Dr. Darshan Patel

Invisibrace

Inspection report

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Overall summary

We carried out this announced inspection on 6 September 2021 under section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. We planned the inspection to check whether the registered provider was meeting the legal requirements in the Health and Social Care Act 2008 and associated regulations. The inspection was led by a Care Quality Commission, (CQC), inspector who was supported by a specialist dental adviser.

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

• Is it safe?

• Is it effective?

• Is it well-led?

These questions form the framework for the areas we look at during the inspection.

Our findings were:

Are services safe?

We found this practice was not providing safe care in accordance with the relevant regulations.

Are services effective?

We found this practice was providing effective care in accordance with the relevant regulations.

Are services well-led?

Summary of findings

We found this practice was not providing well-led care in accordance with the relevant regulations.

Background

Invisibrace is in Surbiton in the London Borough of Kingston-upon-Thames and provides private dental care and treatment for adults and children.

The practice is located close to public transport links and car parking spaces are available near the practice.

The dental team includes a principal orthodontist, one dentist, one dental nurse, one trainee dental nurse, one hygienist, one orthodontic therapist, a business manager, a marketing coordinator, a receptionist and a practice manager. The practice has two treatment rooms.

The practice is owned by an individual who is the principal orthodontist there. They have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated regulations about how the practice is run.

During the inspection we spoke with the principal orthodontist, the dental nurse and the practice manager. We looked at practice policies and procedures and other records about how the service is managed.

The practice is open:

Monday – Saturday: 9:15pm - 5:30pm

(Open 2 Saturdays per month)

Our key findings were:

- The practice appeared to be visibly clean and well-maintained.
- The clinical staff provided patients' care and treatment in line with current guidelines.
- Staff provided preventive care and supported patients to ensure better oral health.
- The provider asked staff and patients for feedback about the services they provided.
- The provider had information governance arrangements.
- The provider had safeguarding processes and staff knew their responsibilities for safeguarding vulnerable adults and children. Improvements were needed to ensure all staff undertook training as required.
- Staff knew how to deal with emergencies. Appropriate life-saving equipment and some medicines were available however, improvements were needed to ensure all medicines were available as recommended and the equipment was within the use-by date.
- Risks to staff and patients from undertaking of the regulated activities had not been suitably identified and mitigated.
- The provider had staff recruitment procedures. Improvements were needed to ensure that checks were carried out consistently for all staff at the time of recruitment and records available.
- There was ineffective leadership and a lack of management oversight for the day-to-day running of the service.
- There were ineffective systems to ensure facilities were safe and equipment was serviced and maintained according to manufacturers' guidance.
- There were ineffective arrangements to monitor staff training and development needs and to ensure 'highly recommended' training was carried out.

We identified regulations the provider was not complying with. They must:

Summary of findings

- Ensure care and treatment is provided in a safe way to patients.
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.

Full details of the regulations the provider was not meeting are at the end of this report.

There were areas where the provider could make improvements. They should:

- Review the practice protocols regarding auditing patient dental care records to check that necessary information is recorded.
- Implement an effective system for identifying, disposing and replenishing of out-of-date stock.
- Take action to ensure the service takes into account the needs of patients with disabilities and to comply with the requirements of the Equality Act 2010.

Summary of findings

The five questions we ask about services and what we found

We asked the following question(s).

Are services safe?	**Requirements notice** 
Are services effective?	**No action** 
Are services well-led?	**Enforcement action** 

Are services safe?

Our findings

We found this practice was not providing safe care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Requirement Notices section at the end of this report). We will be following up on our concerns to ensure they have been put right by the provider.

Safety systems and processes, including staff recruitment, equipment and premises and radiography (X-rays)

Staff knew their responsibilities if they had concerns about the safety of children, young people and adults who were vulnerable due to their circumstances. The provider had safeguarding policies and procedures to provide staff with information about identifying, reporting and dealing with suspected abuse. On the day of the inspection, records were not available to demonstrate all staff had undertaken safeguarding training as required. Staff we spoke to knew about the signs and symptoms of abuse and neglect and how to report concerns, including notification to the CQC.

The provider had a system to highlight vulnerable patients and patients who required other support such as with mobility or communication, within dental care records.

