

Optasia Medical Limited

Quality Report

Mellor House 26 Mellor Road Cheadle Hulme Cheadle Cheshire SK8 5AU

Tel: 01614883770

Website: www.optasiamedical.com

Date of inspection visit: 9 January 2020

Date of publication: 13/03/2020

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	Good	
Are services safe?	Good	
Are services effective?		
Are services caring?		
Are services responsive?		
Are services well-led?	Good	

Overall summary

Optasia Medical Limited is operated by Optasia Medical Limited.

At the time of inspection, the service was not providing any activity in scope of CQC registration, although were liaising with various trusts to set up contracts.

Optasia Medical Limited was actively providing services to US sites at the time of inspection, however this was outside of CQC scope.

Where the report mentions work previously completed, it was based on two UK pilots undertaken with trusts in 2019.

The service provides secondary readings of computed tomography (CT) scans for patients aged 50 and over. Radiologists from an NHS trust undertake the primary reading for a specific reason, for example to identify a

cancer. Optasia undertake a secondary reading aiming to identify missed fractures of the spine, as often these can be missed by the primary reader due to time constraints and resources.

Missed fractures can have a debilitating effect on the patient, and certain types of fractures in the spine can be a sign of osteoporosis. Therefore, offering a secondary reading may identify osteoporosis or other problems and prevent further injuries, complications and hospital admissions, that may have otherwise been missed.

The service also develops software to enable information technology programmes to identify missed fractures, to the same standard of a consultant radiologist. However, this is out of scope of CQC regulation, so was not looked at during the inspection.

The service works closely with experts in osteoporosis from universities and charities to support development of practice in this area.

We inspected this service using our comprehensive inspection methodology. We carried out the inspection on 9 January 2020.

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.

The main service provided by this service was teleradiology.

We have not rated this service before. We rated it as Good overall.

We found the following areas of good practice:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse, and they knew how to apply it.
- The design and maintenance of equipment kept people safe. Staff were trained to use them.

- Staff identified and quickly acted upon patients at risk of deterioration.
- The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.
- Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service.
- The service could be accessed in a timely way and staff could meet targets for scan result turnaround.
- The service had a complaints policy and knew their responsibilities regarding responding to complaints. There were no complaints about the service in the past 12 months.
- Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for staff. They supported staff to develop their skills and take on more senior roles.
- The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. Leaders and staff understood and knew how to apply them and monitor progress.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work and provided opportunities for career development. The service had an open culture where patients, their families and staff could raise concerns without fear.
- Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.
- The service collected reliable data and analysed it. Staff could find the data they needed, in easily

- accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.
- Leaders actively engaged with staff and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for patients.
- All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.

Ann Ford

Deputy Chief Inspector of Hospitals (North)

Our judgements about each of the main services

Service Rating Summary of each main service

Diagnostic imaging

Good



We rated the domains of safe and well led as good. The domain of effective is not rated for this type of service. We were unable to rate the domain of caring and responsive as the service did not have any direct interaction with patients.

Contents

Summary of this inspection	Page
Background to Optasia Medical Limited	7
Our inspection team	7
Information about Optasia Medical Limited	7
The five questions we ask about services and what we found	9
Detailed findings from this inspection	
Overview of ratings	11



Location name here

Services we looked at Diagnostic imaging;

Background to Optasia Medical Limited

At the time of inspection, the service was not providing any activity in scope of CQC registration, although were liaising with various trusts to set up contracts.

Optasia Medical Limited was actively providing services to US sites at the time of inspection, however this was outside of CQC scope.

Where the report mentions work previously completed, it was based on two UK pilots undertaken with trusts in 2019.

Optasia Medical Limited is a diagnostic and screening service. The service is a specialist teleradiology company, specialising in the identification of vertebral fractures found in computed tomography (CT) images. The service accesses chest, abdominal and pelvis CT images of patients aged 50 and over, originally taken for an unrelated purpose. The service provides a secondary analysis of each image to identify vertebral fractures which are often missed during the primary reading at the hospital.

Staff do not interact directly with patients at any time and results are reported back to the hospital through their secure server. The hospital staff, usually a fracture liaison service nurse, follows up with the patient if treatment is required. Fracture liaison services are departments within hospitals which identify osteoporosis and prevent further fractures.

