

Thornbury Radiosurgery Centre Limited

Quality Report

Fulwood Road
Sheffield
Tel: 0114 2661133
Website: www.thornburygammaknife.co.uk

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

Ratings

Overall rating for this location

Requires improvement



Are services safe?

Requires improvement



Are services effective?

Good



Are services caring?

Good



Are services responsive?

Requires improvement



Are services well-led?

Requires improvement



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

Thornbury Radiosurgery Centre (“the centre”) is an independent health care service providing stereotactic radiosurgery (SRS). SRS is a well-established method of treating selected tumours or lesions in the brain. This can include secondary brain tumours (metastases), other tumours (malignant and benign), vascular and functional. In this centre this is undertaken using a specialist Gamma Knife. Procedures are completed as a day case although there are arrangements in place within the hosting hospital, BMI Thornbury Hospital, for overnight stays before and after treatment on the ward.

The service is commissioned by NHS England as a specialist service and Supracentre. This means that the centre was awarded the NHS England contract to treat tier one to four patients. Tier three and four patients generally have more complex conditions and the NHS England service specification for this treatment laid out precise requirements to be met. The service is not contracted to treat children.

The centre is a joint venture between BMI Healthcare and Medical Equipment Solutions Ltd (MESL). Both parties have been shareholders since 2008.

The service provides SRS to NHS and self-funding patients from the local area and all over the UK, and for self-funding patients from elsewhere in the world.

The inspection took place on 20 and 21 September 2016. This was a planned, comprehensive inspection using our new methodology as part of our commitment to inspect and rate all independent hospitals by 31 March 2017. We conducted an unannounced visit to the service on 5 October 2016.

We have reported on the medical care received by patients, acknowledging that these were in the SRS preparation and treatment rooms only.

Overall, we rated this service as requires improvement.

Our key findings were as follows:

Safe

We rated the service as requires improvement for the safety key question.

The centre reported no clinical or non-clinical incidents, deaths or serious incidents or never events from March 2015 to April 2016. Never events 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. However, we found that incidents that met the service’s reporting criteria were not recognised by staff as serious enough to be classified as incidents. Therefore, we were not assured that incidents were routinely formally recorded or acted upon, or that lessons were learned within the service, the wider team at BMI Thornbury Hospital, or staff at MESL’s other centre.

We were concerned about the safety of patients during their journey between the centre and the BMI Thornbury Hospital imaging centre. The route that patients had to take by wheelchair between departments for tests and treatment was difficult to manoeuvre because this was adjacent to the public car park and down a steep slope. The safety of this journey had not been risk assessed.

Compliance with mandatory training for staff at the centre was at 94%. However, there was a lack of evidence of compliance with mandatory training by the consultants working within the service.

Summary of findings

We found that the environment was visibly clean and cleaning schedules were followed, and we observed staff following infection prevention and control practices. The centre met Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) safety requirements for staff skills and practice and for equipment. Staffing levels were appropriate and there had been no sickness or staff turnover in the past year.

Effective

We rated the service as requires improvement overall for the effective key question.

For SRS/SRT nationally there has been a lack of national patient outcome data to allow patient outcomes to be effectively monitored and compared between services. This limited the ability of the centre to allow patient outcomes to be compared with other services. The new NHSE service model and service specification introduces mechanisms for reporting and monitoring of national patient outcome data, and staff at the centre have welcomed this and are working with other organisations to deliver.

We were concerned that the centre did not meet the NHS England service master specification for stereotactic radiosurgery for the additional standards for tier 3 and 4 conditions. This 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, radiographers, clinical nurse specialists, and administrative support. We found that, although the clinical oncologist attended the multidisciplinary (MDT) meetings, they were not present following repeat MRI scans or when patients received treatment.

There was an inconsistent approach to recording consultant competencies, with some staff files not containing evidence of competence. One consultant did not meet the centre's requirement to attend MDT meetings.

We saw that policies and practice were in line with relevant professional guidance and legislation and that regular audits of the effectiveness of the equipment took place.

Patients received appropriate pain relief. We saw staff enquiring as to whether patients could feel any pain during treatment and we observed a consultant providing top up anaesthetic until the patients reported they were pain free.

Staff told us, and we saw in the patient records that we reviewed, that MDT meetings took place at the local NHS trust with consultant staff to discuss patients attending the service.

Caring

We rated the service as good for the caring key question.

We observed staff interactions with patients and saw that staff were caring and treated patients with compassion and understanding. Patient feedback cards were overwhelmingly positive and patients described their experiences of care and respect from all staff.

We saw that staff provided patients with information on their treatment before and during their procedures with sensitivity and respect. Patients were followed by the same clinical team members from arrival in the hospital, through their treatment, and on to discharge. Staff forged good professional but friendly and appropriate relationships with patients, including those with additional or complex needs.

Responsive

We rated the service as requires improvement for the responsive key question.

We were concerned that, following fitting of head frames, the healthcare assistant took patients in wheelchairs for their scans. Patients were in full view of other private hospital patients, staff and public, and wore theatre scrubs. No blanket was provided for warmth and patients appeared uncomfortable being seen with head apparatus in public areas.

Summary of findings

The centre provided information to patients in a number of ways including in leaflets, face-to-face, and over the telephone. Patient information leaflets were only available in English. Translation services were available. However, staff told us that they would sometimes use patient relatives as translators. This meant that there was a risk that patients could be placed in a situation where sensitive information was shared with relatives without their consent or that fully-informed consent may not be given by the patient.

The service was planned and delivered in line with regional needs. The centre had begun recruitment of additional staff and planned to move to a day case model of treatment in order to meet an expected increase in demand for the service.

Patients were able to access the service in a timely manner. The centre met the NHS 18 week waiting time standard in the period April 2015 to March 2016 and the average waiting time for private patients from April 2015 to March 2016 was 3.9 weeks.

Staff told us, and we observed, that patients were routinely offered the opportunity to stay in the private hospital overnight following their treatment, at no extra cost. Staff explained that this was stressed as an option to patients who may be returning home alone or who may not be well enough to be discharged home following their treatment.

Well-led

We rated the service as requires improvement for the well-led key question.

Governance structures and policies were in place, and these were integrated with BMI Healthcare Ltd, BMI Thornbury Hospital, and Medical Equipment Solutions Ltd (MESL) Board. However, we were not assured that clinical governance and risk management processes were robust.

We reviewed the minutes of the BMI Thornbury Hospital clinical governance committee and the medical advisory committee in 2016, which were part of the centre's governance structure. We found that staff from the centre did not regularly attend these meetings. However, the centre had established its own medical advisory committee, which first met in June 2016 and was attended by two of the consultant neurosurgeons together with the MESL chief executive and its registered manager. Managers advised us that this medical advisory committee would meet quarterly going forward.

The Board minutes we reviewed did not refer to discussion of operational or clinical risks or make any explicit reference to matters that required escalation from the clinical governance committee. The centre had adopted the BMI Healthcare Ltd corporate risk management policy and strategy. This policy was past its review date and was not tailored to the centre. Centre-specific risks were recorded in a risk register. Risks were rated, mitigating actions and controls were identified, and each risk was assigned a responsible person. 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 or how frequently they were reviewed and updated.

We were not assured that the service had robust systems in place to ensure compliance with the practising privileges policy. We found that consultant practising privileges files were not up-to-date in relation to confirmation of professional registration status, Disclosure and Barring Service checks, professional indemnity insurance, annual appraisal, and evidence of training undertaken. We raised this with managers at the time of the inspection and confirmation was subsequently received that these issues had been addressed.

The service had a vision and strategy, which staff were aware of, and which was aligned to the new NHS England service specification for stereotactic radiosurgery. Staff spoke positively about the leadership within the centre, and we observed a positive culture.

We identified areas in which action by the provider is required to improve the service.

Importantly, the provider must:

- Ensure that incidents are reported in line with the relevant incident reporting policy.

