drugs kept on the premises.

Records

- People were protected from the risks of unsafe or inappropriate care and treatment because accurate and appropriate patient records were available.
- All the patient notes were available on the days we inspected. Staff told us the availability of notes had improved following a change to the process. The administrator for the centre now collected the notes from medical records at UCLH prior to the treatment days.
- We looked at three sets of paper records and two electronic records. The records were clearly written and signed by staff who had undertaken consultations and procedures.
- Pre-assessment records were recorded and scanned into the electronic patient notes. A checklist of all required documentation and test results were completed a week before the treatment day.

Safeguarding

- The CQC had received no reported safeguarding concerns in relation to the centre.
- The safeguarding lead for the centre was the therapeutic radiographer who was on secondment from UCLH. They had completed level 3 safeguarding adults and children training. We saw records to confirm that all therapeutic radiographers had completed level 3 training in safeguarding children.
- We saw policies and processes were in place to safeguard vulnerable adults and young people although these were not yet adapted to include the paediatric contract.
- Staff we spoke with were all aware of their responsibilities and could tell us what they would do if they had safeguarding concern.
- Staff told us they had received an enhanced disclosure and barring service (DBS) check on appointment at the centre, however we did not find evidence of these checks held for all staff members.

Mandatory training

- Mandatory training included infection control, health and safety, fire safety, conflict resolution and safeguarding and was provided for all staff by UCLH. We saw evidence that all staff were up to date with their mandatory training.
- Staff told us they were achieving mandatory training targets and were given sufficient time to attend the session or complete e-learning.

- Radiography staff told us they were required to complete the Gamma Knife Clinical Staff Training Programme. We saw evidence of their competency which was signed by themselves and their mentor.

Assessing and responding to patient risk

- We were told by staff about a new process in place to ensure all relevant documentation, test results and safety details such as pregnancy status were collected before the patient attended for their treatment. We saw a pre-treatment checklist was completed for each patient prior to the gamma knife treatment.
- We saw that staff checked patients' identity before carrying out any discussion or intervention.
- Staff told us and we observed that an adapted version of the world health organisation (WHO) checklist was used in all gamma knife treatments. This was checked, completed and signed by the therapeutic radiographer and the neurosurgeon. However, this was a new process and an audit of these forms had not been done to check they had been completed correctly and consistently for all patients.
- There was a consultant, medical physics expert and two therapeutic radiographers present at all times during procedures.
- All patients were accompanied to and from the ward to the preparation room, MRI scanner, and radiotherapy procedure room. Following the head frame fitting, patients were taken to the toilet or the MRI machine in a wheelchair to minimise risk of a fall.
- There were written procedures and local protocols / rules in place as required under the IR(ME)R regulations. Staff were aware of the local rules and how to use them in their practice.
- A radiation protection advisor (RPA) could be contacted to give advice to staff when needed.
- Systems were in place to contact an emergency response team if required from the NHNN. Staff were aware of the process.
- Staff told us about a training scenario using a mannequin that had been followed to look at all the risks and requirements for treating paediatrics in the department.

Nursing, Therapeutic Radiography and Radiotherapy Physics staffing

- Within the Gamma Knife Centre there was a core team of six staff; three full time therapeutic radiographers, one of whom was on maternity leave and one on secondment from UCLH to provide maternity cover, one nurse and two administrative staff member.
- There were enough staff to safely care for the patients in the unit, however, managers had acknowledged that team of radiographers would need to be increased to meet the demands of the new contract.
- Although there were no posts vacant at the time of our inspection we were told about plans to take on additional staff in 2017.
- There were no reported staff sickness in the period between July 2015 to June 2016. The new registered manager had only been in post since August 2016 but was an experienced therapeutic radiographer with many years' experience in gamma knife treatment. Two members of the team were on maternity leave at the time of our inspection, one therapeutic radiographer and one admin assistant, and additional staff had been taken on to cover both these roles.
- Staffing levels for radiotherapy physics support were within the guidelines of the Institute for Physics and Engineering (IPEM) recommendations. However, with the high level of complex work undertaken in planning the gamma knife treatments, access to experienced staff to increase capacity for the contract was acknowledged as a challenge.
- We reviewed six staff files, for employees of QSRC. This included three therapeutic radiographers, two admin staff and one nurse. Only three (two therapeutic radiographers and the nurse) had a copy of an enhanced Disclosure and Barring Service check. No evidence for a DBS check had been received or requested for other staff members, two of which were on maternity leave and the other was a recently appointed admin assistant. Only four of the files had a copy of photo identification.
- All files contained copies of signed contracts (or secondment agreement if appropriate) and job descriptions but no references were held for any staff.

