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Midland Smile Centres -Handsworth

Inspection report

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Overall summary

We carried out a comprehensive inspection of Midland Smile Centres – Handsworth (located in Handsworth Wood) on 30 January 2015.

The practice offers both NHS and private treatment services for its patient population. Midland Smile Centres – Handsworth has three dentists, a trainee practice manager and a team of dental nurses and reception staff. The practice is part of a group of practices and staff members worked from other sites if needed. We spoke with a trainee dental practice manager who was responsible for the day to day running of the practice. Other management staff were also present during the inspection. These included the area manager, a support manager and their manager. At the time of our inspection there was one dentist on duty.

We spoke with two patients who used the service on the day of our inspection and reviewed eight CQC comment cards that had been completed by patients prior to the inspection. The patients we spoke with were very complimentary about the service. They told us they found the staff to be friendly and welcoming and felt they were treated with respect. The comments on the CQC comment cards were also very complimentary about the dentists and the service provided.

Our key findings were as follows:

- The practice had systems to monitor patient safety through reporting and learning from incidents and significant events. However, not all incidents were being reported. The premises were generally visibly clean but we saw one treatment room that was not clean to the standard expected.
- Patient's needs were assessed and care was planned and delivered in line with current guidance. This included the promotion of good oral health. We saw evidence staff had received most training considered by the provider to be mandatory. However, staff needed to attend safeguarding adults training.
- The patients we spoke with and all comment cards we reviewed indicated that patients were treated with kindness and respect by staff. We observed that privacy and confidentiality were maintained for patients using the service on the day of the inspection.
- The practice had procedures in place to take into account any comments, concerns or complaints that were made to improve the practice.

Summary of findings

 Staff on duty told us they felt supported by both the principal and practice manager. There was an appraisal system in place and staff told us that training needs were recognised through the process.

We identified regulations that were not being met and the provider must:

- Ensure effective recruitment procedures are in place to ensure staff employed for the purposes of carrying on regulated activities are of good character.
- Ensure all incidents are documented as per practice policy so that any learning could be implemented.
- Training must be adequate for staff roles and appropriate staff members must ensure they attend relevant training.

- Develop a comprehensive business continuity plan.
- Dental waterlines must be flushed according to guidelines to reduce the risk of cross infection.
- Ensure all emergency medical equipment is available and adequately maintained to manage risk of inappropriate and unsafe care.

There were areas where the provider could make improvements and should:

- Ensure dentists have a satisfactory understanding of consent including informed consent from those less than 16 years of age.
- Patient notes should reflect discussions around treatment options.

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

There were protocols in place to raise concerns and report incidents and accidents. However, not all information about safety was recorded, monitored and appropriately reviewed. There were systems in place for infection prevention and control. We found that at times infection control guidance was not always followed. There were arrangements in place to deal with some medical emergencies. However, some medical equipment was not adequately maintained. Recruitment procedures to ensure staff employed for the purposes of carrying on regulated activities were of good character were not robust.

Are services effective?

Patients' needs were assessed and dental care and treatment was planned and delivered in line with their individual treatment plans. The patients we spoke with confirmed that they understood their treatment options and had consented to treatment. However, treatment options discussed with patients were not always recorded when we reviewed a sample of patient dental care records.

The dentist we spoke with had a satisfactory understanding of preventative care. The dentist told us how they supported people to ensure better oral health. Staff working at the practice were clear about their individual roles and responsibilities and had undertaken most core and mandatory training considered by the provider to be mandatory to support them in their roles and to enable them to meet the needs of patients.

Are services caring?

We looked at eight CQC comment cards that patients had completed prior to the inspection. Patients were positive about the care they received from the practice. They commented they were treated with respect and dignity. We observed that privacy and confidentiality were maintained for patients using the service on the day of the inspection.

Are services responsive to people's needs?

We found the practice had an efficient appointment system in place to respond to patients' needs. Staff told us the majority of patients who requested an urgent appointment would be seen within 24 hours. We saw a patient had attended the practice for treatment, unaware that their appointment had been cancelled. However, they were seen by the dentist present during the inspection. We saw the practice had a comments box available inviting patients to make comments and suggestions. Patients could also leave comments on the practice website.