Summary of findings

- Ensure that the service meets the NHS England service specification for stereotactic radiosurgery for the additional standards for tier 3 and 4 conditions for a clinical oncologist to be part of the planning and treatment team.
- Risk-assess the journey that patients take between the centre and the BMI Thornbury Hospital imaging centre.
- Ensure that patients' needs are met when they are transported through public areas, including providing blankets as appropriate.
- Ensure that there are in operation effective governance, reporting, and assurance mechanisms that provide timely information so that performance and outcomes are monitored effectively and in line with the centre's policies, and risks can be identified, assessed, and managed.
- Ensure that there is a robust process for ensuring that medical and 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.

In addition the provider should:

- Consider implementing a formal handover of patients from the centre to the ward.
- Ensure that staff are aware of the risks of asking families to act as interpreters.
- Ensure that information is available to patients, families, and carers about how to make a complaint about the service.

Professor Sir Mike Richards
Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Rating

Summary of each main service

Medical care

Requires improvement



We rated this service as requires improvement overall 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.
- We were concerned about the safety and comfort of patients during their journeys between different departments at the hospital, which had not been risk assessed.
- Compliance with mandatory training was at 94% for the core team. However, there was a lack of evidence of compliance with mandatory training by the consultants working within the service.
- We observed and staff told us that patient handovers between the private hospital ward and the centre were not documented. There was no formal handover guidance or process. However, verbal handovers and transfer of patient notes took place.
- The service's clinical treatment team did not include a clinical oncologist, as required by the NHS England service specification for stereotactic radiosurgery for the additional standards for tier 3 and 4 conditions.
- Governance structures and policies were in place and these were integrated with BMI Healthcare Ltd, BMI Thornbury Hospital and Medical Equipment Solutions Ltd Board (MESL). However, we were not assured that clinical governance and risk management processes were robust.
- We were not assured that the service had robust systems in place to ensure compliance with the practising privileges policy.

However:

- Equipment was well maintained and we observed a safe and clean environment.

Summary of findings

- We saw that record keeping was of a consistently high standard.
 - The service delivered compassionate care and this resulted in a good experience for patients.
 - The service was generally responsive to individual patient needs and we observed staff going out of their way to ensure these were met. This was reflected in patient feedback, which was overwhelmingly positive.
 - Staff told us they enjoyed their work and said that they would feel comfortable in reporting concerns without fear of recrimination.
 - The service had a vision and strategy, which staff were aware of.
 - Staff spoke positively about the leadership within the centre and we observed a positive culture.
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Summary of findings

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Requires improvement



Thornbury Radiosurgery Centre Limited

Services we looked at

Medical care

Summary of this inspection

Background to Thornbury Radiosurgery Centre Limited

The Thornbury Radiosurgery Centre at the BMI Thornbury Hospital is a partnership between BMI Healthcare Group and Medical Equipment Solutions Limited (MESL) providing a radiosurgery service treating brain tumours and other intracranial indications. The service works in partnership with Sheffield Teaching Hospitals NHS Foundation Trust to provide treatment for NHS patients from all over the UK and to offer a worldwide service for private patients.

The centre is a sub-contractor to Sheffield Teaching Hospitals NHS Foundation Trust (STHT), which was awarded the NHS England contract to treat tier one to

four patients as a Supracentre, having held a contract for the service since 2015. A total of 80 patients were treated in the year before our inspection. Of these, 50 were NHS funded patients and 30 were self-funded.

The service is hosted and staffed by BMI Thornbury Hospital. The centre is a joint venture between BMI Healthcare and MESL.

This service has a registered manager, who was appointed to the role in September 2016, immediately prior to our inspection, and has an additional role with MESL. The previous registered manager is an employee of the hosting hospital and helped to plan and prepare for the inspection.

Our inspection team

This inspection was led by a CQC Inspection Manager.

The team included CQC inspectors, a specialist consultant oncologist, and a specialist radiosurgery manager.

How we carried out this inspection

The inspection took place on 20 and 21 September 2016 and 5 October 2016. This was an announced inspection as part of our planned programme of comprehensive inspections of independent healthcare providers.

Before the inspection, we checked the information that we held about the service. This included previous inspection reports and statutory notifications sent to us about the provider. We spoke with three consultant neurosurgeons who worked at the service under practising privileges. We spoke with the registered manager, medical director, chief executive of MESL, and

staff including the lead radiographer, health care assistant, and administrative personnel. We spoke with four patients in the unit who were receiving treatment and two relatives.

We looked at patient care records, staff rotas, training records, logs of concerns, logs of complaints, quality assurance checklists, and other records relating to the management of the service. We asked the provider to submit other specific information whilst on site and used that to inform our findings.

Information about Thornbury Radiosurgery Centre Limited

The Thornbury Radiosurgery Centre at the BMI Thornbury Hospital is a partnership between BMI Healthcare Group and Medical Equipment Solutions Limited (MESL) providing a radiosurgery service treating brain tumours

and other intracranial indications. It works in partnership with Sheffield Teaching Hospitals NHS Foundation Trust to provide treatment for NHS patients and to offer a service for private patients.

Summary of this inspection

The service was registered with the Care Quality Commission to provide the regulated activities of surgical procedures and the treatment of disease, disorder, and injury.

The specialist service is commissioned by NHS England. The centre is a sub-contractor to and works in partnership with Sheffield Teaching Hospitals NHS Foundation Trust (STHT). NHSE have awarded a seven year contract to STHT as the SRS Supracentre for the North and Midlands to treat local patients for secondary brain and skull-based tumours (tiers 1 and 2) and also for rarer/more complex clinical conditions, including vascular and functional (tiers 3 and 4). A new SRS/SRT service specification has been introduced which details

the requirements to be met. The centre is not contracted to treat children. The centre is a joint venture between BMI Healthcare and MESL and has been operational since 2008.

The registered manager was employed by MESL. There were five consultants with practising privileges to practice in the service. A core team of three staff; one full time therapy radiographer, one 0.4 full time equivalent healthcare assistant, and one full time equivalent administrative staff member were employed by BMI Thornbury Hospital. An additional radiographer and nursing staff were also employed by BMI Thornbury Hospital. There was also a team of neuro-radiologists and medical physicists available on treatment days.

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 rated the service as requires improvement for safe because:

- We found that incidents that met the reporting criteria were not recognised by staff as serious enough to be classified as incidents. Therefore, we were not assured that incidents were routinely formally recorded, acted upon, or lessons learned within the service, the wider team at BMI Thornbury Hospital or staff at MESL's other centre.
- The route that patients had to take by wheelchair between departments for tests and treatment was difficult to manoeuvre because this was adjacent to the public car park and down a steep slope. This had not been risk assessed.
- Compliance with mandatory training by the core operational team was at 94 %. However, there was a lack of evidence of compliance with mandatory training by the consultants working within the service.

However:

- The centre met Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) safety requirements for staff skills and practice and for equipment.
- The environment was visibly clean, cleaning schedules were followed and we observed staff following infection prevention and control practices. However, there were no infection prevention and control audits specifically for Thornbury Radiosurgery Centre.
- Medicines were stored safely and securely.
- The department was staffed by a small team and there had been no sickness or staff turnover in the past year.

Requires improvement



Are services effective?

We rated the service as requires improvement for effective because:

- There was an inconsistent approach to recording consultant competencies with some staff files not containing evidence of competence. One consultant did not meet the centre's policy in relation to attending multi-disciplinary team meetings.
- The service's clinical treatment team did not include a clinical oncologist, as required by the NHS England service specification for stereotactic radiosurgery for the additional standards for tier 3 and 4 conditions.

However:

Good



Summary of this inspection

- Policies and practice were in line with relevant professional guidance and legislation.
- Patients received appropriate pain relief.
- All nursing and technical staff had undergone an appraisal.
- Multi-disciplinary team meetings took place at the local trust with consultant staff to discuss patients attending the service.

Are services caring?

We rated the service as good for caring because:

- Staff were caring and treated patients with compassion and understanding.
- Patient feedback cards were overwhelmingly positive and patients described their experiences of care and respect from all staff.
- Staff provided patients with information on their treatment before and during their procedure with sensitivity and respect. They encouraged patients to ask questions and gave reassurance when it was needed.
- Patients were followed by the same clinical team members from the patient's arrival in the hospital, through their treatment and to discharge.
- Staff forged good professional but friendly and appropriate relationships with patients, including those with additional or complex needs.

Good



Are services responsive?