The service is registered to provide diagnostic and screening services and the current registered manager has been in post for approximately one year.

This was the first time the service was inspected since they registered with the Care Quality Commission.

Optasia Medical Limited is operated by Optasia Medical Limited, and established in July 2010. It is a private service in Cheadle Hulme, Cheshire. The company can provide services nationally and internationally as the work is completed remotely.

The service had a registered manager in post since 2016.

Our inspection team

The team that inspected the service comprised a CQC lead inspector. The inspection team was overseen by Judith Connor, Head of Hospital Inspection.

Information about Optasia Medical Limited

The main service provided is teleradiology and is registered to deliver diagnostic and screening activity. Staff provide the service from an office location in Cheadle Hulme and can operate remotely for hospitals anywhere in the country.

There are three full time members of staff and the service contracts a radiologist when required. The service did not have any current contracts at the time of inspection, and therefore were not currently providing a regulated activity.

The service conducted a two-month prospective pilot service at an NHS teaching hospital between September

2018 and December 2018, and an NHS county hospital between April 2019 and July 2019. The pilots were supported by a pharmaceutical company under a joint working agreement.

During the inspection, we visited the main office location and spoke to all three current staff members. We also spoke with the radiologist who is contracted to screen the scans when required. The service does not interact directly with patients or store any confidential information; therefore, we were unable to interview patients or look at records.

This was the first time the service was inspected. There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection.

The service had no serious incident or complaints in the previous 12 months before this inspection.

The service had a service level agreement with a supplier of consultant radiology staff.

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 it as **Good** because:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse, and they knew how to apply it.
- The design and maintenance of equipment kept people safe. Staff were trained to use them.
- Staff identified and quickly acted upon patients at risk of deterioration.
- The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.
- Staff recognised and reported incidents and near misses.

 Managers investigated incidents and shared lessons learned with the whole team and the wider service

Are services effective?

We rated it as **Not rated.** We do not rate effective for this service.

- The service provided care and treatment based on national guidance.
- The service did not collect patient outcomes as it was providing second scans for other providers, although audited the quality of its own reporting.

Are services caring?

We rated it as **Not rated** because:

• We were unable to rate the service for caring as staff did not have any direct contact with patients.

Are services responsive?

We rated it as **Good** because:

- The service could be accessed in a timely way and staff could meet targets for scan result turnaround.
- The service planned care in a way that met the needs of the NHS trusts it provided services for.

Good



• The service had a complaints policy and knew their responsibilities regarding responding to complaints. There were no complaints about the service in the past 12 months.

Are services well-led?

We rated it as **Good** because:

- Leaders had the skills and abilities to run the service. They
 understood and managed the priorities and issues the service
 faced. They were visible and approachable in the service for
 staff. They supported staff to develop their skills and take on
 more senior roles.
- The service had a vision for what it wanted to achieve and a strategy to turn it into action. Leaders and staff understood and knew how to apply them and monitor progress.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work and provided opportunities for career development. The service had an open culture where patients, their families and staff could raise concerns without fear.
- Leaders operated effective governance processes throughout the service. Staff were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service. The service held team meetings however did not record formal minutes.
- Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.
- The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.
- Leaders actively engaged with staff and organisations to plan and manage services. They collaborated with partner organisations to help improve services for patients.
- All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.

Good



Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Good	N/A	N/A	N/A	Good	Good
Overall	Good	N/A	N/A	N/A	Good	Good

Safe	Good
Effective	
Caring	
Responsive	
Well-led	Good

Are diagnostic imaging services safe? Good

Our rating of safe was **good.**

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

The service had two training modules which they expected staff to complete. These were data awareness security and safeguarding level one. There was full compliance with the training modules.

The service contracted a consultant radiologist when required who received appropriate training via their agency.

As there were only three staff it was easy for the manager to monitor compliance with training. The manager was considering a new system to monitor training in the future, if the service expanded.

All staff received an induction handbook which included appropriate policies and procedures, which staff signed to say they had read and understood.

Safeguarding

Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse, and they knew how to apply it.

The service had a clear safeguarding policy that was in date, which we viewed. The policy explained what to do to raise concerns and included contact details for the local authority. Relevant legislation and definitions of abuse were included.