Are services well-led?

The practice was part of a group dental provider and the trainee practice manager was being supported by other managers within the group. Staff were aware of the leadership team and knew who to approach with specific issues. Staff felt supported and were encouraged to extend their learning. We saw there were policies and procedures in place to support the safe running of the service. However, they were not always followed effectively to ensure improvements in service. For example, staff members spoken with gave an example of an incidents that had occured in the practice but they did not follow the practice incident reporting policy which encouraged reporting of incidents and sharing of learning.



Midland Smile Centres -Handsworth

Detailed findings

Background to this inspection

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the practice was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008 and to pilot a new inspection process being introduced by the CQC.

 We carried out an announced inspection on 30 January 2015. This inspection was carried out by CQC inspector and a dental specialist advisor.

We informed the NHS England local area team that we were inspecting the practice. We did not receive any information of concern from them regarding the safety of the service. However, we were aware of some concerns raised by a former member of staff.

We reviewed the information we had about this provider from the previous inspection. The practice sent us their statement of purpose and a summary of complaints they had received in the last 12 months. We also reviewed further information on the day of the inspection.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection.

Are services safe?

Our findings

Learning and improvement from incidents

The practice had a formal procedure for reporting and managing incidents. We saw a protocol was in place with a template to record incidents. Managers we spoke with told us that there were no incidents that had occurred in the previous year. Management staff showed us an accident book which had recorded accidents and needle stick injuries and we saw that the practice had responded appropriately.

Apart from reporting accidents practice staff were not aware of the incident reporting system. This did not ensure that all incidents were being reported including near misses where patient safety could be compromised. For example, the practice had a policy for violence and aggression. The policy stated that staff should report any such event to the practice manager and fill in an incident reporting pro-forma. Staff members we spoke with told us that they had a verbally aggressive patient where the police had been involved. However, this was not reported by staff where learning could be shared.

Reliable safety systems and processes (including safeguarding)

The practice had safety systems in place to help ensure the safety of staff and patients. These included clear guidelines about responding to a sharps injury (needles and sharp instruments). There were adequate supplies of personal protective equipment such as face visors and thick rubber gloves for use when manually cleaning instruments.

The practice had up to date Child Protection and Vulnerable Adult Policies and procedures in place. These provided staff with information about identifying, reporting and dealing with suspected abuse. The policies were readily available to staff. Staff had access to contact details for both child protection and adult safeguarding teams and relevant referral forms to raise any concerns.

The lead for safeguarding in the practice was the trainee practice manager. We looked at training records which demonstrated that staff had received online training for safeguarding children. There was no record of training in

safeguarding adults. The trainee practice manager was unsure about the requirements of their role and the training needed. They had not reached a stage in their training to enable them to take on a lead role.

Staff we spoke with were unsure who the practice's safeguarding lead was but demonstrated knowledge on safeguarding issues such as recognising signs of abuse in older people, vulnerable adults and children. There was a folder with all relevant information and safeguarding contacts at the local authority that they could speak with for more advice.

The dentists at the practice used rubber dams. A rubber dam is a thin, rectangular sheet, usually latex rubber, used in dentistry to isolate the operative site (one or more teeth) from the rest of the mouth. Use of a rubber dam is considered good practice and stops bacteria in saliva from splashing onto the tooth. This is very important for successful root canal treatment, because the bacteria in saliva can re-contaminate the tooth. Other benefits include the prevention of composites or fillings from being inhaled or ingested during removal.

Infection control

Decontamination of dental instruments was carried out in a designated decontamination room on the first floor of the practice. A dental nurse demonstrated the decontamination process from taking the dirty instruments through to clean and ready for use again. We observed that the arrangements ensured that dirty instruments did not contaminate clean processed instruments. The process of cleaning, inspection, sterilisation, packaging and storage of instruments followed a well-defined system of zoning from dirty through to clean. The practice used a system of manual scrubbing and rinsing followed by inspection of each item under a magnifying lamp before sterilisation using an autoclave (equipment used to sterilise instruments).

