

The CyberKnife Centre London

Quality Report

81 Harley Street
London
W1G 8PP
Tel: 020 7034 8588
Website: www.cyberknifecentrelondon.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

Outstanding 

Are services safe?

Good 

Are services effective?

Outstanding 

Are services caring?

Good 

Are services responsive?

Good 

Are services well-led?

Outstanding 

Summary of findings

Letter from the Chief Inspector of Hospitals

The CyberKnife Centre London is operated by Robotic Radiosurgery LLP. Robotic Radiosurgery LLP is an independent health care service and is part of HCA Healthcare UK. The CyberKnife Centre is located within The Harley Street Clinic, also part of HCA, but it is registered separately with CQC.

The CyberKnife Centre London provides stereotactic radiotherapy or radiosurgery treatments for privately funded patients with a wide range of benign and malignant conditions. Stereotactic radiosurgery (SRS) is a non-surgical radiation therapy used to treat functional abnormalities and small tumours of the brain. It can deliver precisely targeted radiation in fewer high-dose treatments than traditional therapy, which can help preserve healthy tissue.

We inspected this service using our comprehensive inspection methodology. We carried out the announced inspection of this service on 15 and 16 December 2016. We inspected this service under the medical care core service.

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

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

We rated this service as outstanding overall because:

- We found that staff were actively engaged in activities to monitor and improve quality and outcomes and that opportunities to participate in benchmarking, peer review, accreditation and research were proactively pursued.
- We saw many examples of innovative practice and staff could tell us about the research being undertaken by the centre and how outcomes were being embedded within clinical practice to benefit patients.
- We found excellent multidisciplinary team working. Staff, teams and services worked collaboratively to find innovative and efficient ways to deliver more joined-up care to patients.
- Feedback from people who use the service and those who are close to them was consistently positive about the way staff treated people. People told us that staff went the extra mile and the care they received exceeded their expectations.
- There was a strong, visible, person-centred culture and patients were active partners in their care. Patients' individual preferences and needs were always reflected in how care was delivered.
- We found approachable and motivational leadership that promoted staff development and career progression, teamwork and high-quality patient-centred care.
- Governance structures were well organised and well embedded and worked effectively to ensure there were clear lines of communication between key groups.
- The service had a clear vision and strategy. Staff were aware of the corporate vision. The vision and strategy of the service was embedded into practice by staff.
- Staff told us they were well supported, and felt valued, by management and felt proud of the organisation as a place to work and spoke highly of the positive and open culture. We found there were high levels of staff engagement and that staff at all levels were actively encouraged to raise concerns.

However, we found areas of practice that required improvement:

Summary of findings

- The risk register did not reflect all risks identified by recent incidents and near misses; managers told us that all risks identified by incidents and near misses should be recorded as risks on the centre's risk register.
- Patient experience survey response rates were variable and were on average 17% for the 12 months prior to our inspection. Only 16 of 92 patients provided with the survey had returned it. We were told action was being taken to try to improve this.
- It was unclear how the results of the patient experience survey were used. We were not provided with any examples of where patient feedback had been used to improve services.

Following this inspection, we told the provider that it should make other improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

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	Outstanding	We rated medical services at The CyberKnife Centre as outstanding overall. The service was rated as outstanding in the effective and well-led domains. We rated safe, caring and responsive domains as good.



Summary of findings

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Outstanding



The CyberKnife Centre London

Services we looked at:

Medical care

Summary of this inspection

Background to The CyberKnife Centre London

The CyberKnife Centre London is operated by Robotic Radiosurgery LLP. Robotic Radiosurgery LLP is a registered provider under the HCA International Ltd. HCA International Ltd is a major shareholder of the company and is the ultimate parent company and guarantor for Robotic Radiosurgery LLP. The CyberKnife Centre is located on the lower ground floor of The Harley Street Clinic, which is also part of the HCA International group.

This service treats privately-funded patients using stereotactic radiotherapy or radiosurgery treatments for a wide range of benign and malignant conditions and provides treatment for private patients from all over the UK and from across the world.

The CyberKnife Centre at The Harley Street Clinic was the first in the UK to offer this treatment and it opened in February 2009 as a joint venture collaboration with a group of 15 founder member consultants.

The service is registered with CQC to provide the regulated activities of the treatment of disease, disorder or injury (TDDI) and, at the time of our inspection, had treated over 900 patients since opening.

The provider's nominated individual for this service is Mr Michael Neeb. The registered manager for the service is Ms Aida Yousefi (CEO).

We carried out the announced inspection of this service on 15 and 16 December 2016.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector, two other CQC inspectors both with radiotherapy experience, and a consultant neurosurgeon specialist advisor with expertise in radiosurgery.

Information about The CyberKnife Centre London

The CyberKnife Centre is located on the lower ground floor of The Harley Street Clinic, which is also part of HCA International group.

The centre had one treatment room, one operational planning room and a patient waiting area that was shared with The Harley Street Clinic's radiation services. During the inspection, we visited all these areas.

Between July 2015 and June 2016, there were 120 day case episodes of care recorded at the service. Of these, 100% were privately funded patients, the service did not treat any NHS-funded patients. All patients were seen on an outpatient or day case basis and no patients stayed overnight at the centre during the reporting period.

During our inspection we spoke with 12 members of staff including consultant oncologists, the registered manager (CEO), the medical director, the medical physics lead, the clinical fellow (a medical doctor seeking postgraduate

training in a specialty), a radiologist and staff including the radiotherapy radiographer, as well as nursing and administrative personnel. We spoke with two patients in the unit who were receiving treatment.

We also received 10 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed three sets of patient records.

