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|  | INTERNATIONAL TELECOMMUNICATION UNION  **TELECOMMUNICATION STANDARDIZATION SECTOR**  STUDY PERIOD 2022-2024 | | FG-AI4H-R-010-A01 | |
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| **Abstract:** | This topic description document (TDD) specifies a standardized benchmarking for AI-based Dental Diagnostics and Digital Dentistry. It covers all scientific, technical, and administrative aspects relevant for setting up this benchmarking (and follows the template structure defined in document FGAI4H-J-105). The creation of this TDD is an ongoing iterative process until it is approved by the Focus Group on AI for Health (FG-AI4H) as deliverable No. 10.17. This draft will be a continuous input- and output document. |
| **Change notes:** | Version 4.7 (submitted as FGAI4H-R-010-A01 for meeting Q; Cambridge, USA)   * Onboarding of new contributors to the topic group * Data set annotations for periapical radiolucencies on PAN * Dental dataset literature review * Preparation of the 2nd TG-Dental Symposium   Version 4.6 (submitted as FGAI4H-Q-010-A01 for meeting Q; Douala, Cameroon)   * Onboarding of new contributors to the topic group * Dental dataset literature review * Publication of Dental-AI curriculum * Experient on Federated Learning for dental radiographs   Version 4.5 (submitted as FGAI4H-P-010-A01 for meeting P; Helsinki, Finland)   * Onboarding of new contributors to the topic group * Preparation of the 1st TG-Dental Symposium   Version 4.4 (submitted as FGAI4H-O-010-A01 for meeting O; Berlin, Germany)   * Onboarding of new contributors to the topic group * Establishment of the subtopic group “Oral Pathology”   Version 4.3 (submitted as FGAI4H-N-010-A01 for e-meeting N; remote)   * Onboarding of new contributors to the topic group * Establishment of the subtopic group “Endodontics”   Version 4.2 (submitted as FGAI4H-M-010-A01 for e-meeting M; remote)   * Onboarding of new contributors to the topic group * Expanding on section 3 by structuring subtopics along the clinical care pathway and along subfields of dentistry.   Version 4.1 (submitted as FGAI4H-L-010-A01 for e-meeting L; remote)   * Onboarding of new contributors to the topic group * Inserting figure 1 that visualizes the thematic structure of subtopics along the clinical care pathway and along subfields of dentistry.   Version 4.0 (submitted as FGAI4H-K-010-A01 for e-meeting K; remote)   * Updating the template structure as defined in document FGAI4H-J-105   Version 3.0 (submitted as FGAI4H-J-010-A01 for e-meeting J; remote)   * Updates for section 2, AI4H Topic group.   + Expanding list of contributors (adding information on Dr Robert Gaudin and Dr Akhilanand Chaurasia) * Adding section 3.5.2 Tooth level metrics for segmentation tasks   Version 2 (submitted as FGAI4H-I-010-A01 for e-meeting I in Geneva)   * Update of TDD abstract * Formatting of the document to emphasis sections not yet populated with text * Updates for section 2, AI4H Topic group.   + Expanding list of contributors (adding information on Tarry Singh and deepkapha.ai)   + Defining tools for communication   + Setting up biweekly calls   + Updating the current status   Version 1 (submitted as FGAI4H-H-010-A01 for meeting H in Brasilia)  This document served as the initial draft for the topic description document (TDD) of the topic group TG-Dental, which is concerned with the standardized benchmarking of AI for dental diagnostics and digital dentistry.  The focus for the first draft was on sections 1. Introduction and 3. Methods.   * Introduction   + Relevance   + Impact   + Existing work * Method   + Anatomical structures   + Pathologies   + Data sets and format   + AI Output Data Structure   + Metrics |

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**FG-AI4H Topic Description Document**

**Topic group - Dental Diagnostics and Digital Dentistry (TG-Dental)**

1. **Introduction**

The topic group Dental Diagnostics and Digital Dentistry (TG-Dental) focusses on diagnostics in dentistry, dental and oral medicine, and associated disciplines (oral and maxillofacial surgery, orthodontics, dental and oral traumatology). Specifically, it deals with the following (not exhaustive) ICD-10 code headings:

* K00 Disorders of tooth development and eruption
* K01 Embedded and impacted teeth
* K02 Dental caries
* K03 Other diseases of hard tissues of teeth
* K04 Diseases of the pulp and periapical tissues
* K05 Gingivitis and periodontal diseases
* K06 Other disorders of the gingiva and edentulous alveolar ridges
* K07 Dento-facial anomalies including malocclusion
* K08 Other disorders of the teeth and supporting structures
* K09 Cysts of oral origin, not elsewhere classified
* K10 Other diseases of jaws
* K11 Diseases of the salivary glands
* K12 Stomatitis and related lesions
* K13 Other diseases of the lip and oral mucosa
* K14 Diseases of the tongue
* J01: Acute sinusitis
* J32: Chronic sinusitis

Diagnostics include the detection, assessment and prognosis of and on these conditions, as well as diagnostics on patients’ risk to experience a condition or its progression. Diagnostics also includes the (image or non-image) assessment of anatomic structures or physiologic functions for the purpose of both detection of conditions, but also treatment planning for various therapies (e.g., implantology).

Dental conditions, like caries, periodontitis or tooth loss, are among the most prevalent diseases of humankind, affecting up to 98% of a population. Direct treatment costs due to dental diseases globally were estimated at US $298 billion annually, corresponding to an average of 4.6% of global health expenditure. The burden emanating from oral diseases is comparable to that from diabetes or cardiovascular diseases. The majority of the world's 1.6 million dentists are based in Europe and the Americas, such that 69% of the world's dentists serve 27% of the global population. Africa has only 1% of the global workforce. The overall workforce in dentistry exceeds 10 million worldwide. Diagnostics in dentistry largely relies on dentists diagnosing diseases via a combination of dental history taking, clinical investigation and imaging as well, if required, further physical, (bio)chemical or microbiological assessments.

AI will help to (1) improve the accuracy of each of these individual tasks, (2) allow the integration of different data with higher effectiveness than the individual can do this, (3) without ease also longitudinally assess these data, compare them over time, and hence allow predictions, (4) reduce the reliance of diagnosis making from the dentist, expanding the scope of dental auxiliary staff, thereby increasing the access and efficiency of dental services, and (5) enable patients and healthy individuals to better participate into their dental health experience and management. AI will pave the way to a more personalized, precise, preventive and participatory dentistry for more people worldwide. It has the potential to aid in overcoming current ineffective, expensive care models.

Expected impact of benchmarking: Benchmarking is expected to yield more robust models and algorithms, with initially lower accuracy compared with current validation strategies (largely in-sample). Benchmarking is further expected to allow transparent comparisons of different models and algorithms.

This topic description document specifies the standardized benchmarking for Dental Diagnostics and Digital Dentistry systems. It serves as deliverable No. 10.17 of the ITU/WHO Focus Group on AI for Health (FG-AI4H).

1. **About the FG-AI4H topic group on Dental Diagnostics and Digital Dentistry**

The introduction highlights the potential of a standardized benchmarking of AI systems for Dental Diagnostics and Digital Dentistry to help solving important health issues and provide decision-makers with the necessary insight to successfully address these challenges.

To develop this benchmarking framework, FG-AI4H decided to create the TG-Dental at the meeting G in New Delhi, 13-15 November 2019.

FG-AI4H assigns a topic driver to each topic group (similar to a moderator) who coordinates the /collaboration of all topic group members on the TDD. During FG-AI4H meeting G in in New Delhi, 13-15 November 2019 Prof. Dr. Falk Schwendicke and Dr. Joachim from Charité – Universitätsmedizin Berlin Germany nominated as topic driver for the TG-Dental.

* 1. **Documentation**

This document is the TDD for the TG-Dental. It introduces the health topic including the AI task, outlines its relevance and the potential impact that the benchmarking will have on the health system and patient outcome, and provides an overview of the existing AI solutions for Dental Diagnostics and Digital Dentistry. It describes the existing approaches for assessing the quality of Dental Diagnostics and Digital Dentistry systems and provides the details that are likely relevant for setting up a new standardized benchmarking. It specifies the actual benchmarking methods for all subtopics at a level of detail that includes technological and operational implementation. There are individual subsections for all versions of the benchmarking. Finally, it summarizes the results of the topic group’s benchmarking initiative and benchmarking runs. In addition, the TDD addresses ethical and regulatory aspects.

The TDD will be developed cooperatively by all members of the topic group over time and updated TDD iterations are expected to be presented at each FG-AI4H meeting.

The final version of this TDD will be released as deliverable “DEL 10.17 Dental Diagnostics and Digital Dentistry (TG-Dental).” The topic group is expected to submit input documents reflecting updates to the work on this deliverable (Table 1) to each FG-AI4H meeting.

**Table 1: Topic group output documents**

|  |  |
| --- | --- |
| **Number** | **Title** |
| FGAI4H-Q-010-A01 | Latest update of the Topic Description Document of the TG-Dental |
| FGAI4H-Q-010-A02 | Latest update of the Call for Topic Group Participation (CfTGP) |
| FGAI4H-Q-010-A03 | The presentation summarizing the latest update of the Topic Description Document of the TG-Dental |

The working version of these documents can be found in on Google Docs.

* https://drive.google.com/drive/u/0/folders/1QvNGaH9hKUHBGuulor5Vm9r-LxMySlu5
  1. **Status of this topic group**

The following subsections describe the update of the collaboration within the TG-Dental for the official focus group meetings.

* + 1. **Status update for meeting H**

After the establishment of the TG-Dental at meeting G the “Call for Topic Group Partizipation Document (CfTGP)“ was drafted and the “Topic Description Document (TDD)” was updated with a focus on the sections 1. Introduction and 3. Methods.

* Introduction
  + Relevance
  + Impact
  + Existing work
* Method
  + Anatomical structures
  + Pathologies
  + Data sets and format
  + AI Output Data Structure
  + Metrics

Further, other academic groups in dentistry that focus on machine learning and deep learning but as well on ethics, public health and economics were contacted.

* + 1. **Status update for meeting I**

The TDD abstract was updated and the TDD was reviewed to emphasize sections not yet populated with text.

In addition, the list of contributors was expanded and Tarry Singh, from deepkapha.ai, Netherlands, as well as Prof Jae-Hong Lee from Wonkwang University, Korea, joined the TG-Dental. The CfTGP was updated accordingly. The contributors of the TG-Dental defined tools for communication and set up bi-weekly calls via the zoom chat room of FGAI4H (<https://itu.zoom.us/my/fgai4h>).

Prof Schwendicke initiated consultations with key opinion leaders from SPIRIT/CONSORT-AI in order to prepare the dissemination in key dental journals. Further, the contributors of the TG-Dental started the drafting of a series of scientific articles on dental AI methods, opportunities and challenges in leading dental journals.

* + 1. **Status update for meeting J**

Two new contributors joined the TG-Dental, Dr. Robert Gaudin from Charite – Universitätsmedizin Berlin, Germany and Dr. Akhilanand Chaurasia from King George Medical University, Lucknow, India.

The TG-Dental contributors drafted a manuscript on *Artificial intelligence for dental image analysis: A Guide for Authors and Reviewers and* shared it for discussion with FGAI4H members.

The TDD was updated in particular on section 4.5, Metrics, where the concept of computing the tooth-based confusion matrix for dental image segmentation tasks was described. This allows the calculation of tooth level metrics for segmentation tasks, which in turn is useful to compare computer vision metrics to clinical data that is widely accessible in clinical studies and trials.

* + 1. **Status update for meeting K**

For meeting K the TDD structure was adapted as defined in document FGAI4H-J-105.

The contributors of TG-Dental in addition with Thomas Wiegand (Chair of the ITU/WHO FGAI4H) and Sergio Uribe (President of the e-Oral Health Network of the IADR) drafted the manuscript *Artificial intelligence in dental research: A Checklist for Authors and Reviewers.* This manuscript highlights the challenge that the number of studies employing artificial intelligence in dentistry is growing fast but that the majority of studies suffer from limitations in planning, conduct and reporting, resulting in low robustness and applicability. The manuscript provides a consented checklist for authors, reviewers and readers of AI studies in dental research. The initial draft of the checklist and an explanatory document were derived and discussed among the members of IADR’s e-oral network and the ITU/WHO focus group “Artificial Intelligence for Health (AI4H)”. The checklist was consented by 27 group members via an e-Delphi process.

In addition, members of TG-Dental contributed to the systematic review and meta-analysis of deep learning for cephalometric landmark detection. From 318 identified records, 19 studies (published 2017-2020), all employing convolutional neural networks, mainly on 2-D-lateral cephalometric radiographs (n=15), using data from publicly available datasets (n=12) and testing the detection of a mean of 30 (SD: 25; median: 19; min.-max.: 7-93) landmarks were included. The reference test was established by two (n=11), 1 (n=4), 3 (n=3) or a set of experts (n=1). Risk of bias was high and applicability concerns detected for most studies. The mean (95% confidence interval) deviation of predicted from reference landmarks was 2.1 (95% CI: 1.2-3.0) mm, while the mean % of landmarks detected with 0.05). The analysis concluded that DL shows relatively high accuracy for detecting landmarks on cephalometric imagery; however, only few studies directly compared DL with clinicians or sufficiently reflected on the dimension of deviation (vertical versus sagittal). The overall body of evidence is consistent, but of limited robustness. The insights of this study will be incorporated into the TDD and inform the state-of-the-art of AI-based cephalometric landmark detection.

* + 1. **Status update for meeting L**

Three new contributors joined the TG-Dental, Janet Brinz, final year dentistry student at Universität Regensburg, Germany; Sergio Uribe, PhD, DDS, specialist in Oral & Maxillofacial Radiology, leading researcher, Bioinformatics Research Unit Riga Stradins University, Riga, Latvia and Associate Professor Universidad Austral de Chile, Valdivia, Chile; and Hossein Mohammad-Rahimi a General Dentist (DDS) graduated from SBMU, Tehran, Iran, Research Assistant, Computer Engineering Department, Sharif University of Technology, Tehran, Iran and

founder of “DeepBites” research group, which applies AI approaches to dentistry.

The topic group members initiated a discussion on the structure of AI in dentistry and developed a figure that thematically structures AI subtopics along the clinical care pathway and along subfields of dentistry (see Figure 1).

In addition, a systematic review of AI applications in dentistry was initialized resulting in over eligible 190 studies, with nearly all of them focusing on either image analysis or shallow machine learning. These studies showed a high risk of bias. Various accuracy estimates and more than 25 different use cases were found. A preliminary conclusion indicates limited consistency and comparability of the studies but reporting quality increased over time. Notably, outcomes beyond accuracy score are scarce and robustness and generalizability remains unclear.

* + 1. **Status update for meeting M**

Seven new contributors joined the TG-Dental. Anahita Haiat, a final year dental student- University of Western Australia, Perth, Australia holding a Master of Engineering and a Bachelor of Mathematics. Jaisri Thoppay, President of the Center for Integrative Oral Health inc. Winter Park, Florida, USA. Nielsen Pereira, a dentist and entrepreneur. Gürkan Ünsal, a dentomaxillofacial radiologist at Near East University, Faculty of Dentistry and member of the Artificial Intelligence in Medicine Research Group at Near East University, DESAM Institute. Ulrike Kuchler, an Associate Professor at the Department of Oral Surgery, Medical University of Vienna, Vienna, Austria. Balazs Feher a junior scientist and lecturer in oral surgery at Medical University of Vienna, Vienna, Austria. Shankeeth Vinayahalingam a PhD student in Oral & Maxillofacial Surgery at Radboudumc Nijmegen, the Netherlands and a Master AI student at Radboud University, Nijmegen, the Netherlands. Figure 1 was revised and updated according to new members joining the group. These new members were assigned to different subdomains according to their expertise and interest. In addition an "infrastructure"-column was added. In this column members are referenced that are in particular interested in technical aspects of the collaboration.

Section 3 and in particular the subtopic descriptions have been significantly advanced.

The TG-Dental successfully published the FGAI4H output document "Artificial intelligence in dental research: A checklist for authors and reviewers (FGAI4H-M-004-A01)". The checklist for dental AI studies was produced as a collaboration of experts from the International Association for Dental Research (IADR), the E-oral Health Network and the ITU/WHO Focus Group on AI for Health. Given that the number of studies employing artificial intelligence (AI), specifically machine and deep learning, is growing fast and that the majority of studies suffer from limitations in planning, conduct and reporting, resulting in low robustness, reproducibility and applicability, this document provides a consented checklist on planning, conducting and reporting of AI studies for authors, reviewers and readers in dental research.

The TG-Dental further conceptualized their first multi-center benchmark study. The goal is to include approximately 10 centers/clinics/practices from all over the world. It is expected that differences in cohort characteristics (age and gender), the dental status (e.g. DMFT) and technical conditions (x-ray machine, image characteristics, etc), among others will be present. In a collaborative effort different DL models will be trained on the data of different centers (or different subsets, etc) and predict on hold-out test sets from the center the model was trained on but as well on centers representing other populations. We would expect differences in those results. We will evaluate the statistical significance of those differences but as well implement inference models and methods of model explainability to evaluate which of the metadata (cohort, clinical and technical) can be associated with those differences.

In addition, this benchmark study was accepted as one more use case for the FG-AI4H Trial Audits 2.0 project. This project is ongoing and for the team formation phase very good progress was reported. In a next phase the "Audit Methodology Design" will be further developed (see Section 3.B under [Trial Audit 2.0 Playbook](https://docs.google.com/document/d/1YPMy2oFc8vr5mGlQ_zVft2Mm31fiRdgHr25kEc2g37Y/edit?usp=sharing)).

* + 1. **Status update for meeting N**

Nineteen new contributors joined the TG-Dental.