When instruments had been sterilised they were pouched and stored until required. All pouches were dated with an appropriate expiry date. The practice had two autoclaves that were used in the decontamination of dirty instruments. Daily logs recorded the results of test strips and pressure and temperature readings to show they were working effectively. This ensured that the practice was

Are services safe?

following essential standards for decontamination as laid out by Health Technical Memorandum 01-05 (HTM 01-05). HTM01-05 is the Department of Health's guidance on decontamination in primary care dental practices.

During our discussion with the dentist and staff we were told the unused treatment room was used by one of the dentists for adjustments to prostheses such as dentures because it had a gas outlet present. The dentist carried out the procedure while the patient stayed in the other treatment room. However, we saw the treatment room appeared dirty including the floor and sink. We observed other areas of the practice to be clean and clutter free.

We also noted that the dental unit water lines were not maintained in accordance with current infection control guidelines to prevent the growth and spread of Legionella bacteria. Flushing of the water lines was carried out for two minutes in the morning only. Guidelines state that they should also be flushed for 30 seconds between patients and two minutes at the end of the day.

A Legionella risk assessment had been carried out by an appropriate contractor and documentary evidence was provided to support this. Legionella is a bacterium found in the environment which can contaminate water systems in buildings.

There were hand washing facilities in each treatment room and staff had access to good supplies of personal protective equipment (PPE) for patients and staff members. Staff and patients confirmed that staff wore protective aprons, gloves and masks during assessment and treatment in accordance with infection control procedures.

Equipment and medicines

We found that all of the equipment used in the practice was maintained in accordance with the manufacturer's instructions. This included the equipment used to clean and sterilise the instruments and the X-ray sets. Portable appliance testing (PAT) was completed in accordance with good practice guidance. PAT is the name of a process which electrical appliances are routinely checked for safety. We also saw evidence that the premises had undergone a satisfactory full electrical safety check.

Monitoring health & safety and responding to risks

We were shown a comprehensive file of risk assessments covering all aspects of health and safety and clinical governance. These were maintained and up to date and highlighted significant hazards, those at risk, existing controls and/or action required.

There was a fire risk assessment that had been reviewed annually. Fire extinguishers were also serviced annually, fire alarms checked regularly and fire drills were held at regular intervals and recorded.

The practice did not have a business continuity plan to deal with any emergencies that may occur which could disrupt the safe and smooth running of the service. The management staff told us that there was a business continuity plan in place and showed us their arrangement for backing up data only. Staff we spoke with were not aware of any business continuity plan. We spoke with the management team about developing a more comprehensive business continuity plan.

Medical emergencies

There were arrangements in place to deal with some medical emergencies. The practice followed guidelines about how to manage emergency medicines in dental practice in accordance with the British National Formulary (BNF). The BNF is a pharmaceutical reference book that contains a wide spectrum of information and advice on medicines.

The emergency medicines were all in date and securely stored in a central location known to all staff. The expiry dates of medicines and equipment were monitored using a book which enabled the staff to replace out of date items and equipment in a timely manner. This demonstrated that the risk to patients during a dental appointment was reduced.

We enquired about the availability of an Automated External Defibrillator (AED). An AED is a portable electronic device that analyses life threatening irregularities of the heart and is able to deliver an electrical shock to attempt to restore a normal heart rhythm. We saw that an AED was locked away out of use because it was due maintenance. We did not see any evidence that arrangements had been made for its maintenance. In the event of a medical emergency where an AED would be required the practice would not be able to respond appropriately.

Are services safe?

Medical oxygen is widely used in healthcare settings and can be applied for the resuscitation of patients in a medical emergency. However, we saw that the oxygen cylinder had not been serviced since 2008. This did not ensure that the oxygen met applicable standards of quality and safety to enable the practice to respond appropriately to a medical emergency where medical oxygen would be required.

