CED Resolution– 2025 Update

Artificial Intelligence in Dentistry

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I – Introduction

The Council of European Dentists (CED) is a European not-for-profit association which represents over 340,000 dentists across Europe. The association was established in 1961 and is now composed of 33 national dental associations from 31 European countries.

Artificial intelligence (AI), machine learning or deep learning are terms that are used to describe the ability of a digital computer or computer-controlled robot to perform tasks commonly associated with intelligent beings.[1]AI is also increasingly applied in healthcare, and dentistry is no exception. It includes a wide range of methods and applications which are meant to provide more precise and objective decisions.

Promotion of AI and exploitation of big data remain at the forefront of EU policy. Through the development of legislation such as the EU Artificial Intelligence Act[2], along with other crucial texts that will drive health data collection forward (e.g. European Health Data Space[3]), AI will become further embedded in healthcare, and in the day-to-day activities of healthcare professionals.

Despite the AI revolution being underway, the ethical and regulatory framework taking into account the development of AI is still fragmented and not comprehensive. In particular, there is a potential lack of clarity about where the responsibility in the decision-making process lies, and who is liable in cases of AI failure in dentistry and the dental field. Achieving clarity on this is of crucial importance, considering that patient safety is at stake. Final involvement of the healthcare professional remains crucial.

National health regulatory systems currently do not fully take into account the rapid developments in new technologies and AI and there are discrepancies among Member States as to the level of advancement in adoption of AI technology. To encourage confidence in AI systems amongst the profession, there needs to be clarity about who is liable for AI failure and misdiagnosis. The limits of the dentist's liability when using AI have to be clearly defined.

As stated by the World Health Organisation, AI is crucial in order 'to revolutionise health and address pressing challenges, such as skilled workforce gaps and resource limitations. However, as technology progresses rapidly, regulatory frameworks often struggle to keep pace with these developments, and adequate capacity to implement AI effectively lags behind[4]'

AI remains an area of strategic importance for the European Union, as an important element in its Digital Decade policy programme[5], highlighting the importance of 'enabling start-ups & SMEs to adopt digital technologies, including cloud, data analytics, and Artificial Intelligence (AI)'[6]. Considering that many dental practices fall under the micro and small enterprise

[1]https://www.britannica.com/technology/artificial-intelligence

[2]EUR-Lex, Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), https://eur-lex.europa.eu/eli/reg/2024/1689/oj/eng

[3]EUR-Lex, REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52022PC0197

[4]World Health Organisation, 'Artificial Intelligence for Health: Supporting countries to deploy responsible AI technologies to accelerate equitable health for all', May 2024: https://cdn.who.int/media/docs/default-source/digital-health-documents/who_brochure_ai_web.pdf?sfvrsn=aa4f4e3b_3&download=true

[5]European Commission, Europe's Digital Decade, https://digital-strategy.ec.europa.eu/en/policies/europes-digital-decade

[6]Ibid.

definition[7], it is important that policy makers prioritise the sector by offering more incentives and enabling dentists to truly benefit from AI.

With the Digital Single Market Strategy, the European Commission has put forward the Ethics Guidelines for Trustworthy AI developed by the High-Level Expert Group on Artificial Intelligence.[8]The Guidelines list several principles such as non-discrimination, transparency, safety, accountability etc. to be fulfilled by the public and private sector, when taking up AI technologies. The Guidelines, developed in 2019 are not standalone, with progress towards more ethical AI activities marked through the EU Artificial Intelligence Act, the first law of its kind on AI in the world. While this places the EU in a leading role, it is necessary to ensure that such ambitious legislation works on the ground, including in the health field. Considering the sensitive nature of health – personal data, patient safety, the ethical responsibility healthcare professionals carry towards their patients – it is important that EU legislation on AI is developed specifically with the health sector in mind, rather than just as a horizontal, 'catch-all' regulation that captures various sectors.