Medical staffing

- There were 13 consultants (eight neurosurgeons, one clinical fellow and four neuro-radiologists) who worked at the Gamma knife Centre under practising privileges. All were employed by UCLH. Three consultants had seen between one and nine patients between July 2015 and

June 2016 and the other consultants had seen between 10 and 99 patients in this same period. There was also a clinical oncologist who was employed by UCLH and attended some of the MDT meetings but was not actively involved in treating patients.

- We were told that the medical advisory board met quarterly and was attended by the executive director and the medical director as well as representatives from the neurosurgical team who were invited to attend. The clinical oncologist did not attend the medical advisory board meetings.
- The granting and review of practicing privileges was said to follow the NHNN policy and that documentation was held centrally within NHNN and the gamma knife centre. We were unable to review any documentation within the centre as it was not held on site, contrary to the process outlined. We did note that two of the consultant's private medical insurance had expired. We were told this had been followed up with the consultant's secretary but a response had not yet been received. We conducted a follow up visit on 1 December 2016 to further look at the requested documentation. We found there was no policy for granting and reviewing practising privileges. The information supplied to CQC in the provider information request (PIR) prior to our inspection did not reflect what we saw in practice. This meant the service did not have oversight of the process and patients were at risk of being exposed to individuals who were not appropriately qualified nor fit to carry out their role.
- Staff told us contractual arrangements were in place for UCLH to provide emergency cover or answer patient queries if required.
- There were no contingency plans in place to arrange cover for the clinical oncologist's annual leave and sickness.

Major incident awareness and training

- Radiotherapy equipment had battery back up in case of power failure.
- There was a major incident policy in place for UCLH, which staff at QSRC would follow. We did not check the details of this with staff during our inspection.

Are medical care services effective?

Requires improvement

We rated effective as requires improvement.

Evidence-based care and treatment

- The centre complied with guidance under IRMER and the Radiation Regulations and had an up to date list of practitioners and operators. An external radiation protection adviser was in place and their 2015 and 2016 safety audits concluded that the centre was compliant with ionising radiation legislation.
- The Gamma Knife Centre was one of only two sites in the country to hold an NHS England contract to use stereotactic radiosurgery (SRS) to treat patients with tiers 3 and 4 conditions. Tiers 3 and 4 conditions are generally rarer or more complicated conditions including vascular conditions and other non-tumour conditions such as trigeminal neuralgia. The second 'sister' site was a radiosurgery centre based in Sheffield also owned by MESL and sharing the same executive director as the Gamma Knife Centre at the National Hospital.
- The centre did not meet the NHS England service specification for stereotactic radiosurgery for the additional standards for tiers 3 and 4 conditions. The specification states that the composition of the SRS Treatment and Planning team will involve neurosurgeons and clinical (radiation) neuro-oncologists supported by paediatric oncologists (where appropriate) neuro-radiologists, medical physics, health technology staff, therapeutic radiographers , clinical nurse specialists and administrative support. We found that the clinical oncologist attended some of the multidisciplinary team (MDT) meetings but were not present for specific gamma knife planning and treatment MDT.
- There was a MDT held every two weeks to discuss all the NHS and private referrals and to decide whether gamma knife treatment was the most appropriate treatment option for each patient Although the clinical oncologist did attend this meeting they told us that they did not attend the specific gamma knife treatment planning MDT which occurred once the decision to treat with

gamma knife had been made. After the inspection, the provider told us that they had introduced a further planning meeting involving all members of the MDT, including the clinical oncologist.

- The neurosurgeons signed off the treatment plans within their own level of expertise and competence. The new service specification requires input from an oncologist at the planning and treatment phase of the patient pathway. This was not in place. The oncologist told us they sometimes reviewed the treatment plan after the treatment had been given.
- The service specification also states that continuous staff education and training to demonstrate competence at tier 3 and tier 4 is essential. Although all the neuro-surgeons were trained and competent as evidenced by their competency portfolios, the clinical oncologist had not undertaken this specific gamma knife training. Despite not having the required training the clinical oncologist was responsible for signing off the neuro-surgeons' treatment plans. This meant that potential error or risks to patient safety might not have been identified.
- The centre followed the Institute of Physics in Engineering Medicine 'Guidelines for the provision of a Physics Service for Radiotherapy' 2002.
- Targeting accuracy for the gamma knife equipment had been audited and approved by NHS England during the contract tendering process.
- We saw that staff carried out daily and monthly checks to ensure that the equipment was appropriately calibrated.
- Staff had access to a shared drive containing relevant policies and procedures. Other policies were accessed via the host trust's intranet. Many policies were adopted from the UCLH as the host trust, this meant they were not always well suited to meet the specific needs of the centre.
- Radiotherapy planning with an up to date MRI scan was carried out immediately before each treatment by a neuro-radiologist, medical physics expert and the neurosurgeon. We observed a comprehensive planning session and saw treatment plan reviewed and signed by the neurosurgeon before proceeding with the treatment. The planning sessions discussed in detail the preservation of unaffected organs. The clinical oncologist was not involved in this stage of treatment planning contrary to the requirements of the service specification.