* Chen Nadler from the Oral-Maxillofacial Imaging Unit, Hadassah Medical Center, Faculty of Dental Medicine, Hebrew University of Jerusalem, Israel
* Sahel Hassanzadeh-Samani from Dentofacial Deformities Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran
* Parisa Motie, Student Research Committee, school of dentistry, Shahid Beheshti University of Medical Sciences, Tehran, Iran
* Ragda Abdalla-Aslan, Oral Medicine Specialist, Department of Oral and Maxillofacial Surgery, Rambam Health Care Campus, Haifa and Department of Oral Medicine, Sedation and Maxillofacial Imaging, Hebrew University-Hadassah School of Dental Medicine, Jerusalem, Israel
* Teodora Karteva, Operative Dentistry & Endodontics, Department of Operative Dentistry & Endodontics, Medical University - Plovdiv, Bulgaria
* Jelena Roganovic, Associate professor, Department of Pharmacology in Dentistry, University of Belgrade, Serbia
* Kunaal Dhingra, Periodontics Division, Centre for Dental Education and Research, All India Institute of Medical Sciences, New Delhi, India
* Dr. Prabhat Kumar Chaudhari, Division of Orthodontics and Dentofacial Deformities, Centre for Dental Education and Research (CDER), All India Institute of Medical Sciences (AIIMS), New Delhi, India.
* Olga Tryfonos, Periodontology Department, ACTA, The Netherlands
* Prof. Marja Laine, Chair Periodontology Department, ACTA, The Netherlands
* Rata Rokhshad, Dental material center, Azad tehran University, Iran
* Fatemeh Sohrabniya, Research Committee , Shiraz University of Medical Science, Iran
* Zeynab Pirayesh, Department of Orthodontics, School of Dentistry, Zanjan University of Medical Sciences, Zanjan, Iran.
* Shada Alsalamah, Technical Officer, Digital Health and Innovations Department, World Health Organization, Geneva, Switzerland and Assistant Professor, College of Computer and Information Sciences, King Saud University, Saudi Arabia, Riyadh.
* Sakher AlQahtani, Associate Professor, College of Dentistry, King Saud University and Honorary Professor, University of Queensland
* Revan Birke Koca-Ünsal, Assistant Professor, Department of Periodontology, Faculty of Dentistry, University of Kyrenia, Kyrenia, Cyprus
* Lubaina T. Arsiwala, Associate researcher, Charité – Universitätsmedizin Berlin  
  Germany
* Francesc Perez Pastor, Collaborating Prof. Master Orthodontics UB, IDISBA Palma, Mallorca, Spain
* Lisa Schneider, Charité – Universitätsmedizin Berlin, Germany

A working group for **Ethics** was established under the leadership of Rata Rokhshad. As AI applications in the dental field raise a wide range of potential ethical concerns and due to the limitation of dental publications about ethics, the main goal of the group is awareness. Further goals are acknowledging and applying privacy and data protection, the communication of the patient and clinician, data diversity, and protecting autonomy. The guidelines for the diversity and quality of data are going to be applied for the current projects. Currently, the group is working on ethical issues in the field of esthetics.

The topic group **Periodontal** updated the TDD. First, a new existing AI solution called “Overjet” was introduced. Overjet provides a FDA approved deep learning AI solution which can measure tooth-related bone loss from radiographic images and help diagnosing periodontitis. The subtopic group is continuously updating and searching for periodontal-related deep learning-based solutions. In addition, a benchmarking was explored about AI for identification and classification of dental implant systems. Not only were a lot of implant images in panoramic or periapical view collected for each company such as Astra, Dentium, Osstem but studies about deep learning algorithms for identification and classification of implants have started. Collecting datasets is ongoing.

The **Surgical** suptopic group expanded from 4 to 12 members in total. Multiple research collaborations within the subtopic are initialized. The strategy of this subtopic group is to review the current literature on AI in oral surgery and implantology and to provide an update regarding the current status of the field. The aim is to update the clinical knowledge of AI in this field and to evaluate the protocols in diagnostics based on AI. Beside this screening, the group has started with collaborative research projects collecting datasets for diagnostic reasons from different centers to test and compare available AI models as well as train new. The application of AI in oral surgery diagnostics (e.g., cystic lesions and tumors) is still limited to research and needs further development and evaluation before clinical utilization. The subtopic has made meaningful strides in this field, with an imminent submission in one of the highest-ranked dental journals. In general, the accuracy of AI models in oral surgery is dependent on the exact task and is therefore challenging in certain settings (e.g., diagnosis of cystic lesions with overlapping anatomical structures in the maxilla). Our aim is to improve and learn with experience through better training and increased availability of datasets.

* The subtopic group **Endodontics** was established under the leadership of Teodora Karteva. Endodontics is the art & science of retaining a natural tooth. Machine learning algorithms can improve the diagnosis, treatment, and prognosis of pulpal and periapical diseases as they assist clinicians in their exploration of the winding pathways of the pulp.

The subtopic group **Orthodontics** is currently conducting two projects, one on Lateral cephalometry, where currently the draft which aims at locating cephalometric landmarks, classification through cephalometric analysis, cervical maturation degree classification is revised and for the upper airway segmentation using deep learning approaches data extraction is ongoing.

During the ongoing **MCBS** more data was collected. Currently 1996 panoramic radiographs from 7 centers within 5 countries were made available. In total 24 annotators contributed to the annotation of 1673, resulting in approx. 41,800 annotated tooth masks.

* + 1. **Status update for meeting O**

Nine new collaborator joined the TG-Dental:

* Parul Khare, GP, Alpha Dental Clinic, Shanghai, China, Associate Professor (adjunct) Saraswati dental College Lucknow, India, Associate Professor (adjunct) Saveetha Dental College, Chennai, India
* Amit Punj, Associate Professor, Montefiore- Einstein, New York, USA
* Manal Hamdan, Oral and Maxillofacial Radiologist, Lincoln, NE, USA
* Zaid Badr, Assistant Professor, University of Nebraska Medical Center, Lincoln, NE, USA
* Tamara Peric, Associate Professor, Clinic for Pediatric and Preventive Dentistry, School of Dental Medicine, University of Belgrade, Serbia
* Dr Mihiri Silva, Senior Lecturer Paediatric Dentistry | Division Lead Cariology, Population Health & Oral Health, Melbourne Dental School, University of Melbourne, AUS, Consultant Paediatric Dentist & Clinician Science Fellow, Murdoch Childrens Research Institute, Royal Childrens Hospital Melbourne
* Ms. Bree Jones, Lecturer and PhD candidate, Melbourne Dental School, University of Melbourne, VIC, AUS
* Prof. Miroslav Radenkovic, Department of Pharmacology, Clinical, Pharmacology and Toxicology, Faculty of Medicine, University of Belgrade, Serbia
* Martha Duchrau, Charité – Universitätsmedizin Berlin, Oral Diagnostics, Digital Health & Health Services Research  
  Germany
* The subtopic group **Oral & Maxillofacial Oncology** was established under the leadership of Dr Parul Khare Sinha. The first initiative is to obtain a diverse dataset of oral histopathological slides in order to classify benign, dysplastic, and carcinomatous pathologies. Therefore, 4000 H&E slides of benign, dysplastic, and squamous cell carcinoma are to be collected from 10 different centers worldwide. Ten oral pathologists will serve as the reviewers and calibrate diagnosis.
* The subtopic group **Cariology** worked on the development of an annotated caries lesion dataset to independently evaluate different ML/DP models for radiographic caries detection and the evaluation of the quality of annotations on dental radiographic datasets. Further, the group worked on knowledge dissemination and published two manuscripts and one white paper in conjunction with the FDI World Dental Federation to inform and provide recommendations on the use of AI in dentistry.
* State of the art deep learning models for radiographic caries detection (J Dent 10.1016/j.jdent.2022.104115)
* Evaluation of the quality of data available for machine/deep learning in dentistry (J Dent Res 10.1177/00220345221101321)

The group on **Ethics** is now preparing a checklist for raising awareness and overcoming ethical issues in dental AI research and applications. Relevant terms and concepts such as, prudence, equity, autonomy, privacy, intimacy, responsibility, democratic participation, solidarity, data diversity, data protection, well-being, development, and patient-clinician relationship, among others, will be discussed.

Under the leadership of Teodora Karteva the public reachout was intensified via a knowledge hub that can be reached by the url: https://www.autodontics.com/.

The efforts with respect to benchmarking continued. During the ongoing **MCBS** more data was collected and an analytical team under the leadership of Lisa Schneider was established to start with the first experiments and model development.

* + 1. **Status update for meeting P**

Nine new collaborator joined the TG-Dental:

* Mohammed Omar, University of Iowa, Iowa City, IA, USA
* Gowri Sivaramakrishnan, Dental Postgraduate Training Department, Ministry of Health, Bahrain
* Saujanya Karki, Postdoctoral Researcher, Research Unit of Population Health, University of Oulu
* Tarja Tanner, Associate Professor, Research Unit of Population Health, University of Oulu
* Marja-Liisa Laitala, Professor, Department of Cariology, Endodontics and Pediatric Dentistry, Research Unit of Population Health, University of Oulu
* Johannes Tanne, Consultant for Regulatory Affairs and Dental AI

In this period we mainly worked on the preparation and organization of the 1st TG-Dental Symposium, which takes place on Sep 19th, 2022.

Diagram

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***Fig. Flyer for the TG-Dental Symposium***

* + 1. **Status update for meeting Q**

Seven new collaborator joined the TG-Dental:

* Sanaa Chala, Professor, Department of endodontics and restorative dentistry,Faculty of dental medicine, Mohammed V University in Rabat, Morocco
* Raphaël Richert, Assistant, Department of Endodontics and Restorative Dentistry, Faculty of Dental Surgery, Claude Bernard University Lyon 1, Lyon, France
* Pierre Lahoud, Clinical Assistant | Ph. D Researcher, Department of Periodontology & Oral Microbiology, OMFS-IMPATH Research Group, Department of Oral and MaxilloFacial Surgery, KU Leuven | UZ Leuven - Leuven, Belgium
* Julien Issa, PhD candidate, Department of Diagnostics, Faculty of Dentistry, Poznań University of Medical Sciences, Poznań, Poland
* Nisha Manila, Assistant Professor, Oral and Maxillofacial Radiology, Department of Diagnostic Sciences, Louisiana State University, School of Dentistry, New Orleans, LA, USA
* Fahad Umer, Assistant Professor, Operative Dentistry and Endodontics, Dentistry, Department of Surgery, Aga Khan University Hospital, Karachi, Pakistan
* Yunpeng Li, Senior Lecturer in Artificial Intelligence, Department of Computer Science, University of Surrey, Guildford, Surrey, UK

The TG started with a Dataset review, where multiple databases (incl. PubMed, Guthub, IEEE etc) were reviewed to collect dental datasets that can be used for AI applications. The data collection will be finished soon, thereafter an analysis will be conducted. We aim to publish the results in an international journal.

Further, the paper “Artificial intelligence for oral and dental healthcare: Core education curriculum” was published in the Journal of Dentistry, on the behalf of the FG-AI4H (https://www.sciencedirect.com/science/article/abs/pii/S0300571222004158). We aimed to define a core curriculum for both undergraduate and postgraduate education, establishing a minimum set of outcomes learners should acquire when taught about oral and dental AI. Therefore, existing curricula and other documents focusing on literacy of medical professionals around AI were screened and relevant items extracted. Items were scoped and adapted using expert interviews with members of the IADR's e-oral health and education group and the ITU/WHO's Focus Group AI for Health. Learning outcome levels were defined and each item assigned to a level. Items were systematized into domains and a curricular structure defined. The resulting curriculum was consented using an online Delphi process. Finally, four domains of learning outcomes emerged, with most outcomes being on the “knowledge” level:

1. Basic definitions and terms, the reasoning behind AI and the principle of machine learning, the idea of training, validating and testing models, the definition of reference tests, the contrast between dynamic and static AI, and the problem of AI being a black box and requiring explainability should be known.
2. Use cases, the required types of AI to address them, and the typical setup of AI software for dental purposes should be taught.
3. Evaluation metrics, their interpretation, the relevant impact of AI on patient or societal health outcomes and associated examples should be considered.
4. Issues around generalizability and representativeness, explainability, autonomy and accountability and the need for governance should be highlighted.

In addition, a study on the feasibility of Federated Learning in dentistry was submitted for expert review. In this study the ML-task of tooth segmentation/classification on dental radiographs was used to study the differences between local, central and Federated learning.

* + 1. **Status update for meeting R**

Three new collaborator joined the TG-Dental:

* Sharon Tan from Saw Swee Hock School of Public Health at National University of Singapore, Singapore
* Gauthier Dot, Assistant Professor of Orthodontics, UFR Odontologie, Université Paris Cité, Paris France
* Sara Haghighat, dentist and researcher at Shiraz University of Medical Sciences, Iran

We continued the annotation process and conducted a 5-times repeated annotation of periapical radiolucencies on panoramic radiographs. We thereby continue our efforts to build a benchmark dataset for dental AI applications.

Further, we prepared and organized the 2nd TG-Dental Symposium, which took place on March 21th, 2023.

Text

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* 1. **Topic group participation**

The participation in both, the Focus Group on AI for Health and in a TG is generally open to anyone (with a free ITU account). For this TG, the corresponding ‘Call for TG participation’ (CfTGP) can be found here:

* https://www.itu.int/en/ITU-T/focusgroups/ai4h/Documents/tg/CfP-TG-Dental.pdf

Each topic group also has a corresponding subpage on the ITU collaboration site. The subpage for this topic group can be found here:

* https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Dental.aspx

For participation in this topic group, interested parties can also join the regular online meetings. The meeting is scheduled for every 2nd Thursday at 08:15 CET. For all TGs, the link will be the standard ITU-TG ‘zoom’ link:

* <https://itu.zoom.us/my/fgai4h>

All relevant administrative information about FG-AI4H—like upcoming meetings or document deadlines—will be announced via the general FG-AI4H mailing list [fgai4h@lists.itu.int](mailto:fgai4h@lists.itu.int).

All TG members should subscribe to this mailing list as part of the registration process for their ITU user account by following the instructions in the ‘Call for Topic Group participation’ and this link:

* <https://itu.int/go/fgai4h/join>

Regular FG-AI4H workshops and meetings proceed about every two months at changing locations around the globe or remotely. More information can be found on the official FG-AI4H website:

* <https://itu.int/go/fgai4h>

1. **Topic description**

This section contains a detailed description and background information of the specific health topic for the benchmarking of AI in Dental Diagnostics and Digital Dentistry and how this can help to solve a relevant ‘real-world’ problem.

Topic groups summarize related benchmarking AI subjects to reduce redundancy, leverage synergies, and streamline FG-AI4H meetings. However, in some cases different subtopic groups can be established within one topic group to pursue different topic-specific fields of expertise. The TG-Dental currently has no subtopics. Future subtopics for Dentistry and Maxillofacial related conditions might be introduced.

Chart, sunburst chart

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**Figure 1: Thematic structure of subtopics along the clinical care pathway and along subfields of dentistry.**

* 1. **Subtopic - TEMPLATE [A]**
     1. **Definition of the AI task**

This section provides a detailed description of the specific task the AI systems of this TG are expected to solve. It is *not* about the benchmarking process (this will be discussed more detailed in chapter 4). This section corresponds to [DEL03](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B7997F2C1-5A1D-4409-B2A0-CBC4E9CE8CDA%7D&file=DEL03.docx&action=default) *“AI requirements specifications*,” which describes the functional, behavioural, and operational aspects of an AI system.

* What is the AI doing?
* What kind of AI task is implemented (e.g., classification, prediction, clustering, or segmentation task)?
* Which input data are fed into the AI model?
* Which output is generated?
  + 1. **Current gold standard**

This section provides a description of the established gold standard of the addressed health topic.

* How is the task currently solved without AI?
* Do any issues occur with the current gold standard? Does it have limitations?
* Are there any numbers describing the performance of the current state of the art?
  + 1. **Relevance and impact of an AI solution**

This section addresses the relevance and impact of the AI solution (e.g., on the health system or the patient outcome) and describes how solving the task with AI improves a health issue.

* Why is solving the addressed task with AI relevant?
* Which impact of deploying such systems is expected (e.g., impact on the health system, overall health system cost, life expectancy, or gross domestic product)?
* Why is benchmarking for this topic important (e.g., does it provide stakeholders with numbers for decision-making; does it simplify regulation, build trust, or facilitate adoption)?
  + 1. **Existing AI solutions**

This section provides an overview of existing AI solutions for the same health topic that are already in operation. It should contain details of the operations, limitations, robustness, and the scope of the available AI solutions. The details on performance and existing benchmarking procedures will be covered in chapter 6.