Role of AI

Algorithms can help dentists in making diagnoses, guided by the principles of patient-centered health care, but they must never replace them in this task. In healthcare, trust and empathy are of crucial importance; they cannot be replaced. The human factor is particularly relevant for professions such as dentists that are relying on patient trust. Decisions about treatments and detailed treatment planning should also take into account the patient's understanding of the importance of oral healthcare, as well as their physical and financial limitations. AI should be a mere tool to this process.

In recent years, and especially during the pandemic, AI also became a negative tool – e.g. through the creation of 'deep-fakes', therefore contributing to the spread of misinformation. In the case of health, this can have dire consequences for the wellbeing of the individual citizen but also for entire sectors of public health. As such, it is crucial to ensure that citizens can make informed decisions and distinguish between such fake information and real expertise: this is once again an area where the healthcare professional must remain the trusted authority. It is important that such endangering uses of AI are addressed, e.g. including via new EU actions, such as the Cybersecurity Action Plan for Hospitals and Healthcare Providers[9], launched in January 2025. This includes enabling healthcare providers with the necessary tool to recognise AI misuse, and to act rapidly by receiving proper support from national and European authorities in cases when security is breached or when misinformation has to be prevented.

The CED supports the assisting role of AI that can help dentists with diagnosing and suggesting possible treatment options at a faster rate. AI can facilitate the decision-making process by analysing large amounts of data in a short time.

Application in dentistry

[7]European Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, section Annex, Article 2): '(…) a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million., (…) a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million.' https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:124:0036:0041:en:PDF#:~:text=The%20category%20of%20micro%2C%20small,not%20exceeding%20EUR%2043%20million

[8]https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines#Top

[9]EUR-Lex, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS: European action plan on the cybersecurity of hospitals and healthcare providers, January 2025: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=comnat:COM_2025_0010_FIN

Apart from diagnosis and treatment, the CED recognises the wider potential for the application of AI in dentistry. Patient management in terms of scheduling appointments, other administrative tasks, as well as alerting about the patient's medical history could significantly facilitate the management of the dental practice.

Digital technologies are already widely used in the field of restorative and prosthetic dentistry where computer-aided design and manufacturing technology have generated dental restorations for decades. An example of recent innovation could be AI-driven orthodontics where 3D scans and virtual models allow for fully customised and personalised appliances. In addition, AI application in implantology and endodontics creates even more opportunities for more precise treatment and preventive actions. However, in this field it is once again necessary to highlight the role of the dentist throughout the entire process, from diagnosis to treatment and follow-ups. CED members have highlighted that in some instances, companies offer AI-driven orthodontics to the public, with little to no involvement from a dentist/specialist orthodontist. This is an example of abuse of the AI opportunities, which can end up causing significant harm to the patient, and creates ethical and liability issues.[10]

When it comes to digital technologies and AI, it is furthermore important to highlight that existing AI legislation also interacts with other regulatory texts such as the European Health Data Space and the Medical Devices Regulation, especially relevant in light of the review of the MDR as well. It is important to clarify the way these interactions impact dentists as end users of medical devices which feature an AI component.

Transparency and Liability

Machine learning, a type of AI, works by identifying patterns in available data and then applying the knowledge to new data.[11] The larger a data set, the better even subtle relations in the data can be discovered. The objective of the Commission is to facilitate the access to data that is a key ingredient for a competitive AI landscape.

In terms of data collection, patient consent must always be obtained, and patients need to be informed about who accessed their medical records and when, ensuring that personal health data is used in a manner which is scientifically sound and ethically acceptable.[12]

The CED stresses a need to ensure algorithmic transparency which would help in understanding exactly how algorithms are making decisions and how to intervene if necessary.This means encouraging 'white box' AI[13], whereby transparency is properly implemented.