Pain relief

- Patients were injected with local anaesthetic at the site where the head frame for surgery was secured. Staff told us that the anaesthetic could be 'topped up' by the treating consultant if patients reported feeling any sensation. We observed one patient asking for extra pain relief and this was quickly provided. The patient reported a decrease in the pain felt due to the frame fitting and confirmed to staff when they felt pain free.
- Further pain medication such as paracetamol was stored within the preparation room. We observed staff asking patients about their level of pain throughout the process.

Nutrition and hydration

- Scoring of patient nutritional needs were carried out with the nursing assessment form. This information was available to staff in the centre within the patient records.
- There was access to food and drink for the patients near the patient waiting bays.
- Staff told us that patients undergoing lengthy treatment were offered breaks to allow them to have a drink.

Patient outcomes

- Clinical protocols were available on a shared drive and staff confirmed they could access these.
- Senior staff told us they had not previously collected specific outcome data but they would comply with the new service specification requirements going forward.
- The centre took part in a national dose audit in August 2016. This indicated there were no major concerns regarding the local practices at QSRC for the specific aspects of dosimetry for cranial stereotactic radiosurgery.
- The previous clinical research fellow undertook a three-year audit study with results published internally in August 2015. This looked at diagnosis, side effects and survival outcomes.
- The current research fellow was analysing the database of patients to present some outcome data to the governance meetings.
- There was limited comparison data of other SRS centres including the sister site in Sheffield.
- There were no unplanned patient transfers, unplanned patient readmissions within 28 days, or unplanned returns to surgery between July 2015 and June 2016.

Competent staff

Requires improvement

Medical care

- The new registered manager had only been with the organisation four months and was yet to have an appraisal. We were told by the executive director that the manager was undertaking training to appraise the other staff. Of the six staff files we reviewed only one had a completed appraisal for the current staff. Reasons given for the delay in completing appraisals included maternity leave and the fact that three staff had been with the centre less than six months. We were told that plans were in place to complete appraisals with all available staff before the end of the year.
- We reviewed all staff files and found that information was incomplete and did not demonstrate a robust recruitment process to ensure staff competency. There were no formal systems in place to review the professional registration of radiographers or nursing staff.
- We were not able to review the validation of registration for doctors working under practising privileges at the time of the inspection or a signed annual declaration to show that they were competent to practice.
- At the time of our inspection we were informed that no staff were subject to restricted practice, suspended, or had their practicing privileges removed. However, the expired indemnity insurance for two consultants had not yet been resolved. We found there was no formal process in place to review or suspend practising privileges.
- Staff described continuous professional development (CPD) opportunities to allow them to enhance their training and skills.
- The new registered manager was reviewing the induction programme for therapeutic radiographer radiographers.
- Gamma Knife operators were IR(ME)R practitioner trained and trained specifically to use the radiosurgery equipment by the manufacturers, Elekta. This group included all therapeutic radiographer s, consultants and medical physics experts. We saw records of staff training with dated competencies on the shared drive.
- Some staff raised concerns around the sometimes ad-hoc nature of consultant engagement.
- There were no SRS trained oncologists available for the service.

Facilities

- The centre did not have its own diagnostic imaging facilities. MRI, CT and angiographic imaging was provided by the NHNN as part of the patient pathway for stereotactic radiosurgery.
- The centre was located within the NHNN and had none of their own patient beds. Any patients requiring an overnight stay were transferred to one of the NHNN wards. We saw that this arrangement worked well on the day of the inspection.

Multidisciplinary working

- We observed strong team working in the centre and staff were comfortable working across professional groups.
- We saw that staff were respectful of each other and their role within the team, particularly within the treatment planning sessions.
- Multidisciplinary planning meetings took place prior to treatment for all patients and there was a strong multi-disciplinary team ethos across the service. All NHS patients, from anywhere in the UK were referred to and discussed at the various UCLH MDTs dependent on their specific condition.
- There was also a fortnightly gamma knife specific MDT however this was not attended by the clinical oncologist contrary to the requirements of the NHSE service specification. We reviewed some of the MDT meeting minutes and saw each patient was discussed in depth.

Seven-day services

- The centre operated Monday to Friday. There were three clinical treatment days in the week. We observed the patients arriving at 7am on the day of treatment.
- Up to three patients were treated per day.
- We were told about plans to expand the number of clinical days to allow more patients to be treated to meet the requirements of the NHSE contract. These plans had not been finalised at the time of our inspection.
- The partnership with UCLH meant there were neurosurgeon consultants available twenty-four hours a day to provide cover as required for either emergencies or for patient queries.