Staff recruitment

Records we reviewed contained evidence that most recruitment checks had been undertaken prior to employment. For example, proof of identification, references, qualifications, registration with the appropriate professional body.

Two of the current dentists working at the practice were the previous providers. The current provider had taken over the practice a couple of years previously. Some of the staff working at the practice had been employed by the previous provider and had undergone Disclosure and Barring Service (DBS) checks. DBS checks help to identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable. However, newer staff employed by the current provider had not undergone DBS checks, one of whom was a dental nurse. We asked the mangers if all clinical staff were subject to DBS checks before employment. The managers told us that they did not consider dental nurses to be clinical staff and told us their policy was to carry out risk assessments instead. If the risk assessment identified a requirement for a DBS check then it was carried out. We saw risk assessments were not robust because it stated that dental nurses were not left on their own with a patient during treatment. This was because we noted one of the dentists left the patient and the nurse while they used another treatment room for prostheses procedures and the risk assessment did not take this into account. Also, dental nurses need to be registered with the General Dental

Council (GDC) similar to dentists. GDC is the statutory body responsible for regulating dentists, dental therapists, dental hygienists, dental nurses, clinical dental technicians and dental technicians.

We reviewed records of a dentist and two dental nurses. We saw evidence that a new dentist recruited recently had undergone a DBS check. However, the dentist had undergone this check at their previous employer and was not transferrable. One of the dental nurse had been employed by the previous provider and had undergone a DBS check. The other dental nurse did not have a DBS check and was employed by the current provider.

Radiography (X-rays)

The practice was working in accordance with the lonising Radiation Regulations 1999 (IRR99) and the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R). They had a named Radiation Protection Adviser and Supervisor and a well maintained radiation protection file. This contained the required information including the local rules and inventory of equipment, critical examination packs for each X-ray machine and the expected three yearly maintenance logs.

We observed appropriate staff had received training in radiography as required by the General Dental Council (GDC) and IRMER. The GDC registers all dental care professionals to make sure they are appropriately qualified and competent to work in the United Kingdom. We looked at examples of X-rays taken by the dentist present during the inspection. X-rays were part of the patient electronic dental care record all radiographs taken were digital. Radiographs were taken in line with national guidance as defined by the Faculty of General Dental Practitioners (FGDP). FGDP is part of the Royal College of Surgeons that aims to promote excellent standards in primary dental care. This ensured that radiographs were only taken when clinically necessary by suitably qualified clinicians and the findings for each radiograph were justified and acted upon.

Are services effective?

(for example, treatment is effective)

Our findings

Consent to care and treatment

The dentist we spoke with told us that they discussed treatment options with patients including private and NHS treatment options. The patients we spoke with confirmed that they understood their treatment options and had consented to treatment. However, this was not always recorded when we reviewed a sample of patient notes. Also, patients booking for an appointment or entering the practice were not asked if they wanted private or NHS treatment until they had gone into the treatment room to see the dentist. A member of reception staff we spoke with told us that they did not discuss fees with patients and this was left for the dentist.

We discussed the process for getting consent with the dentist demonstrated some understanding of obtaining informed consent from children. However, they did not demonstrate full understanding of Gillick competency. Gillick competency is used to help assess whether a child has the maturity to make their own decisions and to understand the implications of those decisions.

Monitoring and improving outcomes for patients

The dentist we spoke with was aware of current National Institute for Health and Care Excellence (NICE) guidelines to assess each patient's risks and needs. For example, they were aware of guidance around antibiotic prescribing, wisdom teeth removal and to determine how frequently to recall patients.

Patient's needs were assessed and dental care and treatment was planned and delivered in line with their individual treatment plans. We looked at a sample of electronic dental care records. The records contained details of the condition of the patient's gums and soft tissues lining the mouth. These examinations were carried out at each dental health assessment.

Working with other services

The practice was part of a group of practices and worked with other professionals within the group through referrals.

We also saw referrals were made to hospitals and specialist dental services for further investigations and orthodontic treatment. We saw referral letters with details with reason for referral and other relevant information. However, referral to an orthodontist at another group practice was not so detailed as it was an internal referral.