The provider had an infection prevention and control policy and procedures. They followed guidance in The Health Technical Memorandum 01-05: Decontamination in primary care dental practices, (HTM 01-05), published by the Department of Health and Social Care. Staff completed infection prevention and control training and received updates as required.

The provider had arrangements for transporting, cleaning, checking, sterilising and storing instruments in line with HTM 01-05. The records showed equipment used by staff for cleaning and sterilising instruments was validated, maintained and used in line with the manufacturers' guidance. The provider had suitable numbers of dental instruments available for the clinical staff and measures were in place to ensure they were decontaminated and sterilised appropriately.

The staff carried out manual cleaning of dental instruments prior to them being sterilised.

The staff had systems in place to ensure that patient-specific dental appliances were disinfected prior to being sent to a dental laboratory and before treatment was completed.

We saw the practice had procedures to reduce the possibility of Legionella or other bacteria developing in the water systems in the form of a risk assessment. We looked at the risk assessment carried out in 2017 and noted that a number of recommendations had been made. These included having a system for disinfecting the dental unit waterlines and monitoring the temperature of hot and cold-water taps. A system had been implemented to disinfect the dental unit waterlines and the nurse was able to show us records to demonstrate this was an ongoing process. However a system to monitor the hot and cold temperatures had not been implemented in line with the risk assessment recommendations and staff training had also not been carried out as recommended.

We saw effective cleaning schedules to ensure the practice was kept clean. When we inspected we saw the practice was visibly clean.

The principal orthodontist described the procedures in place in relation to COVID-19. Additional standard operating procedures had been implemented to protect patients and staff from Coronavirus. These included social distancing and screening measures which had been implemented. We saw evidence that Personal Protective Equipment was in use and staff had been appropriately fit tested for filtering facepiece masks (FFP).

The provider had policies and procedures in place to ensure clinical waste was segregated and stored appropriately in line with guidance. However, on the day of the inspection we noted the clinical waste bin located to the rear of the practice was locked but was not secured as required. Improvements were also needed to ensure important records of waste collections are available and stored according to requirements.

Are services safe?

The dental nurse carried out infection prevention and control audits and the latest one, carried out in June 2021, showed the practice was meeting the required standards. Improvements were needed to ensure the audits were carried out on a six-monthly basis in accordance with HTM 01-05.

The provider had whistleblowing policy. Staff felt confident they could raise concerns without fear of recrimination.

The provider had a recruitment policy and procedure to help them employ suitable staff. These reflected the relevant legislation. On the day of the inspection we looked at four staff recruitment records and found these to be incomplete. Disclosure and Barring Services (DBS) checks had not been carried out, at the time of recruitment, for all members of staff and there was no evidence the risks around this had been considered. Records were also not available for all clinical staff in relation to their vaccination against Hepatitis B and whether the efficacy of the vaccination had been checked. Improvements were needed to ensure risks are mitigated by carrying out all relevant checks at the time of recruitment.

We observed that clinical staff were qualified and registered with the General Dental Council and had professional indemnity cover.

The provider did not ensure all facilities and equipment were safe, and that equipment was maintained according to manufacturers' instructions. On the day of the inspection we noted the fixed-wire electrical installation testing had not been carried out.

There were no records available to assure us that the compressor had been serviced since 2016, nor whether one of the dental chairs had been serviced. Staff were also unaware of the servicing requirements for the ultrasonic bath, used to assist with cleaning instruments, and no servicing records were available.

A fire risk assessment was not available for review on the day of the inspection. We saw there were fire extinguishers and fire detection systems throughout the building and fire exits were kept clear.

We noted that the fire extinguishers had been categorised as 'condemned' at a recent service on the 27 August 2021, no replacement extinguishers had been ordered.

There were no records to indicate that the smoke detectors were tested regularly, and no staff training or fire drills were carried out.

We noted four emergency lights were not working on the day of the inspection and this had initially been recorded in the logbook in 2017.

The practice had arrangements to ensure the safety of the intra-oral X-ray equipment and we saw the required radiation protection information was available.

We saw evidence the clinicians justified, graded and reported on the radiographs they took. The provider carried out radiography audits every year following current guidance and legislation.