The AI has to be validated with different independent sets of data and through different AI systems. This means validation against a standard database of images (or other diagnostic records) and certification for release only if a minimum level of correct responses is achieved.[14]The producer has to clearly announce what percentage of correct responses

[10]CED Position on 'Direct to Consumer Orthodontics', Artificial Intelligence (AI) and Dentistry, 2023: https://www.cedentists.eu/wp-content/uploads/2023/11/CED-DOC-2023-023-E-FIN.pdf

[11]https://ec.europa.eu/digital-single-market/en/news/communication-artificial-intelligence-europe

[12]CED Resolution on Data Sharing as part of eHealth: Workflow, Prescription and Protection

[13] '*In "white box" models, the algorithms used are straightforward to understand and it is possible to interpret how the input features are transformed into the output or target variable. The most important features for predicting the target variable can be identified, and these features are understandable.'*, European Data Protection Supervisor (EDPS), EDPS TechDispatch on Explainable Artificial Intelligence, p.6, https://www.edps.europa.eu/system/files/2023-11/23-11-16_techdispatch_xai_en.pdf

[14] An example of development of such datasets alongside a benchmarking infrastructure can be found through the Global Initiative on AI for Health (in relation to dentistry, the Topic Group Dental is developing such a dataset). *'Launched in July 2023, under WHO, ITU (International Telecommunications Union), and the World Intellectual Property Organization (WIPO), the GI-AI4H stands as a resilient, long-term institutional structure,*

was achieved. Algorithmic transparency is also crucial to ensure patient and consumer rights to information and explanation of how a decision might have been reached. Clear standards and legally binding assessment criteria to ensure transparency of AI systems in healthcare are needed.

In order to not reinforce the disparities in healthcare related to socioeconomic status or other biases, the data criteria selection must be developed on an ongoing basis and regularly verified. Transparent, clinically validated AI and systematic quality checks could foster the acceptance and trust for AI among the end-users; dentists would need to assess the reliability of the proposed AI decisions according to agreed-upon standards.

In general terms, healthcare professions are regulated by several laws including clear legal obligations when it comes to accountability, liability and patient safety. As with the example of remote orthodontics above, there is a risk of unregulated individuals using AI technology on patients. CED therefore believes that in order to allow for a confident application and use of AI by dentists, the EU needs to design a legal framework on liability, in which it clearly defines liability in case of AI failure and/or misdiagnosis specifically for the health field. In the case of dentists, it is crucial to recognise and clearly specify that failure and defects in a machine and machine's functioning cannot result in the dentist's liability, considering that he/she has followed their mandate as healthcare provider for the patient, the user instructions and any additional guidance offered by the AI provider.

Education and CPD

To digitally revolutionise the healthcare system, an educated, well-trained workforce is paramount.Therefore, starting at university level, priority should be given to the implementation of digital skills education into the dental studies curriculum. As part of their professional lives, dentists should address the increased need for improved digital skills through continuing professional development (CPD) arrangements.[15] Professionals should have the opportunity to undertake courses on algorithm functioning, as well as receiving adequate training on AI tools management, which should be supported by appropriate structures in the practicing environment.

Furthermore, the integration of digital skills education into dental studies should emphasise the ethical and responsible use of AI. Students should be taught not only about the technical aspects of AI but also about safety policies, data privacy, and the thoughtful implementation of AI in clinical practice. This foundational knowledge will help future professionals balance AI assistance with human decision-making, ensuring patient trust and optimal care outcomes.

Understanding AI processes and their application is a first step in supporting confidence in AI technologies among dentists.

The explanation of AI methods to the patient is important in terms of patients' right to information. However, it is unlikely that dentists possess detailed technical knowledge. Therefore the role of AI should be limited to a supporting tool which does not affect the dentist's autonomy in the final decision-making process.

AI Implementation

The CED recognises and values the potential of AI in terms of augmenting capabilities, enhancing efficiency and accuracy, as well as reducing costs. However, these benefits can

grounded in its mission to enable, facilitate, and implement AI in healthcare.', https://www.who.int/initiatives/global-initiative-on-ai-for-health

[15] CED Resolution on Continuing Professional Development of dentists - Update

be achieved only with the support of the national health systems over time. AI technologies should be introduced in a well-structured system with a functioning regulatory framework. The workforce needs to be appropriately trained and financially supported during the introduction of AI systems.