* Description of the general status and the maturity of AI systems for the health topic of your TG (e.g., exclusively prototypes, applications, and validated medical devices)
* Which are the currently known AI systems and their inputs, outputs, key features, target user groups, and intended use (if not discussed before)? This can also be provided as a table.
* What are the common features found in most AI solutions that might be benchmarked?
* What are the relevant metadata dimensions characterizing the AI systems in this field and with relevance for reporting (e.g., systems supporting offline functions, availability in certain languages, and the capability to process data in a specific format)?
* Description of existing AI systems and their scope, robustness, and other dimensions.
  1. **Operative and Cariology**

Team members: Falk Schwendicke, Sergio Uribe (PI) **( sergio.uribe@rsu.lv)**

* + 1. **Diagnostic and treatment pathways**

Dental caries is the most prevalent and ubiquitous non-communicable disease affecting humankind today. It was first understood to be an infectious disease, requiring removal of all plaque (biofilm) from the teeth or from affected carious hard tissues (specific plaque hypothesis). This concept, while always debated (i.e. each biofilm being cariogenic under certain conditions; non-specific plaque hypothesis), was later modified, suggesting that the mere presence of biofilm is not sufficient for the pathogenesis of caries, but that an overlapping interaction between the host/teeth, substrate and microbiota is needed. Despite being ‘infected’ (or rather, contaminated) with cariogenic bacteria, a cavitated carious lesion will not develop without a cariogenic diet. Marsh introduced the ecological plaque theory. The microbial composition of the biofilm is stable unless ‘environmental perturbations’ occur which can affect microbial homeostasis, leading to dysbiosis. With respect to caries, diet (mainly free sugars), oral hygiene and salivary factors are the contributing drivers of dysbiosis, leading to a shift in the microbiota towards acidogenic and aciduric microorganisms. The initial (naïve) dental biofilm is influenced by both hereditary and environmental factors, but, as time goes on, the types and proportions of micro-organisms acquired early in life are modified by environmental influences. Currently, the extended ecological plaque hypothesis is accepted to explain the pathogenesis of caries.

This pathogenesis of dental caries involves organic acids, the by-product of microbial metabolism of dietary free sugars. As the pH of the biofilm decreases, it reaches a point where the biofilm fluid at the surface of the tooth is under-saturated with respect to tooth mineral and dissolution occurs to maintain equilibrium. Initially, the dissolution occurs at the surface of the tooth, but, if conditions persist, and the lesion becomes more extensive, minerals from deeper in the enamel (and subsequently dentine) will be lost. While the pathogenesis of dental caries is mainly explained by environmental factors, dental caries has a genetic component, with influencing factors including enamel quality and quantity, immune response, dietary preferences and salivary characteristics. In summary, dental caries is a disease characterized by a process of demineralization of the dental hard tissues, caused by frequent free sugars exposure to the dental biofilm, which shifts the ecological balance towards a cariogenic dysbiosis. For dentin and root caries, cleavage of collagen by bacterial or dentinal enzymes follows early mineral loss and contributes to the loss of the hard tissue.

The former, “traditional” management of the caries process and carious lesions, was influenced by an understanding that caries was a purely infectious disease and could be managed invasively/restoratively by removing all demineralized and ‘contaminated’ tissue. This was grounded in (1) A lack of understanding that the caries process and carious lesions are separate, but related; (2) the incorrect understanding that once a lesion had established and the tooth was “infected”, eradication of microbiota was needed; (3) the erroneous concept that lesion progression was inevitable; and, (4) the fact that the majority of carious lesions dentists encountered in the past were truly “decayed”, i.e. cavitated dentine lesions. Therefore, the professional education of dental *surgeons* concentrated on mechanistic surgical procedures instead of that of dental *physicians* who manage the disease, and remuneration systems incentivized such invasive/restorative therapies.

Nowadays, and building on evidence accrued over several decades, it is clear that (1) The caries process can be controlled by modifying the patient’s caries risk/susceptibility, depending on his/her adherence to behavioural modifications and not only by intervening operatively on carious lesions, yet success/understanding of behavioural interventions on caries control has been limited; (2) The caries process and carious lesions can be managed without removing microorganisms, but by rebalancing the dysbiosis within the tooth surface biofilm and arresting those within the depths of the tissues; (3) Active (progressing) lesions can be inactivated, and progression is usually slow for most lesions; (4) In many high-income countries the spectrum of carious lesions has been and is shifting, especially in younger people, as there are now more non-cavitated lesions being detected.

Hence, the conventional restorative/invasive approach towards managing the caries process and carious lesions is not grounded in current understanding of the disease and it is also not appropriate for managing the broad spectrum of lesions found in many individuals (from very early to large cavitated). It should also be considered that subsequent interventions on restorations are often necessary. This is classically known as the “restorative death spiral”. Given these alternative arguments, there is consensus that invasive/restorative interventions alone are not beneficial for managing the caries process and lesions in all situations. Instead, invasive/restorative interventions represent a late stage in the management puzzle, repairing the gross tissue damage and restoring form, function, aesthetics and cleansability, thereby allowing to control the risk of future loss of function. Invasive strategies may also be used to approach acute caries lesions. Invasive/restorative interventions are an important and relevant tool, but they should be complemented by other (non- or micro-invasive) management strategies.

We distinguish three levels of invasiveness to classify intervention strategies for “treating” existing carious lesions. They are based on the degree of tissue removal associated with each strategy: *Non-invasive* strategies do not remove dental hard tissue and involve, for example, fluorides and other chemical strategies for controlling mineral balance, biofilm control measures and dietary control. *Micro-invasive* strategies remove the dental hard tissue surface at the micrometre level, usually during an etching step, such as sealing or infiltration techniques. *Invasive* strategies remove gross dental hard tissue, such as through use of hand excavators, rotary instruments or other devices. In most cases, this process is associated with the placement of restorations.

For each pathway of management, regardless if it is non-, micro- or invasive, caries detection is needed. Moreover, agreed principles for when to use different intervention strategies have been outlined: Lesion activity, cavitation and cleansability are the main factors to be considered to determine intervention thresholds. Inactive lesions do not usually require any treatment (in some cases, restorations might be placed for reasons of form, function, aesthetics); active lesions do. Non-cavitated carious lesions should be managed non- or micro-invasively, as should cavitated carious lesions which are cleansable. Cavitated carious lesions which are not cleansable usually require invasive/restorative management, also to restore form, function and aesthetics of the tooth. In specific circumstances, mixed interventions may be applicable. On occlusal surfaces, cavitated lesions confined to enamel and non-cavitated lesions radiographically extending deep into dentine (middle or inner dentine third, D2/3) may be exceptions to that rule. On proximal surfaces, cavitation is usually hard to assess tactile-visually. Hence, radiographic lesion depth is used to determine the likelihood of cavitation. Lesions extending radiographically into the middle or inner third of the dentine (D2/3) can be assumed to be cavitated, while those restricted to the enamel (external or middle enamel third, E1/2) are usually not cavitated. For lesions radiographically extending into the outer third of the dentine (D1), cavitation status is unclear. These lesions should be managed as if they were non-cavitated unless otherwise indicated. Individual decisions and clinical judgment should consider factors modifying the described intervention thresholds. Comprehensive diagnostics are the basis for systematic decision-making on when to intervene in the caries process and on existing carious lesions. Patients should be comprehensively informed about treatment options and should provide informed consent accordingly.

* + 1. **Definition of the AI task**

A wide range of AI tasks along these pathways of risk assessment, detection, diagnostics, treatment planning, conduct and re-evaluation are conceivable. Currently, these entail

* Caries prognosis:
  + individual caries risk factors: Is X a risk factor for caries?
  + risk factors models: (Factor Z x.3) + (Factor Y x .3) + (Factor Z x .3) =caries risk 90%
* Predictors of treatment effect: Patients with the X gene undergoing Z treatment have better outcomes than patients without the X gene.
* Caries detection and screening on
  + photos or videos (real time or asynchronous)
  + bitewing radiographs
  + peri-apical radiographs
  + panoramic radiographs
  + Cone Beam CT (CBCT)
  + rare imagery like OCT, NILT
* Caries lesion depth assessment and progression prediction
* Treatment decision-support (decision between management levels and options)
  + 1. **Current gold standard**

It is important to differentiate between a diagnosis validated against a system capable of assessing the actual health status, in what is known as ground truth (i.e., an independent diagnostic confirmation), and a system validated against a consensus or gold standard, which represents an approximation to the true diagnosis. For the imaging diagnosis of caries, there is currently no test that provides a ground truth against which to evaluate the performance of a new test. In vitro, the gold standard is established using destroying preparation and analytic techniques like histology, micro-radiography or (non-destructively) micro-CT. For clinical gathered data, this is not available, and clinical assessment or, for imagery, expert opinion are needed instead, if possible triangulation is used. For example, routine data relies on one expert in the clinical setting assessing the tooth using criteria like those one outlined elsewhere ((<https://pubmed.ncbi.nlm.nih.gov/17518963/>).

If only imagery is available, one or a range of experts annotate each image independently, providing an classification task, i.e. instance label (e.g. caries present), a detection task (e.g. a bounding box around an area) or a segmentation task (e.g. a pixel-wise area) of interest. Unifying such fuzzy labels is now a matter of choice: (1) For instance-based annotations, majority voting schemes are often applied (e.g. 3 or more out of 5 experts need to agree that a pathology is present, otherwise it is assumed not to be present; in some cases, images where the uncertainty is especially high are discarded). (2) It is also possible to combine these annotations with a “master” review process where one or more master experts are reviewing the labels, created by a range of other human annotators, in order to correct them. Hence the annotations can be unionized based on a state of higher information (as all annotations can be seen by the master reviewer) and on the underlying assumption that the master’s experience leads to high-quality final labels. (3) Also, it is possible to discuss uncertain cases by an expert board, which would not be able to jointly assess all images from a dataset given time and resource constraints but can assess the small minority of unclear (“edge”) cases to come to a consensus there.

* + 1. **Relevance and impact of an AI solution**

Caries risk assessment and detection suffer from poor accuracy, low reliability, grounded in either a limited set of predictor variables with poor predictive performance being available, existing prediction models being insufficiently calibrated to individual settings, populations or people, or experts’ limited diagnostics accuracy in routine settings further being modified by their experience.

One area of particular interest where AI could solve an unanswered problem is the capture, organisation and analysis of dietary records in real time, combining the capabilities of wearable devices with analytics to link dietary and clinical information and extract patterns to identify patients at risk of caries and other chronic diseases.

AI support along these tasks promises to increase the accuracy and reliability of assessment, prediction and detection/localization or to at least achieve an expert-level status for a range of tasks. It may further reduce the effort for doing so (efficiency gain), increase safety and contain costs. Notably, as AI will, for a long time, remain a support tool, the final impact (benefit/harm) will largely depend on the user decision after employing AI support.

* + 1. **Existing AI solutions**

In research, a recent review identified 48 studies on caries detection using AI in PubMed.[[1]](#footnote-1) AI for caries lesion localization or progression prediction have not been found, the same applies to decision support. The detection studies were mainly employing radiographs; the minority used photographs or other imagery. Most reports focus on the task of detection (caries yes/no) and classification (healthy/enamel caries/dentin caries). The main algorithm used is CNN. In ten studies general dentists were used as annotators, in two studies radiologists were used, in two other studies non-radiologist specialists were used, and in five reports it is not clear who annotated the training, test and internal validation datasets. The main strategy used to train and test the algorithms was to divide the dataset into a training and test set (28 studies) and in two studies an internal validation was considered. No study reported an independent external validation.

Commercially, to our knowledge only few applications are available for caries detection. To date (Oct 2022) there are three confirmed to have received certifications from regulatory bodies for the caries detection task: Overjet (Boston, USA) and Second Opinion (Pearl, CA, USA) by FDA, and dentalXrai Pro (dentalXrai GmbH, Berlin) by CE/FDA.. Other manufacturers (dentiAI, Toronto,, Videahealth, Boston, ORCA-AI) claim to perform caries detection (on panoramic images - dentiAI, , periapical images - Videahealth), but have so far not received full-scale regulatory approval. No solutions for other use cases are known to us at this point.

* + 1. **Existing work on benchmarking**

Currently, there are no high quality annotated datasets publicly available for the imaging diagnosis of dental caries. Ultimately, any benchmarking of AI models in dentistry should be measured according to how much it helps achieve the WHO goal of (1) reducing oral disease morbidity by 10% and (2) increasing health coverage to 75% of the population.

In 2015 a competition sponsored by the IEEE International Symposium on Biomedical Imaging was held and one of the datasets contained 120 annotated bitewing intraoral radiographs , which was divided into sets of 40 for training, 40 for test and 40 for on-site test within the competition. The dataset is no longer available. The caries-related annotators corresponded to lesions at the enamel and dentin level separately. The information available about the annotators was that they were two experienced clinicians. The metrics evaluated were sensitivity, specificity and F-score. Of nine registered investigator groups, two submitted models (Ronnenberg et al. and Lee et al.), which are detailed below in Table 1 for caries detection.

Table 1.

|  |  |  |
| --- | --- | --- |
| Author | Ronnenberg et al. | Lee et al. |
| Model | u-net | random forest |
| Implementation | Caffe-Framework (C++) | Java |
| CPU and OS | Nvidia-Titan, i7, 32GB Ram, Nvidia GTX980 with 8GB RAM | 2xIntel Xeon E5-2650, 128GB RAM for training and 2xIntel Xeon E5-2687, 16GB RAM |
| Processing time per image | 1.5s | 150s |
| Test 1 |  |  |
| Precision | 0.073 | 0.022 |
| Sensitivity | 0.120 | 0.060 |
| Specificity | 0.998 | 0.989 |
| F-Score | 0.119 | 0.042 |
| Test 2 |  |  |
| Precision | 0.078 | 0.032 |
| Sensitivity | 0.086 | 0.050 |
| Specificity | 0.999 | 0.991 |
| F-Score | 0.131 | 0.061 |

Notably, these low performances differ from what is reported by a range of studies (see above), while it is not clear why that is given that datasets (not necessarily model architectures, U-net is widely used for segmentation of caries lesions) are not longer available.

* + 1. **Suggested metrics for benchmarking AI models for the imaging diagnosis of dental caries**

In order to evaluate clinical performance, metrics are required to estimate the effect of the application at patient (or, for caries, on tooth or surface) level and its effect (harm, benefit, costs) at the societal level, according to the framework described by Fryback and Thornbury (1991).[[2]](#footnote-2) These refer to changes in the patient's diagnosis (% of diagnostic changes) and at the therapeutic level (% of changes in treatment decisions). Relevant metrics include the percentage of patients who improve with the use of AI compared to without AI, morbidity or procedures avoided with the use of AI, as well as cost per effect or utility gained or lost with the AI-test information. The TG Dental is currently generating a high quality annotated dataset of approximately 350 radiographs to be released on a public platform to be defined (e.g. EvalAI, Grand-challenge, Kaggle). This dataset will be divided into training and validation, and testing on developer side. One part will be retained for the independent and developer-blinded evaluation of AI models for radiographic diagnosis of dental caries. Annotator information, detailed diagnostic criteria and demographic metrics of the dataset composition will be provided.

Some recommendations for benchmark reporting of AI models for the imaging diagnosis of dental caries are shown in Table XX2.

Table XX2

|  |  |  |
| --- | --- | --- |
| **Area** | **Description** | **Examples** |
| Annotarors | Detailed description of the annotators and how they perform the annotations | Number  Expertise  Diagnostic criteria  Disagreement resolution |
| Annotations | Ideally, annotations should be made with the ITU/WHO annotation tool or an open access tool. | https://github.com/FG-AI4H/annotation-tool |
| Dataset fairness |  | Description of ethnicity, gender, marital status, age, education, insurance type. |
| Compliance with FAIR principles |  | Compliance with the [core FAIR object assessment metrics](https://www.fairsfair.eu/fairsfair-data-object-assessment-metrics-request-comments) [[3]](#footnote-3) |
| Tasks definition | Classification  Detection  Segmentation | Presence of caries yes/no or cavitated/non-cavitated  Sound/Enamel/Dentin caries  Pixel-wise annotation of lesions |
| Metrics oriented to technical diagnostic efficiency | Usual diagnostic performance metrics | Sensitivity (Recall)  Specificity  Accuracy  Jaccard index  Dice's coefficient  Positive predicted value (Precision)  Negative predicted values  F1 score  Area-under-the-ROC curve (if several diagnostic threshold are being tested) |
|  | Usual diagnostic reliability metrics | Discrete values: Kappa (normal, weighted, Fleiss)  Continuous values: ICC |
| Metric oriented to diagnostic clinical performance | Diagnostic thinking efficacy metrics | Number (percentage) of cases in a series in which image judged ‘helpful’ to making the diagnosis.  Difference in clinicians’ subjectively estimated caries diagnosis probabilities pre- to post-test information.  Empirical subjective log-likelihood ratio for caries positive and negative in a case series. |
|  | Therapeutic efficacy metrics | Number (percentage) of times image judged helpful in planning management of the patient in a case series.  Percentage of times invasive procedure avoided due to image information.  Number or percentage of times therapy planned pretest changed after the image information was obtained (retrospectively inferred from clinical records).  Number of percentage of times clinicians’ prospectively stated therapeutic choices changed after test information. |
| Patient level diagnostic efficacy | Patient outcome efficacy | Percentage of patients with caries with test compared with/without test.  Morbidity (or invasive procedures) avoided when using AI.  Change in quality-adjusted life expectancy.  Expected value of AI in quality-adjusted life years (QALYs).  Cost per QALY saved with AI |
| Societal level diagnostic efficacy | Societal efficacy | Benefit - cost analysis from societal perspective.  Cost - effectiveness analysis from societal perspective .  Decrease in population morbidity attributable to the test (WHO goal -10%)  Increase in population health coverage attributable to the test (WHO goal +75%) |

Ideally, a large, heterogeneous dataset of a clearly defined population should be available and annotated in a transparent way, with an accepted criterion, ideally against a ground truth or consensus (gold standard of an appropriate number of experts).

To benchmark technical metrics, the characteristics of the reports should adhere to the recommendations of Schwendicke et al (2021)[[4]](#footnote-4), with an emphasis on

1. characteristics of the dataset used for training and testing, ideally available publicly
2. demographic characteristics of the persons who provided their information for the generation of the training and testing dataset
3. method of validation, ideally external and independent
4. diagnostic criteria used for annotation
5. characteristics and training of the annotators
6. annotation disagreement resolution methods

For general caries diagnostic AI based systems, the STARD-AI reporting guideline is recommended.[[5]](#footnote-5)

To benchmark the clinical performance of AI models in cariology, clinical studies should adhere to the recommendations of Schwendicke et al. (2021) and the methodological items required by the CONSORT-AI reporting guideline.[[6]](#footnote-6) For any clinical claim, it is required to show how the use of AI systems allows changing the diagnostic or therapeutic decision at the patient level. Additionally, it is necessary to report any potential adverse effects of clinical use of an AI system, including potentially overdiagnosis and overtreatment.

