Dr. Antonia Paolella

The Gentle Dentist

Inspection report

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Overall summary

We carried out an announced inspection on 18 May 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 usually ask five key questions, however due to the ongoing pandemic and to reduce time spent on site, only the following three questions were asked:

• Is it safe?

• Is it effective?

• Is it well-led?

These questions form the main 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 not 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

The Gentle Dentist is located in London's West End of Covent Garden in the London Borough of Camden. Recent published data shows that oral health in Camden was comparable to other London boroughs, however it was higher than England average. The practice provides private treatments to patients of all ages from a converted terraced property. The practice offered conscious sedation to adults which is undertaken by a visiting anaesthesiologist and the principal dentist.

The first two floors of the building consist of four surgeries, a separate decontamination room, reception area and a waiting room. The third floor is a flat where the provider resides. There was also a dental laboratory, however this was a separate entity to the practice.

The practice is situated close to public transportation services and local amenities including supermarkets and a post office.

The dental team includes the principal dentist who leased the practice, a visiting specialist orthodontist, a visiting endodontist, two dental hygienists, two full time dental nurses and a full-time practice manager.

The practice is run by an individual who is the principal dentist 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.

The practice is open:

Monday: 09:00 - 20:00

Tuesday: 09:00 - 21:00

Wednesday: 08:00 - 18:00

Thursday: 08:00 - 18:00

Friday: 08:00 - 16:00

During out of hours, patients are advised to contact the dedicated phone number for advice and or treatment.

On the day of the inspection we spoke with the principal dentist, two dental nurses, one dental hygienist, one receptionist/practice manager. We looked at practice policies and procedures and other records about how the service is managed.

Our key findings were:

- The practice appeared to be visibly clean and well-maintained.
- Staff had access to personal protective equipment (PPE), however they had not been fit tested for respiratory protective equipment.

Summary of findings

- The provider had safeguarding policies and procedures to provide staff with information about identifying, reporting and dealing with suspected abuse.
- The provider had not taken reasonable steps to identify, mitigate and manage the risks to patients specifically to those relating to fire safety, legionella and electrical safety.
- We found patients were at risk of harm as the provider was failing to comply with national guidance on conscious sedation in primary dental care settings.
- We found recruitment checks needed improving to keep patients safe.
- The provider did not have processes to receive patient safety alerts.
- Staff treated patients with dignity and respect and took care to protect their privacy.
- Staff provided preventive care and supported patients to ensure better oral health.
- The appointment system took account of patients' needs.
- Staff felt involved and supported and worked as a team.
- The provider's information governance arrangements needed improving to safeguard patients' personal information.

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

- 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

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

- Take action to ensure all clinicians are adequately supported by a trained member of the dental team when treating patients in a dental setting taking into account the guidance issued by the General Dental Council.
- Improve the practice's complaint handling procedures and establish an accessible system for identifying, receiving, recording, handling and responding to complaints by service users.
- Review all policies and procedures to ensure they reflect the way the practice operates.

Summary of findings

The five questions we ask about services and what we found

We asked the following question(s).

Are services safe?	**Enforcement action**
Are services effective?	**Enforcement 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 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.

The systems, processes and some practices at the dental surgery did not keep patients safe. At the inspection, we found they did not always provide care and treatment in line with current guidance relating to the provision of dental treatment under conscious sedation. We have taken enforcement action against the provider. This prevents them from providing operator-sedationist (where the dentist delivers sedation as well as carries out the required dental treatment) led dental treatments under conscious sedation until they can demonstrate to the Commission that steps have been put in place to improve conscious sedation systems, processes and practices to a safe standard.

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. We saw evidence that staff had received safeguarding training. Staff knew about the signs and symptoms of abuse and neglect and how to report concerns, including notification to the CQC.