There had been one previous inspection since the service was registered with CQC, which took place in October 2013 and found that the service was meeting all standards of quality and safety it was inspected against.

There were 23 consultants who were registered to work at The CyberKnife Centre under practising privileges, however only six were active. There were 10 staff directly employed by the service including radiographers, physicists, a clinical fellow and administration staff.

Summary of this inspection

Between July 2015 and June 2016, the service reported no never events, complaints or incidences of hospital acquired infections. The service reported two clinical incidents and one non-clinical incident for the same period. All were recorded as 'no-harm'.

A number of services including cleaning, portering and radiology diagnostics and reporting were provided under a local agreement with The Harley Street Clinic.

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 safe as good because:

- Equipment was well maintained and checked regularly with appropriate maintenance contracts in place.
- The environment was visibly clean and we observed staff adhering to infection prevention techniques.
- There was a clear incident reporting process in place and staff could describe feedback shared from recent incidents and lessons learnt.
- All staff were compliant with their mandatory training requirements.
- Patient records were clear and comprehensive.

However:

- The centre did not have a staff representative at the hospital's infection prevention and control (IPC) meetings, although we were assured information was provided by the meeting minutes.
- The risk register did not reflect all risks identified by recent incidents and near misses. Managers told us that all risks identified by incidents and near misses should be recorded as risks on the centre's risk register.

Good



Are services effective?

We rated effective as outstanding because:

- We found that staff were actively engaged in activities to monitor and improve quality and outcomes and that opportunities to participate in benchmarking, peer review, accreditation and research were proactively pursued.
- We saw many examples of innovative practice and staff could tell us about the research being undertaken by the centre and how outcomes were being embedded within clinical practice to benefit patients.
- We found excellent multidisciplinary team working. Staff, teams and services worked collaboratively to find innovative and efficient ways to deliver more joined-up care to patients.
- Regular audits were carried out and outcome measures collated and shared both locally and nationally where appropriate.

Outstanding



Summary of this inspection

- Policies and procedures were developed using relevant national best practice guidance and were adapted in response to latest evidence. Staff were suitably trained and developed to improve their practice. Staff told us they were encouraged and supported to undertake further academic qualifications.

Are services caring?

We rated caring as good because:

- We observed staff delivering good patient care and responding to individual patients' needs. We observed a supportive team approach to patient care. There was a well-embedded patient centred culture.
- Feedback we received from patients and relatives about the service was consistently positive. Patients we spoke with were very happy with the care they had received. All of the patient comment cards completed prior to the inspection were positive about the care and treatment.
- We saw that patients' privacy and dignity was maintained and respected by kind, caring and compassionate staff.
- We observed staff providing patients with information on the procedure they were undergoing. Patients were given the opportunity to ask questions and staff responded to provide further explanations where needed.

Good



Are services responsive?

We rated responsive as good because:

- International patients were well supported to access the service via the hospital's dedicated international patient centre staffed by liaison officers.
- Staff within The CyberKnife Centre had access to HCA employed interpreters, based within the main hospital, who spoke Arabic, Greek and Russian, and a telephone language line for all other languages was also available. All patients were provided with a point of contact following their treatment should they have any concerns or need advice.
- Although not required to use national cancer waiting time targets, the department chose to benchmark themselves against the national targets to measure their performance. Referral to treatment time was monitored via an audit and any breaches were investigated.
- A service level agreement was in place for a nearby CyberKnife service to ensure continuing of service for patients should equipment breakdown.

Good



Summary of this inspection

- Patients had access to the hospital's Macmillan accredited information centre which provided specialised information in the forms of booklets, CDs, DVDs and other supportive materials for patients with cancer.
- There had been no formal complaints regarding CyberKnife from June 2015 to July 2016. The staff told us they received very few complaints and could often resolve them quickly and address the concerns immediately.

However:

- Patient experience survey response rates were variable and were on average 17% for the 12 months prior to our inspection. Only 16 of 92 patients provided with the survey had returned it. We were told action was being taken to try to improve this.
- It was unclear how the results of the patient experience survey were used. We were not provided with any examples of where patient feedback had been used to improve services.

Are services well-led?

We rated well-led as outstanding because:

- The leadership, management and governance of the service assured the delivery of high quality person-centre care. There were clear governance arrangements in place that reflected best practice. Care was evidence based and action plans were constantly reviewed.
- We found that staff were actively engaged in activities to monitor and improve quality and outcomes and that opportunities to participate in benchmarking, peer review, accreditation and research were proactively pursued.
- We saw many examples of innovative practice and staff could tell us about the research being undertaken by the centre and how outcomes were being embedded within clinical practice to benefit patients.
- We found excellent multidisciplinary team working. Staff, teams and services worked collaboratively to find innovative and efficient ways to deliver more joined-up care to patients. The service was well supported by an active medical advisory committee.
- The service had a clear vision for The CyberKnife Centre which was integrated into, and supported by, the wider hospital vision and strategy. Staff we spoke with could tell us about the future plans for the centre and said they felt engaged in the planning process.

Outstanding



Summary of this inspection

- Staff were very positive about the leadership team. They felt their concerns could be raised and would be listened to. Staff spoke with pride about the service and reported the culture of the service made them feel valued and respected.
- The service actively engaged with patient forums to give updates and information about the service.

Detailed findings from this inspection






Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Medical care	Good	 Outstanding	Good	Good	 Outstanding	 Outstanding
Overall	Good	 Outstanding	Good	Good	 Outstanding	 Outstanding

Notes

Medical care

Safe	Good 
Effective	Outstanding 
Caring	Good 
Responsive	Good 
Well-led	Outstanding 

Are medical care services safe?

Good 

We rated safe as good.