Available economic analyses[[7]](#footnote-7) show that the use of AI affects the cost of caries treatment, with a slight decrease in the long term. These costs could further decrease if the information provided by the AI system allows cheaper treatment measures to be implemented, which is only sometimes the case. Therefore, it is still being determined whether this effect could be due to changes in the diagnostic decision, treatment decision or both. Notably,, these results refer only to a commercial AI model for caries (dentalXr.ai).

Overall, datasets for AI in cariology should adhere to the FAIR principles: findable, accessible, interoperable, reusable.

Some issues that remain to be resolved:

* What are the characteristics of a dataset to benchmark an AI model for caries (size, geographic diversity, demographics, annotators, annotations, diagnostic criteria and disagreement resolution)?
* Which metric(s) allow to evaluate the fairness of a dataset for cariology?
  1. **Prosthodontics (**[**kunaaldhingra@yahoo.co.in**](mailto:kunaaldhingra@yahoo.co.in)**)**

Prosthodontics involves the diagnosis, treatment planning, and rehabilitation of clinical conditions related to missing or deficient teeth or maxillofacial tissue by using prosthetic substitutes to maintain the oral health, function, comfort and appearance of patients with these conditions. The scope of prosthodontic treatment can range from a single indirect restoration to full mouth rehabilitation using fixed or removable, tooth or implant-supported prosthesis, and guidelines such as the Prosthodontic Diagnostic Index (PDI) have been established to assess the complexity of clinical cases and aid in formulating appropriate treatment plans.

Improvements in the oral health of populations over the last century has led to a significant reduction in edentulism rates and an increasing number of people are retaining most of their teeth throughout their life, and as a result, prosthodontic treatment comprises a large portion of treatments conducted by dental practitioners.

* + 1. **Definition of the AI task**

Artificial intelligence can be envisaged to enhance the processes of prosthodontic diagnostics, treatment planning and procedures, broadly categorized as follows:

- Diagnosis and treatment planning support

- Prediction of treatment outcome and prognosis of teeth and prosthesis

- Support systems for tooth preparation

- Fabrication of prosthesis

* + 1. **Current gold standard**

At present, planning for prosthodontic treatment draws on the clinical judgment and experience of the dental clinician. However, the treatment planning process in this field of dentistry is highly complex, and there is no gold standard as there is often disagreement on the majority of clinical cases, even among specialists in the field. The introduction of digital workflow has changed the face of prosthodontics and fabrication of most types of prosthesis can now be done via the CAD/CAM digital workflow. However, this technology is not available at many dental practices, and improvements still need to be made to the digital to increase the precision of conducted treatments. Preparation of teeth is done by dentists, however even after years of training and clinical practice, this is still a very challenging and error-prone task and imprecision can compromise the final outcome.

* + 1. **Relevance and impact of an AI solution**

Errors during diagnosis, treatment planning and execution of treatment can lead to poor outcomes such as occlusal imbalances, damage to the stomatognathic system, early fracture or failure of restorations, and suboptimal aesthetics. Long-term success of prosthodontic treatment relies on good prognosis of abutment teeth and implants and both tooth level prognostic factors of periodontal, endodontic, reconstructive, as well as patient-specific factors. Additionally, prosthodontics treatment is costly and not easily available to the entity of a population. By implementing AI through the various stages of prosthodontic treatment, it can be possible to improve treatment outcomes and reduce inequalities in access to prosthodontic treatment.

* + 1. **Existing AI solutions**

AI research in prosthodontics is still in its early stages and has been far less explored compared to other fields of dentistry due to the complex diagnostics and treatment required in prosthodontics. A recent literature of AI in prosthodontics identified the following studies. To the best of our knowledge, these applications have not yet undergone regulatory approval and are not available for commercial use.

1. Prosthesis shade selection of maxillofacial prosthesis (Mine et al 2019, available at <https://doi.org/10.1016/j.jpor.2019.08.006>): The traditional approach to color matching for fabrication of maxillofacial prosthesis is a very difficult and time-consuming task and requires the presence of the patient to validate the color match. Hence, this study used a deep artificial neural network to indicate the compounding amount of different pigments to reconstruct the CIE lab color of skin tone.
2. Decision support for extraction of compromised teeth (Cui et al 202, available from<https://doi.org/10.1016/j.prosdent.2020.04.010>): In this study electronic dental records were used as data, for five different machine learning algorithms to solve a classification problem of extraction vs nonextraction. Out of the five algorithms, extreme gradient boost (XGBoost), performed best and achieved high accuracy in correct prediction of decision-making for tooth extraction.
3. Classification of partially edentulous arches (Takahashi et al. 2021, available at<https://doi.org/10.2186/jpr.jpor_2019_354>): In this study, a convolutional neural network was built for the classification of dental arches into four arch types of edentulous, intact dentition, arches with posterior tooth loss, and arches with bounded edentulous areas.
4. Predicting the Debonding of CAD/CAM Composite Resin Crowns with AI (Yamaguchi et al. 2019, available at https://doi.org/10.1177/0022034519867641): This retrospective study utilized 2D images generated from 3D models of dies scanned by a 3D scanner to build and train a convolutional neural network for predicting debonding of CAD-CAM fabricated composite resin crowns. The model was able to successfully predict the debonding of composite resin crowns from the shape of the prepared tooth.
   1. **Periodontal (**[**ljaehong@gmail.com**](mailto:ljaehong@gmail.com)**)** 
      1. **Diagnostic and treatment pathways**

For periodontal disease, especially periodontitis, the severity, complexity of management, extent, rate of progression, and risk factors are classified based on staging (I–IV) and grading (A-C) systems. Due to the highly heterogeneous clinical manifestations and inheritance patterns, dental professionals tend to conduct several diagnostic analyses based on both stage and grade to determine the accurate diagnosis. Several risk factors that may influence the periodontal condition, such as smoking, diabetes mellitus, obesity, specific genetic factors, physical activity, nutrition, and stress, are also systematically and comprehensively examined for a more detailed analysis.

A broad range of periodontitis-related treatment modalities is available, including chemotherapy, resective treatment, periodontal regenerative treatment, periodontal plastic surgery for gingival augmentation, occlusal treatment, preprosthetic periodontal treatment, and extraction and implant surgery. There is no single effective treatment approach for periodontitis. One treatment procedure may be appropriate and cost-effective for one site of the mouth, while another approach may be suitable for other sites.

Table

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* + 1. **Definition of the AI task**

AI systems play a key role in the management of periodontal diseases. AI systems provide a variety of diagnostic and detection methods for periodontal diseases, including dental plaque, calculus, gingivitis, and periodontitis. The use of unsupervised or supervised AI systems will aid in the accurate diagnosis and prediction of periodontal diseases. Periodontal disease-related AI can be applied in the following areas: 1) dental plaque and calculus detection, 2) gingivitis detection, and 3) periodontitis detection.

AI can serve as a second opinion. AI interpretations are based on the experience of professional radiologists and periodontists who participated in setting the AI algorithms. AI training relies on deep learning, especially convolutional neural network algorithms based on thousands of dental periapical and panoramic radiographic images, and continuous training occurs as more data becomes available. Moreover, the classification task is mainly used for periapical images, and the segmentation task is used for panoramic images. Automatic detection of ROIs for pathologies such as alveolar bone loss is also used to provide a detailed diagnosis of the periodontal condition.

* + 1. **Current gold standard**

Clinical diagnostic analyses are generally based on the signs and symptoms of gingival inflammation and periodontal tissue destruction. Common diagnostic tools are used, including clinical and dental radiographic examinations. Typically, the presence of dental plaque, calculus, clinical attachment loss, tooth mobility, bleeding, and pus discharge is detected by clinicians using a periodontal probe, and sometimes, with the aid of panoramic and periapical radiographic images. However, these assessment methods are not only inconvenient but also unreliable and inconsistent. Although several attempts have been made to address or reduce their disadvantages, they still do not provide substantial advantages over existing conventional diagnostic methods, in terms of cost, time, and standardization.

* + 1. **Relevance and impact of an AI solution**

Periodontal disease is a major cause of tooth loss in adults and is one of the most important oral diseases contributing to the global chronic disease burden. More than half of the world’s population has periodontal disease. Periodontal disease is the sixth most prevalent inflammatory disease. Globally, 11% of adults have severe and advanced periodontitis.

Periodontal disease is closely related to various sociodemographic factors (including age, sex, household income, insurance status, and residence area) and comorbidities (including diabetes mellitus, obesity, cardiovascular disease, rheumatoid arthritis, metabolic syndrome, and adverse pregnancy outcomes). Therefore, early detection and accurate diagnosis are very important, not only for personal health but also for reducing the social burden.

AI is particularly useful for the standardized diagnosis of periodontal disease, which is relevant to board-certified periodontists and general dentists. In many cases, periodontal disease can be underdiagnosed by the general dentist due to a lack of experience, skill, time, and cost. A more rapid, accurate, and reliable periodontal diagnosis based on AI algorithms will enable early intervention, enhanced prevention and favorable treatment outcomes. In particular, due to the visualizations of the AI second opinion, the acceptance of earlier detection and treatment or additional examinations will be improved among periodontally compromised patients.

* + 1. **Existing AI solutions**

Currently, the direct use of most AI systems in clinical practice is limited. Most systems are still being used for research and investigational purposes only. For example, there are AI systems, e.g., Denti.AI, that interpret periodontal disease being serviced online but these have not yet been used in clinical practice. Recently, several companies and related research institutes have begun developing automated diagnostics for dental radiographs based on AI. Hence, it is expected that AI products will be available for use in clinical practice soon.

The AI tools or solutions available for the diagnosis of periodontal diseases are as follows:

* Diagnocat: Diagnocat is an AI solution that uses CBCT scans, full mouth series, or panoramic and periapical radiographic images. Diagnocat assists dental professionals in the diagnosis of various oral conditions: periodontal, conservative, endodontic, prosthetic, implant, and surgical. The limitation of this tool is that it mainly focuses on three-dimensional radiographic image analyses.
* OralCam: OralCam is a smartphone application that helps users examine common oral conditions (including dental caries, periodontal disease, and dental calculus). Although it has the advantage of simple self-diagnosis, its accuracy is too low for use in clinical practice. Moreover, diagnosis is mainly confined to the labial surfaces of teeth.
* Overjet: Overjet has obtained FDA approval as a deep learning solution for periodontal disease diagnosis. The major feature of Overjet is its deep learning-based technology that can analyze dental radiographic images in real time. The Overjet is trained to measure tooth-related bone loss from these radiographic images, making it easy for dental professionals to diagnose periodontitis. The program is designed to work in real time and significantly reduce the time between imaging and diagnosis because dental professionals do not need to manually study dental radiographic images to measure periodontally compromised bone levels.

A picture containing text, indoor, screen, spectacles

Description automatically generated

Overjet, FDA-approved periodontal disease diagnosis solution (https://www.overjet.ai)

* + 1. **AI for identification and classification of dental implant systems**

Dental implant is one of the most widely used and commonly accepted treatment modalities for oral rehabilitation of partially and fully edentulous patients. Nevertheless, various major mechanical (e.g., loosening or fractures of screw or fixture) and biological (e.g., peri-implantitis and peri-implant mucositis) complications of dental implants, affecting long-term survival and reintervention outcomes, are a growing concern in the dental community worldwide and a public health problem associated with high socio-economic burden.

Identifying and classifying the dental implant systems after post implant surgery is one of the most important factors in preventing or treating mechanical or biological complications, but there is a fundamental and practical limit to classifying the dental implant systems using postoperative two-dimensional images including periapical and panoramic radiographs.

In the last few years, artificial intelligence-based deep learning technologies, in particular deep and convolutional neural networks, have rapidly become a methodology of choice for two-dimensional and three-dimensional dental image analysis. Recent studies reported that deep learning algorithms emerged as the state of the art in terms of accuracy performance for identifying and classifying various types of dental implant systems, often outperforming the dental professionals specialized in implantology.

A collage of different colored squares

Description automatically generated with low confidence

Image from “Lee et al, Deep learning improves implant classification by dental professionals: a multi-center evaluation of accuracy and efficiency. [*Journal of Periodontal & Implant Science*](https://www.jpis.org/)*,* 2022”

* 1. **Surgical (PI** [**ulrike.kuchler@meduniwien.ac.at**](mailto:ulrike.kuchler@meduniwien.ac.at)**and** [**balazs.feher@meduniwien.ac.at**](mailto:balazs.feher@meduniwien.ac.at)**)**

**3.5.1. Definition of the AI task**

The goal of the implementation of AI in oral surgery, maxillofacial surgery, and implantology is to automatically process the given image data and generate correct diagnostics, risk assessment, and a surgical proposal in case planning. Preoperative virtual planning and 3D printing of surgical templates could take place in house. To this aim, AI must be able to differentiate between compact and spongy bone, determine the dimensions of the available bone, detect relevant anatomical structures (e.g., inferior alveolar nerve, maxillary sinus) and assess the width of the gingival tissue and calculate optimal length and position of implant. Completing all these tasks is considerably challenging due to the large size of the input 3D image dataset. Further, prediction models could be used to approximate implant success rates whilst taking into consideration bone structure, bone density, and implant system, therefore aiding the preoperative decision-making process.

**3.5.2 Current diagnostic and treatment pathways**

In general, diagnostics and treatment planning in oral surgery are dependent on the knowledge, experience, and skills of the oral surgeon. Beside the problem of an inherent bias in all non-SOP human decisions and procedures, the risk of human error is evident. The application of AI and deep learning in diagnostics, disease risk evaluation, treatment planning, and personalized prediction making has enormous potential in the future of oral pathology, oral surgery and implantology, as well as maxillofacial surgery. The implementation on these new technologies raises the chances for further improvement in all fields of dentistry. Machine learning (ML) algorithms are very likely to improve accuracy in detection and diagnostics and may become an effective tool in risk prediction and individual planning. They may help to prevent human errors and lead into objective treatment decisions, which are standardized and reproducible.

**Implantology:** Radiographic examinations are the base for modern implant planning. In addition to clinical examinations (assessment of remaining teeth, height and width of the jaw, mucosal assessment), radiographic imaging in the form of 2D (panoramic radiograph) or 3D imaging (computed tomography [CT] or cone beam CT [CBCT]) is crucial to provide information about anatomical structures and the actual bone volume. Based on this information right now in the most advanced practice the surgeon can determine the length, width and the angle of the implant through an implant planning software. Importantly the quality of this human treatment planning depends on the knowledge, experience and skills of the oral surgeon. Especially in borderline cases, this treatment planning can prove difficult because some implant positions might not be realistic during the surgical procedures and the prosthetic reconstruction might be impossible or not in line with esthetic considerations. After the planning phase the dataset will be transferred to the dental laboratory, which produces a 3D printed drilling template. No

**Reconstruction of bony defects:** Bone defects which do not allow a sufficient and correct stabilization of implants need to be reconstructed before. Depending on the bone deficit, there are different strategies available to do bone reconstructions. The main goal of modern procedures is to avoid patients’ morbidity. If reconstructions cannot be done simultaneously, bone blocks are the standard of care to reconstruct these defects. The donor material can be autologous, allogenic or xenogenic. All have a solid structure in common, which has to be precisely shaped and fitted to the recipient side. The planning of the reconstruction and the volume which will be needed can be calculated and planned with the 3D image dataset of the recipient site. The advantage here is that not only the defect but also the augmented volume can be planned. Depending on the surgical strategy either a sawing template or a precisely shaped bone block can be produced, which fits into the defect with millimeter precision. This is a very reliable procedure with good results. Again, currently the correct planning depends on the knowledge and experience of the surgeon.

**3.5.3 Relevance and impact of an AI solution**

Dental radiography (2D and 3D) is commonly used in daily practices and provides an incredibly rich resource for AI development. This attracts many researchers to develop its application for various purposes. The application of AI in oral surgery, dental implantology, and maxillofacial surgery is very heterogeneous and needs further development and evaluation before clinical utilization. Tasks include object detection, object classification, as well as image segmentation models. Further AI applications in oral surgery include models to predict individual risk and therapy success. Another important task is the treatment of patients especially the task in designing patient-specific implants/templates and optimizing the fit, length, and diameter of dental implants.

With the assistance of novel AI models and a strong collaboration of dental professionals worldwide, the clinical effectiveness in oral surgical and maxillofacial treatments can be optimized.

**3.5.4 Existing AI solutions in oral surgery**

In dentistry, and especially oral surgery, radiographic examination is a standard of care for the evaluation of physiological and pathological structures as well as treatment planning. Treatment planning is based on the education and training of the examiner and essential for the successful treatment of more complex surgeries in patients of different ages and health statuses. At present, much of the preoperative planning is still done by hand, but digital, semi-automatic planning is becoming increasingly common in oral surgery, especially in dental implantology.

In oral and maxillofacial surgery, automated planning has been introduced to simplify the preoperative surgical workflow. Currently bony reconstruction of the face after resection of extensive tumors is a particular challenge in facial surgery. Beside these complex reconstruction cases AI and ML will lead to automation of aesthetic evaluation, smile design, and treatment-planning processes. There are already commercially available software tools for virtual planning of these procedures (Naeni et al 2020). However, most of these tools are not automated and so complicated to use that they are rarely used directly by surgeons and require cumbersome and lengthy communication with service providers.