The provider had infection prevention and control policy and procedures; however, they were not adhering to 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. For example:

- The process and procedures for the transfer of contaminated items from the treatment to the decontamination area as well as the transfer of sterilised instruments needed improving to minimise the risk of infection to patients. We noticed that, the same box was used interchangeably for the transportation of contaminated and sterilised instruments.
- Zoning of the decontamination room was not clearly laid out to demarcate between clean and contaminated areas.
- The dental surgery did not have a dedicated handwashing sink in the decontamination room, and we observed that the sink which was used for cleaning the instruments was also used for handwashing. Following the inspection, we were told builders had begun installing a separate handwashing sink.
- Staff involved with decontamination undertook manual cleaning of instruments using washing up liquid not designed for dental instruments. We raised this with the provider who was unaware and assured us they had now ceased this practice.
- Manually cleaned instruments were rinsed under the running tap instead of in a bowl.
- We noted they had a washer disinfector which was considered best practice had been serviced and maintained, however at the time of the inspection this was not used by staff to clean instruments prior to sterilisation.
- On the day of the inspection, we saw no evidence that staff had received mandatory training in infection prevention and control; we received evidence this had been done following the inspection.
- We were not assured the nominated Infection prevention and control (IPC) fulfilled the requirements of the role. They had not received appropriate training, neither were they able to demonstrate they had knowledge about the policies, HTM 01-05 guidance and sterilisation and decontamination practices. We were emailed evidence following the inspection that proper training was to be undertaken by the staff member on 14 June 2021.

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.

Are services safe?

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.

The provider had not done all that was reasonable to identify, mitigate and manage the risk from the exposure to legionella bacteria. We saw no documentary evidence to indicate the water was regularly tested and the dental unit water lines monitored. We raised this with the provider who told us the dental line was flushed regularly and water lines ran through daily; however, logs were not maintained. We did see evidence a legionella risk assessment was done on 17 May 2021; a copy of this was not received by the Commission at the time of writing.

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

The provider had policies and procedures in place, and we saw evidence of service contracts to ensure clinical waste was segregated and stored appropriately in line with guidance.

The provider carried out infection prevention and control audits twice a year and the latest audit showed the practice was meeting the required standards. However, we noted that the audit failed to highlight areas for improvement, for example, lack of IPC training, availability of handwashing sink and transportation of instruments.

Some arrangements were in place to manage the spread of Covid-19, however, improvements were needed in respect of personal protective equipment (PPE), specifically respiratory protective equipment, for example, FFP2, FFP3 facemasks which were now essential PPE for aerosol generating procedures (AGPs). In addition, this was a Health and Safety requirement.

The practice had a whistleblowing policy and staff we spoke with felt confident they could raise concerns without fear of recrimination.

The dentists used dental dam in line with guidance from the British Endodontic Society when providing root canal treatment. In instances where dental dam was not used, such as for example refusal by the patient, and where other methods were used to protect the airway, we saw this was documented in the dental care record and a risk assessment completed.

The practice had a recruitment policy; however, we found this was not followed, for instance, they had failed to undertake suitable recruitment checks on the trainee dental nurse and the cleaner in that:

- Risk assessments had not been carried out to decide if a Disclosure and Barring Service (DBS) criminal record check was required for the trainee dental nurse, we received evidence following the inspection that an application had been submitted.
- At the time of the inspection, the trainee dental nurse staff file did not include full history of employment.
- There was no documentary evidence of qualifications. The practice manager told us the trainee dental nurse was enrolled on the National Examining Board for Dental Nurses diploma course.

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

We found that the provider had not undertaken appropriate assessments to identify the risks associated with fire. We saw evidence the fire risk assessment was scheduled to take place on 19 May 2021 by an approved external organisation. On the day of the inspection, a visiting engineer mounted fire extinguishers throughout the building. We also noted that fire exits were kept clear.

The practice manager told us they did not carry out fire drills or checked the fire alarms; they told us the fire engineer visiting the next day would train staff how to check and document. We received evidence following the inspection that two members of staff were nominated fire wardens and had received appropriate training and that all other staff members had received training in fire safety.