We rated the service as requires improvement for responsive because:

- We observed staff transporting patients who had been fitted with headframes through public outside areas in theatre scrubs, with no blanket for warmth. We observed patients appearing uncomfortable being seen with head apparatus in public areas.
- There was a lack of information available in languages other than English.
- Staff were not always aware of the risks of asking relatives to act as interpreters.

However:

- The service was planned and delivered in line with regional needs.
- Plans were in place to increase staffing and move to a day case model to increase the number of patients that could be seen.
- The length of patient stay was tailored to their individual needs.
- The service was meeting referral to treatment targets.

Requires improvement



Summary of this inspection

Are services well-led?

We rated well-led as requires improvement because:

- Governance structures and policies were in place and these were integrated with BMI Healthcare Ltd, BMI Thornbury Hospital and Medical Equipment Solutions Ltd Board (MESL). However, we were not assured that clinical governance and risk management processes were robust.
- Staff from the centre were often not present at clinical governance meetings.
- The risk management policy that was in place was not tailored to the centre and did not describe how risks would be identified and escalated within the service or to Board.
- We were not assured that the service had robust systems in place to ensure compliance with the practising privileges policy.
- The service had identified that there was a lack of data available to measure patient outcomes and was working to address this.
- There was some confusion between staff and managers about who was responsible for day-to-day operational oversight of the service

However:

- The service had a vision and strategy, which staff were aware of.
- Staff spoke positively about the leadership within the centre and we observed a positive culture.

Requires improvement



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	Good	Good	Requires improvement	Requires improvement	Requires improvement
Overall	Requires improvement	Good	Good	Requires improvement	Requires improvement	Requires improvement

Medical care

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

Information about the service

The service consisted of a single treatment stereotactic radiosurgery unit. Stereotactic radiosurgery (SRS) is a non-surgical radiation therapy used to treat functional abnormalities and small tumours of the brain. It delivers precisely targeted radiation to treat a specific area. The service provided treatment for brain disorders including metastatic disease, trigeminal neuralgia (facial nerve pain) and acoustic neuroma (tumour on the hearing nerve). There was a treatment room with a Gamma Knife radiosurgery device, a consultation and preparation room, and a planning and administration room. The service was situated within the radiology department at BMI Thornbury Hospital, and accessed MRI and inpatient services from BMI Thornbury Hospital, which is a private hospital.

From April 2015 to March 2016 Thornbury Radiosurgery Centre ("the centre") treated 80 adults from age 18 upwards, including 15 patients over 75 years. From the total number of cases, 50 were NHS-funded and 30 were self-funded. The service did not provide treatment for children. Patients were treated as day cases. Patients were usually admitted to the ward at BMI Thornbury Hospital the evening before treatment and then transferred to the centre for day case treatment. Patients had an option to stay overnight following their treatment.

We inspected the radiosurgery unit and observed staff interactions with patients and staff at the private hospital. We spoke with four patients and two relatives during the inspection. We met three of the five neurosurgeons who were authorised practitioners and operators, one neuro-radiologist and one radiology manager, one therapy radiographer, one medical physics expert, a healthcare assistant, and an administrator who all worked regularly in

the centre. The registered manager worked remotely for Medical Equipment Solution Ltd (MESL) and visited the centre for the duration of our inspection along with MESL's chief executive. BMI Healthcare Group employed all the members of the team – the therapy radiographer, healthcare assistant, and administrator and all had specific responsibilities to Thornbury Radiosurgery Centre. Thornbury Radiosurgery Centre had adopted some of the BMI Healthcare Group policies and procedures.

Medical care

Summary of findings

We rated this service as requires improvement overall 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.
- We were concerned about the safety and comfort of patients during their journeys between different departments at the hospital.
- Compliance with mandatory training was at 94% for core staff. However, there was a lack of evidence of compliance with mandatory training by the consultants working within the service.
- We observed, and staff told us, that patient handovers between the private hospital ward and the centre were not documented. There was no formal handover guidance or process. However, verbal handovers and transfer of patient notes took place.
- The service's on-site clinical treatment team did not include a clinical oncologist, as required by the NHS England service specification for stereotactic radiosurgery for the additional standards for tier 3 and 4 conditions.
- Governance structures and policies were in place and these were integrated with BMI Healthcare Ltd, BMI Thornbury Hospital, and Medical Equipment Solutions Ltd Board (MESL). However, we were not assured that clinical governance and risk management processes were robust.

However:

- Equipment was well maintained, and we observed a safe and clean environment.
- We saw that record-keeping was of a consistently high standard.
- The service delivered compassionate care and this resulted in a good experience for patients.
- The service was generally responsive to individual patient needs, and we observed staff going out of their way to ensure these were met. This was reflected in patient feedback, which was overwhelmingly positive.

- Staff told us they enjoyed their work and said that they would feel comfortable in reporting concerns without fear of recrimination.
- The service had a vision and strategy, which staff were aware of.
- Staff spoke positively about the leadership within the centre, and we observed a positive culture.

Medical care

Are medical care services safe?

Requires improvement 

Incidents

- The centre reported no clinical or non-clinical incidents from March 2015 to April 2016.
- The centre also reported no deaths or serious injuries for patients in its care from March 2015 to April 2016.
- The centre reported no never events from March 2015 to April 2016. Never events 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 no incidents over the 12 months before our inspection. As a result, staff could give no examples of how practice had changed as a result of an incident.
- However, we found posted on a noticeboard a list of five concerns from the previous 12 months that the BMI Healthcare incident policy that had been adopted by the service would have classed as incidents or near miss incidents. These had been documented with the cause and consequence identified for each. This was accessible for all staff to view.
- This showed that some incidents had been recorded informally as concerns but staff did not have a clear understanding of what constituted an incident and how it should be reported. This, in turn, meant that there was a risk that incidents were not formally recorded, discussed, or analysed, and therefore that lessons learned could not be passed onto all staff at Thornbury Radiosurgery Centre, the wider team at BMI Thornbury Hospital, or staff at MESL's other centre.
- Staff told us there had been a recent equipment breakdown where the scanner had stopped working during a patient's treatment. The scanner had automatically powered down and the scan table was withdrawn. No harm had occurred to the patient and the team all agreed that the treatment had been completed so no further action was needed for that particular patient. The engineers had been called immediately. They investigated and corrected the fault. There was no documentation at all regarding this breakdown. Managers told us they were a very small team and everyone understood what had happened. They were satisfied that the fault would not occur again and did not consider it an incident that required reporting. Consultants told us, and we saw, that they were present at all treatments and met with the operational team at planning meetings on site before each treatment, where they discussed news and events, including breakdown of equipment.
- Radiotherapists were aware of Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R) requirements and the need to report radiation incidents to CQC. They did this through their Radiation Protection Supervisor, who was the therapy radiographer, and through the Radiation Protection Advisor, who was available to them as part of the service level agreement (SLA) with Aurora Ltd.
- There had been no reportable radiation incidents in the 12 months prior to our inspection.
- The BMI Healthcare Group incident policy stated that the functional lead was responsible for 'ensuring any incidents risk assessed as high or extreme are escalated and that the findings are shared with those involved, in accordance with any contractual and duty of candour requirements'. However, this policy did not include incidents leading to moderate harm, which also require their findings to be shared with the individuals they have affected. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain notifiable safety incidents and provide reasonable support to that person. Medical staff understood their responsibilities regarding duty of candour. However, no incidents had occurred that met the duty of candour threshold in terms of patient harm.

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

- BMI Thornbury Hospital gathered data on infection rates across the hospital. However, at the time of our inspection it was not possible for the data to be broken down to service level.
- Patients were seen for day case treatment only, and there had been no reported injuries, healthcare acquired infections, or surgical site infections in the centre.