The induction handbook had a box for staff to sign to say they had read and understood the safeguarding policy.

The service had a safeguarding lead and all staff were trained in safeguarding adults level one. Staff were not required to undertake safeguarding training to a higher level as they did not have any direct contact with patients.

Staff knew to escalate any concerns noted on scans via the registered manager. If staff noted anomalies on the scan they would highlight this as a 'red flag' and escalate to the trust. There were established procedures to do this which all staff were aware of.

Cleanliness, infection control and hygiene

Not applicable to the service.

Environment and equipment

The design and maintenance of equipment kept people safe. Staff were trained to use them.

Reporting monitors complied with the Royal College of Radiologists standards. All new staff were provided with new monitors.

The service had an open plan office, with side offices available. There were monitors in all areas for viewing scans. All images were accessed through the hospital's systems. The service did not have its own picture archiving and communication system.



Radiologists working for the service were provided with the equipment, including a monitor, to review images remotely from their home.

Assessing and responding to patient risk

Staff identified and quickly acted upon patients at risk of deterioration.

There were clear processes in place for staff to escalate unexpected or significant findings. When the service set up contracts with an NHS trust they agreed procedures, including how risks should be escalated and to whom. This included a dedicated text box on the secure server to clearly highlight any concerns. Managers followed this up via email on the secure NHS network, and telephoning the fracture liaison service to make sure the message was picked up.

Staff we spoke with knew how to escalate and had put contingency plans in place in case the lead person was away.

The service had a system in place to check consistency of the radiologist's interpretation of scans. The same radiologist reviewed five percent of scans from the previous week and the manager looked at the notes to review whether the radiologist reached the same conclusion. All of these processes were tested during the pilot work.

For future contracts, the service told us that requirements for follow up would be agreed during the set up of the contract.

Nurse staffing

Not applicable to the service.

Medical staffing

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.

Optasia Medical Limited used a recruitment agency to find and contract consultant radiologists. The radiologist received a full staff induction including general health and safety, general service introduction and standard operating procedure and patient confidentiality procedures.

Where second opinions were required, the service worked with two radiologists with expertise in vertebral fractures on a consultancy basis.

The manager established staffing levels at the start of each contract. The contract included how many patients would be reviewed. The manager could work out staffing levels based on this and time taken to review scans and recruited accordingly.

The manager wanted to set up a formal staffing system to record and verify staff timesheets.

Records

The service did not store any confidential patient records electronically or in paper form.

The service used a secure server to log on to the NHS trust's systems to view scans remotely and made notes directly onto the system. Scans did not have any identifiable patient information, instead each scan had a unique code.

The service did not use email to communicate with trust staff about patient scans, they only used the secure platform.

Medicines

Not applicable to the service as they did not store, prescribe or administer any medicines.

Incidents

Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service.

The service had an incident reporting policy and we saw all three incidents reported during the pilots for. All incident reports showed level of harm and actions taken.

Staff used service incident reporting forms to record. The forms included incident detail, initial actions taken, person responsible for investigating, findings, actions and recommendations. Staff were aware of their duty of candour responsibilities. Duty of candour is a regulation placed on providers to be open and honest about when things go wrong in the care.

Safety Thermometer (or equivalent)



Not applicable to the service.

Are diagnostic imaging services effective?

We do not rate effective for this type of service.

Evidence-based care and treatment

The service provided care and treatment based on national guidance.

Staff provided services based on nationally recognised guidelines. The service worked in partnership with the Royal Osteoporosis Society and consulted with the Royal College of Radiologists to establish pathways, reporting standards and service delivery in line with good practice.

The service was involved in supporting the work of the Royal Osteoporosis Society, especially within the area of using technology to interpret scans.

Nutrition and hydration

Not applicable to the service.

Pain relief

Not applicable to the service.

Patient outcomes

The service did not collect patient outcomes as it was providing second scans for other providers, although audited the quality of its own reporting.

The service was reliant on NHS trusts collecting information about outcomes for patients. The service was looking at ways to support trusts to collate information, as this would also support the wider aims of establishing osteoporosis evidence-based practice.