Incidents

- There had been no serious incidents or Never Events reported by the service between June 2015 and July 2016. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- During the same reporting period, there were two clinical incidents and one non-clinical incident. All were recorded as ‘no-harm’. We saw evidence that these incidents had been correctly reported and reviewed. The staff we spoke with fully understood their responsibility for raising concerns, recording safety incidents and reporting them using the electronic reporting system.
- We noted from the incident reports and subsequent root cause analysis (RCA) that lessons had been identified and steps were taking place to ensure staff embedded those lessons in their ongoing practice. We spoke with two members of staff who were fully aware of the incidents and their outcomes.
- The service used the HCA corporate incident reporting, management & investigation policy which required staff to report all incidents via the electronic reporting system. Staff we spoke with were aware of the incident

reporting policy and knew where to access it along with other related policies on the internal system. The service had processes in place to learn from incidents. Staff told us incidents were discussed at staff meetings and other forums and that they received feedback on any incidents reported.

- We found that a clear record of all clinical and non-clinical incidents was maintained, however when we reviewed the risk register during our inspection and we did not find that recent incidents were recorded as risks. As part of our pre-inspection information request managers told us that as part of the hospital’s radiation oncology service, CyberKnife’s risks were recorded in the radiotherapy risk register. We were told that the risk register contained all risks that have been identified by staff or through incidents and near misses, but we did not find this to be the case.

Clinical Quality Dashboard or equivalent (how does the service monitor safety and use results)

- Patient safety information was reported and measured using the hospital’s own quality and safety dashboard. Outcomes were reported and compared nationally against other hospitals in the HCA group on a quarterly basis.

Cleanliness, infection control and hygiene

- All areas of the CyberKnife Centre were visibly clean. There was a system for ensuring all equipment was clean and ready for use, for example, ‘I am clean’ stickers displaying date of cleaning.
- Cleansing gel was available at the entrance to the CyberKnife room and in the waiting area. We observed staff and patients using the gel throughout our visit.



Medical care

- We saw that staff complied with the hospital's 'arms bare below the elbow' policy in all clinical areas.
- A corporate hand hygiene policy and audit schedule monitored staff compliance. The hospital had an infection prevention lead, who carried out regular infection prevention and control audits on a hospital-wide basis. Information from these were fed into the regular clinical governance meetings. No issues had been reported for The CyberKnife Centre within the 12 months prior to our inspection..
- We looked at the results of the monthly hand hygiene audit between September and November 2016 which showed 100% compliance.
- The service was covered by the hospital's infection prevention and control (IPC) policy. All staff received mandatory training relating to this and at the time of the inspection 100% of staff had attended the training.
- We looked at the minutes from the IPC meetings from June to September 2016. There were no attendees from the CyberKnife service but staff told us they had access to the meeting minutes. We were told that there was no specific representative from The CyberKnife Centre due to their small team size but that all relevant feedback was provided to the team.
- We saw that clinical waste and sharp objects were disposed of safely. All containers were labelled correctly.
- The CyberKnife Centre had access to the co-located radiotherapy department for use of their magnetic resonance imaging scans (MRI) and computerised tomography scans (CT).
- A full maintenance contract was in place to support the ongoing running of the CyberKnife machine. There was also a comprehensive contract in place to service the large safety door across the entrance to the CyberKnife treatment room. Staff told us this had caused recent problems due to a breakdown and the service was suspended at the location for several weeks. An essential part was replaced and further work done with the maintenance firm to ensure this part was more readily available in the future. We were told this had been put on the risk register but we did not find this to be the case. The risk register we reviewed during the inspection did not record any specific risk around equipment failure.
- The radiation warning lights were present and in working order. These were checked as part of daily quality assurance checks.
- Other daily quality assurance checks such as imaging accuracy and radiation output were uploaded onto the computer system for medical physics to review any trends or outlying results. We observed staff undertaking these checks.
- The door of the CyberKnife room was closed when not in use.

Environment and equipment

- The CyberKnife Centre was located in the basement of The Harley Street Clinic. Senior staff told us the unit has been designed to ensure the area was fit for purpose.
- We reviewed the resuscitation trolley which was located in the nearby radiotherapy department. The equipment followed national resuscitation council guidelines. The trolley we reviewed had been checked on a daily and weekly schedule and the seal was intact. A basic resuscitation kit was available within The CyberKnife Centre.
- Access to the lower ground floor where The CyberKnife Centre was located was protected by swipe card access. Clear warning signs were in place to warn of the danger of being exposed to radiation and information was displayed in other languages outside the entrance to the CyberKnife treatment room.
- We saw competency checklists to ensure staff were properly trained in the use of treatment equipment.
- Audits of compliance with IR(ME)R 2000 were completed and Radiation Safety Committee meetings were held quarterly to monitor radiation safety throughout the hospital.

Medicines

- No controlled drugs or other medications were stored or administered in The CyberKnife Centre. A hospital pharmacist was available seven days a week, during normal working hours on weekdays and in the mornings on weekends if any support was required.



Medical care

- Medication policies and incidents were reviewed by managers at the monthly clinical governance meetings for the hospital. Staff had access to these minutes for information.

Records

- The patient records for The CyberKnife Centre were paperless and all recorded on the bespoke electronic system.
- We reviewed three sets of patient notes. All notes had the appropriate information completed.
- We spoke with the administration staff. They assisted with preparing meeting agendas, writing minutes and sending information packs to patients.
- All patients seen in The CyberKnife Centre had a valid referral letter. Staff told us if a patient self-referred to the centre, their request would be reviewed by the clinical fellow working within CyberKnife before sending to a relevant consultant.
- We saw that all referral letters, multidisciplinary team meeting outcomes and any other relevant data were scanned onto the patient record database.
- We reviewed the audit undertaken in October 2016 to ensure complete medical records were maintained. A random sample of six patients' electronic notes were reviewed against the audit tool. Compliance of 94.9% overall was achieved against a target of 90%.