Are services safe?

The practice had some arrangements to ensure the safety of the X-ray equipment; annual electrical and mechanical servicing was not carried out. We saw evidence this was scheduled to be done in July 2021.

The surgery maintained a folder with all the required radiation protection information.

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

We saw evidence clinical staff completed continuing professional development in respect of dental radiography.

Risks to patients

We found that not all systems to assess, monitor and manage risks kept patients safe from the risk of harm.

The practice offered conscious sedation for patients. This included patients who were very anxious about dental treatment and those who needed complex or lengthy treatment. We found these were not in accordance with guidelines published by the Royal College of Surgeons and Royal College of Anaesthetists in 2015 and improvements were needed to ensure service users were kept safe, For examples:

- We reviewed three dental care records for patients who had undergone dental care treatment under conscious sedation. We found only one patient had a record of the American Society of Anaesthesiologists (ASA) physical classification system score (ASA score) in their clinical notes and this was done by the visiting sedationist. The other two dental care records had no documented notes that the ASA score was checked pre-operatively. There was insufficient evidence on the day that satisfactory patient assessment was regularly undertaken.
- There was no evidence to suggest that the dental team, except the visiting sedationist, had the appropriate skills, knowledge and training to safely undertake conscious sedation, for examples:
- Immediate Life Support (ILS) training was last undertaken by the registered provider on 2 March 2018. This training, from the documents shown to us had a validity of one year.
- On reviewing patients' dental care records, we saw that one of the patients had been sedated with a combination of oral temazepam (30-40mg) and intravenous midazolam. As this involves two routes of administration, and a combination of drugs, this is considered an advanced technique. Drug combinations have less predictable effects than single drugs, and some anaesthetic drugs and infusions used for sedation have narrower therapeutic indices. Consequently, advanced sedation techniques are likely to have reduced margins of safety, potentially increasing the risk of adverse events.
- The provider had not ensured that the dental nurse assisting with conscious sedation procedures had received appropriate training. The dental nurse was enrolled on the National Examining Board for Dental Nurses (NEBDN) sedation course and were awaiting the final examination which got delayed due to the on-going pandemic.
- We found that there was lack of appropriate clinical monitoring of patients while they were undergoing the dental care procedure under conscious sedation. For example, two of the records we reviewed lacked details relating to the level of consciousness of sedation, airway patency, respiration and pulse monitoring. We saw evidence that blood pressure, pulse and oxygen levels were monitored; however, this was not done consistently. For example, they were only documented once for one patient who received conscious sedation for dental treatment. As a minimum, pre-operative, intra-operative and post-operative recordings should be taken and documented throughout the sedation event until point of discharge.

The practice's health and safety policies, procedures and risk assessments were reviewed and helped to mitigate some potential risks. The provider had current employer's liability insurance.

We looked at the practice's arrangements for safe dental care and treatment. The staff followed the relevant safety regulation when using needles and other sharp dental items. A sharps risk assessment had been undertaken.

The provider had a system in place to ensure clinical staff had received appropriate vaccinations, including vaccination to protect them against the Hepatitis B and Corona virus, and that the effectiveness of the vaccination was checked.

Are services safe?

Although staff had not completed sepsis awareness training, the clinical staff had knowledge of the recognition, diagnosis and early management of sepsis.

Staff knew how to respond to a medical emergency and had completed training in emergency resuscitation and basic life support.

Emergency equipment and medicines were available as described in recognised guidance except that the provider did not have Buccal Midazolam (Oromucosal Midazolam) as part of their standard emergency drugs. We raised this with the principal dentist who told us this was because they would use the midazolam used for sedation; this was rectified following our inspection.

We found staff kept records of their checks of these to make sure they were available and in working order. We found that the practice stored the Glucagon Hypokit outside of the fridge which was acceptable; however, they could not demonstrate the expiration date on the medicine had been revised as per current guidance.

