Trustworthy AI in dental care beyond Artificial Intelligence Act

Natália Slosiarová[1,*,†], Matúš Mesarčík[1,2,†], Peter Jurkáček[3,†] and Juraj Podroužek[1,†]

[1]Kempelen Institute of Intelligent Technologies, Sky Park Offices Bottova 7939/2A 811 09 Bratislava – Staré Mesto Slovakia

[2]Comenius University in Bratislava, Faculty of Law, Šafárikovo nám. č. 6, 811 01 Bratislava, Slovakia

[3]AID s.r.o., Námestie SNP 3, 811 06, Bratislava, Slovakia

Abstract

This paper presents our position on the use of AI systems in dental care, associated ethical, social, and legal risks, and tools that can be used to identify them. We suggest that the development of trustworthy AI in dental care requires a multi-faceted approach that takes into account not only technical factors but also ethical principles and human rights considerations together with close engagement of relevant stakeholders. First, we introduce a preliminary list of ethical and societal risks based on a literature review validated by our own experience with ethics-based assessment of a medical image analysis AI system for dental practitioners with a focus on human rights and the alignment of such system with requirements for trustworthy AI. Identified risks are further analyzed through the lens of the proposal for the EU Artificial Intelligence Act and related legislation in the EU. Our analysis shows that several identified risks will not be mitigated by compliance with these laws including broader societal risks.

Keywords

AI in healthcare, AI in dental care, AI regulation, AI ethics

1. Introduction

Advancements in artificial intelligence (AI) have shown great promise in revolutionizing many aspects of everyday life and healthcare is no different. Benefits of utilising AI in the field of medicine including early and more accurate diagnosis, increase in efficiency, or cost savings [1] are motivating more companies to launch new AI systems in hopes of innovating healthcare.

Dentistry is no exception, and extensive research has already been conducted on its benefits in this field [2, 3, 4, 5, 6]. AI impacts dental specialists' decision-making processes, including diagnostics, treatment planning, management of clinics, and patient outcomes across dental specialties such as orthodontics [7], oral and maxillofacial surgery [8, 9], orofacial pain [10], therapeutic dentistry, oral pathology [11], periodontology [12], endodontics [13], prosthodontics [14], and anesthesiology [15]. AI mostly helps address the subjectivity of dental specialists

IAIL'23: 2nds International Workshop on Imagining the AI Landscape After the AI Act (In conjunction with The second International Conference on Hybrid Human-Artificial Intelligence), June 26–27, 2023, Munich, Germany

*Corresponding author.

†These authors contributed equally.

natalia.slosiarova@kinit.sk (N. Slosiarová); matus.mesarcik@kinit.sk (M. Mesarčík); juraj.podrouzek@kinit.sk (J. Podroužek)

0009-0004-7657-8340 (N. Slosiarová); 0000-0003-3311-5333 (M. Mesarčík); 0000-0002-9691-0310 (J. Podroužek)

and reduces their burnout [16], or affects patients' trust in dentists' diagnosis. [6] Most of the current research discusses narrow intelligence trained on specific modalities or combinations of modalities, such as text, X-ray scans, photographs, CBCT, and MRI [17, 18, 19]. Human supervision is necessary for this AI [4], however, with the introduction of promptable AI, such as [20], its potential can be further enhanced.

Nonetheless, the development, deployment, and use of AI come with certain legal, ethical, or societal risks that need to be identified and addressed to prevent unintended negative consequences for all parties involved. Legal requirements for creating safe and trustworthy AI systems are yet to be presented by the European Union (EU). Based on what is currently known of the contents of the proposal of the Artificial Intelligence Act (AIA), a horizontal regulation of AI systems in the EU, it seems there is room for improvement when it comes to proper identification and prevention of risks associated with AI systems[21, 22] specifically in fields such as dentistry and healthcare generally.

While legal requirements certainly play an important role in the development of safe AI systems, there have also been attempts at creating non-binding frameworks for the facilitation of trustworthy AI solutions [23] in various domains including healthcare. One of the most recent initiatives, Future-AI, offers guidelines and a checklist composed of actionable questions that should support developers and evaluators in delivering medical AI systems that are trustworthy and optimised for real-world practice [24]. The U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) have also jointly identified 10 guiding principles for the development of Good Machine Learning Practice [25]. There are also first attempts to summarize specific ethical and societal issues arising in dental care [26, 27, 28, 29, 30]. Yet, to our knowledge, there are no comprehensive guidelines for trustworthy AI specific to this domain.