Medical care

Cleanliness, infection control and hygiene

- We saw that staff washed their hands regularly before attending to each patient. Hand gel stations were provided for use by patients, relatives, and staff, and we saw staff and visitors using the hand gel.
- The centre provided sufficient supplies of personal protective equipment (PPE), including disposable gloves and aprons. Staff disposed of used PPE safely and correctly. We saw PPE being worn when treating patients.
- We observed a consultant wearing a plastic apron and 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.
- All patient areas at the centre, including the consultation, preparation, and treatment rooms, were visibly clean and tidy.
- There was a contract in place with the private hospital to keep the premises clean.
- We saw that staff ensured treatment rooms and equipment in all departments were cleaned regularly. Staff cleaned and checked diagnostic imaging equipment regularly. Staff cleaned and decontaminated chairs and the therapy table with disinfectant wipes after use. We saw checklists where staff had signed every entry to show they had completed cleaning practices according to centre policy and procedures.
- Staff told us they sent reusable equipment for decontamination off-site under a service level agreement with a specialist company. Equipment was returned sterile and stored safely, ready for use.
- Safe disposal of clinical waste was managed by BMI Thornbury Hospital.
- We saw that staff segregated and disposed of waste appropriately and used sharps bins correctly.
- Training records showed radiosurgery staff received their infection prevention and control training through BMI Thornbury Hospital. Staff told us they were up-to-date with their mandatory training requirements, but the training matrix we saw showed that update training for two out of three staff was overdue. However, following the inspection the service provided further information and an explanation to show that staff compliance was 94%.

- Staff at the centre told us that, as an outpatient procedure, patients attending for stereotactic radiosurgery were only tested for signs of infection on the day of treatment. This meant that procedures could be cancelled at short notice, results of any tests might not be available until after treatment was completed, and therefore staff could not assess infection risks to themselves, the patient, or the environment.
- We saw that an infection prevention and control audit had been undertaken by BMI Thornbury Hospital staff in June 2016 and showed 100% compliance. However, this audit had been labelled as “Radiology” and did not appear to be specifically for this service.

Environment and equipment

- The rooms in use to provide the service were suited to their purpose and comprised a dedicated SRS unit within the radiology department at the private hospital. The consulting and preparation areas, treatment room, and administration areas were well equipped with everything staff needed to provide the service.
- The environment was clean, light, spacious, and accessible to people with a disability.
- The centre did not have its own toilet facilities but staff, patients, and visitors used those provided by the private hospital. These were single, disabled-access toilets, and these areas were clean.
- There were no obvious radiological environmental hazards observed within the centre at the time of our inspection.
- There were appropriate clinical and treatment rooms for storage and preparation of medicines, stock and for applying head-frames to patients who were to undergo Gamma Knife surgery.
- Staff told us resuscitation trolleys were available in the private hospital radiology and endoscopy departments. Staff told us these were managed, maintained, and checked by the private hospital.
- Equipment throughout the centre was calibrated and maintained within the manufacturers’ timescales. We saw maintenance contracts and service level agreements for specialist equipment including the Gamma Knife. Following service and maintenance, Elekta engineers followed the controlled area and equipment handover protocol with the radiographer. We saw documentation from equipment handovers, including that following the incident involving breakdown of the scan table mechanism.

Medical care

- The design of the environment within the radiosurgery treatment area was appropriate. Waiting and clinical areas were clean. There were radiation warning signs at doors leading to the treatment area. Imaging treatment room 'no entry' signs were clearly visible and in use throughout the centre at the time of our inspection.
- We saw, and staff confirmed, that there was enough equipment to meet the needs of patients within the centre. Staff told us they were confident to raise any immediate concerns to ensure they were rectified quickly or escalated to the department manager.
- Staff used mobile dosimeters (small devices to measure radiation) in radiosurgery areas to ensure that any exposure to higher levels of radiation than considered safe was identified and accurately recorded. The medical physics expert collected dosimeters and sent them for testing every month.
- Staff in the centre demonstrated safe working methods to record patient doses for radiation.
- Staff told us, we saw checklists, and we observed, that they carried out quality assurance checks for all radiosurgery equipment. These were mandatory (must do) checks based on the Ionising Radiation Regulations 1999 and IR(ME)R 2000. Their completion and compliance with IR(ME)R regulations ensured staff protected patients, themselves, and other staff against unnecessary exposure to harmful radiation.
- We saw that centre policies and processes complied with guidance under IR(ME)R and the Radiation Regulations. An external radiation protection adviser audited compliance, and reports we observed on site showed the centre met all IR(ME)R regulations.
- We saw documentation to show consultant neurosurgeons were registered IR(ME)R practitioners and radiographers and physicists were registered IR(ME)R operators.
- The lead radiographer was the radiation protection supervisor and carried out risk assessments with ongoing safety indicators for all radiosurgery equipment and its use by staff. These were easily accessible to all centre staff.
- The radiotherapist told us the Gamma Knife equipment had been inspected by Elekta under their annual audit process. We saw the radiation protection advisor and medical physics expert reports showing that equipment operated within the acceptable and safe performance range.

Medicines

- We saw that medicines were stored safely and securely. Staff told us, and records showed, that the therapy radiographer checked drugs regularly and rotated stock appropriately. There was an audit trail of what had been ordered and staff told us they had a good foresight of cases coming in and could order appropriate to need.
- 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 treatment room. We checked that daily room temperatures were recorded on the days that treatment was provided.
- There were no controlled drugs kept on the premises.
- Records we looked at showed no recording of known patient allergies.

Records

- Data indicated that during the preceding 12 months records had always been available when needed.
- We looked at 13 complete sets of paper records and saw that they were complete, contemporaneous, and all staff had clearly signed their entries. Records clearly indicated who had undertaken procedures, who had assisted, and what equipment had been used.
- Electronic records were also complete and showed imaging, the full treatment planning process, and treatment given to each patient on each occasion.
- The service did not conduct any audits of patient records.
- Staff explained that, as part of the patient pathway, the referral forms requested all relevant information be provided prior to a consultation. If this was not provided the referrer would be contacted for the information, and an appointment was not arranged until the information was received.
- At the time of our inspection, referrals for NHS patients were arranged by the local NHS trust. Patient notes and diagnostic imaging were securely transferred to the centre in advance of any appointment.
- Patient records were stored securely in paper and electronic formats. Follow-up patient information was stored electronically and NHS patient records were returned to the trust.

Medical care

- We observed a consultant dictating discharge letters immediately following patients' treatment at the centre.
- Staff at the centre explained that consultants holding practising privileges must also be registered as independent data controllers with the Information Commissioner's Office to ensure any patient-identifiable information removed from the hospital premises was secure at all times.

Safeguarding

- The CQC had received no reported safeguarding concerns in relation to the centre.
- The safeguarding lead for the centre was a senior staff member at the private hospital and was trained to level 3 in safeguarding adults and children.
- The centre provided copies of policies and processes that were in place to safeguard vulnerable adults and young people.
- Staff training records showed all three operational staff were trained in safeguarding adults and children. Although the centre did not treat children, all local private hospital staff were trained in safeguarding children to level one.
- Staff we spoke with were all aware of their responsibilities and could articulate what they would do if they had safeguarding concerns.
- Managers told us doctors with practising privileges included compliance with their substantive post NHS trust safeguarding training in their renewal applications; however, we did not see evidence of compliance with safeguarding training in any of the five consultants' practising privileges files that we reviewed.
- Managers told us that all staff, including doctors with practising privileges, were checked by the disclosure and barring service (DBS). However, some consultants had been appointed several years ago so their DBS checks were not recent, and we did not see evidence on two of the five consultant files that we reviewed that updated DBS checks had been obtained.

Mandatory training

- Managers told us consultants were compliant with mandatory training through practising privileges review. We reviewed five consultant files. None of them contained evidence that the consultants were up-to-date with mandatory training.
- Radiosurgery staff told us they were up-to-date with mandatory training provided by the private hospital

and, because treatment was only provided on certain days each week, they had no difficulties accessing their training. However, the training matrix supplied to us showed that staff were only 75% compliant with general training but 100% compliant with clinical skills training. The matrix showed due dates for training but did not show how often training was required to be updated. The service provided information following the inspection explaining that staff mandatory training was at 94% compliance. At the time of the inspection, the matrix had not shown details of modules completed, and it was highlighted that the three core staff had completed 34 of 36 modules.