The service completed internal audits on all aspects affecting service provision annually, ensuring any non-conformities were identified and corrected in a timely and responsive manner. The service performed clinical audits by ensuring the accuracy of diagnostic reports

During the recent three-month trials, a total of 5,338 scans were analysed and underwent a quality check throughout the process. These quality checks included the vertebral fracture diagnoses, verification of the

vertebral levels and content of reporting the results. During this process any errors were corrected, and discrepancies were discussed and acted on if necessary. Five percent of the total number of scans underwent a secondary quality assurance audit.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.

The service used a recruitment agency to find and contract consultant radiologists. The agency staff induction included general health and safety, general service introduction including standard operating procedures and patient confidentiality procedures.

The agency specialised in medical recruitment and checked candidates had undergone disclosure and barring service (DBS) checks, insurance, continuing professional development including safeguarding procedures, appraisals and license validation/revalidation. We saw the service level agreement which indicated consultant radiology staff must have indemnity insurance and DBS check.

Staff were encouraged to access training both internally and externally to support their continuing professional development.

All staff appraisals were up to date.

Multidisciplinary working

Not applicable to the service.

Seven-day services

Not applicable to the service.

Health promotion

Not applicable to the service.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Not applicable to the service.



Are diagnostic imaging services caring?

We did not inspect caring and were unable to rate as the service did not interact directly with patients.

Compassionate care

Not applicable to the service.

Emotional support

Not applicable to the service.

Understanding and involvement of patients and those close to them

Not applicable to the service.

Are diagnostic imaging services responsive?

Due to the nature of the service we were unable to rate responsive.

Service delivery to meet the needs of local people

The service planned care in a way that met the needs of the NHS trusts it provided services for.

The service provided a second opinion to patients aged 50 and over, who had a computed tomography (CT) image containing the spine. Staff told us they could tailor the service to meet the needs of the trust. This included information technology solutions, clinical pathway, reporting wording and evaluation of service outcomes.

In addition to the pilot work, the service recently performed retrospective clinical audits in five NHS trusts. This helped trusts understand how many vertebral fractures were being missed/reported, compared to how many the service offered could identify.

The service were looking at ways to help NHS trusts offer virtual fracture liaison services in the future. The service planned to employ nursing staff to base themselves within the fracture liaison service and support service delivery.

Meeting people's individual needs

Not applicable to the service.

Access and flow

The service could be accessed in a timely way and staff could meet targets for scan result turnaround.

The service had a target of a 10-working day reporting turnaround time. This ensured adequate time to account for sickness or unexpected holiday. The CT images already received a primary read by the hospital's radiologist, eliminating the need for immediate emergency reporting.

The service analysed images in the order received from the NHS trust. They were not prioritised due to being a secondary non-emergency screen. During the setup of contracts, the service identified how many scans would be received over an agreed period to resource appropriately and avoid waiting lists or delays.

The service agreed a process with individual trusts should there be a technical problem with accessing or uploading the scans.

The manager monitored turnaround via a spreadsheet. This was effective at the time of inspection due to the low level of work undertaken. However, management acknowledged more sophisticated methods would be required if the service expanded and were exploring other tools and tracking systems in response.

Learning from complaints and concerns

The service had a complaints policy which was relevant and in date. Staff knew their responsibilities regarding responding to complaints. There were no complaints about the service in the past 12 months.

Are diagnostic imaging services well-led?

We rated it as **good.**

Leadership

Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for staff. They supported staff to develop their skills and take on more senior roles.



The service had a chief executive who reported to the board. There was also a registered manager and two other full time, permanent members of staff.

The service made training available in order to equip staff with the necessary skills and abilities to undertake their role. This was especially around the technology that staff were required to use. Leaders realised that due to the small size of the service, all staff were required to have necessary skills to ensure continuity of service should someone be on leave or sick leave.

Managers had a robust recruitment process to ensure they hired staff with skills and values in line with that of the company.

Staff kept up to date with developments from the Royal Osteoporosis Society, for example in technology, and patient and care pathways.

The service was keen to promote management training and the chief executive had 30 years' experience in leadership. All staff contributed to a personal objective plan to help develop skills and abilities.

Vision and strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action. Leaders and staff understood and knew how to apply them and monitor progress.

Managers had a clear vision of the service and described their mission as 'to provide next-generation technology and services to help care providers minimise the human suffering and societal costs of osteoporosis'. They described themselves as the leading provider of technology and services for osteoporosis care.