Access to information

Requires improvement

Medical care

- All staff we spoke with had access to internal IT systems that allowed them to track patient progress and clinical information. This included access to electronic imaging undertaken on site, or sent electronically to the centre where imaging had been performed at another provider.
- Staff had access to the system to manage the work flow, patient appointments and other key clinical information. We saw there were sufficient terminals and laptops for the staff to access.
- Staff were also able to access relevant policies and guidance for the centre via the NHNN intranet and their own internal shared drive.
- Staff explained that paper based treatment information for NHS patients were sent to the local trust following treatment being completed. The local trust would provide discharge information and treatment information to the referring consultant.
- We saw onsite MRI imaging taken at the NHNN was available to planning staff within minutes.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- Patients' consent to treatment was obtained at the clinical consultation phase. Patients confirmed their consent at the pre-treatment visit and prior to treatment on the day.
- We reviewed five consent forms and the consent procedure and confirmed that the process had been followed.
- Staff understood the Mental Capacity Act and were able to describe the appropriate steps to take.

Are medical care services caring?

Good

We rated caring as good.

Compassionate care

- We saw that staff approached patients in a caring way and patients were treated with compassion, dignity and respect.
- Patients told us that staff spoke to them in a kind manner and took the time to care for their needs. They were highly complementary about the care they received.
- We received 30 comment cards from patients and nine from relatives. They all gave positive descriptions of the experience of care, dignity and respect from all staff in the centre. One patient said, "The staff have all been great and I felt very cared for during the whole procedure."
- During treatment staff were not allowed to stay in the room. We saw that staff could communicate with the patients via an in-room microphone. We observed staff reassuring the patient throughout the treatment.
- The patient survey was sent home with the patient post treatment with a stamped addressed envelope to post back to the centre. We were told about 50% of patients returned the survey.
- We saw the patient feedback survey results for the 60 patients who had responded in the 12-month period prior to our inspection. We saw that 81% of patients said there was nothing they would change about the day but there was no information about the 19% who would like changes. Overall experience was rated by these 60 patients on average as 7.8 out of 10.

Understanding and involvement of patients and those close to them

- We spoke to the relatives of the patients receiving treatment on the day of the inspection. They told us they felt they had also been involved in the treatment and were able to ask questions too.
- We observed staff providing patients with information on the procedure they were undergoing. Patients were given the opportunity to ask questions and staff responded to provide further explanations where needed.
- Patients told us that they understood the procedure they were undergoing and that they had received appropriate clinical information. However, the patient survey showed that only 88% of patients received a telephone call prior to the treatment and 83% had received an information leaflet. These scores were low when taking into account the number of patients treated per day.
- The centre invited patients to meet with members of the team and to visit the centre approximately a week prior to radiosurgery. This provided an opportunity for patients to meet with their key worker, raise questions about the treatment day and familiarise themselves with the surroundings including the head frame.

Requires improvement

Medical care

Emotional support

- The therapeutic radiographers were designated as key workers for the patients and acted as point of contact should the patient have any queries or concerns before or after their treatment.
- Staff told us they all worked hard to ensure all the needs of the patient were met.
- Patients told us they felt supported at each step of the pathway and were able to ask as many questions as needed around their care.
- We observed a friendly but professional approach from all the staff. The atmosphere within the centre felt supportive at all times with the patient's needs at the forefront of the service delivery.

Are medical care services responsive?

Good

We rated responsive as good.

Service planning and delivery to meet the needs of local people

- The service had secured a seven-year contract with NHS England, in partnership with UCLH and Great Ormond Street, as a specialist provider of stereotactic radiosurgery for adults and children. The QSRC service is now the 'SupraCentre' for London and the South of England.
- The centre had not yet begun recruitment of additional staff in order to meet an expected increase in demand for the service. Staff told us they needed more resources to meet the expected increase in patient numbers. Although there were sufficient staff to undertake the duties required at this present time, the current staffing and environmental capacity did not meet the increased demand of the new contract.
- The centre mostly operated a day case model of treatment whereby the patient would arrive at 7am onto the designated ward within the NHNN.
- Staff told us they tried to work closely with patients who need overnight accommodation due to distance and could sometimes offer a slightly later start time.
- There had been a previous agreement in place with another SRS centre to allow patients to continue their treatment if there were any contingency plans required. This agreement had lapsed by the time of our inspection.
- The centre told us they had no patients that did not attend (DNA) for treatment and the majority of patients were telephoned directly before the treatment day.