Assessing and responding to patient risk

- We were concerned when we followed the journey that patients had to take between the centre in the main hospital building and the separate MRI scan building. This route was adjacent to the public car park and down a steep slope. Patients, fitted with a head frame, were escorted in a wheelchair by a healthcare assistant. Staff advised that this journey had not been risk assessed.
- Staff told us, and we saw from patient records, that each individual case was discussed by the team prior to treatment. NHS patients were discussed in a multidisciplinary team (MDT) meeting held at the NHS Trust at Sheffield Teaching Hospitals. All cases were also discussed in a planning meeting on the day of treatment, to identify risks and the best possible clinical and therapeutic approach to take. Records we saw included individualised care plans for all 10 patients reviewed, and six of those ten records included completed NHS hospital pre-assessments.
- We looked at 13 sets of patient records, and it was apparent that staff did not use any form of medical risk protocol or documentation. This meant that staff may not identify or respond to early signs of deterioration in the patient's condition either within the centre or on the ward.
- Notes taken by staff on the ward at admission, the day before treatment, included a hospital 'combined risk assessment for up to 23 hour surgical stay' that incorporated assessments for pain and moving and handling. However, we did not see staff in the centre review these during or following the procedures we observed.
- We saw that staff checked patients' identities before carrying out any discussion or intervention.

Medical care

- We saw radiosurgery staff using a safety checklist as part of the procedure for readying patients for Gamma Knife surgery.
- We saw the consultant assess an individual patient's risks before fitting the head frame, and that the placement of the frame was adjusted accordingly.
- There were a consultant, a medical physics expert, and a therapy radiographer present at all times during procedures.
- There were up-to-date policies and procedures in the imaging department to ensure that the risks to patients from exposure to harmful substances were managed and minimised.
- All patients were accompanied to and from the ward to the preparation room, MRI scanner, and radiosurgery procedure room.
- There were written procedures and local protocols/rules in place, as required under the IR(ME)R regulations.
- A radiation protection advisor could be contacted to give advice to staff when needed. Staff told us they were available to provide regular advice and support.
- Staff told us patients who had been identified as living alone would stay on the ward for the night following their treatment to ensure they could be observed and cared for should they need additional support.
- Staff explained that they could access medical support in an emergency from the private hospital resident medical officer. Staff could organise a blue light ambulance to take the patient to the local NHS trust.
- There were no posts vacant at the time of our inspection. However, a new therapy radiographer had been appointed and was due to begin working at the centre the week following our inspection.
- No bank or agency staff were used in the period March 2015 to April 2016.
- There was no reported staff sickness in the period from April 2015 to March 2016. There had also been no staff turnover within this period.
- The centre told us that patient cases were reviewed at a multi-disciplinary meeting and at outpatients' appointments. Staffing was then determined based on the planned number of patients attending the service. Staff told us that, where they identified that a patient would need additional care, they would request additional resources from the private hospital to meet the needs of the patient or there would be a reduction of the number of patients treated for a particular treatment day.

Medical staffing

- The centre employed five consultants under practising privileges. At the time of our inspection, one consultant was new in post. One consultant, who treated patients regularly in his substantive NHS practice, had seen between one and nine patients from March 2015 to April 2016. The other three had seen between 10 and 99 patients in this period.
- All consultants had to meet the criteria set out in Thornbury Radiosurgery Centre's policy to be granted authorisation to undertake the care and treatment of patients in the centre.
- Consultants made themselves available for contact and support for 24 hours following each procedure.
- The private hospital provided an RMO for 24 hour medical cover, should this be needed.

Major incident awareness and training

- The private hospital had comprehensive business continuity plans to make sure that the service was able to continue to provide services in the case of a major incident. These covered staffing shortages, electronic system failures, and equipment breakdowns.
- Radiosurgery equipment had battery back-up in case of power failure.

Radiosurgery staffing

- Within the centre there was a core team of three staff: one full time therapy radiographer; one 0.4 full time equivalent healthcare assistant; and 1 full time equivalent administrative staff member. The team could access additional radiographer support from the lead radiographer at BMI Thornbury Hospital or therapy radiographer support from a sister radiosurgery centre at Queen's Square, London.
- Stereotactic radiosurgery guidance states that two trained IR(ME)R operators must be present during stereotactic treatment. We observed that a trained therapy radiographer and an IR(ME)R trained neurosurgeon were both present throughout patient treatment.
- There were enough staff to safely care for the patients in the unit.

Are medical care services effective?

Medical care

Good 

Evidence-based care and treatment

- Thornbury Radiosurgery Centre provided evidence to show that it met the NHS England service specification for stereotactic radiosurgery. The centre was also compliant with guidance from professional bodies, including The Royal College of Radiologists and the Society and College of Radiographers. The centre followed the Institute of Physics in Engineering Medicine 'Guidelines for the provision of a Physics Service for Radiosurgery' 2002.
- However, we were concerned that the centre did not meet the NHS England service specification for stereotactic radiosurgery for the additional standards for tier 3 and 4 conditions. This 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, radiographers, clinical nurse specialists, and administrative support. We found that, although the clinical oncologist attended the multidisciplinary (MDT) meetings for NHS referred patients, they were not present on the day of treatment.
- Targeting accuracy for the Gamma Knife equipment had been audited and approved by NHS England. We saw that staff carried out daily and monthly checks to ensure that the equipment was appropriately calibrated.
- A folder specifying the policies relating to the centre was kept on site. Staff explained that the full policies were accessed online via BMI Thornbury Hospital's intranet. Staff signed a log to confirm that they had read and interpreted the policies relating to the centre. This was up to date at the time of our inspection.
- Multidisciplinary planning meetings took place prior to treatment for all patients. All NHS patients, from anywhere in the UK, were referred to and discussed at a local NHS Trust neurosurgery MDT, and private patients were discussed in fortnightly meetings at the centre. Radiosurgery planning was carried out immediately before each treatment with an up to date MRI scan by a neuroradiologist, a medical physics expert, and the neurosurgeon.

- Staff told us that patients attending for treatment were offered painkillers and temazepam on the evening and morning of treatment. This was administered whilst they were on a ward within the private hospital, by the private hospital staff.
- Patients were injected with local anaesthetic at the site where the head frame for surgery was applied. Staff told us that this could be 'topped up' by the treating consultant if patients reported feeling any sensation.
- We observed patients undergoing local anaesthetic injections. We saw that staff enquired whether patients could feel any pain and that they provided top-up anaesthetic until the patients reported they were pain-free.
- Other than injectable local anaesthetic, no pain medication was stored within the centre. Staff told us that if patients did request further pain relief then they would contact BMI Thornbury Hospital or the resident medical officer to request assistance.
- The centre used the private hospital's patient feedback system. This provided patients with the opportunity to comment on any issues in regard to pain relief. No patients had raised concerns about pain relief at the time of our inspection.

Nutrition and hydration

- Scoring of patient nutritional needs was carried out on the private hospital ward when a patient was admitted. Nurses completed a malnutrition universal screening tool (MUST) score. This was available to staff in the centre within the patient's records.
- Patients were offered food and drink on the private hospital ward before attending for treatment and whilst staff were planning their care.
- Staff told us that patients undergoing lengthy treatment were offered breaks to allow them to have a drink. A patient who had previously attended the service told us that they had been provided with a break in their treatment.

Patient outcomes

- There had been no unplanned transfers to other hospitals or readmissions to the centre in the period April 2015 to March 2016.

Pain relief

Medical care

- Staff at the centre explained that there were no national audit systems in place for stereotactic radiosurgery. However, they had taken part in an NHS England quality assurance audit of stereotactic radiosurgery centres in 2016 and had met the required standards in full.
- The centre had undertaken audits relating to historic clinical trials to gather evidence for case studies and for research purposes. However, this tended to be limited to specific cohorts of patients. It had also compared data with those at other centres using published literature and through the network of personal contacts of the consultants and physicist. They had reported no formal outcomes. Staff told us this was due to the informal nature of the review and the small community of practitioners providing SRS.
- The centre told us that going forward it would be submitting the recently collected data to the national neurosurgical audit programme and the national radiosurgery data set. Previously, neither had covered stereotactic radiosurgery treatment. The centre had also been active in working with staff at NHS Trusts towards the development of a national Stereotactic Radiosurgery/Stereotactic radiotherapy registry/database.
- The centre confirmed that its new service specification with NHS England also required reporting on a number of targets, including metrics to measure patient outcomes. It was working with commissioners and partners in the Supracentre (the commissioned providers within the area) to develop a Data Quality Improvement Plan from quarter three of 2016/17.
- Following MRI scan results, the treatment team – consultant neuro-surgeon, consultant neuro-radiologist, and medical physics expert – planned in detail the treatment to be carried out and the radiographer programmed coordinates into the radiosurgery device. We observed that the clinical team members were available during the procedure, which included continuous monitoring of the positioning of the patient within the machine. The team repeated all checks post-operatively to ensure procedures had been carried out appropriately, all areas identified for treatment had been treated, and patients were suitable for discharge. However, there was no neuro-oncologist involved in the final stages of planning or treatment as required and noted in Additional Standards for Providers of Tier 3 and

Tier 4 Conditions: Composition of the SRS/SRT MDT, which state that “A neuro oncologist must be present for planning and in particular where new lesions are identified on repeat MRI”.