Health promotion & prevention

The dentist we spoke with had a satisfactory understanding of preventative care. The dentist told us how they supported people to ensure better oral health. Fluoride applications for children, smoking cessation and dietary advice were provided. There was a selection of leaflets also available to help patients and a dental nurse was trained in oral health education so that they could provide oral health advice to patients under the direction of a dentist.

Staffing

Staff had received most core training considered by the provider to be mandatory. They included cardiopulmonary resuscitation (CPR), infection control and safeguarding children. However, staff had not been trained in safeguarding adults.

We saw evidence of regular appraisals conducted by management. Any learning identified was then incorporated into a personal development plan. For example, we spoke with a staff member who told us that they were given the role of team leader. This role was to supervise other dental nurses and to ensure appropriate infection control guidance is being followed. They were provided with internal training for the role. The staff member also told us that they discussed the needs of their role during their appraisal with the trainee practice manager who had identified an appropriate course for them to attend. The staff member also told us that they had attended some courses as part of maintaining their continuous professional development (CPD) which was paid for by the practice. CPD refers to the process of tracking and documenting the skills, knowledge and experience gained both formally and informally at work, beyond any initial training.

Are services caring?

Our findings

Respect, dignity, compassion & empathy

We observed all staff treated patients with dignity and respect. The patients we spoke with were positive about the care and treatment they had received from the practice. They told us they were given choices and options with respect to their dental treatment in language they could understand. They said they were treated with respect and dignity at all times.

Staff and patients told us all consultations and treatments were carried out in the privacy of a surgery and we observed this to be the case. We observed the treatment room door was closed during consultations and that conversations taking place in these rooms could not be overheard.

Involvement in decisions about care and treatment

The practice displayed information in the waiting area that gave details of NHS dental charges and also private fees. However, we found the private fees difficult to understand and confusing especially around initial consultations as it was price matched to NHS fees but did not include other services such a scale and polish.

The dentist we spoke with confirmed treatment options, risks and benefits were discussed with each patient to ensure the patient understood what treatment was available so they were able to make an informed choice. However, these discussions were not recorded on the patient notes we looked at. Furthermore, we were told by the staff and the dentist that options for private and NHS treatment was only offered once the patient had been to see the dentist.

Records we looked at showed that patients were given a copy of their signed treatment plan and associated costs.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting patient's needs

The practice provided patients with information about the services they offered on their practice website and in the waiting area. We found the practice had an efficient appointment system in place to respond to patients' needs. There were no emergency appointment slots available but we were told by the practice staff that any emergency patients were always seen within the day.

We observed that appointments ran smoothly on the day of the inspection and patients were not kept waiting. Patients commented that they had sufficient time during their appointment and that they were seen promptly.

During the inspection we saw a patient register with the practice for treatment. The patient told staff that they suffered from memory loss. The staff member informed them that they would send them text message reminders for their appointment. The patient was provided with all the information they needed including a medical history form so that any medical needs could be taken into account before treatment.

On the day of our inspection a patient had attended for an appointment that had been cancelled. The practice had sent a text message reminder to the patient but the patient had not updated their details with the practice and had not received the text. The patient was seen by another dentist and their records were updated on the practice computer system.

Tackling inequity and promoting equality

Staff told us that they were able to arrange an interpreting service if needed. Some of the staff were able to speak other languages spoken in the community including Urdu and Punjabi and Serbian.

A reception staff member told us that they had large print leaflets available. They were unable to find it on the day of the inspection but told us that they usually have large print leaflets. They also told us that they normally worked at another group practice where they had large print leaflets but would ensure to request some for this practice.

A staff member we spoke with told us that they had recently introduced evening appointment times every Thursday between 6pm and 9pm. The staff member confirmed that both NHS and private patients were booked in these slots.

Access to the service

The practice displayed its opening hours in their premises and on the website. There was a folder in the reception area with information on services available and the costs. The practice had clear instructions for patients requiring urgent dental care when the practice was closed. CQC comment cards showed patients felt they had good access to routine and urgent dental care.