Access and flow

- Between July 2015 and June 2016, there were 120 episodes of care recorded at the centre. Of these, the majority (70%) were NHS funded.
- The centre had cancelled no patient procedures for non-clinical reasons in the 12 months prior to our inspection.
- In the data provided during the inspection there were seven breaches against the NHS 18 week waiting time target. Reasons were documented for the breaches and they were all due to patient choice. Staff confirmed that the centre routinely met a two-week target for patients with cerebral metastases.
- Data provided by the centre during the inspection showed that the average waiting time for referrals was eight and a half weeks.
- As part of the ongoing development of the service contract in partnership with the local NHS trust, staff told us that reporting of referral to treatment times was to be recorded on one tracking list, rather than the two being used at the time of the inspection. This would improve the accuracy of the data.
- We observed two patients being discharged from the centre. They were provided with appropriate information about their follow up care and contact details for how to contact the service.
- The centre was located on the lower ground floor of the National Hospital along with the host trust's other radiotherapy and radiology services and therefore patients did not need to leave the building to have an MRI scan.

Meeting people's individual needs

- The centre provided patients with patient information both prior to and post-surgery. Patients that we spoke to on the day told us they had received this information.

Requires improvement

Medical care

- Patient information leaflets were only available in English but staff told us they could book an interpreter if required. There were no large print or braille leaflets available.
- Staff told us that patients who needed to travel long distances were given the options of visiting the centre on the most convenient day to reduce several visits. Patients with certain conditions were offered the option of an overnight stay in the NHNN.
- Staff had access to the learning disability lead at UCLH.

Learning from complaints and concerns

- The centre had received no complaints between July 2015 and June 2016.
- The centre used UCLH's complaint procedure.
- If patients were unhappy with the response they could escalate complaints to the regional level and then to an independent external review.
- Complaints were a standing agenda item on the monthly operational meeting.
- We did not see any evidence of an action plan following feedback from the patient survey in which 60 patients rated their overall experience as 7.8 out of 10.

Are medical care services well-led?

Inadequate

We rated well-led as inadequate.

Leadership and culture of service

- The service was led by the managing director of QSRC, who was also executive director of QSRC's parent company MESL, together with the newly appointed registered manager who was also one of the two lead therapeutic radiographers for the centre.
- The registered manager was new to the organisation and had been working at the centre for less than six months at the time of the inspection.
- The registered manager reported to the executive director and was in the process of taking over line management responsibilities for some of the other QSRC staff members. They told us that they felt very well supported by the centre's leadership team and had been provided with opportunities to develop their management skills.
- The previous registered manager had left the organisation approximately 12 months prior to the appointment of the new manager. The service had not had an interim manager during this time. The CQC were not informed of the gap without a registered manager until the inspection was announced. The staff we spoke with felt the new manager was very experienced in gamma knife processes and procedures but needed more managerial experience. The registered manager confirmed they were being supported to access courses in leadership and management.
- The centre's clinical lead and medical director was employed by UCLH and was one of the eight consultant neurosurgeons with practising privileges at the centre.
- The majority of staff spoke positively about the leadership within the centre. Staff told us they felt supported by management and were confident in speaking to management to raise any concerns.
- Staff told us that the new team within the centre worked well together and were a dynamic team.
- We observed a highly professional manner within the service at all times. Staff expressed a culture of openness and honesty and gave examples of informing patients of any issues within the running of the service, such as equipment breakdown and re-arranging appointments.

Vision and strategy for this this core service

- The centre's vision was taken from the parent company MESL: 'to provide a service which puts the patient first, providing exceptional patient care and experience, working to make stereotactic radiosurgery accessible to all that can benefit'.
- We discussed with staff the requirements of the new NSHE contract. Whilst the leadership team were able to articulate the development plans for the service, we were unable to see a single strategic growth plan with partnership wide sign-off. Other staff we spoke with were not clear of the vision and direction for the service.
- There was a general agreement from staff that the current facilities and staffing were unable to provide the level of increase required of the service. Clinical activity was set to increase from 120 cases in one year to approximately 400 under the new NHSE contract requirements.
- The business plan for 2016 to 2017 contained robust financial information but no details about the resourcing required for expansion.

