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| **Abstract:** | This document contains the Framework and Checklist of the Ethical Considerations on Artificial Intelligence in Dentistry. |

**Ethical Considerations on Artificial Intelligence in Dentistry: A Framework and Checklist**

**Short title: Ethics in AI for dentistry**

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**Ethical Considerations on Artificial Intelligence in Dentistry: A Framework and Checklist**

**Abstract**

*Objective:* Artificial Intelligence (AI) refers to the ability of machines to perform cognitive and intellectual human tasks. In dentistry, AI offers the potential to enhance diagnostic accuracy, improve patient outcomes and streamline workflows. The present study provides a framework and a checklist to evaluate AI applications in dentistry from this perspective.

*Methods:* Lending from existing guidance documents, an initial draft of the checklist and an explanatory paper were derived and discussed among the groups members.

*Results:* The checklist was consented to in an anonymous voting process by 29 group members. Overall, 11 principles were identified (diversity, transparency, wellness, privacy protection, solidarity, equity, prudence, law and governance, sustainable development, accountability, and responsibility, respect of autonomy, decision-making).

*Conclusions:* Providers, patients, researchers, industry, and other stakeholders should consider these principles when developing, implementing, or receiving AI applications in dentistry.

*Clinical Significance:* While AI has become increasingly commonplace in dentistry, there are ethical concerns around its usage, and users (providers, patients, and other stakeholders), as well as the industry should consider these when developing, implementing, or receiving AI applications based on comprehensive framework to address the associated ethical challenges.

Keywords:  Artificial intelligence, bioethics, deep learning, dentistry, machine learning

**Introduction**

The term Artificial intelligence (AI) was initially defined as “the science and engineering of making intelligent machines”, i.e., machines that can solve problems that usually require human intelligence to do so [1-4]. The majority of AI applications in healthcare employ machine learning, where machines learn human tasks without being explicitly programmed. A popular subfield of machine learning is deep learning, which uses complex, multi-layered algorithmic structures and is especially suited for data such as images or speech [3,5,6].

In dentistry, many AI applications are researched, developed, implemented, and clinically used [5,7]. Specifically, dental image analysis using AI has been found useful, with diagnostic accuracies similar or superior to those of experts, in detecting or classifying oral mucosal lesions, dental implant types, dental caries, and cephalometric landmark, for example [6,8-13].

As a discipline of philosophy, ethics examines human behavior rigorously using structured and meticulous analyses to determine its correctness, morality, and potential harm or benefit. Unlike morality, which focuses on enacting behaviors deemed appropriate, ethics explores what constitutes right and good. The dental profession values philanthropy, professionalism, ethics, and morality, even though there are distinctions between them [14]. Three decades ago, a biomedical ethics model was proposed that shaped dental professionalism. Principles such as nonmaleficence, beneficence, justice, autonomy, and veracity are considered guiding principles of this model [14, 15]. With the rise of new technologies and their adoption into clinical practice, new and unexpected challenges will occur [1]. Technology usually also comes with ethical implications that must be recognized and addressed by users – be it patients, providers, or other stakeholders – and developers [2-4]. While several frameworks and checklists have been developed to guide the dental community towards optimal conducting and reporting of AI research or AI education in dentistry, no such framework or checklist is available to reflect ethical challenges and demands [2,16]. This study aimed to systematically develop a framework around fundamental ethical principles relevant to dental AI applications. The resulting checklist should be helpful to assess dental AI applications systematically and comprehensively with an ethical lens and to develop, implement and receive ethical AI.

**Methods**

*Scoping and developing the checklist*

To derive the checklist, existing guidance documents around ethical aspects of AI for healthcare from the World Health Organization [17], and a recently published scoping review on ethics reporting in dentistry were evaluated [7]. Eventually, the steering committee selected ten relevant items: diversity, transparency, wellness, privacy protection, solidarity, equity, prudence, sustainable development, accountability and responsibility, respect for autonomy, and decision-making. In one-to-one interviews with 29 members of the Topic Group Dental Diagnostics and Digital Dentistry, ITU/WHO Focus Group AI on Health, and 3 AI ethics experts, items were discussed, revised or new items added. The resulting item list and an accompanying guidance document were discussed among the group members, resulting in further revision.

*Delphi process*

All members of group were contacted and invited to participate in an anonymous online Delphi process. Google Forms were used for voting on each item of the checklist. We reached 59 individuals, 29 of whom eventually participated. The consensus group represented dental clinicians, researchers from the dental and technical disciplines, methodologists, journal editors and reviewers, regulatory professionals, policymakers, industry representatives, and patients. The guidance document itself was not submitted to this consensus process. Reporting of the Delphi follows the Guidance on Conducting and Reporting Delphi Studies (CREDES).