On the day of the inspection, records were not available for all clinical staff in relation to radiation protection training. Checks should be introduced to ensure clinical staff carry out updated training at the required interval.

The practice had a cone beam computed tomography (CBCT) X-ray machine. On the day of the inspection we could not be assured that all clinical staff, involved in taking this form of X-ray, had received training in the use of it. There were also no records available to demonstrate that the CBCT equipment was tested and checked in accordance with current national regulations and guidance.

Risks to patients

The provider had ineffective systems to assess, monitor and manage risks to patient safety.

Are services safe?

The provider had health and safety policies and procedures; however, improvements were needed to the practice's risk management processes. There was no general practice health and safety risk assessment available for review on the day of the inspection.

The provider had current employer's liability insurance.

We looked at the practice's arrangements for safe dental care and treatment. A risk assessment had been carried out for the dentist who chose not to use Safer-Sharps while carrying out dental treatments; however, a general sharps risk assessment was needed that considered risks relating to all forms of sharps.

The risks associated with having latex products, such as orthodontic elastic-bands, had not been considered and mitigated in the form of a risk assessment. The provider told us they would check the patient's medical history for any allergies.

Staff told us they had received appropriate vaccinations. Improvements were needed to ensure records were available to demonstrate that clinical staff had received appropriate vaccinations, including vaccination to protect them against the Hepatitis B virus, and that the effectiveness of the vaccination was checked.

Staff had discussed the signs and symptoms of sepsis and posters were available in the practice. This helped ensure staff made triage appointments effectively to manage patients who present with dental infection and where necessary refer patients for specialist care.

Staff knew how to respond to a medical emergency however improvements were needed to ensure records are available to demonstrate all staff complete training in emergency resuscitation and basic life support as per current guidance.

On the day of the inspection we found the medicines used to treat medical emergencies, were available as recommended, with the exception of the medicine used to treat epileptic seizures. The provider took action on the day of the inspection and this was available for use the following day.

The medicine used to treat low blood sugar was stored in a locked fridge and the risks around this had not been considered. The provider took steps immediately after the inspection to mitigate the risks. We also noted the fridge temperature was not being monitored to ensure that medicines and dental care products were being stored in line with the manufacturer's guidance.

The provider had also not considered the risks of not having repeat doses of Adrenaline available for use in the event of Anaphylaxis.

The provider had a system for monitoring the Automated External Defibrillator (AED) and improvements were needed to include all the medical emergency equipment and medicines; to make sure they were available, within their expiry date, stored correctly and in working order. For example, on the day of the inspection we noted the paediatric pads, for use with the AED were beyond their use-by date and no replacements had been ordered. We received confirmation these were ordered immediately after the inspection.

A dental nurse worked with the clinicians when they treated patients in line with General Dental Council Standards for the Dental Team.

On the day of the inspection, the provider had information available in relation to the Control of Substances Hazardous to Health (COSHH). Improvements were needed to ensure the information is organised and easily accessible. Risk assessments are also required for individual materials to ensure they are up-to-date and mitigating actions are available.

Information to deliver safe care and treatment

Staff had the information they needed to deliver safe care and treatment to patients.

Are services safe?

We discussed with the clinicians how information to deliver safe care and treatment was handled and recorded. We looked at dental care records with clinicians to confirm our findings and observed that individual records were typed and managed in a way that kept patients safe. Dental care records we saw were complete, legible, were kept securely and complied with General Data Protection Regulation requirements.

The provider had systems for referring patients with suspected oral cancer under the national two-week wait arrangements. These arrangements were initiated by National Institute for Health and Care Excellence to help make sure patients were seen quickly by a specialist.

Safe and appropriate use of medicines

The clinicians were aware of current guidance with regards to prescribing medicines.

Improvements were needed to the monitoring system to ensure out of date materials were disposed of appropriately. On the day of the inspection we found some out of date materials in one of the surgeries. We raised this with the practice and they immediately took steps to adequately dispose the out of date materials.

Track record on safety, and lessons learned and improvements

The provider had implemented systems for reviewing and investigating when things went wrong. Staff monitored and reviewed incidents. In the previous 12 months there had been no safety incidents. We saw evidence that safety incidents were investigated, documented and discussed with the rest of the dental practice team to prevent such occurrences happening again.