Competent staff

- Documentation that we reviewed showed that all three staff at the centre had had an appraisal during the current appraisal year. The centre had also achieved 100% compliance in its previous appraisal year. Staff told us that their appraisals were up-to-date.
- Staff at the centre told us they had achieved 100% completion rate of validation of registration for doctors working under practising privileges. However, upon our review of five files for consultants working under practising privileges, we found that one did not contain any evidence that the consultant’s professional registration was up-to-date.
- At the time of our inspection, no staff were subject to restricted practice, suspended, or had their practising privileges removed.
- We reviewed the files of five consultant staff members. These showed an inconsistent approach to recording competence. For example, only three of the five files showed evidence of an up-to-date appraisal.
- To be eligible for practising privileges with Thornbury Radiosurgery Centre, the centre’s policy stated that consultants must hold a substantive or honorary NHS contract and attend regular MDT meetings. Four consultants held substantive NHS posts at Sheffield Teaching Hospitals NHS Trust. However, one consultant had been retired from NHS work for three years. They did not attend multi-disciplinary team meetings and it was not clear how they or the centre ensured their practice was safe and up-to-date. We raised this with the centre at the time of inspection and were subsequently advised of the action that the centre had taken to address these concerns.
- Consultant staff were asked to sign an annual declaration to show that they were competent to practice. Three of the five files did not have an up-to-date declaration. However, the majority of consultant staff were still practising in the local NHS hospital.
- A full local induction programme had been developed for the new radiographer who was due to start the week following our inspection. This included site-specific safety information and competency checks.

Medical care

- 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 radiographers, consultants, and medical physics experts.
- Radiosurgery staff told us they were trained in the use of each piece of equipment and were assessed as being competent in their use. There was a competency framework in place that had been developed by the radiology manager. The radiographer in post had been assessed as competent against that framework. Plans had been developed for peer review of all radiographers across the group. We saw a programme of competency assessments had been prepared for a new radiographer who was due to commence in post the week following our inspection.

Facilities

- The centre did not have its own diagnostic imaging facilities. MRI and CT imaging was provided by the private hospital as part of the patient pathway for stereotactic radiosurgery.
- The centre was located within BMI Thornbury Hospital. The centre had no patient beds. Any patients requiring patient accommodation were placed within the hospital wards.

Multidisciplinary working

- The centre had previously developed an on-site multi-disciplinary team (MDT) to discuss patient needs. This was now being superseded by an MDT at the local NHS trust for NHS patients.
- The referral system operated by the centre ensured that patients were identified as being discussed at relevant MDTs (for example, in a neuro-oncology MDT at the local trust) prior to any NHS referral being accepted. We saw evidence of documented MDT review in all the patient records that we reviewed.
- For private patients, staff told us that at present there was a more informal MDT arrangement. Documentation in patient notes showed this involved a review of the records by relevant staff members within the centre (for example, neurosurgeons, oncologist, and neuro-radiologist). Management staff told us that they hoped that this would change going forward to allow private patients to be incorporated into the NHS MDT.
- We observed, and staff told us, that patient handovers between the private hospital ward and the centre were

not documented. There was no formal handover guidance or process. Verbal handovers and transfer of patient notes took place. Staff from the hospital ward and Thornbury Radiosurgery Centre told us that this included a description of any patient-specific needs. This handover was not documented.

Seven-day services

- The centre was open Monday to Thursday. Staff explained that treatments usually began at 8am with treatment normally being completed by 4pm. Up to three patient treatments were completed per day.
- The centre's three lead neurosurgeon consultants were available 24 hours a day to provide cover as required for any stereotactic radiosurgery emergencies or for patient queries.

Access to information

- 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 were also able to access relevant policies and guidance for the centre via the private hospital intranet.
- Staff explained that paper-based treatment information for NHS patients was sent to the local trust following treatment being completed. It was then the local trust that would provide discharge information and treatment information to the referring consultant.
- For private patients, a paper discharge letter was sent directly to the referring consultant by the centre.
- We saw that on-site imaging taken at the private hospital was available to staff within a matter of minutes.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- NHS patients consented to treatment prior to their day of treatment. This took place during their outpatient appointments at the centre or at their appointments at the referring NHS trust. Staff told us, and we observed, that the consultant neurosurgeon then had a further discussion with patients attending for treatment to confirm they understood the procedure.
- Private patients' consent was taken by the consultant neurosurgeon in clinic prior to any treatment taking place.

Medical care

- We reviewed three consent forms. These showed that consent had been taken at the patients' outpatient appointments in August 2016. Records showed that treatment followed within two to three weeks of the original consent being taken. We saw confirmation that consent had been recorded on the day of the procedure in two of the three patient records.
- Staff within the centre completed Mental Capacity Act and Deprivation of Liberty Safeguards (DoLS) training as part of the Adult Safeguarding training module. This meant that staff would be able to identify and address the needs of patients attending with capacity issues. We observed and spoke with staff and they were able to identify additional needs of patients in these circumstances.

Are medical care services caring?

Good



Compassionate care

- We observed patients being treated with compassion and respect. Patients told us that staff spoke to them on an appropriate level and were caring.
- One patient told us that staff treated them with "compassion and understanding, but not with sympathy, which is exactly what I need".
- We received 13 comment cards which, without exception, gave positive descriptions of experience of care, dignity, and respect from all staff in the centre.
- Friends and family test and patient survey information was collected as part of the wider information gathered by the private hospital. It was not possible for the centre to provide a breakdown of these results specific to its service at the time of our inspection.
- The centre was in the process of re-introducing a service-specific questionnaire. This was being developed jointly with the local NHS Trust and the Supracentre.

Understanding and involvement of patients and those close to them

- 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 procedures they were undergoing and that they had received appropriate clinical information.
- Staff provided examples of where patients' care was discussed in more detail with them. For example, staff informed patients attending with brain metastases that additional metastases could be identified on the MRI scan they underwent immediately prior to surgery. This was due to the time since their last scan or greater quality of the image at the centre. This ensured that patients were prepared to receive news of additional lesions.
- The centre invited patients to meet with members of the team and to visit the centre prior to surgery. This provided an opportunity for patients to meet with their key worker, raise questions about the treatment day, and familiarise themselves with the surroundings.
- Patients were encouraged to bring music of their choice to be played during their procedure. There was also a wide range of music for patients to choose from at the centre.
- We observed staff asking whether patients wanted to ask questions at several stages throughout their care in the centre. Staff offered reassurance when it was necessary and took into account individual patient needs throughout the whole time they were attending.

Emotional support

- Patients were provided with contact details for their key worker should they require any support or have any questions. Staff told us that key workers would often 'go the extra mile' to book accommodation or transport on behalf of patients.
- We saw that patient cases were followed by the same clinical team members from arrival in the hospital, through their treatment, and on to discharge. Staff told us that this allowed for a strong rapport and understanding to develop with the patient and their family.
- Patients told us that staff were supportive and that they would feel comfortable seeking advice or guidance around their care.

Medical care

- We observed staff interactions with a patient with complex additional needs and their relative. It was clear that staff had already forged a good professional but friendly and appropriate relationship with them. Staff had made an effort to find out about the patient's interests and engaged them in conversation during the frame-fitting procedure. Following a request for consent from the patient, their relative was welcomed into the fitting room to provide additional support should it be needed.