A maximum of two stages were planned. Each round was scheduled to be closed after two weeks. Two reminders via email were designed for each round. We asked for an agreement on each item on a scale of 1-10 (do not at all agree to agree fully). There was the option not to answer single questions (opt-out) and to suggest additional or revised items at the end of the survey. The following consensus rules applied. (1) Agreement to an item was defined by marking grades 7-10 on the described scale from 1-10. (2) Minimum of 70% of all participants needed to agree to an item for this to be consensually accepted. Items not meeting these criteria after the planned two rounds were to be dropped. As we achieved stable agreement on all items in the first round, with all items being agreed on, no second round was needed, and hence the potential second stage was dropped.

**Results**

The results of the Delphi process are summarized in Figure 1. All items were graded 7-10 by at least 70% of participants (72%-100%). Ten items were graded 7-10 by more than 80% of participants. The complete list of items can be found in the Table. In the subsequent paragraphs, we will briefly discuss each item.

*Transparency and participation*

Transparency is crucial in effectively communicating the outcome of an AI model. Transparency requires thorough documentation on different levels [18,19]. Complete information should be available regarding the dataset and inclusion and exclusion criteria, labelling strategy, training, and testing data [2,18], the employed algorithms, and their validation. Practitioners and patients should discuss and approve the decision to use such technologies [19-23].

*Diversity*

AI applications should reflect the diversity of social, ethnic or racial backgrounds, genders, and sexual orientations [20,21]. There are generally four different types of diversity: internal (ethnicity, age, nationality, gender, cultural identity), external (education, socioeconomic status, or religious beliefs), organizational (employment, financial status), and worldview (political or moral beliefs) [22]. Diversity in training and test datasets ensures the generalizability and fairness of AI [23-29].

*Wellness (Beneficence)*

AI should improve individuals’ wellness, i.e. be beneficial to their health and overall status [30,31]. Moreover, organizational wellness should be considered [30].

*Respect for autonomous decision-making*

AI may facilitate deception, manipulation, or coercion and hence contravene human autonomy [32-34]. Ethical AI should aim to benefit society and be human-centric [35]. Legal frameworks to support autonomy must be established [17]. Decision-making should remain built on a consensus between the clinician, patient, and dental technician, even if AI supports decisions.

*Protection of Privacy*

As AI is a data driven technology, privacy concerns are relevant [36], especially for dental data as these show high potential for identifying individuals, and de-identification is challenging. Alternatives like federated learning may be employed to overcome privacy concerns [1,36,37]. The use of generative data could similarly alleviate privacy concerns, too [36].

*Accountability and responsibility*

The use of AI in medical decisions raises questions about accountability and responsibility. Current AI tools merely support dentists, who remain accountable for their final role in the decision-making process [16,35,36,38-41]. In cases where individuals would be directly affected by algorithmic decisions, questions about who is responsible and accountable emerge; these are currently unanswered [17].

*Equity*

Equity corresponds to the ethical practice of fairness in line with the needs of each individual [42,43]. There are three key aspects of equity: algorithmic fairness to avoid bias, making AI technology available to all groups, and using AI to improve health equity [7,42,43]. No technology should perpetuate or worsen existing forms of bias and discrimination [17]. As dental AI tools are provided by industry, they generate costs; these costs may aggravate existing inequities, and beneficial AI may hence not be accessible to all individuals.

*Prudence (capacity and expertise)*

The prudence principle states that “when the misuse of AI systems endangers public health or safety and has a high probability of occurrence, it is prudent to restrict open access and public dissemination” [44,45]. Prudence is necessary when addressing the adaptability issues of (dynamic) AI technologies [20].

*Sustainability*

The association between AI and sustainable development is one aspect that received little to no attention in dental research. The question is whether AI could promote more sustainable dentistry. On the one hand, AI may reduce transportation efforts and optimize dental care delivery, while training or deploying AI requires considerable resources. The double-edged relationship between AI and accessibility – another dimension of sustainability – has been discussed [44,45].

*Solidarity*

Solidarity describes a sense of unity and mutual support among individuals [46], and addressing solidarity is partially reflected by our discussion around equity. To promote solidarity among individuals, it is important to thoroughly assess an AI applications’ potential impact, and to inform responsible decision-makers accordingly [46].

*Governance and Law*

To ensure patient protection and regulate the use of AI in dental research and clinical practice, laws and regulations related to data privacy, informed consent, quality control and conformity must be applied [47]. Further development of such laws and regulations, including considerations of the laid-out ethics principles, is needed. In the future, notably, the usage of AI itself may become a standard for certain tasks. AI hence gain some normative character, posing additional ethical challenges for society and our profession [3,48].