Safeguarding

- Safeguarding policies and procedures were in place. These were available electronically for staff to refer to.
- Staff were aware of their roles and responsibilities and were clear on how to raise safeguarding concerns appropriately.
- The CyberKnife staff had achieved 100% compliance with safeguarding adults and children level 2, which was the level required for this service.
- There was one member of clinical staff trained to level 3 safeguarding for children. The service had not treated any children but were registered to do so if required. We spoke with this individual and they were aware of their responsibilities should a child be treated at the centre in the future.

Mandatory training

- Staff within The CyberKnife Centre were required to complete mandatory training in a range of subjects.
- Training records showed 100% compliance in all subjects including manual handling, fire safety, information governance, health and safety and those already mentioned within the report.
- Mandatory training completion was linked to the staff annual appraisal system. Failure to complete mandatory training would not allow staff to receive their pay award.
- Staff told us the training was good and helped them to do their jobs well.

Assessing and responding to patient risk

- The CyberKnife Centre had local rules in place to monitor the safe use of radiation.
- All staff are required to read and sign the local rules. The service had a radiation protection supervisor (RPS) who was responsible for ensuring that the local rules were applied to protect staff, patients and the public.
- Staff were clear on their response should a patient become unwell during the treatment. Staff were able to escalate their concerns to the resident medical officer (RMO) to assess and treat the patient. The internal cardiac arrest number was clearly displayed throughout the centre.
- The three point patient identification check was used for patients undergoing CyberKnife treatment as required by the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)(2000). In addition, we saw staff in radiotherapy check patients against their digital photograph attached to their specific electronic notes to confirm their identity.
- We observed safe and responsive use of the CyberKnife machine imaging capabilities in pausing and re-evaluating the treatment of a patient who had a bout of coughing. The imaging capabilities were utilised to review the tumour position and return to the treatment after ensuring optimal coverage was attained. We saw the service had a comprehensive set of risk assessments with control measures in place. For example, access to the gas cylinders was restricted to only CyberKnife and



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physics staff. We also saw only trained staff would replenish the gas and the gas pressure was checked on clinical days to ensure that no escape of gas had occurred.

Allied health professional and medical staffing

- The CyberKnife Centre was staffed by one lead radiotherapist, two radiographers, one clinical fellow, two administration staff and four physicists. The staff ratios were sufficient to meet the demands of the service.
- Radiographer staff from the radiotherapy service were able to rotate through The CyberKnife Centre to gain experience in radiosurgery and help support the pool of staff to cover any vacancies and sickness.
- As of July 2016 there were 23 consultants registered with practising privileges within the CyberKnife service. In the reporting period there were 10 consultants who had not treated any patients, nine who had treated between one and 10 patients and four who had treated between 10 and 99 patients. We were told that the MAC chair had oversight of all consultants with practising privileges and reviewed access rights. Any consultants that were out of practice were required to resubmit their competences and scope of practice to be allowed to continue to practice within the centre.
- Practising privileges were processed centrally by The Harley Street Clinic with the CEO and medical advisory committee (MAC) providing oversight, with privileges being reviewed annually. Consultants for the CyberKnife service were identified through the MAC or within the multidisciplinary team (MDT) meetings.
- The hospital employed 16 RMOs. RMOs are doctors of varying experience that are full time hospital employees. The RMOs provided medical cover in case of patients requiring to be seen urgently or in need of prescriptions if their consultant was unavailable.

Emergency awareness and training

- There was an internal emergency incident and business continuity plan in place which described actions to be taken in the event of fire, flooding and loss of power.
- The CyberKnife equipment had safety mechanisms in place to safely abort procedures should the electricity fail.

Are medical care services effective?

Outstanding



We rated effective as outstanding.

Evidence-based care and treatment

- The CyberKnife service had access to The Harley Street Clinic's hospital wide policies and procedures. These had been developed nationally by the HCA group and took account of relevant best practice guidance including that issued by the National Institute for Health and Care Excellence (NICE), The Department of Health (DoH) and relevant Royal Colleges. The Stereotactic Ablative Radiotherapy (SABR) UK consortium guidelines were referred to in practice. We looked at a selection of four policies and all were within their review date.
- The service ensured all patients were treated in line with the Royal College of Radiologists (RCR) publication, "The timely delivery of Radiotherapy: standards and guidelines for the management of unscheduled treatment interruptions".
- The CyberKnife Centre had received accreditation from the Caspe Healthcare Knowledge Systems (CHKS) for the ISO 9001:2015 quality management system. This quality management system ensured the centre had a regular audit programme for continual review of work policies against working practices.
- Routine audits as indicated in the audit schedule were conducted by the CyberKnife staff and results discussed at local level and through the governance structure to ensure actions were implemented and re-audited for effectiveness. NICE guidance and other relevant publications were reviewed regularly at the MAC and compliance assessed accordingly. We saw minutes from the MAC in August 2016 recording that following publication of new guidelines for stereotactic radiotherapy from NHS England a paper should be published outlining the effective practice followed within The CyberKnife Centre.
- Patient treatment eligibility was in line with criteria for stereotactic radiosurgery (SRS) as defined by the NHS Commissioning board's Clinical Commissioning Policies. Staff told us that each case was discussed fully at the



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MDT and the outcomes recorded and disseminated to all relevant staff involved. Staff also told us that an additional meeting was held to discuss all patients accepted for CyberKnife treatment to ensure optimum scans and immobilisation were requested for treatment planning purposes.