The provider had a system for receiving and acting on safety alerts. Staff learned from external safety events as well as patient and medicine safety alerts. We saw they were shared with the team and acted upon if required.

Are services effective?

(for example, treatment is effective)

Our findings

We found this practice was providing effective care in accordance with the relevant regulations.

Effective needs assessment, care and treatment

The practice had systems to keep dental professionals up to date with current evidence-based practice. We saw clinicians assessed patients' needs and delivered care and treatment in line with current legislation, standards and guidance supported by clear clinical pathways and protocols.

The orthodontist carried out a patient assessment in line with recognised guidance from the British Orthodontic Society. An Index of Orthodontic Treatment Need was recorded which would be used to determine whether a patient was eligible for NHS orthodontic treatment. The patient's oral hygiene was also assessed to determine if the patient was suitable for orthodontic treatment.

Helping patients to live healthier lives

The clinicians prescribed high concentration fluoride products if a patient's risk of tooth decay indicated this would help them.

The clinicians where applicable, discussed smoking, alcohol consumption and diet with patients during appointments.

The clinicians described to us the procedures they used to improve the outcomes for patients with gum disease. This involved providing patients with preventative advice, taking plaque and gum bleeding scores and recording detailed charts of the patient's gum condition.

Records showed patients with severe gum disease were recalled at more frequent intervals for review and to reinforce home care preventative advice.

Consent to care and treatment

Staff obtained consent to care and treatment in line with legislation and guidance.

The practice team understood the importance of obtaining and recording patients' consent to treatment. The staff were aware of the need to obtain proof of legal guardianship or Power of Attorney for patients who lacked capacity or for children who are looked after. The clinicians gave patients information about treatment options and the risks and benefits of these, so they could make informed decisions. We saw this documented in patients' records.

The practice's consent policy included information about the Mental Capacity Act 2005. The team understood their responsibilities under the act when treating adults who might not be able to make informed decisions. The policy also referred to Gillick competence, by which a child under the age of 16 years of age may give consent for themselves in certain circumstances. Staff were aware of the need to consider this when treating young people under 16 years of age.

Staff described how they involved patients' relatives or carers when appropriate and made sure they had enough time to explain treatment options clearly.

Monitoring care and treatment

The practice kept detailed dental care records containing information about the patients' current dental needs, past treatment and medical histories. The clinicians assessed patients' treatment needs in line with recognised guidance.

Improvements were needed to the quality assurance processes to encourage learning and continuous improvement. The provider should review the practice protocols regarding auditing patient dental care records to check that necessary information is recorded and share the results of these audits, the resulting action plans and improvements with staff.

Are services effective?

(for example, treatment is effective)

Effective staffing

Overall we found staff had the skills, knowledge and experience to carry out their roles; however improvements were needed to ensure staff have adequate training when using equipment; in particular, records were not available to assure us all staff operating the CBCT had undergone the required level of training

Staff new to the practice had a structured induction programme. Improvements were needed to the monitoring systems to ensure all clinical staff carried out training as recommended by the General Dental Council professional standards.

Co-ordinating care and treatment

Staff worked together and with other health and social care professionals to deliver effective care and treatment.

The clinicians confirmed they referred patients to a range of specialists in primary and secondary care for treatment the practice did not provide.

The practice was a referral clinic for orthodontic procedures, and we saw staff monitored and ensured the dentists were aware of all incoming referrals daily. Staff monitored referrals through a referral and tracking system to ensure they were responded to promptly.

Are services well-led?

Our findings

We found this practice was not providing well-led care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Enforcement Actions section at the end of this report).

We will be following up on our concerns to ensure they have been put right by the provider.

Leadership capacity and capability

We found that there was ineffective leadership which impacted on the practice's ability to deliver safe, high

quality care. The principal orthodontist could not assure us that they and their senior staff understood risks pertaining to the management of the service and the delivery of care.

Culture

Staff we spoke with stated they enjoyed and were proud to work in the practice.

Leaders at all levels were visible and approachable. Staff told us they worked closely with them to make sure they prioritised compassionate and inclusive leadership.