This paper presents our position on the advent of AI systems in dental care, associated ethical and legal risks, and tools that can be used to identify them. We introduce a preliminary list of risks based on a literature review validated by an ethics-based assessment of a medical image analysis AI system for dental practitioners that was conducted by our team. The main focus was on human rights impacts and the alignment of such a system with requirements for trustworthy AI. Additional tools that were utilised during the facilitation of the ethics-based assessment process include Assessment List for Trustworthy AI (ALTAI) [31], a well-known ethical framework in Europe, and Human Rights, Ethical and Social Impact Assessment (HRESIA) [32], a risk assessment focusing on human rights also encompassing social and ethical values.

It is of the essence, to address the meaning of trustworthy AI before delving into any further discussions or analyses. For the purposes of this paper we derive our definition from the Ethics Guidelines for Trustworthy AI (EGTAI) [33]. In order for an AI system to be deemed trustworthy, it should be lawful, ethical, and both technically and socially robust. Each of these components is crucial and they should all work in harmony. This may, however, pose a challenge in practice yet EGTAI calls for a collective effort to ensure that all three components are met and trust in development, deployment and further use of AI is secured.

The paper proceeds as follows. After the introduction, the preliminary analysis of legal and ethical risks concerning AI systems in dental care is presented. The next part provides a discussion on the identified risks from the regulatory point of view taking into account the Artificial Intelligence Act and related EU legislation. The final part of the article represents

conclusions and further research opportunities.

By highlighting the main risks, we hope to contribute to the ongoing discussion around responsible AI development in healthcare with a special focus on dental care and to inspire the creation of comprehensive guidelines for the development and implementation of trustworthy and accountable AI systems in this domain.

2. Ethical and Social Risks

The development of AI for medical purposes has shown promising potential to improve diagnostic accuracy, reduce workload, and improve patient outcomes. However, as with any emerging technology, there are risks associated with its development, deployment, and subsequent use. In this chapter, we discuss some of the most important risks that were identified by other scholars or by us during our ethics-based assessment [34] of an AI x-ray image diagnosis system for dental professionals.

Algorithms learning from humans tend to repeat **human biases and stereotypes** [35]. According to the AI Now Institute, the AI sector is facing a diversity crisis across gender and race [36]. Even industry giants such as Apple are falling behind. The development team behind Apple's HealthKit app did not include any women and for example, until iOS 9 neglected to include a women's menstrual cycle tracker [37]. Technological companies and teams are unbalanced which might suggest that the stereotypical predictions might not be flagged by developers working to validate the outputs of the model. During our assessment of the aforementioned medical image analysis AI system, which was developed in central Europe, we noticed a risk of representation bias mainly in the form of racial bias because most, if not all, of the data used for model training, was data from Caucasian patients.

The deployment of machine learning models in dental care contributes to the importance of having fair and accountable AI systems. However, the opaque nature of deep learning models serves as an obstacle to establishing accountability for discrimination [38] and to ex post debiasing of such AI systems. Deployment of heavily biased models also interferes with the right to **equal provision of healthcare** which is one of the fundamental human rights guaranteed by the Charter of the fundamental rights of the EU (Charter, Article 35) [39].

While it is widely believed that AI will promote growth, create wealth, and have beneficial results, numerous possible consequences of its use need to be perceived in a broader social context [38] [28]. Optimistic assumptions are often made about the state of infrastructure and readiness of healthcare institutions where AI will be deployed. In some low-income countries, financial resources and information and communication technology infrastructure lag behind those of high-income countries, and the significant investments and effort that would be required might discourage the deployment and further use of new technology [40]. This can widen the **technological and economic gap** between developed and developing countries, leaving the latter at a disadvantage. Moreover, our experience from the assessment suggests that dentists working in bigger clinics with the latest equipment had more incentive to implement and benefit from AI systems than sole practitioners. Patients can therefore have contrasting experiences when coming to different dentists with a toothache and it might represent another threat to the right to equal provision of healthcare. This risk applies to the work of dentists within the same

country or in different countries.