The dentists were always supported by either a trainee or qualified dental nurse when they treated patients. The dental hygienist told us that at times they worked without chairside support, however we did not see any evidence they had risk assessed this in line with the General Dental Council Standards for the Dental Team.

The provider had risk assessments to minimise the risk that can be caused from substances that are hazardous to health.

Information to deliver safe care and treatment

Staff did not always have access to the most up to date information they needed to deliver safe care and treatment to patients.

We discussed with the dentist 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. Non-sedation dental care records we saw were complete, legible and for most part complied with General Data Protection Regulation requirements. Staff, however, did not always lock or log off the computers when unattended.

The systems for referring patients with suspected oral cancer under the national two-week wait arrangements was not formalised in that they had no way of following up on referrals. Following the inspection, we received evidence all staff had completed training in Oral Cancer awareness and a “referral log” was now in place. The two-week 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

There was a stock control system of medicines which were held on site. This ensured that medicines did not pass their expiry date and enough medicines were available if required. The provider told us antibiotics were seldomly prescribed and that if and when needed, prescriptions were electronically generated through individual dental care records.

Track record on safety, and lessons learned and improvements

The provider told us they had systems for reviewing and investigating when things went wrong. We reviewed incident/ significant policies and found them to be to a fair standard, however we saw no evidence staff proactively identified and recorded incidents; they told us in the previous 12 months there had been no administrative or clinical safety incidents.

The provider did not have a system for receiving and acting on safety alerts, for example those received from Medicines and Healthcare products Regulatory Agency (MHRA).

Are services effective?

(for example, treatment is effective)

Our findings

We found this practice was not providing effective 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.

Effective needs assessment, care and treatment

The practice had some systems to keep dental professionals up to date with current evidence-based practice. It was not always demonstrable that clinicians assessed patients' needs and delivered care and treatment in line with current legislation, standards and guidance.

Dental implants

The practice offered dental implants. These were placed by the principal dentist at the practice who had undergone appropriate post-graduate training in the provision of dental implants. We saw the provision of dental implants was in accordance with national guidance.

Helping patients to live healthier lives

The practice provided preventive care and supported patients to ensure better oral health in line with the Delivering Better Oral Health toolkit.

The dentists and dental hygienist 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 practice had a selection of dental products for sale and provided leaflets to help patients with their oral health.

The dental hygienist 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 principal dentist had a good understanding of the need to obtain proof of legal guardianship or Power of Attorney for patients who lacked capacity and gave us examples of this. The dentists 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' dental care 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.

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

Are services effective?

(for example, treatment is effective)

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

The provider undertook annual clinical record keeping audits sometimes with the input of an external peer reviewer. Staff kept records of the results of these audits, the resulting action plans and improvements.

Effective staffing

Staff did not always demonstrate they had the skills, knowledge and experience to carry out their roles effectively.

Staff new to the practice did not always receive a structured induction programme. For example, we found that the trainee dental nurse had changed role from cleaner to dental nurse, however the practice had failed to formalise this arrangement. The staff nominated as the Infection Prevention and Control lead had not received adequate training to ensure they were fit for the role.

We confirmed clinical staff completed the continuing professional development required for their registration with the General Dental Council.

Co-ordinating care and treatment

Staff worked together and with other health and social care professionals to deliver effective care and treatment, for example, visiting sedationist and orthodontist delivered specialist treatment to patients.

The dentists confirmed they referred patients to a range of specialists in secondary car services for treatment the practice did not provide. The referrals we reviewed included all the necessary information; however, the provider should take steps to improve and embed a more formalised approach.

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

Staff told us the principal dentist was visible and approachable and that they felt comfortable raising issues with them. On the day we observed staff members working as a team, for example, phone duties were not solely restricted to the receptionist/practice manager.

Although we identified concerns around the running of the service, the management team so far has been responsive, and we found there was a willingness to learn and improve the service.