Requires improvement

Medical care

Governance, risk management and quality measurement for this core service

- We were not assured that clinical governance and risk management processes were robust. We found that whilst plans for the centre's governance structure had been developed, in practice, the service's governance structures were not yet fully embedded and the reporting structure and responsibilities within the service were not clear.
- We were told by the centre's executive director that overall responsibility for clinical governance of the Gamma knife centre sat with the host trust, UCLH via the National Hospital for Neurology and Neurosurgery (NHNN). We found there was a lack of clarity around how this governance structure relationship worked in practice between the trust and QSRC.
- Staff were not always clear about their role and what they were accountable for. The registered manager was new to the role and was still in the process of developing a clear understanding of the responsibilities of this role. From speaking to staff it was clear there was some confusion as to who was responsible for oversight of incident reporting and investigation.
- We were told that management meetings took place on a monthly, quarterly and six monthly basis. However, we found that although there was a governance structure plan, at the time of our inspection, this had not yet been fully implemented and meetings did not always take place regularly.
- The centre's clinical governance policy stated it had last been reviewed in November 2015 and was due for its next review in September 2016. This had not yet been reviewed at the time of the inspection. The policy stated that QSRC would establish a Gamma Knife governance committee which would meet every six months. The committee would report to the trust governance team through the centre's medical director. The policy did not set out who would sit on this committee or the date of the first meeting, although it listed the audits that the committee would be expected to review.
- We reviewed a copy of the trust's 'Stereotactic Service Governance Structure' document dated May 2016. This stated that a quarterly stereotactic radiosurgery/ stereotactic radiotherapy (SRS/SRT) clinical governance committee and operation group meetings took place and included the NHNN and the QSRC management teams as well as members of the SRS/SRT multidisciplinary team. Both were chaired by the centre's medical director and fed into the host trust's Stereotactic Service Programme Board. However, this document stated that the date of the first meeting was still to be confirmed. We were not provided with any minutes from these meetings and saw no evidence that this structure was operational at the time of our inspection.
- We asked the provider for copies of the minutes of any clinical governance meetings that had taken place in the 12 months prior to our inspection. We were provided with six sets of minutes for the trust's 'Queen Square division' clinical governance committee meetings held between October 2015 and September 2016. These meetings were not attended by any representatives of The Gamma Knife Centre's leadership team nor did the minutes make any specific reference to QSRC or The Gamma Knife Centre. We were told by the managing director of QRSC that due to the growing contract, going forward there would be a duplication of clinical governance meetings by QSRC as well as the trust.
- We were told that the medical advisory committee (MAC) meetings were held quarterly however we found that meetings did not always take place regularly. We were told that the medical advisory board had responsibilities in relation to clinical governance with particular focus on clinicians' performance. We reviewed three sets of minutes from the meetings dated January, April and November 2016. We saw that only on one occasion had anyone other than the managing director and the medical director attended these meetings. On this occasion, in January 2016 one of the consultant neurosurgeons with practising privileges had attended. However, on both other occasions two of the centre's consultant neurosurgeons had been invited to join but had sent their apologies. The clinical oncologist was not invited to attend the MAC meetings.
- In the minutes of the MAC meeting held in November 2016 it was noted that the last meeting had been held on 11 April 2016 but there was no explanation for the gap of seven months where no meeting had taken place.
- The main standing agenda items were recorded as the NSHE contract and tender process, activity/case mix and budget. The item 'Risks/ complaints and never events' was low down on the agenda and was only referred to say that there was nothing new to discuss. There was one incident discussed, at the November 2016 meeting,

which related to a patient being allergic to the anaesthetic. The second incident that we were told of during our inspection was not recorded as being discussed within any of the MAC meetings minutes. Although the minutes did record that HR updates were a standing item on the agenda and that new appointments were recorded, such as the new clinical fellow in the November 2016 minutes, there was no specific discussion or review of admitting rights or practising privileges.

- The MAC minutes from November 2016 stated that a new combined clinical governance and MAC group had been formed and that the first meeting was due to be held on the 5 December 2016. All neurosurgeons, oncologists and paediatrics consultants were to attend. After our inspection, the provider shared with us a copy of the minutes of this first meeting combining the QSRC medical advisory board and clinical governance committee. The meeting was chaired by the centre's medical director and was attended by representatives from neurology, oncology, medical physics and radiotherapy as well as the management team. The date for the next meeting had not been agreed at the meeting, but it was recorded that they would be held quarterly going forward.
- We were provided with minutes of two QSRC board meetings which took place in December 2015 and June 2016. Meetings were attended by the centre's executive director and the board's chairman, along with the company secretary. Both meetings had been called for a specific purpose, the first to sign off the company accounts and the second to hear the outcome of litigation against the company. No reference was made to any other topics such as operational or clinical risks or any matters that required escalation from the clinical governance committee.
- We reviewed a copy of the centre's risk register dated June 2016. We were told that this was reviewed by the management team on annual basis. Risks were categorised as red, amber or green and rated according to their impact and likelihood. There were 11 risks identified on the register, divided into five categories: patients, governance, resource, security and financial. The risks identified to patients included failure in quality assurance, equipment failure and not meeting the NSHE service specification requirements. Not all risks identified during our inspection were reflected on the risk register. For example, we were told by staff that patients were at risk of fainting whilst wearing the head frame and to reduce this risk patients were supervised closely by staff and moved through the centre using a wheelchair. We did not see this risk recorded anywhere.
- Although each risk was assigned to an accountable individual (either the executive or medical director or both) there were no controls identified to mitigate the risks or any timescales for action or review. It was also unclear when each risk had been added. Therefore, it was not possible to determine how long risks had been on the risk register for or how frequently they were reviewed and updated.
- MAC meeting minutes made limited reference to the risk register to state there had been no changes. In the minutes of the meeting held 11 April 2016 it was recorded that that a new risk register would be produced to take account of the NHSE contract by June 2016. However, in the following meeting's minutes in November 2016 no mention of this action was recorded.
- We were told by the director that responsibility for granting and reviewing practising privileges sat with the host trust but that local management oversight of the process was maintained via the MAC. QSRC and The Gamma Knife Centre did not have its own policy on practising privileges but instead referred to the trust's policy. We did not see any evidence from the minutes of the MAC meetings that consultant's applications to practise were reviewed.
- We reviewed files for both directly employed staff and consultants with practising privileges. We found that there was a lack of documentation to evidence appropriate recruitment checks had been carried out. This meant patients were at risk of being exposed to individuals who are not appropriately qualified, or otherwise not fit, to carry out their role.
- Prior to our inspection as part of CQC's provider information request we asked for information about the provider's process for granting practising privileges. We were told that documentation was held centrally by the trust's honorary contracts office and within the centre and was easily accessible for review. However, we found this not to be the case and during our initial inspection on 22-23 November 2016 this documentation was not made available to us.
- We were told that for initial granting of practising privileges a detailed admitting rights application pack was completed including a DBS check, a requirement for references, copy of practising privileges policy,