Another major concern when it comes to the deployment of AI systems in dental care is tied to **over-reliance** [31] or **automation bias** [41]. It represents a process of decision-making leading to commissive or omissive errors where a dentist heavily relies on the output of the AI limiting his/her professional capacities. There is a great deal of evidence suggesting that humans tend to over-trust machines which leads to decreased vigilance and auditing of such systems [42]. There is no such proof regarding automation bias in dental care but a study investigating the impact of decision support on the accuracy of ECG interpretation found that while correct decision support classification increased clinician accuracy, incorrect decision support classification decreased their accuracy [43]. This can be especially dangerous when the health of an individual is at stake.

Regarding the risk of **low transparency and user awareness**, in the field of medicine, the institute of informed consent plays an important role. It refers to the process by which individuals are fully informed about the risks, benefits, and potential alternatives to medical intervention and based on that information make a voluntary decision about whether to participate or not. This obligation, however, clashes with the nature of AI systems and tools used in dental care. As we have mentioned, these systems often deploy deep learning methods that serve as *black boxes* with low levels of explainability and interpretability [44]. Whenever an AI system outputs a decision or recommendation on how to medically intervene, with the current state of explainability methods, it is troublesome for the patient and maybe even for the dentist to understand how and why is the output the way it is [45]. As a result, the possibility for the patient to give full and informed consent crumbles, and another fundamental right, the right to the integrity of the person (Charter, Article 3) [39], may be endangered.

For an AI system to be effective and bring all the aforementioned benefits to both patients and dental professionals, it needs to be trusted and used. The *trustworthiness* of AI in the eyes of dental practitioners, however, is often negatively affected by the inability of the system to present the outputs in a medically acknowledgeable format [46]. Based on our experience from the assessment this usually means a lack of confidence rate, accuracy, precision, and subsequent binary decision-making of the AI system. A growing number of healthcare workers are also suffering from change fatigue [37]. Innovations in healthcare are booming and their frequent implementation might be tiring and cause aversion in healthcare professionals. During our assessment, we also encountered similar risk, especially among the older generation of dentists. When presented with the opportunity to implement and use an AI system to analyse dental X-ray images, the answer was usually negative and the reasoning behind corresponded with either distrust of the system and its accuracy or change fatigue.

Another category of risks associated with using AI in dental care naturally relates to various issues around **privacy and data protection** [38] since such systems make use of personal and sensitive data such as dental X-rays. However, patients might not be fully aware that their personal data is also used for the purposes of training AI models. Additional risks are associated with potential data breaches. If divulged, collected data may reveal significant private information to the public since it consists of medical diagnosis and health status of individuals. But not only individual privacy is at stake when dealing with dental datasets. There is also the possibility to create country-specific or ethnicity-specific datasets with precise information on the health of these groups that might be exploited commercially. The aforementioned risks to

privacy and data protection are often in contrast with the potential benefits of using personal health data to generate new knowledge and cannot be minimised, such as in the case of testing much-needed drugs and vaccines (as currently highlighted by the COVID-19 crisis)[37].

A risk that is covered in literature much less than any of the aforementioned concerns the **unclear environmental sustainability** of complex AI systems. Training of AI models requires vast computational power, leading to significant energy consumption, emission of carbon, and freshwater expenditure. In consequence, training AI models and their subsequent functioning poses a great threat to the environment and its conservation. According to a paper focusing on the carbon footprint of deep learning models for medical image analysis, the underlying energy costs of training a baseline model on one 2D dataset can equal an annual carbon footprint of about 27 people from a low-income country [47]. In some cases when a model is large and widely used, such as the OpenAI's ChatGPT, the amount of freshwater consumed can equal filling a nuclear reactor's cooling tower [48]. On the other hand, better dental care and prevention supported by such AI systems could potentially lead to energy and water savings. Higher sustainability would be achieved due to less frequent occurrence of patients with severe diagnoses resulting in less frequent visits of dental practitioners.

3. Risks beyond AI regulation

Most of the presented risks associated with the use of AI in dental care shall be also observed from the point of regulation. The proposal of the Artificial Intelligence Act (AIA), which will be the landmark piece of legislation in the field of AI in the future, represents a horizontal regulation requiring a risk-based approach. AIA proposes four categories of AI systems based on the risk they pose for fundamental rights, health, and safety (AIA, Recital 13) with a focus on setting obligations for the category of high-risk AI systems. What constitutes a high-risk AI system is defined by the proposed Annex II for AI systems as safety components covered by specific EU legislation and Annex III of AIA via specific areas and applications. Considering the AI system used in dental care, it shall be observed that health care is currently not stipulated as a specific area of high risk. However, medical devices regulation is explicitly stated in Annex II triggering the requirements from AIA for AI systems as medical devices [49]. This in practice means that AIA will complement procedures established by medical devices regulations.