Culture

The practice had a mission statement and that was "creating smiles with a gentle touch; reassuring, gentle care for all." We discussed the business and sustainability and the practice manager was able to give examples of medium and long term plans they had to offer patients more treatment options.

Most of the employed and visiting staff were all long standing members of the team and stated they felt respected, supported and valued. They were proud to work in the practice.

We did not see evidence staff discussed their training needs at annual appraisals or one to one meetings in the last two years.

The staff focused on the needs of patients and this was reflected by working closely with visiting specialists offering more complex treatments.

We saw one example of where the provider used the systems in place to deal with staff poor performance.

The provider told us openness, honesty and transparency were applied when investigating and responding to incidents and complaints because there were no records to review. The practice manager gave an example of when they responded to a patient who was unhappy about the appointment offered. They told us they apologised, explained what went wrong and that patient was happy with the outcome.

A whistleblowing policy was available, and staff told us they could raise concerns and were encouraged to do so, and had confidence that these would be addressed.

Appropriate and accurate information

The provider had some arrangements in place for information governance. However we saw evidence staff compromised patient's confidential information several times throughout the inspection, for instance, we noted computers in the surgeries on the first floor were left unattended and they had not utilised the operating system's screen locking function or logging out options. We raised this with the practice manager who told us action would be taken to remedy appropriately.

Governance and management

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

Are services well-led?

The provider had a system of clinical governance in place which included some policies, protocols and procedures that were accessible to all members of staff; they told us these were reviewed annually. We found that the governance processes were ineffective for most part and that the provider had not ensured staff understood their roles and responsibilities fully. The team was small and although they told us dialogue was regular and ongoing, we found these processes to be informal.

The provider had not sought to establish effective systems, processes and arrangements for managing risks, issues and performance. For examples:

- They did not always follow up-to-date guidance, for example, the provider had not ensured staff were fit tested for facemasks as stipulated in the most recent Covid-19 standard operating procedure (SOP).
- They failed to maintain up to date documentation for staff.
- They did not have formal induction arrangements in place for new employees or those changing roles.
- The lack of legionella, fire and electrical wiring risk assessments.
- They were failing to adhere to current guidance in relation to conscious sedation and infection prevention and control (IPC).
- They had no systems in place to monitor staff training and appraisals.
- Lack of oversight of the above demonstrated ineffective governance arrangements.

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.** There were no systems or processes that enabled the registered person to assess, monitor and improve the quality and safety of the services being provided. In particular: • The provider had no process to ensure safety alerts were received, reviewed, discussed and cascaded with team members. • The provider had no system to monitor staff training. • There was no formalised system which allowed the provider to keep up to date with current guidance, for example, fit testing of mask and infection control. • The lack of system for two-week wait referrals to secondary services. • The lack of oversight to ensure infection procedure and control (IPC) standards reflected published guidance. • The provider had not implemented effective system for recording, investigating and reviewing incidents or significant events with a view to preventing further occurrences and ensuring that improvements are made as a result. 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: • The practice's recruitment policy and procedures were not followed to ensure accurate, complete and detailed records are maintained for all staff.

This section is primarily information for the provider

Enforcement actions

- They had not ensured risk assessments were undertaken in relation to fire safety, legionnaires disease and lone working.
- Emergency lighting, main electrical wiring and gas safety checks were all not routinely checked or maintained.
- X-ray units did not have an annual electrical and mechanical service.
- The lack of formalised processes around outgoing referrals.
- They had not ensured certain medicines were stored appropriately.

Regulation 17 (1)

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **How the regulation was not being met** 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 delivered under conscious sedation. In particular: • A lack of maintenance of contemporaneous records in relation to monitoring of patients undergoing conscious sedation procedures. • The dental sedation team was not trained and experienced in the use of advanced sedation techniques i.e. oral and intravenous sedation. • No evidence the second appropriate person had received training in conscious sedation. • There was a lack of evidence staff undertaking and assisting with conscious sedation had received mandatory training in immediate life support (ILS) or similar. **Regulation 12 (1)**