self-declaration and confidentiality agreement together with various guidance. However, we saw no evidence of this. We were told that the decision to appoint practising privileges was confirmed in writing by the executive director however; again, we did not see any evidence of this.

- The executive director said that all recruitment checks were performed by the NHS trust who employed and vetted the consultants, and that confirmation of these checks had been completed was provided via email. However, we did not see any evidence that these checks had been carried out. We found that there was no formal process in place for reviewing, suspending or restricting practising privileges.
- During our return visit on 1 December 2016, we were provided with a file containing information for 12 consultants who were all employed through the NHS trust recruitment process. In addition, we saw recruitment information for staff who were directly employed by the Gamma Knife Centre. In the consultant files, there was no evidence of any DBS checks being completed for any of the consultants, although there was evidence that this had been requested since our inspection on 22-23 November 2016.
- We also found that only two of the 12 consultants had proof of photographic identification. In addition, there was also no evidence of references held for any of the consultants, nor any documentary evidence of qualifications, training, appraisal or revalidation being completed. We found there was no recruitment information available for either of the clinical fellows, one of whom was treating NHS patients at the centre.
- There was no formal process to ensure staff working under practising privileges had an appropriate level of valid professional indemnity insurance in place. We found that two of the 12 consultants who had practising privileges at the centre had out of date indemnity certificates. We brought this to the attention of the director who was unaware of this issue and assured us that action would be taken to obtain valid certificates. Responsibility for this process was delegated to admin staff and we found there was no formal process in place to review this. The management did not have oversight of this process.
- We reviewed all six files for staff directly employed by QSRC. Only three staff had evidence of a DBS check being completed and there was no evidence that DBS checks had been received or requested for the other staff members. Evidence of photographic identification was only available for four members of staff. Although all staff files we reviewed had evidence of a signed contracts (or secondment agreement if appropriate) and job descriptions, there was no evidence of references held for any staff. This meant there was a risk that patients could be exposed to unsafe care and treatment because staff had not been verified as appropriately qualified or otherwise fit, to carry out their role.
- As part of their contract with NHS England (NHSE) to treat tiers 3 and 4 patients, the centre was required to meet the standards of the NHSE's new service specification for stereotactic radiosurgery (SRS). We found that not all of the standards were being met. Specifically the requirements state that the SRS MDT meetings must be attended by a neuro-oncologist and that the oncologist must be trained to demonstrate competence in gamma knife. We found this not to be the case. The clinical oncologist had not had any specific gamma knife training and was not involved with the treatment planning. Despite this, they held responsibility for signing off the neurosurgeon's treatment plans. There was a lack of oncology oversight and input into the treatment planning process and managers were not aware that this was an issue. This meant that potential error or risks to patient safety might not be identified.

Public and staff engagement

- The centre encouraged patient engagement through the use of their patient experience survey. However, we did not see any evidence of an action plan following feedback from the patient survey in which 60 patients rated their overall experience as 7.8 out of 10.
- Communication with staff was on an informal basis as it was such a small team.
- Staff told us that they were kept informed and involved in service developments and felt they could offer their opinions on how to develop and improve the service. We were not told of any specific engagement activities but staff felt able to contribute at the local staff meetings.