- We looked at the specific CyberKnife protocols which had been written according to available clinical evidence and guidelines. We spoke with the clinical fellow who told us how protocols had been adapted to reflect current research evidence such as lymph node oligometastases and dose refractionation. We were told that research outcomes were being embedded within clinical practice to benefit patients; for example using multiple tracking markers wherever possible to improve radiation targeting and reduce the risk of toxicity to the patient.
- Following collaborative work with a centre in the United States of America, an evaluative dose tool and patient risk map was now used in practice. The clinical fellow told us the information could be used in consenting patients for treatment, by providing patients with more accurate information about the risks of treatment. The clinical fellow had updated the consultants in the MAC so they could also update their practice in regards to tolerance doses for healthy tissue and use the new data in conversations with patients.

Pain relief

- Patients had their level of pain assessed prior to commencement of treatment. We spoke with one patient prior to and after his treatment and he told us he had felt no pain.
- In the very rare event of the patient's consultant or the clinical fellow not being available, the RMO's could be used to assess the patient and prescribe relevant medication in cases requiring urgent attention.

Nutrition and hydration

- Nutritional leaflets were provided as part of the Macmillan Information Centre located near the entrance to the hospital.
- There was access to cold water within the small waiting area for the CyberKnife service and hot beverage facilities were available free of charge in the main waiting area.

Patient outcomes

- Collecting and reviewing patient outcome data for radiotherapy and radiosurgery in the United Kingdom for both the NHS and independent sectors is an area that needs significant development, however The CyberKnife Centre had a proactive stance in this area. We were shown evidence of presentations on the long-term outcome results on SABR for oligometastatic breast cancer; duodenal dose constraints when treating pancreatic cancer with CyberKnife and SBRT for treatment of recurrent breast cancer presenting with Internal Mammary Chain lymph node metastasis or sternal disease. Although some of the data we were shown was still in the early stages we were assured by managers and staff that the centre would continue to develop and further establish this part of the service.
- The centre had treated over 900 patients since it opened in 2009 and 120 patients in the reporting period. Staff told us that follow-up data was requested from the patient's primary clinician every three months in the first year post treatment then subsequently at 18, 24, and 36 months. Data was not always sent back by referring clinicians, however the centre would continue to request at the next interval, any data received was entered into a patient database and the data analysed. The clinical fellow told us the results were used to present outcome data nationally and internationally.
- The clinical fellow on behalf of the centre presented at the Royal Statistical Society Scientific Meeting in 2016 in Orlando, USA regarding the "Dose Volume Histogram analysis of SBRT treatment of pancreatic cancer: establishing risk levels." This study was aimed to provide more data to the scientific community in regards to the radiation tolerance of the duodenum, an organ near the stomach and pancreas, whose tolerance to radiation is not well established. Benefits of the results of this research to the centre's patients included better informed consent as more detailed information was available on the risks of treatment and the likely success rate.
- We were shown data that was retrospectively reviewed for breast cancer patients treated between 2009 and 2014 whose cancer had returned and spread to the lymph nodes after already being treated by conventional radiotherapy. The data showed that overall survival rates for patients treated with CyberKnife was 100% at 18 months and 75% at two years post



Medical care

treatment, this data was comparable to similar studies done in the United States by other radiosurgery centres, furthermore this data showed favourable results when compared to conventional surgery at 18 months.

- We were shown data that was a retrospective study of breast cancer patients treated between 2009 and 2014 whose cancer had spread to other parts of the body and formed new tumours. The data showed that the survival rate without disease progression at the treated site for the tumours of the brain was 74% at two years and for other parts of the body was 92% at two years. The results showed that The CyberKnife Centre had largely favourable outcomes when compared to similar studies conducted worldwide at two year post treatment survival.
- Results from a retrospective study that looked at data over four years in the treatment of base of skull tumours showed that the centre achieved 100% local tumour control with minimal severe side effects at 19 months, this was a favourable outcome when compared to similar studies conducted in the United States and the European Union.
- Results from a retrospective study that looked at data over two years in the treatment of spinal tumours showed that the centre achieved 91% local tumour control at 11 months and 75% improvement in pain at six months, this was a comparable outcome in regards similar studies worldwide.
- At the time of the inspection The CyberKnife Centre clinical fellow was in the process to publish more outcome data and to review further patient data, we were shown examples of this. We were told by managers that the centre had recently funded a post to help with the data entry for the dose volume histogram evaluator project.
- The outcomes of CyberKnife treatment for acoustic neuroma and meningioma were shared with charitable groups and patient forums by presentations in Oxford and London to the British Acoustic Neuroma Association groups and the Meningioma UK, Cambridge branch. We were told that the centre had received positive feedback from those who had attended the presentations as many were patients with these conditions who benefited from having information on the treatment options available to them.

Competent staff

- All staff received an induction prior to commencing work at the hospital. This included a combination of corporate and local induction policies and procedures.
- We spoke with two members of staff who confirmed they had their competences assessed on a regular basis. We looked at the competency checklists on the electronic files and saw that staff had completed these.
- Staff were trained to differing competency levels to reflect their input to the service delivery. For example, those on rotation would be trained to a different competency level to those who worked within the service full-time.
- Staff told us they were encouraged and supported to undertake further academic qualifications. The organisation had a strong focus on academic excellence and many staff were on a master's training programme.
- A training programme was attended by consultants working within CyberKnife run by the manufacturers of the machine.
- There was a robust procedure in place for the granting and monitoring of practising privileges of consultants. This was overseen by the medical advisory committee. The applicant would attend a first interview with the hospital Chief Executive Officer so as to become acquainted with the applicant's reasons for applying and requirements before being considered by the MAC. Consultants requesting practising privileges were required to submit a practising privileges application form and provide the relevant supporting documentation such as a copy of their annual appraisal and evidence of revalidation with the General Medical Council (GMC). There was an annual review of practising privileges, including scope of practice and activity.
- Any concerns raised about consultants were dealt with through the 'responding to concerns' policy via the local Decision Making Group (DMG) and then the corporate DMG if required.
- One hundred percent of the staff employed by The CyberKnife Centre had completed their appraisals.