Are medical care services responsive?

Requires improvement 

Service planning and delivery to meet the needs of local people

- The service was formerly designated by NHS England as a specialist provider of stereotactic radiosurgery. The service had subsequently secured a seven year service contract (in conjunction with a local NHS trust) for the North and Midlands region stereotactic radiosurgery 'Supracentre.'
- All patients seen within the service were adults aged 18 years and older.
- The centre had begun recruitment of additional staff in order to meet an expected increase in demand for the service. This was as a result of the awarding of the NHS England service contract. Staff told us that this would ensure that they had the resources to meet the expected increase in patient numbers.
- The centre was planning to move to a day case model of treatment. This would mean that the majority of patients would not need to attend the day prior to surgery. At the time of our inspection, management were in the process of mapping this process and identifying what additional resources would be required to meet this model.
- For NHS patients, the centre worked closely with the local NHS trust to plan and deliver care to patients requiring surgery. This included a commitment to see a minimum number of patients per year. There was also an agreement in place with the NHS trust to allow patients scheduled to attend the centre to instead attend the trust if there were any equipment problems that would mean surgery could otherwise not go ahead.
- The centre told us they had no patients that did not attend for treatment. The centre would occasionally be asked to rearrange surgery by patients in advance but, to the knowledge of management staff, no patient had ever failed to attend for surgery.
- The centre was located within the private hospital. This provided adequate car parking and an on-site restaurant. There were also public transport routes providing patients with bus services that stopped directly outside of the private hospital grounds.

Access and flow

- From April 2015 to March 2016 there were 80 day case episodes of care recorded at the centre. Of these, the majority were NHS funded.
- From April 2015 to March 2016, there were also 89 reported outpatient attendances.
- In its response to our data request, the centre clarified that it only undertook outpatient appointments for consultant-led consultation. It also undertook day case treatment, but this was also classified as an 'outpatient procedure' by NHS England.
- The centre had not cancelled any patient procedures for non-clinical reasons in the 12 months prior to our inspection.
- The centre reported no breaches against the NHS 18 week waiting time standard in the period April 2015 to March 2016. Staff confirmed that the centre routinely met a two week target for all patients with cerebral metastases. Data provided by the centre during the inspection appeared to show that there had been two 18 week breaches from April 2015 to March 2016. We asked the centre for further information on this and the service confirmed that 'the clock had been stopped' on these cases due to patient choice. Due to this, there had been no breach in waiting time targets.
- Data provided by the centre during the inspection showed that the average waiting time for private patients from April 2015 to March 2016 was 3.9 weeks. Staff explained that waiting times were impacted on by patient choice as to when they wanted to receive surgery.
- As part of the ongoing development of services with the local NHS trust, staff told us that reporting of referral to treatment times was being strengthened to allow greater analysis of trends and performance. This would then be used to influence future resource and capacity planning.

Medical care

- We observed a patient being discharged from the centre. They were provided with appropriate information about their follow-up care and contact details for the service.

Meeting people's individual needs

- Following fitting of a head frame, the healthcare assistant took patients in a wheelchair for their scan. Patients were in full view of other private hospital patients, staff, and public, and wore theatre scrubs. There was a policy in place directing staff to explain the journey patients would make and to offer a blanket if necessary. However, we observed three patients' head frame fittings but did not hear staff explaining the journey or that it would involve being seen in public and going outside in a wheelchair. No blanket was provided for warmth on any outbound journey, and patients appeared uncomfortable being seen with head apparatus in public areas. Following an inspector commenting on the cool conditions outside, we observed that staff offered patients a blanket for the return journey.
- The centre provided all patients with patient information booklets both prior to and post-surgery. Patients told us that they had received these booklets. We reviewed the booklets and they contained relevant information about treatment as well as advice and contact numbers should patients require any further assistance.
- Staff told us that patients from all over the world were referred to the service. However, patient information leaflets were only available in English. Staff told us that it was not possible to order leaflets in other languages. There were also no large-print or braille leaflets.
- Face-to-face translation services were available and could be booked in advance of consultations or surgery. Staff told us that they would sometimes use patients' relatives as translators. This meant that there was a risk that patients could be placed in a situation where sensitive information was shared with relatives without their consent or that fully-informed consent may not be given by the patient.
- Staff gave patients the option to undertake their initial consultation via telephone. Where patients took this option, staff would then send additional information to patients via post or e-mail.
- Patients also told us that they had been shown a computer presentation prior to undergoing their procedure. This used slides and multimedia to help explain the procedure.
- Staff told us that patients were routinely offered the opportunity to stay in the private hospital the night following their treatment. Staff explained that this was stressed as an option to patients who may be returning home alone or who may be at risk of any complications, to ensure that they were provided with appropriate care following treatment. Overnight stays prior to and following treatments were included in the cost of treatments for NHS and private patients, so patients were never asked to pay for their stay.
- During our inspection, we saw that a patient who was due to return home alone was advised to stay in hospital and was provided with a bed in the private hospital for that evening.

Learning from complaints and concerns

- The centre had received no complaints from April 2015 to March 2016.
- The centre staff told us they used the private hospital's complaint procedure. Staff told us all comments about the centre were received by the private hospital, which would then acknowledge receipt. The private hospital would then pass comments to the centre to investigate. Once any investigation was complete and a response approved the private hospital would send out the final response.
- If patients were unhappy with the response they could escalate complaints to the regional level and then to an independent external review. However, we saw no evidence of this in practice.
- Management staff explained that any complaints directed to the NHS in respect of NHS patients would be discussed at a project board meeting with the local NHS trust. No complaint had been received or raised about the centre at these meetings.
- The centre told us that copies of the private hospital's 'Please tell us...' leaflets were located throughout the private hospital, and within the centre, to inform patients, relatives, and carers about how they could raise a complaint. During our inspection, we did not see copies of the leaflet or any other information within the centre that advised patients of how to make a complaint. We did see questionnaire forms that invited patients to tick answers anonymously.

Medical care

Are medical care services well-led?

Requires improvement 

Vision and strategy for this this core service

- The centre's vision was "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".
- Staff we spoke with were aware of the centre's vision and strategic direction, and this was included in the centre's induction for new members of staff.
- The service's strategy was focused on building partnerships to enable data and information to be shared and training to be offered, building external relationships, and ensuring financial stability. This strategy was shared with its partner organisation, Sheffield Teaching Hospitals NHS Trust and was aligned with the new NHS England service specification for stereotactic surgery. Monitoring of the implementation and delivery of the strategy was through a joint project board with Sheffield Teaching Hospitals.

Governance, risk management and quality measurement for this core service

- Governance structures and policies were in place and these were integrated with BMI Healthcare Ltd, BMI Thornbury Hospital, and Medical Equipment Solutions Ltd Board (MESL). However, we were not assured that clinical governance and risk management processes were robust.
- The centre had adopted the BMI Healthcare Ltd corporate clinical governance policy but was in the early stages of work with its partner organisation, Sheffield Teaching Hospital NHS Foundation Trust, to develop some shared clinical governance arrangements.
- Managers advised us that a member of the management team attended the hospital's clinical governance committee meetings. Although these meetings were supposed to take place monthly this did not always happen due to scheduling issues and staffing levels.
- We reviewed four sets of minutes of clinical governance committee meetings, from January, February, April, and May 2016. They showed that a member of the centre's

management team was in attendance at only one of the clinical governance committee meetings. The minutes showed that no matters specifically relating to the centre were discussed at any of the meetings.