Innovation, improvement and sustainability

Requires improvement

Medical care

- Staff were proud of the developments in the service and for securing the NHSE contract. However, concerns were raised by staff of the ability of the service to recruit suitably qualified staff for the expansion of the service.
- The service had just organised and hosted the first UK Radiosurgery Summit in September 2016 attended by a range of professionals.
- A series of research projects was being undertaken at the centre and patients were invited to take part.
- An evaluation of the stability of the head frames was currently being written up for publication by a previous research fellow at the centre.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that there is a robust process for ensuring that consultants and all other staff have the skills, competency, professional registration and good character to practise in the centre, including evidence of current professional registration, indemnity insurance, up-to-date appraisal and training and Disclosure and Barring Service checks (DBS) and that practising privileges are reviewed in-line with the relevant policy.
- The provider must ensure that there are effective governance, reporting and assurance mechanisms that provide timely information so that performance and outcomes are monitored effectively and in line with hospital policy and risks can be identified, assessed and managed. Reporting structures and responsibilities should be clearly set out and adhered to.
- The provider must ensure that the risk register is up to date and fit for purpose and reflects current clinical and corporate risks. There should be clear controls and review timescales identified for each risk.
- The provider must ensure that incidents are reported in-line with the relevant incident reporting policy. The provider must ensure that the incident reporting process is clear and consistently applied and understood by staff. Learning and feedback from incidents should be shared with staff.
- The provider must ensure that the service meets the NHS England service specification for stereotactic radiosurgery including the additional standards for tier 3 and 4 conditions requiring a gamma knife trained clinical oncologist to be part of the planning and treatment team.

Action the provider SHOULD take to improve

- The provider should review contingency plans to address the risk of equipment break down or if a medical physicist or other key staff were unavailable at short notice. The provider should ensure there is a business continuity plan to minimise the impact of events that stop or reduce the service to patients' care and treatment.
- The provider should ensure staff are aware of the duty of candour policy and their obligations.
- The provider should ensure that patient outcome data is collected and that benchmarking with equivalent sites is carried out.
- The provider should review patient feedback and take appropriate action to identify areas for improvement.
- The provider should ensure there is a clearly documented strategy for the development and expansion of the service to meet the requirements of the NHS England (NHSE) contract.

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
Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **Regulation 12 (1) states that care and treatment must be provided in a safe way for service users. To comply with this the provider must do the following:** **2(a) assess the risks to the health and safety of service users of receiving care and treatment;** **2(b) do all that is reasonably practicable to mitigate any such risks** **2(c) ensure that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely.** **The provider was not meeting this regulation because**: • The standards within the NHS England service specification for stereotactic radiosurgery were not fully complied with. The additional standards for tier 3 and 4 conditions require a gamma knife trained clinical oncologist to be part of the treatment planning team. We found that the clinical oncologist was not involved in treatment planning and had not had specific gamma knife training. • We found that the risks identified on the provider's risk register did not have control measures and were not regularly reviewed. This meant that the provider was not taking appropriate steps to mitigate potential risks to patient safety. • We found that not all staff were aware of incidents that had taken place. We did not see that learning from incidents was consistently shared with staff.

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Surgical procedures

Treatment of disease, disorder or injury

Regulation 17 HSCA (RA) Regulations 2014 Good governance

Regulation 17(1) states that systems or processes must be established and operated effectively. To comply with this the provider must do the following:

2(a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services);

2(b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying of the regulated activity.

The provider was not meeting this regulation because:

- Staff did not always recognise incidents that met the service's reporting criteria and staff were not following the formal process for reporting incidents. It was not clear who was responsible for reporting or investigating incidents. Not all incidents were discussed at the medical advisory committee (MAC) or governance meetings.
- Arrangements for clinical governance were unclear and we did not see evidence that regular meetings took place. The centre's clinical governance policy was out of date and had not been reviewed since November 2015.
- MAC meetings were held infrequently and were not fully attended. Minutes of the meetings we reviewed showed that discussion around incidents and risks was limited.
- Minutes of the board and management meetings we reviewed did not refer to discussion of operational or clinical risks or any explicit reference to matters that required escalation to the trust's clinical governance committee.
- The risk register did not state when a risk had been identified or when it was last reviewed. Therefore, it was not possible to determine how long risks had been on the risk register for or how frequently they were reviewed and updated.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed **Regulation 19, (1)(a)(b)(2)(a)(3)(a), Fit and proper persons employed, of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.** We found that the provider had failed to implement safe recruitment procedures to provide assurance that employees and consultants working under practising privileges are fit and proper persons. They were unable to provide evidence of proof of identity, disclosure and barring service (DBS) checks, employment references and other documentation required under Schedule 3 of Regulation 19(3)(a), for all staff and consultants working at the centre. We did not see any evidence that the provider had a formal process in place for reviewing, suspending or restricting practising privileges. This meant, because the service leaders did not have oversight of the process, there was a risk that patients could be exposed to unsafe care and treatment because they had not verified that staff were appropriately qualified, or otherwise fit, to carry out their role.