Currently many AI models have been developed for automatic diagnosis, the detection of pathologies the prediction of disease risk (Krishna et al 2020). AI in this field has the potential to revolutionize and simplify these complicated processes.

* 1. **Oral Medicine and Maxillofacial Radiology (**[**chaurasiaakhilanand49@gmail.com**](mailto:chaurasiaakhilanand49@gmail.com)**)**

Detection and diagnosis of oral lesions is of crucial importance in dental practices because early detection significantly improves prognosis. Diagnosis and classification of bone diseases (cysts, tumours). Till date the majority of oral diagnostics are based on manual workouts and personalized perceptions. AI has potential to revolutionize the diagnostic accuracy and prediction of disease course, outcomes and prognosis.

1. Diagnosis and classification of systemic diseases based on oral manifestations
2. Diagnosis and classification of periodontal disease
3. Use of immunologic parameters to diagnose aggressive periodontitis.
4. Classification of halitosis based on identification of periodontal pathogens in saliva.
5. Predicting recurrence of aphthous ulcers.
6. Diagnosis and classification of Head and Neck Syndromes
   * 1. **Temporomandibular joint disorders (TMD)**
7. Use of magnetic resonance imaging to determine the prognosis of TMD.
8. Use of screening questions to aid in treatment of TMD.
9. Identification of subgroups of internal derangement of the temporomandibular joint.
10. Classification of TMD on the basis of clinical sign and symptoms
11. Automated TMD diagnostics
    * 1. **Oral Cancer**
12. Diagnosis and classification of Oral precancers and cancer
13. Prognosis of oral cancer considering lesion histology and genetic characteristics.
14. Assessment of hyper-nasal speech following treatment of oral/or pharyngeal cancer.
15. Risk assessment for oral cancer.(Prediction)
16. Prediction of Cervical lymph node metastasis of oral squamous cell carcinoma
    * 1. **Masticatory Muscle diseases**
17. AI based Classification of masticator muscle disorders
18. Prediction of masticator muscle disorders on the basis of chewing pattern
    * 1. **AI Based Differential Diagnostic Systems for oral diseases based on Clinical and radiographic features**
      2. **Oral and Maxillofacial Radiology**

Artificial intelligence is being studied in relation to various topics in the field of maxillofacial radiology.Radiographic imaging is very useful for diagnostic purposes and to ensure proper treatment. Maxillofacial radiologists as professionals understand the basic principles and characteristics of radiographic imaging and interpret them in terms of various diseases and continue to play an important role in artificial intelligence-related research.

Radiographs of Interests for AI based Diagnostics in oral and maxillofacial radiology are-

**a. Conventional Radiographs**

· Periapical

· Bitewings

· Panoramic Radiograph

· Lateral Cephalogram

Hand and Wrist Radiograph

**b. Advanced Imaging**

· Plane CBCT, 3D CBCT scans

· CT Scan

· MR sans

* + 1. **Radiographic diagnosis**

In the field of OMF radiology, artificial intelligence can be used for the diagnosis of a broad range of oral diseases, dental caries, periodontal disease, osteosclerosis, odontogenic cysts and tumours, diseases of the maxillary sinus or temporomandibular joints**,**vertical root fractures, periapical pathosis and cysts and tumours of jaw bone. Detection of the filling or filled teeth (for prediction of the index DMFT - Decayed, Missing and Filled Permanent Teeth)

Diagram

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Fig.1A schematic flow diagram of the Mask-RCNN algorithm used for detecting and segmenting maxillofacial BL in CBCT axial slices. Mask-RCNN algorithm uses a Feature Pyramid Network (FPN) backbone for feature extraction from each slice and then applies a Region Proposal Network (RPN) to propose Regions of Interest (ROIs) which may contain BL. The proposed ROIs are then resized to yield an aligned-similar size for all ROIs in order to classify them as a normal region or a region containing a bone lesion. Then, the algorithm generates a pre-segmentation bounding box (yellow rectangle) for each detected bone lesion and adds an instant segmentation process for producing a mask (red marking) for the lesion within each bounding box.

Diagram

Description automatically generated

Fig.2-3D segmentation of a bone lesion.

**-**Graphical user interface, application, chat or text message

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Fig.3-Overview of the diagnostic pipeline. (**a**) First, the object detection model detects cystic lesions and marks them with a bounding box. (**b**) Next, multiple segmentation models are employed which segment structures of maxilla, mandible, mandibular canal, maxillary sinuses, the complete dentition, as well as each individual tooth. (**c**) The overlaps between the marked bounding box and segmented structures are then calculated. (**d**) Finally, the Random Forest classifier gives a preliminary diagnosis based on the computed overlaps for each sample.

**Interpretation of radiographic lesions and automated interpretation of dental radiographs**

• Caries detection: detection and characterization of proximal caries

• Diagnosis of vertical root fractures on CBCT images of endodontically treated and intact teeth.

• To stage tooth development.

• Computer based digital subtraction imaging

• Computer-assisted image analysis is useful to visualize and evaluate the bone architecture directly from the dental panoramic radiograph.

• 3-dimensional orthodontics visualization using patient models and OPGs.

• Bone density evaluation to predict osteoporosis using OPGs.

• Automatic segmentation of mandibular canal.

• Forensic dental imaging: Personal Identification System Using Dental Panoramic Radiograph

• Dental biometric

* + 1. **Radiographic analysis**

Image analysis using artificial intelligence in dentistry has been applied to various tasks-

· Tooth segmentation or localization,

· Bone quality (osteoporosis,Osteopenia) assessment

· Cephalometric landmark localization.

· Automated bone age assessment studies by setting interest in the hands and wrists on radiographs

· Classification of dental implant systems.

* + 1. **Forensic dentistry**

For age and sex determination in forensic odontology, Dentalradiology based methods being non-invasiveand accurateare beneficial over conventional methods like sectioning or extracting teeth. They can therefore be used for both living and deceased individuals.

· Automated age estimation based on anatomical landmarks and tooth structures

· Automated sex estimation based on anatomical landmarks and tooth structures

· Identification of deceased based on dentition and tooth structures

* 1. **Endodontics (PI** [**tedy.karteva@gmail.com**](mailto:tedy.karteva@gmail.com)**)**
     1. **Definition of the AI task**

AI algorithms learn the relationship between the characteristics of the given data and the ground truth. In Endodontics, their current use encompasses classification, prediction, and segmentation tasks:

* Screening and Diagnosis
  + Periapical pathosis detection
  + Vertical root fracture
  + Determination of working length
* Treatment planning
  + Determination of working length
  + Apical foramen determination
  + Tooth-root morphology determination
* Prognosis
  + Prognosis prediction in endodontic microsurgery
  + Predicting treatment failure

The data utilized by the algorithms encompass:

* Numeric data - patient age, exam scores, etc
* Categorical data - disease labels
* Image data - Radiographic analysis (OPG, PA, CBCT)

The ground-truth used by the studies so far is:

* Specialist estimation (single operator /a panel of two or more operators)
* Semiautomated (supervised computer-aided segmentation of pathologies on 2D and 3D images)
* Simulated lesions

Scope for future AI applications in Endodontics:

* AI-assisted patient management software
* Comprehensive diagnostic and prediction algorithms based on medical, dental, clinical, and paraclinical patient data
* AI-assisted treatment planning & personalized care

The current goal of the use of AI in endodontics is:

* Establishing adequate ground truth for data labeling with the notion that trained CNNs can reach or surpass the diagnostic performance of experienced clinicians (Pauwels et al., 2021)
* Establishing adequate generalizability of the trained models so that they can adequately predict on data which sources differ from those involved in the model training (Krois et al., 2021)
  + 1. **Current gold standard**

The current gold standard in Endodontics:

* Diagnosis
  + A blend of information gathered from the medical & dental history, the clinical examination, the clinical and paraclinical tests
    - Dental and medical history
    - Extra and intraoral examination
    - Clinical test: percussion, palpation, mobility, periodontal examination, pulp tests (vitality/vascularity), staining and transillumination, selective anesthesia
    - Radiographic examinations (PA, OPG, CBCT)
    - Clinical classification of pulpal and periapical diseases
* Treatment planning
  + A decision-making process on the necessity and modality of treatment is executed by the clinician based on the collected data based on best practices
* Prognosis
  + Acquisition of clinical and paraclinical data during the follow-up period and an educated prediction based on the published cases in the literature and the clinician’s own experience

The current gold standard of the diagnostic and treatment pathways in endodontics is limited by the country-specific discrepancies in patient data collecting protocols, the sensitivity and specificity of the devices, disease classification variations, access to dental materials, variations in treatment modalities and materials, the patient’s payment capacity and the expertise and experience of the clinician interpreting the data and performing the treatment.

* + 1. **Relevance and impact of an AI solution**

The application of AI algorithms in Endodontics has the following potential:

* Diagnosis
  + Improve time efficiency
  + Improve accuracy and precision
  + Empower patient-clinician education
* Treatment planning
  + Automate laborious tasks (working length determination)
  + Referral suggestions
  + Suggest alternative treatment protocols
  + Highlight potential difficulties during the treatment
* Prognosis
  + Improved prognosis prediction based on objective data

The successful overall implementation of AI algorithms in the daily dental practice will improve quality of care, efficiency in time, cost, and labor.

As AI algorithms have already found their way into the market, benchmarking grows even more paramount to ensure:

* Robustness of the AI model
* Generalizability of the AI model
  + 1. **Existing AI solutions**

An expanding range of AI applications are already available:

* Diagnosis
  + Periapical pathosis detection
  + Vertical root fracture
  + Determination of working length
* Treatment planning
  + Determination of working length
  + Apical foramen determination
  + Tooth-root morphology determination
* Prognosis
  + Prognosis prediction in endodontic microsurgery
  + Predicting root canal failure
  1. **Orthodontics (**[**chaurasiaakhilanand49@gmail.com**](mailto:chaurasiaakhilanand49@gmail.com)**,** [**ramtin.rhm@gmail.com**](mailto:ramtin.rhm@gmail.com)**)**
     1. **Diagnostic and treatment pathways**

Orthodontic treatments aim at correcting the malocclusion and repositioning the dentition in relation to the craniofacial structures in the most harmonious way. In order to accomplish a successful orthodontic treatment, it is necessary to conduct a patient interview, an examination, and gather proper records with the purpose of a comprehensive diagnosis. Clinical evaluations have to be systematic and organized so the clinician does not override any of the diagnostic items that include patient questionnaires and interviews, as well as an extra-oral and intra-oral clinical examination and para-clinical assessments. This can then result in an appropriate treatment plan and desirable treatment outcome. The following data is required before designing a comprehensive treatment plan:

**1.** Personal details

2. Chief complaint

3. Medical history

**4.** Dental History

**5.** TMJ assessment

6. Clinical examination

7. Para-clinical assessment

A. Facial/Intraoral Photographs

B. OPG Radiographs

C. Lateral Cephalometry

D. Study Casts

E. Cone Beam Computed Tomography

F. Hand and Wrist Radiograph

Due to the limitations in the length of this document, we go straight to the para-clinical data modalities since they are more applicable in the AI context.

*A) Facial/Intraoral Photographs*

Following items can be evaluated on facial or intraoral photographs:

1. The shape of head (Mesocephalic, Dolichocephalic, and Brachycephalic)

2. Facial form (Mesoprosopic, Euryprosopic, Leptoprosopic)

3. Facial symmetry

4. Facial proportions

5. Facial profile

6. Facial divergence

7. Anterior-posterior tooth/jaw relations

8. Lips examination

9. Nose examination

10. Chin examination

11. Nasolabial angle

12. Palatal evaluation

13. Frenal attachments

14. Overjet

15. Overbite

16. Transverse mal relations

17. Arch form

18. Smile analysis

19. General esthetic evaluation

*B) OPG Radiographs*

It is necessary to assess general conditions regarding patients' dentition, before treatment planning. The following items can be evaluated on OPG radiographs:

1. Absence and presence of teeth, supernumerary teeth

2. Evaluation of dentition age

3. Evaluation of root formation

4. Status of deciduous teeth

5. General oral health (caries, previous restoration, etc)

6. Presence of any pathologies

*C) Lateral cephalograms*

The main data modality used in orthodontics is lateral cephalograms. Main dental and skeletal orthodontics problems can be diagnosed through lateral cephalograms. Diagnosis in lateral cephalograms are based on the anatomic landmarks and their quantitative relations. The main landmarks are as follows:

Diagram

Description automatically generated

Image from “https://personalpages.manchester.ac.uk/staff/claudia.lindner/default\_files/curr\_project\_ceph.htm”

Main orthodontics problem analysis, based on landmarks, are as follows:



Image from “Wang et al, A benchmark for comparison of dental radiography analysis algorithms. *Medical image analysis,* 2016”

Other than the mentioned items, skeletal maturation degree can be evaluated on lateral cephalograms. Determination of skeletal maturation degree is necessary for treatment timing and reaching a desirable treatment outcome. The most common classification approach is based cervical vertebrae maturation degree and is as follows:

Graphical user interface, text

Description automatically generated

Image from “McNamara et al, The cervical vertebral maturation method: A user's guide, *The Angle Orthodontist*, 2018”

*D) Study Casts:*

Following items can be evaluated on orthodontics study casts:

1. Occlusion

2. Space analysis

3. Arch form

4. Arch symmetry

5. Curve of spee

6. Arch width

*E) Cone Beam Computed Tomography (CBCT)*:

Nowadays, CBCTs are becoming more popular in orthodontics. In clinical orthodontics, CBCT can provide volumetric information in three-dimensional form. As a result of advancements in CBCT technology, compared to conventional radiography, CBCT provides much more accurate and reliable information regarding diagnosis, treatment, and follow-up. CBCTs can be used in the following cases:

1. Evaluation of impacted and transposed teeth

2. Evaluation of root resorption of adjacent teeth

3. Evaluation of affected temporomandibular joints contributing to malocclusion

4. Air-way morphology analysis

5. Midpalatal suture maturation evaluation

6. Orthognathic surgery treatment planning

7. Locating the best temporary anchorage site for skeletal anchorage

*F) Hand and Wrist Radiograph*

Hand and Wrist radiograph have been used to predict the correct bone age (skeletal maturity) that can be compared with the patient’s chronological age.

* + 1. **Definition of the AI task**

Various AI tasks can be defined in each modality for the purpose of enhancing orthodontic diagnosis and treatment planning. Due to the limitations in the length of this document, we only mention only those which already been addressed in the literature:

1) Facial/Intraoral Photographs

a) Landmark detection

b) Facial attractiveness score (as regression task)

c) Facial asymmetry and distortion (as a classification task) \*

2) OPG Radiographs

· All the AI tasks in dentistry can be beneficial in case of orthodontics, e.g. tooth numbering, caries detection, etc

3) Lateral Cephalometrics

a) Landmark detection

b) Lateral cephalometric analysis (as a classification task) \*

c) Cervical maturation degree (as a classification task) \*

4) Study Casts

a) Arch form predication (as a classification task) \*

5) Cone Beam Computed Tomography

a) Maxillary suture assessment (as a segmentation task)

\* These tasks can be defined in the context of AI in three different approaches:

1. One-stage automatic approach

· The AI model decides on its prediction as an end-to-end model, the model will be fed with the raw image and the diagnostic class will be the model's output.

2. Two-stage automatic approach

· The AI model is trained to detect landmarks. Then through some quantitative calculations between landmarks, they predict the diagnostic class.

3. Semi-automatic approach

· The AI model is trained on manually extracted data to predict the diagnostic class, e.g. some studies defined landmarks around cervical vertebrae and fed their models with features based on the relations between these landmarks. However, this approach has many shortcomings, and the practitioners can not use all the advantages of AI in their practice.

* + 1. **Current gold standard**

As it can be seen, most orthodontics diagnoses are based on clinical and paraclinical evaluation. Almost in all of the AI tasks mentioned, there are no definitive gold standards and diagnoses are made by orthodontists. There is even very low inter/intra-observer agreement in some cases. To encounter this challenge, most diagnostic criteria are defined based on quantitative relations based on landmarks (angle, proportions, distance, *etc*). However this approach is very time-consuming and prone to the error itself.

* + 1. **Relevance and impact of an AI solution**

In the diagnosis and evaluation of orthodontic problems, AI can be effective. Orthodontic diagnosis and treatment planning for malocclusion can be a very difficult and time-consuming procedure. New practitioners often have trouble making these decisions since they are traditionally made on the basis of clinical experience. AI approaches might be helpful for solving these problems. Cephalometric analysis, for example, is frequently used to detect skeletal and dental anomalies in orthodontics. Manually locating cephalometric landmarks requires a lot of time and is prone to error. The use of deep learning models for landmark detection has achieved outstanding results in recent studies.

Precision medicine is one of the most important applications for AI-based systems in orthodontics. To enhance treatment outcomes, researchers are considering customized treatment approaches based on the characteristics of each patient. Orthodontic and precision medicine advancements have led to breakthroughs in the development of customized treatment approaches. Precision orthodontics has been reported to be the next paradigm shift in orthodontic treatments. AI is capable of enabling and enriching precision medicine approaches based on data.

* + 1. **Existing AI solutions**

In research, a recently published scoping review identified 49 studies that used AI approaches in orthodontics. It has been reported that the number of publications in this field is growing.

Chart, bar chart

Description automatically generated

Image from “Mohammad-rahimi et al, Machine learning and orthodontics, current trends and the future opportunities: A scoping review. *American Journal of Orthodontics and Dentofacial Orthopedics*, 2021”

Most of the studies reported the AI model's application on the lateral cephalometry landmark detection and they reached a good performance here. However, we are at the very beginning of orthodontics utilizing AI diagnosis and decision making.