Openness, honesty and transparency were demonstrated when responding to incidents and complaints. The provider was aware of and had systems to ensure compliance with the requirements of the Duty of Candour.

Staff could raise concerns and were encouraged to do so, and they had confidence that these would be addressed.

Governance and management

The principal orthodontist had overall responsibility for the management and clinical leadership of the practice and the practice manager was responsible for the day to day running of the service.

Staff knew the management arrangements and their roles and responsibilities.

The practice did not have effective systems for governance in relation to the management of the service.

The practice policies and procedures were reviewed regularly.

The processes for managing risks were ineffective. The practice did not have adequate systems in place for recognising, assessing and mitigating risks in areas such as the medicines used to treat emergencies, storage and handling of sharps, fire safety and Legionella.

Where risks had been highlighted and recommendations made in risk assessments, there were no systems in place to ensure the relevant audits, reviews and training had been carried out. This included, for example the Legionella risk assessment.

Appropriate and accurate information

Staff acted on appropriate and accurate information.

The provider had information governance arrangements and staff were aware of the importance of these in protecting patients' personal information.

Engagement with patients, the public, staff and external partners

Staff involved patients, the public, staff and external partners to support the service.

Are services well-led?

The provider used patient surveys and encouraged verbal and online comments to obtain staff and patients' views about the service.

The provider gathered feedback from staff through meetings and informal discussions. Staff were able to offer suggestions for improvements to the service.

Continuous improvement and innovation

The provider had some quality assurance processes to encourage learning and continuous improvement. These included audits of disability access and infection prevention and control. Improvements were needed to ensure these audits were carried out at the required intervals and were reflected in the practice protocols. On the day of the inspection we saw a disability access audit that was not reflective of the facilities available at the practice to support patients with additional needs.

On the day of the inspection we could not be assured all staff completed 'highly recommended' training, for example in relation to Basic Life Support (BLS), as per General Dental Council professional standards.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 CQC (Registration) Regulations 2009 Statement of purpose **The registered person had not done all that was reasonably practicable to mitigate risks to the health and safety of service users receiving care and treatment. In particular:** • The fixed-wire electrical installation testing had not been carried out. • There was no evidence the compressor had been serviced since 2016. • We could not be assured one of the dental chairs had been serviced. • There was no evidence a fire safety risk assessment had been carried out and the risks associated with fire had been appropriately assessed and mitigated. • We could not be assured the fire safety equipment such as smoke alarms and emergency lighting were tested and checked. • The only fire extinguishers available on the day of the inspection had been certified as 'condemned' at a recent inspection on 27 August 2021 and had not been replaced. **Regulation 12 (1)**

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **Systems or processes must be established and operated effectively to ensure compliance with the requirements of the fundamental standards as set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.** **The registered person had systems or processes in place that operated ineffectively in that they failed to enable the registered person to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk. In particular:** • There were ineffective systems for assessing the risks and monitoring the medicines and equipment used for the treatment of medical emergencies taking into account relevant guidance. • There was no general sharps risk assessment at the practice that considered the risks associated with all forms of sharps and the provider had not considered nor mitigated those risks to staff. • Individual risk assessments had not been carried out in relation to the storage and handling of hazardous substances and the information available was disorganised. • There was no risk assessment available to consider general health and safety risks. • Recommendations made in the Legionella risk assessment carried out 10 January 2017 had not been implemented. In particular, the provider did not carry out water temperature monitoring as part of an ongoing process to assess and mitigate the risks associated with Legionella or other bacterial growth in the water systems. • We could not be assured that the Cone Beam Computed Tomography (CBCT) equipment was tested and checked in accordance with national regulations.

This section is primarily information for the provider

Enforcement actions

There were no systems or processes that ensured the registered person had maintained securely such records as are necessary to be kept in relation to persons employed in the carrying on of the regulated activity or activities. In particular:

- There were ineffective arrangements to monitor staff training and development needs.
- There were ineffective systems for ensuring staff recruitment files where up-to-date and contained evidence that all important checks had been carried out at the point of recruitment.
- There were ineffective systems to ensure all staff operating the CBCT had undergone the required level of training.

Regulation 17 (1)