Prior to placing any high-risk AI system on the market, the provider of the AI system is obliged to undergo a conformity assessment that is a part of the auditing mechanisms provided by the AIA. The content of the conformity assessment is framed by requirements on quality management systems (AIA, Article 9 and Article 17) including appropriate data governance practices, human oversight, record keeping, or cybersecurity. For medical devices, requirements stemming from medical devices regulation also apply. For this reason, the medical technology industry calls for close alignment of relevant legislation [50]. However, it shall be noted that medical devices regulations do not provide substantive framework for AI systems used in healthcare. These regulations do not contain requirements for transparency, human-oversight or accountability of AI systems. [51] Therefore, it is of the essence to focus on requirements provided by AIA. In the following paragraphs, we will examine how these requirements reflect risks identified in the previous chapter.

The first discussed group of risks pertains to algorithmic **biases and the quality of training datasets** including the broader context of the provision of health care. Article 10 of the AIA sets forth rules for using representative datasets of sufficient quality. *Inter alia* data governance and management practices shall include "examination in view of possible biases" reflecting requirements for datasets to be relevant, representative, free of errors, and complete (AIA, Article 10 [2] [f] and [3]). Compliance with the requirement shall mitigate potential bias and discrimination. However, it does not tackle the issue of equality of dental care provision from the broader social context. Although one of the protected values of AIA is health, requirements for providers of AI systems focus on the health of an individual rather than the healthcare system as a whole.

Another group of risks pertains to the **over-reliance** of individuals on the outputs of AI. The issue relates to the legal requirement of human oversight set forth in the AIA Article 14. The rationale behind this is to require developers of high-risk AI systems to implement procedures and interfaces that allow high-risk AI systems to "be effectively overseen by natural persons during the period in which the AI system is in use" (AIA, Article 14 [1]). At the same time, implemented measures shall enable the individuals to whom human oversight is assigned to remain aware of automation bias, especially in cases where outputs are used for the decisions of an individual (AIA, Article 14 [4] [b]). It remains questionable if being vigilant is sufficient for dental professionals in the light of proven decrease in the accuracy of clinical practitioners. Such requirements shall be complemented by specific liability schemes.

The risk of not being able to understand the medical intervention is linked to the issue of **informed consent and transparency**. AIA primarily governs transparency requirements for (business) users of high-risk AI systems (AIA, Article 13) therefore placing clinical practitioners at the core of the obligation. Individuals, including patients, do not have a specific right to explanation according to the AIA. It shall be noted that the existence of the right to an explanation of specific decisions according to the EU General Data Protection Regulation also remains unclear [52]. The risk of transparency is not sufficiently governed by current or proposed regulations.

Regarding **trustworthiness**, rules laid down by AIA are aimed to support the objective of the development and deployment of trustworthy AI (AIA, Recital 5). In general, specific requirements stipulated for high-risk AI systems are indirectly aimed to foster trustworthiness. However, legislation is not always the most suitable option for promoting trust in general as it is often narrow in scope and applicable to a limited number of situations or products. The same applies to AIA. Also, the comparison of requirements of AIA and questions and areas discussed in ALTAI shows significant gaps between these instruments [34].

Privacy and processing of personal data are issues already covered by EU legislation[53]. As discussed above, Article 10 of AIA contains rules for data governance. However, the ethical risks discussed in the previous part of the article go beyond regulatory requirements in AIA or EU data protection laws. The latter is especially relevant in the case of the awareness of individual's data being used for training models or commercial dataset exploitation. These risks shall be mitigated with tools and processes stretching further than regulatory compliance.

Although AIA explicitly protects the health of individuals, the **governance of environmental sustainability** of high-risk AI systems is absent. Only recently, requirements for transparency of the high-risk AI systems' energy consumption were discussed in the legislative

process[54]. This may come as a surprise since the benefits of AI systems for the environment are specifically discussed in the impact assessment of the AIA[55].