In industry, there are a few companies trying to provide AI solutions in orthodontics. They can be divided into these categories:

1. *Diagnostic assistant tools*
   1. WeDoCeph: This company provides a tool for cephalometric tracing analysis on 2D lateral or PA X-rays
   2. CephX: This company provides a tool for cephalometric tracing analysis on 2D lateral cephalometry and 3D CBCTs. It also can do airway volume analysis on 3D CBCTs.
2. *Patient management and monitoring*
   1. Dental monitoring: Engage new patients using AI-generated reporting and smile simulations.
3. *AI-based aligners*
   1. 3D Predict
   2. Soft Smile
   3. **Implantology (**[**tryfonosolga@gmail.com**](mailto:tryfonosolga@gmail.com)**)**
      1. **Definition of the AI task**
4. What is the AI doing?

AI in dental implantology is used for various purposes, including diagnosis, treatment planning, surgical guidance, and postoperative assessment. By leveraging machine learning algorithms and computer vision, AI can analyze dental imagery, identify potential risks, and suggest optimal treatment plans. AI can also help automate repetitive tasks, making dental professionals more efficient, and enhancing patient outcomes.

1. What kind of AI task is implemented (e.g., classification, prediction, clustering, or segmentation task)?

AI tasks implemented in dental implantology involve a combination of classification, prediction, segmentation, and clustering. Some examples include:

* 1. Classification: Identifying the type of bone and its quality, which is crucial for proper implant placement and success.
  2. Prediction: Estimating the success rate of a dental implant based on patient-specific factors and the chosen treatment plan.
  3. Segmentation: Separating anatomical structures such as nerves, blood vessels, and sinuses in dental images, which is essential for precise planning and surgical guidance.
  4. Clustering: Grouping similar dental implant cases to identify patterns and trends that can help enhance treatment plans and surgical approaches.

1. Which input data are fed into the AI model?

AI models in dental implantology require various types of input data, including:

1. Dental images: Cone-beam computed tomography (CBCT) scans, panoramic radiographs, and intraoral photographs.
2. Patient information: Medical and dental history, demographic data, and risk factors such as smoking or systemic conditions.
3. Implant specifications: Implant type, size, material, and other relevant details.
4. These data are preprocessed and used to train and test AI algorithms, enabling them to make accurate predictions and assessments.
5. Which output is generated?

AI models generate several types of outputs in dental implantology, such as:

1. Diagnosis: Identification of potential issues, such as insufficient bone volume, that may impact implant success.
2. Treatment plans: Recommendations for optimal implant placement, including angulation, depth, and location, based on the patient's unique anatomy.
3. Surgical guides: Customized 3D-printed guides that assist in accurate implant placement during surgery.
4. Predictive outcomes: Estimates of implant success rates and potential complications, helping clinicians make informed decisions and set realistic patient expectations.
   * 1. **Current gold standard**

This section provides a description of the established gold standard of the addressed health topic.

* How is the task currently solved without AI?
* Do any issues occur with the current gold standard? Does it have limitations?
* Are there any numbers describing the performance of the current state of the art?
  + 1. **Relevance and impact of an AI solution**

This section addresses the relevance and impact of the AI solution (e.g., on the health system or the patient outcome) and describes how solving the task with AI improves a health issue.

* Why is solving the addressed task with AI relevant?
* Which impact of deploying such systems is expected (e.g., impact on the health system, overall health system cost, life expectancy, or gross domestic product)?
* Why is benchmarking for this topic important (e.g., does it provide stakeholders with numbers for decision-making; does it simplify regulation, build trust, or facilitate adoption)?
  + 1. **Existing AI solutions**

This section provides an overview of existing AI solutions for the same health topic that are already in operation. It should contain details of the operations, limitations, robustness, and the scope of the available AI solutions. The details on performance and existing benchmarking procedures will be covered in chapter 6.

* Description of the general status and the maturity of AI systems for the health topic of your TG (e.g., exclusively prototypes, applications, and validated medical devices)
* Which are the currently known AI systems and their inputs, outputs, key features, target user groups, and intended use (if not discussed before)? This can also be provided as a table.
* What are the common features found in most AI solutions that might be benchmarked?
* What are the relevant metadata dimensions characterizing the AI systems in this field and with relevance for reporting (e.g., systems supporting offline functions, availability in certain languages, and the capability to process data in a specific format)?
* Description of existing AI systems and their scope, robustness, and other dimensions.
  1. **Oral and Maxillofacial Oncology (**[**parulsinha02@gmail.com**](mailto:parulsinha02@gmail.com)**)**

**3.10.1 Definition of the AI task**

This section provides a detailed description of the specific task the AI systems of this TG are expected to solve. It is *not* about the benchmarking process (this will be discussed more detailed in chapter 4). This section corresponds to [DEL03](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B7997F2C1-5A1D-4409-B2A0-CBC4E9CE8CDA%7D&file=DEL03.docx&action=default) *“AI requirements specifications*,” which describes the functional, behavioural, and operational aspects of an AI system.

The AI is making a classification between five classes: benign, mild epithelial dysplasia, moderate epithelial dysplasia, severe epithelial dysplasia, and invasive squamous cell carcinoma (SCC). A change to this classification is undergoing validation at multiple institutions – renaming mild dysplasia to low-grade dysplasia, and combining moderate and severe dysplasia into a category of high-grade dysplasia. This binary classification of dysplasia has not yet been completely validated in the oral cavity.

This will be a classification task for the aforementioned five categories (as well as testing the performance of the binary dysplasia classification system). After the development of this classification algorithm, we will also re-evaluate the quality of ancillary data available to evaluate the possibility of exploring a predictive regression to establish risk of transformation to invasive squamous cell carcinoma; preliminary data suggests that obtaining the quality of outcomes data will be very challenging.

Minimally, the data will consist of 4,000 whole slide histopathology images (WSI) scanned at 40x magnification as well as the original diagnosis for the slide. After receipt of the images, 10 oral and/or head and neck pathologists will make their diagnosis; the target classification value will be the majority opinion of these 10 pathologists. Ancillary data will also be collected for the possibility of future use, including the diagnosis initially given for that image, patient age (maxed at 90 to comply with USA HIPAA regulations), whether or not a patient had SCC in the future, the length of time the patient has been disease-free, how their disease was treated, and whether or not the patient had SCC in the past.

The output is a classification per the five classes as defined above as well as an indicator of the algorithm’s confidence in that diagnosis (this may be a percentage confidence interval or a rank order list of the likelihood that this could represent any category).

**3.10.2 Current gold standard**

This section provides a description of the established gold standard of the addressed health topic.

The oral cavity is subject to continuous trauma that results in many reactive lesions. In addition, immunological and systemic conditions can occur in the oral cavity. Most of these lesions can clinically mimic true leukoplakia. Leukoplakia appears clinically as a thick white patch and histopathologically ranges from benign hyperkeratosis to epithelial dysplasia to invasive squamous cell carcinoma (the most common cancer affecting the oral cavity). Epithelial dysplasia is considered a premalignant condition that should be recognized early; treatment with excision helps to prevent progression into invasive squamous cell carcinoma. Because leukoplakia can histologically present as multiple different pathologic entities of variable severity, biopsies are done to provide a definitive diagnosis to direct clinical management.

The histopathological distinction between clinically white and/or red lesions is not always simple because some reactive epithelial atypias can be indistinguishable from true epithelial dysplasia. Further complicating the histologic diagnostic process, epithelial dysplasia is classified according to its severity as mild, moderate, and severe; as the severity increases the likelihood of transformation into an invasive squamous cell carcinoma also increases. Thus, these categories modify the management of disease, as more severe dysplasias receive more aggressive treatment. Despite the importance of this classification, the histopathological classification of epithelial dysplasia is highly subjective between pathologists and demonstrates a high interrater observability.

Depending on the study, the rate of interrater observability when using the WHO criteria for grading oral epithelial dysplasia (as published in the WHO Classification of Head and Neck Tumors) rarely exceeds a Cohen’s kappa of 0.5; most studies show an interrater observability of 0.2-0.4.

**3.10.3 Relevance and impact of an AI solution**

This section addresses the relevance and impact of the AI solution (e.g., on the health system or the patient outcome) and describes how solving the task with AI improves a health issue.

Because of the high interrater observability with gold standard histopathologic diagnosis, a standardized tool that lacks subjectivity with the ability to classify normal and/or reactive epithelium, epithelial dysplasia (with grading as mild, moderate, or severe), and invasive squamous cell carcinoma would improve the diagnosis of these lesions and assist in guiding clinical decision-making in the management of these processes. Recent studies show promising results using AI in classifying mucosal epithelium as invasive vs. non-invasive. Therefore, the use of AI may act as an aiding tool that helps pathologists achieve a precise diagnosis.

If the machine learned how to accurately differentiate between normal, reactive, dysplastic, and neoplastic epithelium, this will result in a tremendous improvement in diagnosing one of the most challenging and clinically significant use cases of the oral cavity, resulting in receiving the appropriate management for the patient. For example, if a pathologist misdiagnoses early epithelial dysplasia and interprets it as reactive changes secondary to inflammation, the patient will not have the lesion removed, allowing a dysplasia to possibly progress a more severe dysplasia or SCC. If this progress is also not identified, it is more likely that the patient would require adjuvant treatment such as neck dissection, chemotherapy, and/or radiotherapy. Therefore, early diagnosis and early intervention can improve patient outcomes as well as reduce health system costs by avoiding adjuvant treatments required in advanced stage disease.

Benchmarking is important because it facilitates the assessment of the existing work in the context of AI in dental diagnostics and digital dentistry. It evaluates different aspects of the existing work on benchmarking of AI systems (e.g., relevant scientific publications, benchmarking frameworks, software, results, annotation, and histopathological evaluation attempts). Evaluating and collecting all relevant data from previous benchmarking will help us to implement the most appropriate process needed in this topic group. Additionally, other disease entities throughout the body have a similar pattern of disease progression (e.g., SCC of the skin) and may benefit from the experiences of this group.

**3.10.4 Existing AI solutions**

This section provides an overview of existing AI solutions for the same health topic that are already in operation. It should contain details of the operations, limitations, robustness, and the scope of the available AI solutions. The details on performance and existing benchmarking procedures will be covered in chapter 6.

A recent overview of studies assessing the classification and prognostication found that some early studies using clinicopathologic variables (and fewer using histology images, usually whole slide images) highlighted promising results when AI is applied to a binary classification of invasive SCC vs. non-invasive disease. For those that used histology images, different ML approaches were used to demarcate specific histological features of interest to compare differences in spatial architectural patterns for differentiation between benign and malignant lesions. However, the vast majority of these studies use datasets comprising fewer than 1,000 patients, raising the question of the ability of these algorithms to respond reliably to data from other institutions.

More importantly, there is extremely limited data on the use of AI to diagnose oral dysplasias based on histology alone. Few reports exist of using AI in the context of cytology as well as various ancillary diagnostic techniques such as infrared spectroscopy. We were only able to find a single in-press publication using 203 whole slide images from a single institution that was able to have high agreement (Cohen’s kappa of ~0.8) with humans. Because our dataset is larger, more diverse, and with a greater number of human interpretations, this project would be able to offer unique diagnostic assistance to pathologists while also providing that assistance with materials conventionally created in the context of patient care and without the assistance of other costly devices.

To our knowledge, there are no validated medical tests addressing the classification of oral malignant and/or premalignant conditions.

Studies for identifying SCC use clinicopathologic data (e.g., staging criteria) and/or whole slide images of SCC and non-SCC disease entities. Some studies use a convolutional neural network or fully connected network approach on the whole slide images, while others may use subfeatures (e.g., tumor-infiltrating lymphocytes, nuclear features such as pleomorphism, and the clinicopathologic data) to create a final classification or regression prediction. An overview and table providing a summary of current progress can be found in Sultan et al. (2020).

Many benchmarks that would benefit this project would also benefit other projects relating to cancer, including nuclear features (pleomorphism, hyperchromasia), mitotic activity, and architectural patterns suggesting invasive disease. The WHO Classification of Head and Neck Tumors (5th edition) contains a table more broadly delineating features of dysplasia that pathologists interpret during the diagnosis of dysplasia.

In order to be broadly available to a wide audience, we suggest that a front-end website is made available allowing for an image upload with a return of the AI output. Translation would be made available in this context.

As discussed above, the scope of AI systems in this domain typically involves either a classification of invasive vs. non-invasive disease, prognostication of invasive SCC, or uses machine learning in combination with ancillary testing to determine severity of dysplasia. These are all relatively small studies with limited validation testing on a broad variety of data to ensure that their findings are compatible with data from other institutions.

Research was started with 10 countries on board with duly signed agreements aiming to collect 2000 samples worldwide. The core team of oral pathologists and AI scientists from New York, Berlin and India are collecting data and working on it.

1. **Ethical considerations (PI:** [**ratarokhshad@gmail.com**](mailto:ratarokhshad@gmail.com)**)**

Artificial intelligence is widely used in mobile health and digital medicine, in particular in the context of deep learning. Research studies are increasingly using artificial intelligence, specifically machine learning and deep learning. It can be used in a variety of ways, including robotic devices and machine learning systems, to assess disease risk and research treatment efficacy. The number of AI-related studies has increased rapidly since 2005. Recent publications suggest that artificial intelligence technology could prove a viable option for dentistry ; however, many ethical concerns arise at the same time. As a result of poor planning, poorly conducted, and poorly reported studies, they lack robustness, reproducibility, and applicability. Dentists may also be at risk, since AI studies face significant methodological and reporting limitations that inhibit transparency and reproducibility.

AI applications in the dental field raise a wide range of potential ethical concerns. Due to the limitations of dental publications about ethics, the main goal of the group is awareness. Further goals are acknowledging and applying privacy and data protection, the communication of the patient and clinician, data diversity, and protecting autonomy. The guidelines for the diversity and quality of data are going to be applied for the current projects. Currently, the group is working on ethical issues in the field of esthetics.

**4.1 Ethical considerations in the real world:**

The Ethics subgroup had provided a list of issues facing using AI in dentistry. The items were derived from the guideline for using AI in healthcare and reviews about ethical AI. Moreover, after having some pools and forms, eleven items were selected.

* Prudence
* Equity
* Autonomy
* Privacy and intimacy
* Responsibility
* Democratic participation
* Solidarity
* Data Diversity
* Data Protection
* Well-being
* Development
* Patient-clinician relationship
* Law and governance

Diagram, schematic

Description automatically generated

**4.2 Ethical implications of introducing benchmarking**

The following question is an important ethical issue: Is developments and applications of AI helping individuals?

The Merriam-Webster dictionary defines wellness as “the quality or state of being in good health, especially as an actively sought goal”. In that way, hardware and software breakthroughs, especially in mobile and wearable devices have been combined with computational advances in artificial intelligence (AI) to scale wellness coaching and automate promotion of health. Moreover, these technologies are now tightly converging with the rapid development of powerful AI systems. AI systems are now a tool for supplementing clinicians’ decision making, for providing customized and tailored health management plans, for predicting the next health crisis, and for designing personalized treatments using precision medicine. Still, how AI algorithms can improve wellness assessment, aid in personalizing intervention strategies to promote healthier lifestyle behaviors, and uncover previously unknown disease risk factors is still under investigation.

At this point we can distinguish three types of wellness AI. The first type – intangible AI does not have a physical form. Instead it exists in communications through sound, notifications on devices, or invisible computations running in the background and called upon on demand for information or advice. The second type – tangible AI refers to that which is embodied in a physical form which humans can interact with, such as AI in vehicles, robotic arms, or sophisticated medical equipment. Finally, the third type – embedded AI refers to AI that is fused with our brain in some way through an invasive or non-invasive mechanism, thus representing a futuristic form of brain-computer interface that has the capability to augment the functions and capacities of the human brain including intelligence and mood.

Apart from the conventional patient-clinician relationship, the whole new entity includes organizational wellness, currently explored in the context of AI. The concept of organizational wellness consists of several factors, for instance, safety, performance, and employee wellness. As AI can facilitate work processes, organizations will have the opportunity to focus more on activities they consider more vital.

All these technologies are useful approaches in improving wellness, but they invoke certain critical ethical implications and consequences. Namely, the consequences may vary between biases, data interpretation errors, privacy issues, accountability, loss of trust by medical practitioners, and irresponsible usage. In addition, the decision-making process in the medical setting is subjective and contextual depending on a patient case-by-case basis. And of course, the integration of information from different wellness factors, facilitated by AI, can lead to holistic health monitoring systems, which requires special consideration, as well.

**4.3 Ethical implications of collecting the data for benchmarking**

One of the most important issues facing benchmarking is data diversity. Data diversity is often necessary in order to increase the diversity of AI technologies. The method does not, however, provide sufficient protection against biases inherent in the design. For minimizing and identifying potential biases, software developers need to include more experts in the design and development process who know about bias, contexts, and regulations, as well as consultation with stakeholders, data labeling, and testing. Using datasets covering all genders -not just male, and females-, and different nationalities help the diversity.

Moreover, Most AI technologies used in medicine and dentistry were developed in the US, Europe, or China, raising the question of their utility in other parts of the world. AI algorithms are often developed on non-representative samples evaluating one ethnic or socioeconomic group and a lack of diversity in training data could have serious implications on decision-making. 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). If an AI algorithm fails to account for this diverse data, it can perpetuate human biases that could leave out underrepresented populations or put them at a health risk.