Multidisciplinary working



Medical care

- A standard team was present during every treatment session, consisting of two radiographers. The treatment was previously planned by a consultant, radiologist and two physicists. The team were available for advice and support throughout the treatment.
- Staff involved with the CyberKnife service were actively engaged with the specific multidisciplinary team (MDT) meetings held on a fortnightly basis. The purpose of these meetings, attended by a wide range of health professionals with expert knowledge, were to review the patient's clinical condition, assess the appropriateness of CyberKnife treatment and/or any other interventions which may benefit the patient.
- All staff we spoke with told us how the MDT meetings were well attended and were expertly run to achieve the best outcome for the patient.
- We were provided with the MDT meeting minutes for 13 meetings held between June and November 2016. At each meeting patient referrals were discussed in detail and a decision was recorded as to whether they would be accepted for treatment. We reviewed the meeting minutes for 13 October 2016 and of 15 patients reviewed, 11 were accepted for CyberKnife treatment. In each case the patient's diagnosis, status and previous treatment were carefully considered before a decision was made. Decision notes recorded the reason for each decision and any considerations for future treatment.
- Staff told us patients lacking capacity to make an informed decision would be extremely rare. In these cases clinicians followed appropriate national guidelines for acting in the patient's best interest in line with the Mental Capacity Act 2005. Staff had access to the appropriate policies online.
- The consent process was undertaken by a consultant prior to the treatment taking place. Consent was confirmed on the day of treatment and recorded in the patient record. We reviewed two examples of the correct documentation of consent in the patient records.
- We spoke with one patient on the day of inspection who told us they had been fully consented by the consultant and the risks and side effects of the treatment had been explained.

Are medical care services caring?

Good



We rated caring as good.

Compassionate care

- Patient experience survey results for the period July to September 2016 demonstrated one hundred percent of patients would recommend the service to others. One hundred percent of patients who completed the survey also found the staff caring.
- We saw staff interactions with patients were consistently kind and compassionate. One of the comment cards we received said, "the CyberKnife team have been very caring and attentive," and another said, "the staff are all very friendly and caring."

Understanding and involvement of patients and those close to them

- Relatives were welcome to accompany the patient to the reception area for support and speak with the patient through the control room microphone if needed, however due to the nature of treatment they could not be inside the treatment room.
- We were told the radiographers would greet the patients at the time of their diagnostic imaging scans to give support before the CyberKnife treatment commenced.

Seven-day services

- This service did not operate as a seven-day service. Treatment was usually provided Monday through to Friday. However, we were told that the service offered flexibility outside of these days if required.

Access to information

- All documentation was available electronically. Staff told us the information was easy to access.
- Images from the diagnostic imaging department were also shared electronically.
- Formal requests for information access were sent to the Caldicott lead for the hospital for approval and to ensure policy was followed.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards (medical care patients and staff only)



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- Staff took time to explain information leaflets to patients to aide their understanding. Information leaflets contained details about the treatment planning process, the multidisciplinary team involvement and the treatment itself.. One patient told us the information provided had been very helpful.
- Patients were informed about side effects, discharge and follow up; patients we spoke with confirmed this.
- The dedicated CyberKnife clinical fellow was also available during treatment sessions to offer advice and support to patients.
- Staff told us they felt it was important for patients to fully understand the process and to actively involved in their care.
- The hospital, including the CyberKnife service had been recently awarded the Macmillan Quality Environment mark requiring the service to be: welcoming and accessible, respectful of privacy and dignity, supportive to users' comfort and well-being, giving choice and control to service users, and listening to the voice of the user.

Emotional support

- We were told that the CyberKnife patients had full access to the counselling service and complimentary therapies including massage, aromatherapy and reiki free of charge if required.
- Patients could access the full range of support services through The Macmillan Centre on the ground floor of the hospital.
- Staff understood and demonstrated an understanding of the impact that a person's condition, treatment and care would have on their wellbeing.
- Patients and their relatives were spoken to in an unhurried manner. Staff were reassuring and knowledgeable. One patient we spoke with said, "the staff are fantastic and have made a difficult time more bearable."
- Patients were given detailed advice on what to do and who to contact if they needed any further support at home.

Are medical care services responsive?

Good



We rated responsive as good.

Service planning and delivery to meet the needs of local people

- The service had planned its activities around the needs of the population accessing CyberKnife. They accepted referrals from a worldwide population but referral criteria and patient suitability for CyberKnife were closely managed through the MDT.
- The hospital had a dedicated international patient centre staffed by liaison officers. This service was designed to meet the needs of the large demographic of international patients the hospital received. The centre arranged visa's and handled all payments, liaising with insurance companies if required, additionally the centre arranged the entire process from pre-visit to after care including services such as; translation, escorting patients to appointments, accommodation booking, travel booking and arranging tourist activities.
- As the majority of CyberKnife procedures were day cases only, the patients were provided with a point of contact following their treatment should they have any concerns or need advice.