4. Conclusion

The development of trustworthy AI in dental care requires a multi-faceted approach that takes into account not only technical factors but also ethical principles and human rights considerations. In this paper, we tried to demonstrate how ethics-based assessments and human rights impact assessments can serve as a superstructure for a better understanding of various ethical and social risks that can help with the development of trustworthy AI in dental care.

AI regulations like AIA will play an important role in regulating the development and deployment of AI systems in dental care, but as we have seen, it does not address all the concerns that arise to the full extent. Additionally, negotiations on the content of legal frameworks move slowly but risks emerge dynamically. It is of the essence to tackle risks generated by the use of AI on an ongoing basis and not wait and count on future compliance with hard regulation.

Moving forward, it will be important to continue to engage in conversations and collaborations that prioritize the ethical and human rights implications of AI in dental care and its impact on various stakeholders[34]. This way we can work towards the development of specific ethical frameworks and guidelines that can ensure the safe, responsible, and ethical deployment of AI in dental care and beyond.

References

[1] P. Rajpurkar, E. Chen, O. Banerjee, E. J. Topol, AI in health and medicine 28 (2022) 31–38. URL: https://www.nature.com/articles/s41591-021-01614-0. doi:10.1038/s41591-021-01614-0, number: 1 Publisher: Nature Publishing Group.

[2] A. Thurzo, W. Urbanová, B. Novák, L. Czako, T. Siebert, P. Stano, S. Mareková, G. Fountoulaki, H. Kosnáčová, I. Varga, Where Is the Artificial Intelligence Applied in Dentistry? Systematic Review and Literature Analysis, Healthcare 10 (2022) 1269. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9320442/. doi:10.3390/healthcare10071269.

[3] P. P. Kale, S. Rajendiran, J. D, A. Mani, R. G. Mustilwar, A. N. Shetti, Exploring the boundless potential of artificial intelligence (AI) in dentistry, The Journal of Dental Panacea 5 (2023) 25–28. URL: https://www.jdentalpanacea.org/article-details/18658. doi:10.18231/j.jdp.2023.006.

[4] S. S. Mahdi, G. Battineni, M. Khawaja, R. Allana, M. K. Siddiqui, D. Agha, How does artificial intelligence impact digital healthcare initiatives? A review of AI applications in dental healthcare, International Journal of Information Management Data Insights 3 (2023) 100144. URL: https://www.sciencedirect.com/science/article/pii/S2667096822000878. doi:10.1016/j.jjimei.2022.100144.

[5] H. Ding, J. Wu, W. Zhao, J. P. Matinlinna, M. F. Burrow, J. K. H. Tsoi, Artificial intelligence in dentistry—A review, Frontiers in Dental Medicine 4 (2023). URL: https://www.frontiersin.org/articles/10.3389/fdmed.2023.1085251.

[6] E. Kosan, J. Krois, K. Wingenfeld, C. Deuter, R. Gaudin, F. Schwendicke, Patients' Perspectives on Artificial Intelligence in Dentistry: A Controlled Study, Journal of Clinical Medicine 11 (2022). doi:10.3390/jcm11082143.

[7] J. Faber, C. Faber, P. Faber, Artificial intelligence in orthodontics, APOS Trends in Orthodontics 9 (2019) 201–205. doi:10.25259/APOS_123_2019.

[8] S. Rasteau, D. Ernenwein, C. Savoldelli, P. Bouletreau, Artificial intelligence for oral and maxillo-facial surgery: A narrative review, Journal of Stomatology, Oral and Maxillofacial Surgery 123 (2022) 276–282. URL: https://www.sciencedirect.com/science/article/pii/S2468785522000271. doi:10.1016/j.jormas.2022.01.010.

[9] T. Eschert, F. Schwendicke, J. Krois, L. Bohner, S. Vinayahalingam, M. Hanisch, A Survey on the Use of Artificial Intelligence by Clinicians in Dentistry and Oral and Maxillofacial Surgery, Medicina 58 (2022) 1059. URL: https://www.mdpi.com/1648-9144/58/8/1059. doi:10.3390/medicina58081059, number: 8, Publisher: Multidisciplinary Digital Publishing Institute.

[10] M. Kreiner, J. Viloria, A novel artificial neural network for the diagnosis of orofacial pain and temporomandibular disorders, Journal of Oral Rehabilitation 49 (2022) 884–889. doi:10.1111/joor.13350.