Staff within the service were passionate about improving earlier diagnosis for osteoporosis and were proactive in attempting to reach NHS trusts with this vision across the country. We saw from board papers that the service communicated with fracture liaison service nurses or hospital bone health teams within hospitals.

To further achieve their vision the service established good links with osteoporosis focussed charities.

The service had a clear and thorough business plan.

Culture

Staff felt respected, supported and valued.

Staff described good levels of communication at each level. The team aimed to be inclusive of one another and support each other where required.

The service could effectively resolve conflict where required to enable the service to be effective.

Governance

Leaders operated effective governance processes throughout the service. Staff were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

Optasia Medical Limited was governed by a board of directors, who meet on a regular basis.

The chief executive met with the board and provided reports which included financial and management reporting, and risks to viability of the service. We reviewed a sample of board meeting minutes which showed effective communication and governance.

Staff had regular team meetings and items discussed included finance, risk, regulatory issues and software products. We saw meeting agendas however there was no formal structure to record minutes of team meetings; staff recorded their own notes.

We reviewed a sample of finance reports from 2019 and saw that revenue and expenses were monitored and analysed.

Managing risks, issues and performance

Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

The service undertook resource planning annually, during an infrastructure review.

There was a risk management procedure in place alongside a risk register. The risk register included a risk rating, risk owner and actions to mitigate.



Managers were aware of top risks to the service which included financial. This was important as they had not yet established long term contracts with NHS trusts. Financial issues were noted in board meeting minutes which we saw. Senior managers ensured links were maintained with their financial partners in order to mitigate this risk and sustainability of the service. The service received the majority of their funding via venture funds. The service was also proactive in securing contracts with hospitals outside of the UK.

The service coped well with unexpected events to ensure continuity and had a business continuity plan which we saw. This included procedures for events such as loss of computer system, electricity supply and incapacity of staff. An example of this was action was when a member of staff took unexpected sick leave, the service continued to run smoothly because staff were aware of their roles and responsibilities.

The service put together performance improvement plans when they identified a need to develop. For example, we saw the information governance improvement plan which included actions such as undertaking security audits.

When contracts started, the service established clear joint working agreements which we were able to see. These agreements set out clear aims and objectives of the project, and expectations of each party.

Leaders were clear about their own roles and remit to avoid overlap of responsibilities.

Managing information

The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

We saw that the service had conducted a data protection impact assessment to help identify how to comply with data protection requirements and minimise privacy risks.

The service had a strong commitment to maintaining confidentiality of patient details and had an established

process to manage this with NHS trusts. We saw the documentation management policy which included a flow chart and detailed description of how documents were stored.

Staff would visit the hospital to set up a secure server within the NHS trust. The NHS trust uploaded scans onto the dedicated server, and staff at Optasia accessed the scans via this system. Scans did not include any identifiable information, other than a specific number. Once the radiologist had interpreted the scan, the results were also noted on the same system.

An example of commitment to security included when a hospital consultant attempted to send an email outside of the secure network. Staff telephoned them to advise they were not willing to open the message in this form.

Engagement

Leaders actively engaged with staff and organisations to plan and manage services. They collaborated with partner organisations to help improve services for patients.

Optasia sought feedback from their partners through service evaluations.

We saw meeting minutes of the service feedback following the recent teaching hospital pilot. This captured good information about the setting up of the pilot, and how the trust would prefer to receive information. Staff noted they learned a lot from service evaluations to improve their service for future projects. For example, feedback showed that fracture liaison services were set up differently in each hospital; therefore, Optasia designed the service to fit in with the different clinical pathways.

There were regular team meetings where all staff could contribute and share ideas. Staff said they felt able to discuss and raise concerns and issues.

Staff did not engage with patients as there was no direct contact with patients.

Learning, continuous improvement and innovation



All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.

The service was committed to participating in research schemes and worked with local universities on relevant projects.

An example of this was the service developed and improved the algorithm's efficiency and accuracy, using

data from the studies already conducted and future opportunities. In addition, the services worked alongside key opinion leaders in vertebral fracture identification. Optasia used their knowledge and expertise to improve the service.

The service used innovate practice around developing software to interpret scans to the same level as a radiologist.