Access and flow

- Referral to treatment times were measured from the date of the MDT referral to the CyberKnife treatment date. The service provided data in relation to monitoring these waiting times.
- The CyberKnife Centre as part of independent health was not required to use national cancer waiting time targets; however, the department chose to benchmark themselves against the national targets to measure their performance.
- Audit data for the period to April 2016 showed there had been three minor breaches of the 31 day target for cancer patients to receive first definitive treatment. The audit had been analysed and the breaches were concluded to be from issues that were not related to



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service capacity and were instead due to patient choice or further treatment being required before CyberKnife could commence and further restaging scans to allow for accurate treatment planning.

- Staff told us the team always took every reasonable step to avoid patients breaching the 31 day treatment target. The most common reason for a breach was always patient choice which may be because of travelling from abroad, work commitments or holidays. Another common reason for breach has been further medical treatment and further fiducial placement required which are both unavoidable and in the patient's interest.
- On the days of our inspection, the patients we spoke to had been seen in a timely manner and no concerns were raised about their waiting times.
- A service level agreement was in place with a nearby CyberKnife service. Senior staff told us this had recently been used during a period of downtime due to a faulty door. This meant patients' treatment were not unnecessarily delayed.

Meeting people's individual needs

- The information leaflet for CyberKnife was available in Arabic as well as English.
- Staff within The CyberKnife Centre had access to HCA employed interpreters, based within the main hospital, who spoke Arabic, Greek and Russian, a telephone language line for all other languages was also available.
- We were told how one patient requested a male radiographer. There were no male radiographers working within the service and so one was provided by the larger radiotherapy department. The male radiographer attended all CyberKnife sessions for this patient.
- The sign posting for The CyberKnife Centre was not overly clear. However, the main hospital employed concierge staff to escort patients around the site and staff from The CyberKnife Centre would often escort patients directly down to the centre. One patient commented that they found the reception area in the basement very small.

- The hospital had the only private Macmillan accredited information centre which provides specialised information in the forms of booklets, CD's, DVD's and other supportive materials for patients with cancer.
- The Macmillan Centre has a designated quiet room for the use by patients and relatives but we noted there was no specific prayer centre for those who may wish to use one.

Learning from complaints and concerns

- There had been no formal complaints regarding CyberKnife from June 2015 to July 2016. The staff told us they received very few complaints and could often resolve them quickly and address the concerns immediately.
- Patients were actively encouraged by staff to complete their feedback forms and were given them to take home in advance of their treatment day, with a stamped addressed envelope. However, we saw that response rates were variable and were on average 17% (16 out of 92) for the 12 months prior to our inspection. We were told that action had been taken to try to improve this response rate including assigning a dedicated person to coordinate return of the completed surveys. Despite this, at the time of our inspection there had not been an improvement in patient response rate and it was not clear what other action the service was taking to ensure patients' experiences, views and feedback were captured and used to improve service delivery.
- Staff told us that any complaints and lessons to be learnt were discussed in monthly team meetings.

Are medical care services well-led?

Outstanding



We rated well-led as outstanding.

Leadership and culture of service

- We found that the local leadership of the CyberKnife team had the skills, knowledge and understanding to lead the team forward. This included the clinical fellow who had a strong commitment to research, collaboration and service improvement.



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- We spoke with the hospital CEO and the medical director for the service. Both were extremely articulate and passionate about the running of the service and the quality they wanted to provide.
- We received positive feedback from staff who had respect for other members of the team. They enjoyed their work and were happy to be part of the team. Senior staff were very proud of their staff. They told us they were hardworking and offered excellent patient care.
- We saw a culture of openness and transparency. The day-to-day working culture was friendly and patient focused.
- In speaking to staff, it was clear they felt supported in their roles. Access to postgraduate education and the hospital study leave support supported staff in gaining MSc level education.
- Staff told us the CEO was very visible and approachable. One member of staff told us the CEO was, 'inspirational and a good leader of people.' Staff told us there was clear leadership of the service and they felt proud to be part of the local service and wider organisation.
- Medical staff reported excellent working relationships with managers and key personnel within the centre.
- There was a strong radiation safety culture. The physicists told us there was an excellent relationship with the radiography team with strong lines of communication.

Vision and strategy for this core service

- The hospital's vision was "Together we consistently deliver exceptional care". The CyberKnife service was very much part of the wider hospital service and benefitted from this clear vision and strategy to support their service and take forward service delivery and improvement.
- Delivery against the strategy was monitored at the executive meetings and staff demonstrated a forward-looking approach.
- The CyberKnife staff told us the short term goal for the department was to integrate further with the radiotherapy department under the leadership of a joint service manager. Medium term goals included further developing current staff competencies and helping to

train and develop rotating staff from the radiotherapy department within the team. Longer term plans included replacing the current CyberKnife machine with a higher-spec model allowing the department to further advanced stereotactic body radiotherapy techniques.

- Senior managers explained that there were plans underway to further integrate the HCA sister hospital oncology pathways with the longer term goal to create a cancer network, allowing the current separate services to work more closely together. This was especially prominent for The Harley Street Clinic as all HCA cancer patients would be referred to the their radiotherapy department for treatment. The reasoning behind this strategic development was to provide a seamless consistent level of care for patients using the service.
- There was a strong focus on research and development for CyberKnife and using research outcomes to benefit patients by informing treatment planning.