[11] A. B. Krishna, A. Tanveer, P. V. Bhagirath, A. Gannepalli, Role of artificial intelligence in diagnostic oral pathology-A modern approach, Journal of Oral and Maxillofacial Pathology : JOMFP 24 (2020) 152–156. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7269295/. doi:10.4103/jomfp.JOMFP_215_19.

[12] S. Sachdeva, A. Mani, H. Vora, H. Saluja, S. Mani, N. Manka, Artificial intelligence in periodontics – A dip in the future, Journal of Cellular Biotechnology 7 (2021) 1–6. doi:10.3233/JCB-210041.

[13] M. I. Karobari, A. H. Adil, S. N. Basheer, S. Murugesan, K. S. Savadamoorthi, M. Mustafa, A. Abdulwahed, A. A. Almokhatieb, Evaluation of the Diagnostic and Prognostic Accuracy of Artificial Intelligence in Endodontic Dentistry: A Comprehensive Review of Literature, Computational and Mathematical Methods in Medicine 2023 (2023) e7049360. URL: https://www.hindawi.com/journals/cmmm/2023/7049360/. doi:10.1155/2023/7049360, publisher: Hindawi.

[14] S. A. Bernauer, N. U. Zitzmann, T. Joda, The Use and Performance of Artificial Intelligence in Prosthodontics: A Systematic Review, Sensors (Basel, Switzerland) 21 (2021) 6628. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8512216/. doi:10.3390/s21196628.

[15] D. A. Hashimoto, E. Witkowski, L. Gao, O. Meireles, G. Rosman, Artificial Intelligence in Anesthesiology: Current Techniques, Clinical Applications, and Limitations, Anesthesiology 132 (2020) 379–394. URL: https://doi.org/10.1097/ALN.0000000000002960. doi:10.1097/ALN.0000000000002960.

[16] A. S. of Anesthesiologists, Using ai to create work schedules significantly reduces physician burnout, American Society of Anesthesiologists (2022). URL: https://www.asahq.org/about-asa/newsroom/news-releases/2022/01/using-ai-to-create-work-schedules-significantly-reduces-physician-burnout, [Accessed: April 20, 2023].

[17] K. F. Hung, A. W. K. Yeung, M. M. Bornstein, F. Schwendicke, Personalized dental medicine, artificial intelligence, and their relevance for dentomaxillofacial imaging, Dentomaxillofa-

cial Radiology 52 (2023) 20220335. URL: https://www.birpublications.org/doi/10.1259/dmfr.20220335. doi:10.1259/dmfr.20220335, publisher: The British Institute of Radiology.

[18] R. Urban, S. Haluzová, M. Strunga, J. Surovková, M. Lifková, J. Tomášik, A. Thurzo, AI-Assisted CBCT Data Management in Modern Dental Practice: Benefits, Limitations and Innovations, Electronics 12 (2023) 1710. URL: https://www.mdpi.com/2079-9292/12/7/1710. doi:10.3390/electronics12071710, number: 7, Publisher: Multidisciplinary Digital Publishing Institute.

[19] S. Talpur, F. Azim, M. Rashid, S. A. Syed, B. A. Talpur, S. J. Khan, Uses of Different Machine Learning Algorithms for Diagnosis of Dental Caries, Journal of Healthcare Engineering 2022 (2022) e5032435. URL: https://www.hindawi.com/journals/jhe/2022/5032435/. doi:10.1155/2022/5032435, publisher: Hindawi.

[20] A. Kirillov, E. Mintun, N. Ravi, H. Mao, C. Rolland, L. Gustafson, T. Xiao, S. Whitehead, A. C. Berg, W.-Y. Lo, P. Dollár, R. Girshick, Segment Anything, 2023. URL: http://arxiv.org/abs/2304.02643. doi:10.48550/arXiv.2304.02643, arXiv:2304.02643 [cs].

[21] A. Y. Marchenko, M. L. Entin, Artificial intelligence and human rights: What is the EU's approach?, Digital Law Journal Vol. 3 (2022) 43–57. URL: https://www.digitallawjournal.org/jour/article/view/116. doi:10.38044/2686-9136-2022-3-3-43-57.

[22] M. Veale, F. J. Z. Borgesius, Demystifying the draft EU artificial intelligence act, CoRR abs/2107.03721 (2021). URL: https://arxiv.org/abs/2107.03721. arXiv:2107.03721.