The CED acknowledges the difficulty of creating the 'ideal' environment for AI implementation and advocates for early inclusion of dentists in the discussion on the process of healthcare AI design and development as well as professional oversight over AI clinical validation. Dentists should be represented in the relevant advisory bodies at EU and national level. It would allow the early detection of the most urgent practical challenges, ensure a user-centred approach and allow to adjust it to the needs of dental patients and dentists, instead of creating an additional burden or increasing the cost to dental practices. The involvement of healthcare professionals at the early stages of every discussion on digital technologies in healthcare is a prerequisite in making the system operational.[16]

CED RECOMMENDATIONS

- New digital technologies that use algorithms can help dentists in making diagnosis, but they should never replace them in this task.
- Algorithmic transparency is crucial to ensure the need to respect patient rights to information and explanation. 'White box' AI systems must be actively encouraged for use in healthcare.
- Privacy of the individual patient must be safeguarded.
- The dental practice must be empowered to dedicate its time to the care and treatment of patients. As such, the obligations imposed from existing and new AI legislation to healthcare professionals have to be clearly communicated and explained. The administrative burden it would impose to healthcare practices must be limited to a minimum. Interactions and requirements between existing legislations must also be clarified as to the role of healthcare professionals.
- In terms of data collection, patient consent must always be obtained.
- An educated, well-trained workforce is paramount to the successful introduction of new technologies into healthcare.
- An ethical and regulatory framework is needed. CED calls on the European Commission to design a tailored legal framework for liability with respect to the use of AI in healthcare.
- All healthcare professionals and citizens alike have to develop deeper understanding and ability to recognise AI misuse and misinformation, and have to be provided with concrete tools and reporting outlets to address such situations.
- The involvement of healthcare professionals at an early stage of every discussion on digital technologies in healthcare is essential.
- Insurance for AI systems should be encouraged and included in professional insurances for dentists, covering costs and damages in cases of breached security and algorithmic failures. National authorities can support dental practices (especially the ones that fit into the small and micro enterprise definition) by offering vouchers and other means of financial support for such insurance. This is similar to what is offered in the Action Plan on Cybersecurity for Hospitals and Healthcare Providers, where it is recommended for Member States to '*consider targeted measures like Cybersecurity Vouchers for micro, small, and medium-sized hospitals and healthcare providers. These vouchers would provide financial assistance to put in place specific cybersecurity measures.*'[17]

[16] CED Resolution on Data Sharing as part of eHealth: Workflow, Prescription and Protection

[17] EUR-Lex, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS: European action

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ANNEX:

Glossary of Basic Artificial Intelligence Terms for Dentists

1. **Artificial Intelligence (AI)** - A broad term used to describe the simulation of human cognitive functions by computers or computer-controlled systems. In dentistry, this could refer to algorithms that assist in diagnosis or treatment planning.
2. **Training Data** - The dataset used to train an AI model. In dentistry, these could include X-ray images, records of previous treatments, or other relevant patient information.
3. **Validation Data** - Data used to check the accuracy of the AI model during development but before final testing. This helps adjust the model for better performance.
4. **Test Data** - An independent set of data used to assess how well the AI model applies what it has learned to new situations. In dentistry, this might involve applying the model to new images or health records.
5. **Neural Networks** - A type of AI algorithm that mimics how the human brain operates, allowing the AI model to learn from complex and extensive data sets.
6. **Deep Learning** - A subset of AI that uses large neural networks with many layers to extract highly sophisticated patterns from large data sets.
7. **Overfitting** - A scenario where an AI model is too closely fitted to the training data and fails to generalise effectively to new data. This can lead to inaccurate diagnoses or treatment recommendations in real-world scenarios.
8. **Underfitting** - The opposite of overfitting, where the AI model is not complex enough to understand the patterns in the data, leading to poor accuracy.
9. **Algorithm** - A set of rules or instructions designed to perform calculations or other data processing operations by a computer.
10. **Semantic Interoperability** - The ability of different systems and organisations to exchange data with a clear and mutual understanding of the meaning of that data.
11. **Machine Learning** - A field of artificial intelligence that allows software applications to become more accurate in predicting outcomes without being explicitly programmed to do so.

plan on the cybersecurity of hospitals and healthcare providers, January 2025: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=comnat:COM_2025_0010_FIN