- Consultants from the service attended the BMI Thornbury Hospital medical advisory committee. The medical advisory committee had responsibilities in relation to clinical governance with particular focus on clinicians' performance.
- We reviewed two sets of minutes of medical advisory committee meetings, from May and July 2016. They showed that topics such as incidents, complaints, and practising privileges were discussed. However, none of the consultants that held practising privileges at the centre attended either meeting.
- In June 2016, there had been the first meeting of the Thornbury Radiosurgery Centre specific medical advisory committee. This was attended by two of the consultant neurosurgeons, together with the MESL chief executive and the registered manager. The minutes of the meeting showed that risks, complaints, and never events were discussed. Managers advised us that this medical advisory committee would meet quarterly going forward.
- The MESL Board met a minimum of every six months. The Board comprised a national representative from BMI Healthcare Ltd, MESL directors (clinical and non-clinical), a legal advisor, and a finance manager.
- We reviewed two sets of minutes of Board meetings, from February and June 2016. The minutes included reference to discussion of financial risks, staffing, and concerns arising from the medical advisory committee. However, there was no reference to discussion of operational or clinical risks or any explicit reference to matters that required escalation from the clinical governance committee.
- The centre had adopted the BMI Healthcare Ltd corporate risk management policy and strategy. This policy was past its review date. The policy was not tailored to the centre and did not describe how risks would be identified and escalated within the service or to the Board.
- Centre-specific risks were recorded in a risk register. We reviewed the risk register. Risks were categorised and rated red, amber, or green according to their impact and likelihood. Mitigating actions and controls were identified and each risk was assigned a responsible person. However, the risk register did not state when a

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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.

- Managers told us that the risk register was reviewed and discussed at Board meetings. We could see no reference to the risk register in the minutes of Board meetings that we reviewed.
- The centre used a tracker to monitor activities relating to each patient seen. We reviewed the tracker. It contained information about key dates within the patient pathway (for example, date of referral, date of multi-disciplinary team review, performance against the 18 week referral time standard). This tracker was reviewed weekly by the registered manager and the MESL chief executive to monitor activity and performance within the service.
- Daily 'communication cell' meetings took place within the wider hospital. These routinely took place early in the morning and provided a forum for daily activity and incidents to be discussed. Staff in the centre told us that they would not normally attend these meetings as they were treating patients. Instead, staff told us that any relevant information from the radiology or hospital wide communication cell was passed to them at the end of the working day by the hospital's radiology manager.
- Staff told us that formal team meetings did not take place. Instead, staff explained that informal discussions would take place about the service and patient care as and when required. Staff told us that this was due to the small number of staff.
- There was limited assurance about safety and effectiveness in some areas, for example, infection prevention and control, patient records, and patient outcomes. However, the service had identified reporting on clinical outcomes as a key work stream which was being addressed through the service improvement plans which formed part of the strategic partnership with Sheffield Teaching Hospitals NHS Foundation Trust.
- The centre had adopted the BMI Healthcare practising privileges policy. Practising privileges were granted and reviewed by the BMI Thornbury Hospital executive director, in consultation with the medical advisory committee. Consultant's practising privileges files were maintained and updated by the hospital.

- We were not assured that the service had robust systems in place to ensure compliance with the practising privileges policy.
- There were gaps in the information held in the consultants' practising privileges files. We reviewed the practising privileges files for all five consultants within the service. In one file there was no evidence that the consultant's professional registration status had been confirmed within the last 12 months.
- We did not see any evidence in two of the files that that updated Disclosure and Barring Service checks had been obtained or up-to-date professional indemnity insurance was in place. There was no evidence of the most recent annual appraisal in three of the files reviewed, and the annual fitness to practise declaration was not held on two of the files reviewed. There was no evidence of training undertaken or of biennial review of the consultant's practising privileges on any of the files we reviewed. We raised this with managers at the time of the inspection, and confirmation was subsequently received that these issues had been addressed.

Leadership and culture of service

- The BMI Thornbury Hospital radiology manager was responsible for line management of the three core members of staff at the centre.
- The registered manager was employed by Medical Equipment Solutions Ltd. The registered manager worked remotely but attended the centre around one day per week.
- Staff spoke positively about the leadership within the centre. Staff told us that they felt supported by management and were confident in speaking to management staff to raise any concerns. However, there was some confusion between staff and managers about who was responsible for day-to-day operational oversight of the service.
- Staff told us that the team within the centre worked well together. We observed a friendly culture within the service, with staff interacting with colleagues and patients in a polite and professional manner.

Public and staff engagement

- Staff at the centre told us that they worked with charities to gain further insight into patient needs.
- The centre was in the process of establishing a patient forum alongside Sheffield Teaching Hospitals NHS Trust and the Supracentre.

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- Staff told us that, as a small team, staff engagement was informal. This included regular feedback on the progress and achievements of the centre. Staff told us that they were also kept informed about and involved in service developments.
- Staff told us that they felt engaged by leaders. This had included being able to offer opinion and input into proposed new models of delivering care.

Innovation, improvement and sustainability

- The service had developed a joint service improvement plan with its partner organisation Sheffield Teaching Hospitals NHS Trust to deliver the new NHS England service specification for stereotactic radiosurgery.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- Ensure that incidents are reported in line with the relevant incident reporting policy.
- Ensure that the service meets the NHS England service specification for stereotactic radiosurgery additional standards for tier 3 and 4 conditions which state that a clinical oncologist must be part of the planning and treatment team.
- Risk-assess the journey that patients take between the centre and the BMI Thornbury Hospital imaging centre.
- Ensure that patients' needs are met when they are transported through public areas, including providing blankets as appropriate.
- Ensure that there are in operation 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.

- Ensure that there is a robust process for ensuring that medical and other staff have the skills, competency, professional registration, and good character to practise in the centre, including evidence of current professional registration, indemnity insurance, and up-to-date appraisal, training and Disclosure and Barring Service checks (DBS), and that practising privileges are reviewed in line with the relevant policy.

Action the provider **SHOULD** take to improve

- Consider implementing a formal handover of patients from the centre to the ward.
- Ensure that staff are aware of the risks of asking families to act as interpreters.
- Ensure that information is available to patients, families, and carers about how to make a complaint about the service.

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 9 HSCA (RA) Regulations 2014 Person-centred care (1) The care and treatment of service users must— - be appropriate, - meet their needs, and - reflect their preferences. How the regulation was not being met: - Following fitting of a head frame, the healthcare assistant took patients in wheelchairs for their scans. Patients were in full view of other private hospital patients, staff, and public, and wore theatre scrubs. No blanket was provided for warmth and we observed patients appeared uncomfortable being seen with head apparatus in public areas.
Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment 2(a) assessing the risks to the health and safety of service users of receiving the care or treatment; (b) doing all that is reasonably practicable to mitigate any such risks. How the regulation was not being met: The provider had not risk-assessed the journey that patients took between the centre and the BMI Thornbury Hospital imaging centre.

Requirement notices

- The service's clinical treatment team did not include a clinical oncologist, as required by the NHS England service specification for stereotactic radiosurgery for the additional standards for tier 3 and 4 conditions.

Regulated activity

Surgical procedures
Treatment of disease, disorder or injury

Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

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).

How the regulation was not being met:

- Staff did not always recognise incidents that met the service's reporting criteria and staff were not following the formal process for reporting incidents.
- Staff did not regularly attend the BMI Thornbury Hospital clinical governance committee or medical advisory committee meetings.
- Minutes of the Board meetings we reviewed did not refer to discussion of operational or clinical risks or any explicit reference to matters that required escalation from the clinical governance committee

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.

How the regulation was not being met:

- The BMI Healthcare Ltd corporate risk management policy and strategy that was adopted by the centre was past its review date. The policy was not tailored to the centre and did not describe how risks would be identified and escalated within the service or to Board.
- 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 for how long risks had been on the risk register or how frequently they were reviewed and updated.

Requirement notices

- Managers told us that the risk register was reviewed and discussed at Board meetings. We could see no reference to the risk register in the minutes of Board meetings that we reviewed.

Regulated activity

Surgical procedures
Treatment of disease, disorder or injury

Regulation

Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed

1. Persons employed for the purposes of carrying on a regulated activity must—
 - A. be of good character,
 - B. have the qualifications, competence, skills and experience which are necessary for the work to be performed by them...

How the regulation was not being met:

- We found that consultant practising privileges files were not up to date in relation to confirmation of professional registration status, Disclosure and Barring Service checks, professional indemnity insurance, annual appraisal and evidence of training undertaken.
- One consultant had been retired from NHS work for three years. They did not attend multi-disciplinary team meetings and it was not clear how they or the centre ensured their practice was safe and up to date.
- Consultant staff were asked to sign an annual declaration to show that they were competent to practice. Three of the five files did not have an up to date declaration.