Governance, risk management and quality measurement

- The service had a robust structure in place for working with the Medical Advisory Committee (MAC) for the CyberKnife service and for the MAC for the hospital in general. We reviewed the minutes of the meetings held in May and August 2016. These were detailed minutes and covered topics such as risks, performance, training, practicing privileges, complaints and clinical trials. We saw from the minutes that the MAC meetings were well attended by representatives from the CyberKnife team including the clinical fellow.
- The MAC received reports on the performance of the CyberKnife service including patient waiting times. This meant there was oversight of the service at a senior level to ensure appropriate challenge.
- It was evident through speaking with all levels of staff that they were fully aware of the risks and challenges the service faced. They were clear on how to manage and mitigate against the risks and clear plans were in place. For example, recruiting staff with the appropriate skills and knowledge was a challenge but the service had started a programme with radiotherapy to train a larger pool of staff and mitigate against this risk.
- Managers told us that as part of the hospital's radiation oncology service, CyberKnife's risks were recorded in the



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radiotherapy risk register. We were told that the risk register contained all risks that have been identified by staff or through incidents and near misses, but we did not find this to be the case. We reviewed the CyberKnife risk register and saw that it recorded six risks specific to the radiotherapy service. These included ensuring adequate staffing cover was available and avoiding staff exposure to radiation. All risks had detailed controls recorded as being in place and had dates for review. We did not see that recent incidents we had been told about, including the broken door which had stopped service for several weeks, were reflected as risk on the register. However, it was clear that all incidents had been reported and reviewed appropriately in line with the organisations incident reporting and management policy.

- There were quarterly clinical governance meetings attended by senior staff members, service leads and service managers. Minutes of the clinical governance meeting confirmed audit results and quality improvement programs were discussed at clinical governance and quality meetings. Additionally the meetings looked at comments, compliments and complaints by patients and staff. The staff we spoke with were aware of the meetings and told us that key messages were discussed at their own team meetings.
- There were regular team meetings to discuss issues, concerns and complaints. Staff were given feedback at these meetings about incidents and lessons learnt by their line managers.
- Radiation Safety Committee meetings were held quarterly to ensure that clinical radiation procedures and supporting activities in the radiotherapy department and CyberKnife Centre were undertaken in compliance with ionising and non-ionising radiation legislation.
- The radiotherapy department and CyberKnife Centre held monthly quality assurance meetings where members of the quality assurance team would meet to discuss internal department governance, quality management and research and development.
- Regular auditing took place and action plans were in place to monitor improvement, as part of the ISO 9001:2015 quality management system. This included auditing of patient outcomes by following up on patient

progress for up to three years after treatment. We saw that monitoring of patient outcomes formed the basis of research into improving treatment success rates and reducing side effects.

Public and staff engagement

- The hospital provided forums and workshops for sharing the vision and values.
- Staff told us they felt engaged with the service and could suggest changes and improvements. Staff told us they could approach and talk to the CEO or other executive members any time.
- All patients were asked to complete satisfaction surveys following treatment. Feedback was discussed at monthly quality meetings and at the staff meetings.
- Staff told us they had good email communication within their own team and from the other hospital teams.
- The service actively engaged with patient forums to give updates and information about the service and share the outcomes of recent research, providing relevant and up to date information to help patients decided on their treatment options.

Innovation, improvement and sustainability

- The clinical fellow told us about, and showed us evidence of a wide range of publications, presentations and academic awards they had been involved in. The clinical fellow provided expert support to the medical director, treating consultants, radiography, physics staff and patients by helping to translate research findings and developments into clinical practice for the benefit of the patients.
- Examples of change in working practices from analysing treatment and outcome data were provided to us. One example was the use of the data from the dose volume histogram project which resulted in the centre utilising multiple organ tracker markers instead of just the normal one tracker marker when treating in the pancreas area, this allowed the CyberKnife machine to track the movement of the pancreas more accurately. This practice had one fifth the risk of patient developing serious side effects when compared to just using a single marker.
- Other examples have shown to have changed the information provided to patients at the consent process,



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where patients have been able to receive more specific and accurate guidance on how the CyberKnife treatment may affect their disease. Examples were also provided to show where treatment regimes, the amount of radiation prescribed over a period of time, had been altered to allow the best result possible for the patient.

- The department recently offered some of the world's first 'CyberHeart' treatment for atrial fibrillation. This required a collaboration of expertise across CyberKnife, radiology and cardiology and an industry technology company. This provided a new non-invasive treatment for this condition, benefiting patients by reducing the risks of treatment.
- The service supported the development of radiographers from the radiotherapy department. This facilitated staff development but also enabled a larger pool of staff to support the smooth running of the service.
- The service had developed a bespoke fault logging system for the CyberKnife machine. This actively recorded the faults in real time which could then be addressed by the physics team. The system also allowed for auditing the breakdown log to look for any recurring patterns or themes, allowing problems to be identified, escalated and resolved more quickly.

Outstanding practice and areas for improvement

Outstanding practice

- The multidisciplinary team working was excellent. There was strong collaboration and support amongst the professionals and this was evident during the inspection.
- We found approachable and motivational leadership at all levels. We found managers and staff were passionate about delivering a high-quality service to their patients.
- Systems and processes were in place to ensure patient's individual needs were fully met.
- There was a strong focus on patient waiting times and referral to treatment times were closely monitored and any breaches investigated and shared at the MAC meetings.
- The feedback from patients using the service was overwhelmingly positive.
- Training, staff development and competency was seen as a priority for the service.
- We found there was a continual review and analysis of treatment and outcome data, which has resulted in changes in working practices to provide more accurate consent information and more favourable treatment results to the patient.
- Working in collaboration with an industry technology company the centre had provided pioneering 'CyberHeart' treatment for the treatment of atrial fibrillation.

Areas for improvement

Action the provider SHOULD take to improve

- The provider should review their patient experience survey results and response rates and gather and use patient feedback to help improve their service where appropriate.
- The provider should review their process for reflecting incidents and near misses on their risk register and ensure this is consistent with their incident reporting policy.