**4.4 Risks facing individuals and society when benchmarking is wrong, biased, or inconsistent with reality on the ground**

As AI is partaking in medical decisions regarding diagnosis and treatment, the issue of accountability and responsibility arises. The question as to who takes the blame when something goes inadvertently wrong must be addressed. Should the developing company, dentist or both be held responsible for any mishaps? Perhaps the answer lies in the role of AI in that particular case. It should be emphasized that AI tools that are merely supporting the dentist’s role are treated as such, meaning that the dentist is held accountable for their final decision making. However, as autonomous tools are being developed, complexities surface in interpreting liability. Regulatory bodies need to assess the role of the developers in shaping the final outcome of patient care. Though, most developers will have end users sign agreements to cover them against any future claims for misdiagnosis. Liability in those instances is complex. Nonetheless, it’s been suggested that AI tools should be treated as hospital/clinic tools, with any errors in diagnosis ultimately falling on the clinician’s shoulders. Future regulations need to close the gap in the current laws as more products are being developed. Recent advances in deep learning allow for the rapid screening of diversity of data and possible discrimination by race, sex, ethnicity or other parameters. Assessing the diversity using the deep neural networks and eliminating the human factor may lead to development of unbiased AI technology. .Ensuring diversity in algorithms’ data is a necessity in order AI technology to broadly benefit diverse populations from around the world. Otherwise, AI could lead to exacerbation of existing health disparities, existing within one country or between developed and developing countries.

**4.5 Data protection and privacy of personal health information**

Medical information is extremely sensitive and a legally protected data type. In dentistry, several companies have curated deep learning tools that currently support and may one day replace a physician’s opinion. However, their black box nature compounded with the lack of transparency on how results are achieved could lead to ethically problematic outcomes. One of the major resulting issues that needs to be addressed is patient privacy and confidentiality. In order for patient data to be protected from misuse or unauthorized access, it must be protected from unauthorized parties. Patients' data should be protected by robust data security and privacy policies. There is a fine balance between the pros of sharing certain protected medical information that would help the deep learning tool perform better and the cons of putting patient health information at risk of exploitation and identification. There is a need to change how we think about privacy and confidentiality as we move into the era of deep learning, but as we make this transition, certain protocols must be respected to ensure utmost protection of patients’ privacy. Patients must first give informed consent for the harvesting of their data. Next, this confidential data should be deidentified and protected from the bodies collecting them and from cyberattacks. Furthermore, data collection should meet local ethical, regulatory and legal standards. In addition, data storage should be decentralized with federated learning schemes applied. The enormous volume of data collected and the increasing presence of deep learning applications only mean that security and privacy regulations will incessantly be challenged and mandate periodic regulatory updates.

**4.6 Benchmarking data are representative and an AI offers the same performance and fairness**

Equity and fairness corresponds to the ethical practice of fairness in line with the needs of the individual in relation to the needs of the whole society. Thus, equity refers to the equal treatment of those with equal needs but also recognizes specific needs of disadvantaged communities1. Equity in dentistry mainly implies equal access to dental care and equal quality of dental care, regardless of gender, age or ethnic, social, cultural or economic factors. From the perspective of dental practice applying AI technology as clinical decision support systems, three major aspects of equity should be acknowledged:

* Algorithmic fairness, which addresses bias related to data collection and/or algorithmic design of AI, regarding ethnicity, socio-economic status, age or gender. The bias occurs either when predefined data are treated differently than others or when an algorithm produces results that are systemically prejudiced due to erroneous assumptions in the machine learning process. Nevertheless, due to the bias, the decision-making process is compromised.
* Availability of AI technology to all interested groups, which is vital in order not to limit the benefits of medical progress to selected and privileged groups.
* Use of AI technology to improve health equity in public and population health, which is recognized recently as a strategy for human bias mitigation. Namely, AI technology could assist with better design of interventions and improved prediction of intervention outcomes leading to reduced costs, time and medical errors, better allocation of resources and greater attention to disadvantaged communities.

**4.7 Experiences and learnings from addressing ethics**

A revolution in dentistry could be achieved through the use of AI, which can improve diagnosis, treatment planning, and patient outcomes. To ensure responsible and ethical use of the technology, these issues must also be addressed. A number of experiences and learnings related to addressing ethics in dentistry can be found below:

To increase transparency and participation, AI can be designed with open-source software or source code available to the public. Open-source software offers the benefit of users contributing and providing feedback, allowing them to understand how the system works, to identify potential problems, and to extend and adapt it. Open-source software must be accessible and transparent as well as engaging.

**4.8 Recommendations for addressing ethics in the AI studies**

The subgroup is providing a checklist for ethical challenges for study design and clinical use for AI applications. Furthermore, the subgroup is working on a study regarding using AI tools for smile design and its ethical challenges.

Chart, sunburst chart

Description automatically generated

1. **Existing work on benchmarking**

This section focuses on the existing benchmarking processes in the context of AI and Dental Diagnostics and Digital Dentistry for quality assessment. It addresses different aspects of the existing work on benchmarking of AI systems (e.g., relevant scientific publications, benchmarking frameworks, scores and metrics, and clinical evaluation attempts). The goal is to collect all relevant learnings from previous benchmarking that could help to implement the benchmarking process in this topic group.

* 1. **Operative and Cariology (**[**sergio.uribe@gmail.com**](mailto:sergio.uribe@gmail.com)**)**
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* Which scores and metrics have been used?
* How were test data collected?
* How did the AI system perform and how did it compare the current gold standard? Is the performance of the AI system equal across less represented groups? Can it be compared to other systems with a similar benchmarking performance and the same clinically meaningful endpoint (addressing comparative efficacy)?
* How can the utility of the AI system be evaluated in a real-life clinical environment (also considering specific requirements, e.g., in a low- and middle-income country setting)?
* Have there been clinical evaluation attempts (e.g., internal and external validation processes) and considerations about the use in trial settings?
* What are the most relevant gaps in the literature (what is missing concerning AI benchmarking)?

* + - 1. **Publications on benchmarking systems**

Two published peer review articles address the two major challenges in AI modeling in Endodontics: robustness and generalizability.

* + - * 1. **Generalizability**

Krois et al. (2021) assess the generalizability of deep learning models for dental image analysis. The authors concluded that the generalizability of deep learning models to detect apical lesions on panoramic images was not given and that the models’ performance would significantly differ on test data from different centers.

**Reasons**

* Image characteristics
* Population characteristics

**Mitigation strategies**

* Data augmentation
* Cross-center training

**Conclusions**

* Data augmentation has limited capacity for mitigation as image characteristics may not be the main reason for limited generalizability
* Cross-center training can mitigate the lack of generalizability to some degree.
* Generalizability is not bidirectional in our experiments - differences in the dental status of the two populations is a key factor

**The black box**

Krois et al. (2021) hypothesize the underlying reason for the limited generalizability is that the model exploits correlations between apical lesions and root-canal fillings or restorations.

**Solutions**

* Manual image cropping to ROI
* Zheng et al. (2021) suggest the use of “anatomical knowledge” rules limiting the search space for the deep learning algorithm to find the optimal parameters.

* + - * 1. **Robustness**

The field of Endodontics is often referred to as a combination of “art and science”. The notion lies in the combination of gathering a blend of subjective symptoms and objective data and interpreting it subjectively. Artificial intelligence algorithms echo the patterns they are shown, ergo any model trained by clinicians will inherit their own biases.

Radiology is the science of perception. The basic concept is that the truth is in the eye of the beholder is especially valid for radiologic assessment. Studies that attempt to teach AI algorithms to diagnose diseases on images standardly use specialist estimation and different strategies to limit their bias: experienced specialists selection, inter-observer, and intra-observer variability assessment, multiple doctors’ independent annotation, cross-annotation, examiner calibration, arbitration, review. However, as disease diagnostic thresholds for different imaging modalities (periapical radiographs, CBCT images) are still debatable, objective findings are hard to reach which may lead to suboptimal algorithms training.

**Solutions**

Pauwels et al. (2021) proposed the use of simulated lesions for perfect annotation of training and validation data. This study aimed to explore the use of CNNs for the detection of simulated periapical lesions on intraoral radiographs and to compare the performance of trained CNNs with that of human observers. The authors concluded that the overall performance of trained CNN models surpassed that of oral radiologists.

* + 1. **Benchmarking by AI developers**

All developers of AI solutions for Dental Diagnostics and Digital Dentistry implemented internal benchmarking systems for assessing the performance. This section will outline the insights and learnings from this work of relevance for benchmarking in this topic group.

* What are the most relevant learnings from the benchmarking by AI developers in this field (e.g., ask the members of your topic group what they want to share on their benchmarking experiences)?
* Which scores and metrics have been used?
* How did they approach the acquisition of test data?
  + 1. **Relevant existing benchmarking frameworks**

Triggered by the hype around AI, recent years have seen the development of a variety of benchmarking platforms where AIs can compete for the best performance on a determined dataset. Given the high complexity of implementing a new benchmarking platform, the preferred solution is to use an established one. This section reflects on the different existing options that are relevant for this topic group and includes considerations of using the assessment platform that is currently developed by FG-AI4H and presented by deliverable [DEL07\_5](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B8BFCFF21-3908-4BAD-AB9C-9814EB3F9B36%7D&file=DEL07_5.docx&action=default) *“FG-AI4H assessment platform”* (the deliverable explores options for implementing an assessment platform that can be used to evaluate AI for health for the different topic groups).

* Which benchmarking platforms could be used for this topic group (e.g., EvalAI, AIcrowd, Kaggle, and CodaLab)?
* Are the benchmarking assessment platforms discussed, used, or endorsed by FG-AI4H an option?
* Are there important features in this topic group that require special attention?
* Is the reporting flexible enough to answer the questions stakeholders want to get answered by the benchmarking?
* What are the relative advantages and disadvantages of these diverse solutions?
  1. **Orthodontics (**[**ramtin.rhm@gmail.com**](mailto:ramtin.rhm@gmail.com)[**chaurasiaakhilanand49@gmail.com**](mailto:chaurasiaakhilanand49@gmail.com)**)**
     1. **Publications on benchmarking systems**

While a representative comparable benchmarking for Dental Diagnostics and Digital Dentistry does not yet exist, some work has been done in the scientific community assessing the performance of such systems. This section summarizes insights from the most relevant publications on this topic. It covers parts of the deliverable DEL07 *“AI for health evaluation considerations,”* [DEL07\_1](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B565EEC0A-D755-41C8-AC68-37B4C38C953F%7D&file=DEL07_1.docx&action=default) *“AI4H evaluation process description,”* [DEL07\_2](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B58679341-C738-40F0-A822-3AC2B24DD09F%7D&file=DEL07_2.docx&action=default) *“AI technical test specification*,*”* [DEL07\_3](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7BA3088882-F82B-493B-B1C5-49CFF0EEEFA8%7D&file=DEL07_3.docx&action=default) *“Data and artificial intelligence assessment methods (DAISAM),”* and [DEL07\_4](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7BB846B260-373A-41FC-A892-EE5BBCFE3CF8%7D&file=DEL07_4.docx&action=default) *“Clinical Evaluation of AI for health”*.

* What is the most relevant peer-reviewed scientific publications on benchmarking or objectively measuring the performance of systems in your topic?
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* Which scores and metrics have been used?
* How were test data collected?
* How did the AI system perform and how did it compare the current gold standard? Is the performance of the AI system equal across less represented groups? Can it be compared to other systems with a similar benchmarking performance and the same clinically meaningful endpoint (addressing comparative efficacy)?
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* Are there important features in this topic group that require special attention?
* Is the reporting flexible enough to answer the questions stakeholders want to get answered by the benchmarking?
* What are the relative advantages and disadvantages of these diverse solutions?

1. **Benchmarking by the topic group**

This section describes all technical and operational details regarding the benchmarking process for the Dental Diagnostics and Digital Dentistry AI task including subsections for each version of the benchmarking that is iteratively improved over time.

It reflects the considerations of various deliverables: [DEL05](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B2012357A-941E-44BD-B965-370D7829F52C%7D&file=DEL05.docx&action=default) *“Data specification”* (introduction to deliverables 5.1-5.6), [DEL05\_1](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B19830259-F63B-42D4-A408-48C854D6C124%7D&file=DEL05_1.docx&action=default)*“Data requirements”* (which lists acceptance criteria for data submitted to FG-AI4H and states the governing principles and rules), [DEL05\_2](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B25141F77-E59A-45F1-B081-185C2194FE67%7D&file=DEL05_2.docx&action=default) *“Data acquisition”*, [DEL05\_3](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B05D8938E-BC2A-4A62-BCB0-1FD46AA72235%7D&file=DEL05_3.docx&action=default) *“Data annotation specification”*, [DEL05\_4](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7BF267A95C-4C5B-4D63-A135-58AF487C3AD3%7D&file=DEL05_4.docx&action=default) *“Training and test data specification”* (which provides a systematic way of preparing technical requirement specifications for datasets used in training and testing of AI models), [DEL05\_5](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B71FE8B9D-ACB3-48CE-AA3F-136409B550A4%7D&file=DEL05_5.docx&action=default) *“Data handling”* (which outlines how data will be handled once they are accepted), [DEL05\_6](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B5C95327E-96A5-4175-999E-3EDB3ED147C3%7D&file=DEL05_6.docx&action=default) *“Data sharing practices”* (which provides an overview of the existing best practices for sharing health-related data based on distributed and federated environments, including the requirement to enable secure data sharing and addressing issues of data governance), [DEL06](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7BF5967277-90C8-4252-A0B9-43A5692F35E2%7D&file=DEL06.docx&action=default) *“AI training best practices specification”* (which reviews best practices for proper AI model training and guidelines for model reporting), [DEL07](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B47E77197-F87B-49F4-80B3-2DD949A5F185%7D&file=DEL07.docx&action=default)*“AI for health evaluation considerations”* (which discusses the validation and evaluation of AI for health models, and considers requirements for a benchmarking platform), [DEL07\_1](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B565EEC0A-D755-41C8-AC68-37B4C38C953F%7D&file=DEL07_1.docx&action=default) *“AI4H evaluation process description”* (which provides an overview of the state of the art of AI evaluation principles and methods and serves as an initiator for the evaluation process of AI for health), [DEL07\_2](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B58679341-C738-40F0-A822-3AC2B24DD09F%7D&file=DEL07_2.docx&action=default) *“AI technical test specification”* (which specifies how an AI can and should be tested *in silico*), [DEL07\_3](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7BA3088882-F82B-493B-B1C5-49CFF0EEEFA8%7D&file=DEL07_3.docx&action=default) *“Data and artificial intelligence assessment methods (DAISAM)”* (which provides the reference collection of WG-DAISAM on assessment methods of data and AI quality evaluation), [DEL07\_4](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7BB846B260-373A-41FC-A892-EE5BBCFE3CF8%7D&file=DEL07_4.docx&action=default)*“Clinical Evaluation of AI for health”* (which outlines the current best practices and outstanding issues related to clinical evaluation of AI models for health), [DEL07\_5](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B8BFCFF21-3908-4BAD-AB9C-9814EB3F9B36%7D&file=DEL07_5.docx&action=default) *“FG-AI4H assessment platform”* (which explores assessment platform options that can be used to evaluate AI for health for the different topic groups), [DEL09](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B3E940987-8D75-44B8-85E4-F0E475964F15%7D&file=DEL09.docx&action=default) *“AI for health applications and platforms”* (which introduces specific considerations of the benchmarking of mobile- and cloud-based AI applications in health), [DEL09\_1](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B1A2EC8D5-53CA-4C8C-9B09-B61CA6F428C5%7D&file=DEL09_1.docx&action=default) *“Mobile based AI applications,”* and [DEL09\_2](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B3B5A31DE-D3B1-4EC1-A261-2C2E19F73810%7D&file=DEL09_2.docx&action=default) *“Cloud-based AI applications”* (which describe specific requirements for the development, testing and benchmarking of mobile- and cloud-based AI applications).

**TEMPLATES**

* 1. **Subtopic [A]**

*Topic driver: Please refer to the above comments concerning subtopics.*

The benchmarking of Dental Diagnostics and Digital Dentistry is going to be developed and improved continuously to reflect new features of AI systems or changed requirements for benchmarking. This section outlines all benchmarking versions that have been implemented thus far and the rationale behind them. It serves as an introduction to the subsequent sections, where the actual benchmarking methodology for each version will be described.

* Which benchmarking iterations have been implemented thus far?
* What important new features are introduced with each iteration?
* What are the next planned iterations and which features are they going to add?
  + 1. **Benchmarking version [Y]**

This section includes all technological and operational details of the benchmarking process for the benchmarking version [Y] (latest version, chronologically reversed order).

* + - 1. **Overview**

This section provides an overview of the key aspects of this benchmarking iteration, version [Y].

* What is the overall scope of this benchmarking iteration (e.g., performing a first benchmarking, adding benchmarking for multi-morbidity, or introducing synthetic-data-based robustness scoring)?
* What features have been added to the benchmarking in this iteration?
  + - 1. **Benchmarking methods**

This section provides details about the methods of the benchmarking version [Y]. It contains detailed information about the benchmarking system architecture, the dataflow and the software for the benchmarking process (e.g., test scenarios, data sources, and legalities).

* + - * 1. ***Benchmarking system architecture***

This section covers the architecture of the benchmarking system. For well-known systems, an overview and reference to the manufacturer of the platform is sufficient. If the platform was developed by the topic group, a more detailed description of the system architecture is required.

* How does the architecture look?
* What are the most relevant components and what are they doing?
* How do the components interact on a high level?
* What underlying technologies and frameworks have been used?
* How does the hosted AI model get the required environment to execute correctly? What is the technology used (e.g., Docker/Kubernetes)?
  + - * 1. ***Benchmarking system dataflow***

This section describes the dataflow throughout the benchmarking architecture.