The practice treatments rooms were on the first floor of the premises. Staff members we spoke with told us that they would refer patients to a group practice if they could not be treated at this surgery if they had difficulties with their mobility.

Concerns & complaints

The practice had a complaints policy and procedure was in place for handling complaints. The area manager was responsible for handling any concerns or complaints raised. We saw that the website informed patients of the complaints procedure and patients were able to make a complaint directly to the complaints manager online if they were unhappy with the service. Staff we spoke with were familiar with the guidance and told us the area manager was responsible for handling complaints and any issues would be forwarded to them to respond.

We looked at the complaints record and saw that the practice had received two complaints in the last year. We saw both complaints were received via NHS England and were still in the process of being resolved.

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

Our findings

Leadership, openness and transparency

There was a quality policy displayed in the reception area so that patients were made aware of the practices quality assurance process to deliver quality care. The practice had a statement of purpose that described their vision, values and objectives which was submitted to the Care Quality Commission (CQC) before the inspection.

There were arrangements for sharing information across the practice including practice meetings which were documented for those staff unable to attend. Staff members we spoke with told us that they were able to add agenda items to the meetings if they wanted to discuss or needed clarification.

There was a clear leadership structure with the trainee manager responsible for day to day running of the practice. It was clear that the trainee practice manager was developing in the role and needed support from the other managers. The other managers we spoke with told us that they were supporting the trainee manager who had started in the role recently.

The practice had a whistle blowing policy which was available to all staff. However, some staff members we spoke with were unaware of the policy.

Governance arrangements

The practice had identified a number of leads in relation to governance. These included health infection prevention control, the audit process, safeguarding, training and complaint handling. Leadership was provided by the trainee practice manager and they were supported by other managers within the group.

A system was in place to regularly audit the services provided. We looked at several audits on the day of our inspection. These included patient records, medical emergencies, infection prevention control and X-ray audits. However, when we spoke with the dentist they told us that

they were not involved in audits. The management team were present at the time and they told us later that they carried out all the audits and shared this with the dental team.

Practice seeks and acts on feedback from its patients, the public and staff

The practice had a comments box and we saw evidence of comments collected every month which were kept in a folder. The practice also conducted regular monthly surveys which were also kept in a folder. The practice gathered feedback from patients by inviting comments and feedback. Staff told us that they acted on the comments but did not regularly review these for any trends. Surveys we looked at, patients we spoke with and comments cards we received showed that patients were generally happy with the service being provided.

Staff we spoke with told us their views were sought at appraisals, team meetings and informally. They told us their views were listened to and ideas adopted.

Management lead through learning and improvement

There was an appraisal process used to identify developmental, learning and training needs of staff members to improve performance. A staff member we spoke with told us that they had taken on a lead role and their training needs were identified through the appraisal process.

All dentists and nurses who worked at the practice were registered with the General Dental Council (GDC). The GDC registers all dental care professionals to make sure they are appropriately qualified and competent to work in the United Kingdom. Staff were encouraged and supported to maintain their continuous professional development (CPD) as required by the GDC.

We saw evidence that feedback from patients was sought through regular surveys and comments via the comments box. However, they were not always reviewed effectively to improve service. There was a complaints system and we saw that the practice was dealing with two complaints. Learning had yet to be identified and shared with the staff as the complaints was still on-going.

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider did not ensure service users were protected against the risks of inappropriate or unsafe care by identifying, assessing and managing risks relating to their health and welfare. This includes maintenance of emergency equipment, adequate flushing of dental water lines, managing risk to business continuity and ensuring staff attend relevant training. This was in breach of regulation 9 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, which corresponds to regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity

Diagnostic and screening procedures

Surgical procedures

Treatment of disease, disorder or injury

Regulation

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

The provider did not operate effective recruitment procedures in order to ensure that staff employed for the purposes of carrying on regulated activities were of good character. Risk assessments in place were not robust.

This was in breach of regulation 21 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010, which corresponds to regulation 19 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.