[23] J. Ayling, A. Chapman, Putting AI ethics to work: are the tools fit for purpose? Vol. 2 (2022) 405–429. URL: https://doi.org/10.1007/s43681-021-00084-x. doi:10.1007/s43681-021-00084-x.

[24] Future AI, Assessment Checklist, 2023. URL: https://future-ai.eu/checklist/.

[25] C. f. D. a. R. Health, Good machine learning practice for medical device development: Guiding principles (2022). URL: https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles, publisher: FDA.

[26] Y.-K. Huang, L.-P. Hsu, Y.-C. Chang, Artificial intelligence in clinical dentistry: The potentially negative impacts and future actions Vol. 17 (2022) 1817–1818. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9588846/. doi:10.1016/j.jds.2022.07.013.

[27] L.-P. Hsu, Y.-K. Huang, Y.-C. Chang, The implementation of artificial intelligence in dentistry could enhance environmental sustainability Vol. 17 (2022) 1081–1082. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9201627/. doi:10.1016/j.jds.2022.02.002.

[28] C. Mörch, S. Atsu, W. Cai, X. Li, S. Madathil, X. Liu, V. Mai, F. Tamimi, M. Dilhac, M. Ducret, Artificial intelligence and ethics in dentistry: A scoping review Vol. 100 (2021) 1452–1460. URL: https://doi.org/10.1177/00220345211013808. doi:10.1177/00220345211013808, publisher: SAGE Publications Inc.

[29] A. Jobin, M. Ienca, E. Vayena, The global landscape of AI ethics guidelines Vol. 1 (2019) 389–399. URL: https://www.nature.com/articles/s42256-019-0088-2. doi:10.1038/s42256-019-0088-2, number: 9 Publisher: Nature Publishing Group.

[30] M. Ducret, C.-M. Mörch, T. Karteva, J. Fisher, F. Schwendicke, Artificial intelligence for sustainable oral healthcare Vol. 127 (2022) 104344. URL: https://www.sciencedirect.com/

science/article/pii/S0300571222003992. doi:10.1016/j.jdent.2022.104344.
[31] E. Commission, C. Directorate-General for Communications Networks, Technology, The Assessment List for Trustworthy Artificial Intelligence (ALTAI) for self assessment, Publications Office, 2020. doi:doi/10.2759/002360.
[32] A. Mantelero, Beyond Data: Human Rights, Ethical and Social Impact Assessment in AI, Springer Nature, 2022. URL: https://library.oapen.org/handle/20.500.12657/57009. doi:10.1007/978-94-6265-531-7.
[33] Ethics guidelines for trustworthy AI | shaping europe's digital future, 2019. URL: https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai.
[34] A. Gavornik, J. Podroužek, M. Mesarcik, S. Solarova, S. Oresko, M. Bielikova, Utilising the assessment list for trustworthy AI: Three areas of improvement, volume 3275, CEUR-WS.org, 2022, p. 8. URL: https://ceur-ws.org/Vol-3275/paper3.pdf.
[35] H. Suresh, J. V. Guttag, A framework for understanding sources of harm throughout the machine learning life cycle, in: Equity and Access in Algorithms, Mechanisms, and Optimization, 2021, pp. 1–9. URL: http://arxiv.org/abs/1901.10002. doi:10.1145/3465416.3483305. arXiv:1901.10002 [cs, stat].
[36] AI Now Institute, Discriminating Systems: Gender, Race, and Power in AI - Report, Technical Report, AI Now Institute, 2019. URL: https://ainowinstitute.org/publication/discriminating-systems-gender-race-and-power-in-ai-2.
[37] Organisation for Economic Co-operation and Development, Trustworthy Artificial Intelligence in Health, OECD Health Working Papers 125, OECD Publishing, Paris, 2021. URL: https://www.oecd.org/health/trustworthy-artificial-intelligence-in-health.pdf.
[38] B. C. Stahl, T. Leach, Assessing the ethical and social concerns of artificial intelligence in neuroinformatics research: an empirical test of the European Union Assessment List for Trustworthy AI (ALTAI), AI and Ethics (2022). URL: https://doi.org/10.1007/s43681-022-00201-4. doi:10.1007/s43681-022-00201-4.
[39] Charter of Fundamental Rights of the European Union, 2012. URL: http://data.europa.eu/eli/treaty/char_2012/oj/eng, legislative Body: EUMS.
[40] WHO, Ethics and governance of artificial intelligence for health, 2021. URL: https://www.who.int/publications-detail-redirect/9789240029200.
[41] M. Sujan, D. Furniss, K. Grundy, H. Grundy, D. Nelson, M. Elliott, S. White, I. Habli, N. Reynolds, Human factors challenges for the safe use of artificial intelligence in patient care, BMJ Health & Care Informatics 26 (2019) e100081. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7252977/. doi:10.1136/bmjhci-2019-100081.
[42] S. Krügel, A. Ostermaier, M. Uhl, ChatGPT's inconsistent moral advice influences users' judgment, Scientific Reports 13 (2023) 4569. URL: https://www.nature.com/articles/s41598-023-31341-0. doi:10.1038/s41598-023-31341-0, number: 1 Publisher: Nature Publishing Group.
[43] T. L. Tsai, D. B. Fridsma, G. Gatti, Computer Decision Support as a Source of Interpretation Error: The Case of Electrocardiograms, Journal of the American Medical Informatics Association : JAMIA 10 (2003) 478–483. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC212785/. doi:10.1197/jamia.M1279.
[44] R. Guidotti, A. Monreale, S. Ruggieri, F. Turini, F. Giannotti, D. Pedreschi, A survey of methods for explaining black box models, ACM Comput. Surv. 51 (2018). URL: https:

//doi.org/10.1145/3236009. doi:10.1145/3236009.
[45] M. Ghassemi, L. Oakden-Rayner, A. L. Beam, The false hope of current approaches to explainable artificial intelligence in health care, The Lancet. Digital Health 3 (2021) e745–e750. doi:10.1016/S2589-7500(21)00208-9.
[46] T. Shan, F. Tay, L. Gu, Application of Artificial Intelligence in Dentistry, Journal of Dental Research 100 (2021) 232–244. URL: https://doi.org/10.1177/0022034520969115. doi:10.1177/0022034520969115, publisher: SAGE Publications Inc.
[47] R. Selvan, N. Bhagwat, L. F. W. Anthony, B. Kanding, E. B. Dam, Carbon footprint of selecting and training deep learning models for medical image analysis 13435 (2022) 506–516. URL: http://arxiv.org/abs/2203.02202. doi:10.1007/978-3-031-16443-9_49. arXiv:2203.02202 [cs, eess].
[48] P. Li, J. Yang, M. A. Islam, S. Ren, Making AI less "thirsty": Uncovering and addressing the secret water footprint of AI models, 2023. URL: http://arxiv.org/abs/2304.03271. doi:10.48550/arXiv.2304.03271. arXiv:2304.03271 [cs].
[49] T. E. Union, Regulation (eu) 2017/745 of the european parliament and of the council of 5 april 2017 on medical devices, amending directive 2001/83/ec, regulation (ec) no 178/2002 and regulation (ec) no 1223/2009 and repealing council directives 90/385/eec and 93/42/eec, 2017. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745.
[50] M. Europe, Medtech europe views on the artificial intelligence act, 2022. URL: https://digital-strategy.ec.europa.eu/en/library/impact-assessment-regulation-artificial-intelligence.
[51] A. Kiseleva, Ai as a medical device: Between the medical devices framework and the general ai regulation, 2021. URL: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4219937.
[52] S. Wachter, B. Mittelstadt, L. Floridi, Why a right to explanation of automated decision-making does not exist in the general data protection regulation, International Data Privacy Law 7 (2017) 76–99. doi:10.1093/idpl/ipx005.
[53] T. E. Union, Regulation (eu) 2016/679 of the european parliament and of the council of 27 april 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing directive 95/46/ec (general data protection regulation), 2016. URL: https://eur-lex.europa.eu/eli/reg/2016/679/oj.
[54] L. Bertuzzi, Ai act: European parliament headed for key committee vote at end of april, 2023. URL: https://www.euractiv.com/section/artificial-intelligence/news/ai-act-european-parliament-headed-for-key-committee-vote-at-end-of-april/?utm_source=substack&utm_medium=email.
[55] T. E. Commission, Impact assessment of the regulation on artificial intelligence, 2021. URL: https://digital-strategy.ec.europa.eu/en/library/impact-assessment-regulation-artificial-intelligence.