**Discussion**

AI uptake in dentistry is happening at high speed, and dental research as well as regulation has so far mainly focused on the technical and clinical yield of AI; a focus on the wider impact and challenges, including ethical ones, is by large missing [49]. The outlined 11 ethical principles are fundamental to successfully developing and using AI technology in dentistry. They outline the specific traits and attributes that an AI software should possess, such as being open-source, user-friendly, understandable, generalizable, relevant, health-promoting, healthcare-promoting, controlled, interpretable, fair, available, accountable, confidential, secure, supervised, scrutinized, capable, expert, cost-effective, efficient, collaborative, ubiquitous, regulated, and lawful. It is a shared responsibility among manufacturers, regulators, dentists, and patients to ensure ethical AI's effective and sustainable implementation. Notably, AI may benefit disadvantaged communities and promote justice and social equity or aggravate them by perpetuating existing inequities (e.g., accessibility). As manufacturing AI is costly, particularly in medicine and dentistry (due to high regulatory standards and associated development and quality management efforts), providing fair AI may be a specific challenge here, as manufacturers will not regularly be able to provide AI for free, or to comply with the outlined transparency requests [43].

The present study comes with several limitations. First, our sample size was limited, and sampling focused on the Focus Group AI4 Health of ITU/WHO. Notably, this group represents a diverse range of nationalities, ages, genders, backgrounds, and perspectives. Second, to develop a comprehensive checklist on ethical considerations, we first built on existing guidance documents, namely the World Health Organization's guidance on ethical considerations in AI for healthcare, and a recently published scoping review on ethics reporting in dentistry. While both sources provided valuable insights, neither was entirely applicable to our specific goal and the context of AI in dentistry. Therefore, we then expanded and revise any identified items, mainly tailoring them as needed and making them as comprehensive as possible and feasible. Notably, the checklist itself is not supported by any theoretical framework, while it needs highlighting that it was consented by a broad representation of relevant stakeholders. Last, one may argue that existing guidelines in other medical disciplines may sufficiently cover dental AI, too. Notably, particularly for AI the consideration of the web of multiple stakeholders, including patients, clinicians, developers, and society, as well as the specific requirements, needs and constraints of the targeted medical specialty may be relevant; existing guidelines from medicine will not be entirely applicable to dentistry (while of course there will be overlap). Providing a specific framework and checklist on dental AI may, notably, facilitate dissemination into the dental domain and help to optimize dental AI towards its ethical foundations, too.

**Conclusion**

Researchers, clinicians, patients, manufacturers and other stakeholder should consider diversity, transparency, wellness, privacy protection, solidarity, equity, prudence, law and governance, sustainable development, accountability, and responsibility, respect of autonomy and decision-making when developing, implementing or receiving dental AI.

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Table 1- The eleven ethical pillars which should be considered when researching, marketing, or using an AI tool in dentistry.

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| Transparency | A thorough documentation of the model is necessary. The inclusion and exclusion criteria for any data used for training and testing the annotation as well should be clearly described in an accessible way. The usage of AI in the clinical environment should be clearly communicated to patients. |
| Diversity | The dataset should reflect on the target population and not be biased according to ethnicity, age, gender or health conditions. |
| Wellness | AI should support patients, clinicians’ and organizational well-being. |
| Respect of autonomous decision-making | AI should support patients gaining control over their surroundings and life and should not decrease patients’ role in decision making. |
| Protection of privacy | Data used developing AI should be protected according to local data protection regulation. Developers of AI should ensure that collected data is not misused. |
| Accountability and responsibility | Clinicians, jointly with patients, carry the responsibility for any decisions made supported by AI. |
| Equity | Fairness and equity should be fostered by AI; AI should not aggravate existing inequalities. |
| Prudence | Developing and using AI in dentistry requires knowledge, skills and consideration. Clinicians should command the required digital literacy to interpret AI and its outcomes and act upon it appropriately. |
| Sustainable development | AI should foster sustainability in line with WHO Sustainable Development Goals. Resources used to develop or use AI should be critically appraised against sustainability gains by implementing AI in care. |
| Solidarity | AI should foster solidarity among stakeholders of care. |
| Governance | The development and usage of AI in dentistry should follow applicable regulations and oversight. |

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Figure 1- Grades 7-10 (the green shade) were used to determine agreement, and for an item to be consensually accepted, at least 70% of all participants must agree with it. All included items were graded 7-10 by at least 70% of participants.

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