* How do benchmarking data access the system?
* Where and how (data format) are the data, the responses, and reports of the system stored?
* How are the inputs and the expected outputs separated?
* How are the data sent to the AI systems?
* Are the data entries versioned?
* How does the lifecycle for the data look?
  + - * 1. ***Safe and secure system operation and hosting***

*From a technical point of view, the benchmarking process is not particularly complex. It is more about agreeing on something in the topic group with potentially many competitors and implementing the benchmarking in a way that cannot be compromised. This section describes how the benchmarking system, the benchmarking data, the results, and the reports are protected against manipulation, data leakage, or data loss. Topic groups that use ready-made software might be able to refer to the corresponding materials of the manufacturers of the benchmarking system.*

This section addresses security considerations about the storage and hosting of data (benchmarking results and reports) and safety precautions for data manipulation, data leakage, or data loss.

In the case of a manufactured data source (vs. self-generated data), it is possible to refer to the manufacturer’s prescriptions.

* Based on the architecture, where is the benchmarking vulnerable to risk and how have these risks been mitigated (e.g., did you use a threat modelling approach)? A discussion could include:
* Could someone access the benchmarking data before the actual benchmarking process to gain an advantage?
* What safety control measures were taken to manage risks to the operating environment?
* Could someone have changed the AI results stored in the database (your own and/or that of competitors)?
* Could someone attack the connection between the benchmarking and the AI (e.g., to make the benchmarking result look worse)?
* How is the hosting system itself protected against attacks?
* How are the data protected against data loss (e.g., what is the backup strategy)?
* What mechanisms are in place to ensure that proprietary AI models, algorithms and trade-secrets of benchmarking participants are fully protected?
* How is it ensured that the correct version of the benchmarking software and the AIs are tested?
* How are automatic updates conducted (e.g., of the operating system)?
* How and where is the benchmarking hosted and who has access to the system and the data (e.g., virtual machines, storage, and computing resources, configurational settings)?
* How is the system’s stability monitored during benchmarking and how are attacks or issues detected?
* How are issues (e.g., with a certain AI) documented or logged?
* In case of offline benchmarking, how are the submitted AIs protected against leakage of intellectual property?
  + - * 1. ***Benchmarking process***

This section describes how the benchmarking looks from the registration of participants, through the execution and resolution of conflicts, to the final publication of the results.

* How are new benchmarking iterations scheduled (e.g., on demand or quarterly)?
* How do possible participants learn about an upcoming benchmarking?
* How can one apply for participation?
* What information and metadata do participants have to provide (e.g., AI autonomy level assignment (IMDRF), certifications, AI/machine learning technology used, company size, company location)?
* Are there any contracts or legal documents to be signed?
* Are there inclusion or exclusion criteria to be considered?
* How do participants learn about the interface they will implement for the benchmarking (e.g., input and output format specification and application program interface endpoint specification)?
* How can participants test their interface (e.g., is there a test dataset in case of file-based offline benchmarking or are there tools for dry runs with synthetic data cloud-hosted application program interface endpoints)?
* Who is going to execute the benchmarking and how is it ensured that there are no conflicts of interest?
* If there are problems with an AI, how are problems resolved (e.g., are participants informed offline that their AI fails to allow them to update their AI until it works? Or, for online benchmarking, is the benchmarking paused? Are there timeouts?)?
* How and when will the results be published (e.g., always or anonymized unless there is consent)? With or without seeing the results first? Is there an interactive drill-down tool or a static leader board? Is there a mechanism to only share the results with stakeholders approved by the AI provider as in a credit check scenario?
* In case of online benchmarking, are the benchmarking data published after the benchmarking? Is there a mechanism for collecting feedback or complaints about the data? Is there a mechanism of how the results are updated if an error was found in the benchmarking data?
  + - 1. **AI input data structure for the benchmarking**

This section describes the input data provided to the AI solutions as part of the benchmarking of Dental Diagnostics and Digital Dentistry. It covers the details of the data format and coding at the level of detail needed to submit an AI for benchmarking. This is the only TDD section addressing this topic. Therefore, the description needs to be complete and precise. This section does *not* contain the encoding of the labels for the expected outcomes. It is only about the data the AI system will see as part of the benchmarking.

* What are the general data types that are fed in the AI model?
* How exactly are they encoded? For instance, discuss:
  + The exact data format with all fields and metadata (including examples or links to examples)
  + Ontologies and terminologies
  + Resolution and data value ranges (e.g., sizes, resolutions, and compressions)
  + Data size and data dimensionality
    - 1. **AI output data structure**

Similar to the input data structure for the benchmarking, this section describes the output data the AI systems are expected to generate in response to the input data. It covers the details of the data format, coding, and error handling at the level of detail needed for an AI to participate in the benchmarking.

* What are the general data output types returned by the AI and what is the nature of the output (e.g., classification, detection, segmentation, or prediction)?
  + How exactly are they encoded? Discuss points like:
    - The exact data format with all fields and metadata (including examples or links to examples)
    - Ontologies and terminologies
* What types of errors should the AI generate if something is defective?
  + - 1. **Test data label/annotation structure**

*Topic driver: Please describe how the expected AI outputs are encoded in the benchmarking test data. Please note that it is essential that the AIs never access the expected outputs to prevent cheating. The topic group should carefully discuss whether more detailed labelling is needed. Depending on the topic, it might make sense to separate between the best possible output of the AI given the input data and the correct disease (that might be known but cannot be derived from the input data alone). Sometimes it is also helpful to encode acceptable other results or results that can be clearly ruled out given the evidence. This provides a much more detailed benchmarking with more fine-grained metrics and expressive reports than the often too simplistic leader boards of many AI competitions.*

While the AI systems can only receive the input data described in the previous sections, the benchmarking system needs to know the expected correct answer (sometimes called ‘labels’) for each element of the input data so that it can compare the expected AI output with the actual one. Since this is only needed for benchmarking, it is encoded separately. The details are described in the following section.

* What are the general label types (e.g., expected results, acceptable results, correct results, and impossible results)?
* How exactly are they encoded? Discuss points like:
  + The exact data format with all fields and metadata (including examples or links to examples)
  + Ontologies and terminologies
* How are additional metadata about labelling encoded (e.g., author, data, pre-reviewing details, dates, and tools)?
* How and where are the labels embedded in the input data set (including an example; e.g., are there separate files or is it an embedded section in the input data that is removed before sending to the AI)?
  + - 1. **Scores and metrics**

*Topic drivers: This section describes the scores and metrics that are used for benchmarking. It includes details about the testing of the AI model and its effectiveness, performance, transparency, etc. Please note that this is only the description of the scores and metrics actually used in* ***this*** *benchmarking iteration. A general description of the state of the art of scores and metrics and how they have been used in previous work is provided in section 3.*

Scores and metrics are at the core of the benchmarking. This section describes the scores and metrics used to measure the performance, robustness, and general characteristics of the submitted AI systems.

* Who are the stakeholders and what decisions should be supported by the scores and metrics of the benchmarking?
* What general criteria have been applied for selecting scores and metrics?
* What scores and metrics have been chosen/defined for robustness?
* What scores and metrics have been chosen/defined for medical performance?
* What scores and metrics have been chosen/defined for non-medical performance?
  + Metrics for technical performance tracking (e.g., monitoring and reporting when the performance accuracy of the model drops below a predefined threshold level as a function of time; computational efficiency rating, response times, memory consumption)
* What scores and metrics have been chosen/defined for model explainability?
* Describe for each aspect
  + The exact definition/formula of the score based on the labels and the AI output data structures defined in the previous sections and how they are aggregated/accumulated over the whole dataset (e.g., for a single test set entry, the result might be the probability of the expected correct class which is then aggregated to the average probability of the correct class)
  + Does it use some kind of approach for correcting dataset bias (e.g., the test dataset usually has a different distribution compared to the distribution of a condition in a real-world scenario. For estimating the real-world performance, metrics need to compensate this difference.)
  + What are the origins of these scores and metrics?
  + Why were they chosen?
  + What are the known advantages and disadvantages?
  + How easily can the results be compared between or among AI solutions?
  + Can the results from benchmarking iterations be easily compared or does it depend too much on the dataset (e.g., how reproducible are the results)?
* How does this consider the general guidance of WG-DAISAM in [DEL07\_3](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7BA3088882-F82B-493B-B1C5-49CFF0EEEFA8%7D&file=DEL07_3.docx&action=default) “Data and artificial intelligence assessment methods (DAISAM)”?
* Have there been any relevant changes compared to previous benchmarking iterations? If so, why?
  + - 1. **Test dataset acquisition**

Test dataset acquisition includes a detailed description of the test dataset for the AI model and, in particular, its benchmarking procedure including quality control of the dataset, control mechanisms, data sources, and storage.

* How does the overall dataset acquisition and annotation process look?
* How have the data been collected/generated (e.g., external sources vs. a process organized by the TG)?
* Have the design goals for the benchmarking dataset been reached (e.g., please provide a discussion of the necessary size of the test dataset for relevant benchmarking results, statistical significance, and representativeness)?
* How was the dataset documented and which metadata were collected?
  + Where were the data acquired?
  + Were they collected in an ethical-conform way?
  + Which legal status exists (e.g., intellectual property, licenses, copyright, privacy laws, patient consent, and confidentiality)?
  + Do the data contain ‘sensitive information’ (e.g., socially, politically, or culturally sensitive information; personal identifiable information)? Are the data sufficiently anonymized?
  + What kind of data anonymization or deidentification has been applied?
  + Are the data self-contained (i.e., independent from externally linked datasets)?
  + How is the bias of the dataset documented (e.g., sampling or measurement bias, representation bias, or practitioner/labelling bias)?
  + What additional metadata were collected (e.g., for a subsequent detailed analysis that compares the performance on old cases with new cases)? How was the risk of benchmarking participants accessing the data?
* Have any scores, metrics, or tests been used to assess the quality of the dataset (e.g., quality control mechanisms in terms of data integrity, data completeness, and data bias)?
* Which inclusion and exclusion criteria for a given dataset have been applied (e.g., comprehensiveness, coverage of target demographic setting, or size of the dataset)?
* How was the data submission, collection, and handling organized from the technical and operational point of view (e.g., folder structures, file formats, technical metadata encoding, compression, encryption, and password exchange)?
* Specific data governance derived by the general data governance document (currently [F-103](https://www.itu.int/en/ITU-T/focusgroups/ai4h/Documents/FGAI4H-F-103-DataPolicy.pdf) and the deliverables beginning with [DEL05](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B2012357A-941E-44BD-B965-370D7829F52C%7D&file=DEL05.docx&action=default))
* How was the overall quality, coverage, and bias of the accumulated dataset assessed (e.g., if several datasets from several hospitals were merged with the goal to have better coverage of all regions and ethnicities)?
* Was any kind of post-processing applied to the data (e.g., data transformations, repackaging, or merging)?
* How was the annotation organized?
  + How many annotators/peer reviewers were engaged?
  + Which scores, metrics, and thresholds were used to assess the label quality and the need for an arbitration process?
  + How have inter-annotator disagreements been resolved (i.e., what was the arbitration process)?
  + If annotations were part of the submitted dataset, how was the quality of the annotations controlled?
  + How was the annotation of each case documented?
  + Were metadata on the annotation process included in the data (e.g., is it possible to compare the benchmarking performance based on the annotator agreement)?
* Were data/label update/amendment policies and/or criteria in place?
* How was access to test data controlled (e.g., to ensure that no one could access, manipulate, and/or leak data and data labels)? Please address authentication, authorization, monitoring, logging, and auditing
* How was data loss avoided (e.g., backups, recovery, and possibility for later reproduction of the results)?
* Is there assurance that the test dataset is undisclosed and was never previously used for training or testing of any AI model?
* What mechanisms are in place to ensure that test datasets are used only once for benchmarking? (Each benchmarking session will need to run with a new and previously undisclosed test dataset to ensure fairness and no data leakage to subsequent sessions)
  + - 1. **Data sharing policies**

This section provides details about legalities in the context of benchmarking. Each dataset that is shared should be protected by special agreements or contracts that cover, for instance, the data sharing period, patient consent, and update procedure (see also [DEL05\_5](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B71FE8B9D-ACB3-48CE-AA3F-136409B550A4%7D&file=DEL05_5.docx&action=default) on *data handling* and [DEL05\_6](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B5C95327E-96A5-4175-999E-3EDB3ED147C3%7D&file=DEL05_6.docx&action=default) on *data sharing practices*).

* Which legal framework was used for data sharing?
* Was a data sharing contract signed and what was the content? Did it contain:
  + Purpose and intended use of data
  + Period of agreement
  + Description of data
  + Metadata registry
  + Data harmonization
  + Data update procedure
  + Data sharing scenarios
    - Data can be shared in public repositories
    - Data are stored in local private databases (e.g., hospitals)
  + Rules and regulation for patients’ consent
  + Data anonymization and de-identification procedure
  + Roles and responsibilities
    - Data provider
    - Data protection officer
    - Data controllers
    - Data processors
    - Data receivers
* Which legal framework was used for sharing the AI?
* Was a contract signed and what was the content?
  + - 1. **Baseline acquisition**

The main purpose of benchmarking is to provide stakeholders with the numbers they need to decide whether AI models provide a viable solution for a given health problem in a designated context. To achieve this, the performance of the AI models needs to be compared with available options achieving the same clinically meaningful endpoint. This, in turn, requires data on the performance of the alternatives, ideally using the same benchmarking data. As the current alternatives typically involve doctors, it might make sense to combine the test data acquisition and labelling with additional tasks that allow the performance of the different types of health workers to be assessed.

* Does this topic require comparison of the AI model with a baseline (gold standard) so that stakeholders can make decisions?
* Is the baseline known for all relevant application contexts (e.g., region, subtask, sex, age group, and ethnicity)?
* Was a baseline assessed as part of the benchmarking?
* How was the process of collecting the baseline organized? If the data acquisition process was also used to assess the baseline, please describe additions made to the process described in the previous section.
* What are the actual numbers (e.g., for the performance of the different types of health workers doing the task)?
  + - 1. **Reporting methodology**

*After the benchmarking, the next step is to describe how the results are compiled into reports that allow stakeholders to make decisions (e.g., which AI systems can be used to solve a pre-diagnosis task in an offline –field –clinic scenario in central America). For some topic groups, the report might be as simple as a classical AI competition leader board using the most relevant performance indicator. For other tasks, it could be an interactive user interface that allows stakeholders to compare the performance of the different AI systems in a designated context with existing non-AI options. For the latter, statistical issues must be carefully considered (e.g., the multiple comparisons problem). Sometimes, a hybrid of prepared reports on common aspects are generated in addition to interactive options. There is also the question of how and where the results are published and to what degree benchmarking participants can opt in or opt out of the publication of their performance.*

This section discusses how the results of the benchmarking runs will be shared with the participants, stakeholders, and general public.

* What is the general approach for reporting results (e.g., leader board vs. drill down)?
* How can participants analyse their results (e.g., are there tools or are detailed results shared with them)?
* How are the participants and their AI models (e.g., versions of model, code, and configuration) identified?
* What additional metadata describing the AI models have been selected for reporting?
* How is the relationship between AI results, baselines, previous benchmarking iterations, and/or other benchmarking iterations communicated?
* What is the policy for sharing participant results (e.g., opt in or opt out)? Can participants share their results privately with their clients (e.g., as in a credit check scenario)?
* What is the publication strategy for the results (e.g., website, paper, and conferences)?
* Is there an online version of the results?
* Are there feedback channels through which participants can flag technical or medical issues (especially if the benchmarking data was published afterwards)?
* Are there any known limitations to the value, expressiveness, or interpretability of the reports?
  + - 1. **Result**

This section gives an overview of the results from runs of this benchmarking version of your topic. Even if your topic group prefers an interactive drill-down rather than a leader board, pick some context of common interest to give some examples.

* When was the benchmarking executed?
* Who participated in the benchmarking?
* What overall performance of the AI systems concerning medical accuracy, robustness, and technical performance (minimum, maximum, average etc.) has been achieved?
* What are the results of this benchmarking iteration for the participants (who opted in to share their results)?
  + - 1. **Discussion of the benchmarking**

This section discusses insights of this benchmarking iterations and provides details about the ‘outcome’ of the benchmarking process (e.g., giving an overview of the benchmark results and process).

* What was the general outcome of this benchmarking iteration?
* How does this compare to the goals for this benchmarking iteration (e.g., was there a focus on a new aspect to benchmark)?
* Are there real benchmarking results and interesting insights from this data?
  + How was the performance of the AI system compared to the baseline?
  + How was the performance of the AI system compared to other benchmarking initiatives (e.g., are the numbers plausible and consistent with clinical experience)?
  + How did the results change in comparison to the last benchmarking iteration?
* Are there any technical lessons?
  + Did the architecture, implementation, configuration, and hosting of the benchmarking system fulfil its objectives?
  + How was the performance and operational efficiency of the benchmarking itself (e.g., how long did it take to run the benchmarking for all AI models vs. one AI model; was the hardware sufficient)?
* Are there any lessons concerning data acquisition?
  + Was it possible to collect enough data?
  + Were the data as representative as needed and expected?
  + How good was the quality of the benchmarking data (e.g., how much work went into conflict resolution)?
  + Was it possible to find annotators?
  + Was there any relevant feedback from the annotators?
  + How long did it take to create the dataset?
* Is there any feedback from stakeholders about how the benchmarking helped them with decision-making?
  + Are metrics missing?
  + Do the stakeholders need different reports or additional metadata (e.g., do they need the “offline capability” included in the AI metadata so that they can have a report on the best offline system for a certain task)?
* Are there insights on the benchmarking process?
  + How was the interest in participation?
  + Are there reasons that someone could not join the benchmarking?
  + What was the feedback of participants on the benchmarking processes?
  + How did the participants learn about the benchmarking?
    - 1. **Retirement**

*Topic driver: describe what happens to the benchmarking data and the submitted AI models after the benchmarking.*

This section addresses what happens to the AI system and data after the benchmarking activity is completed. It might be desirable to keep the database for traceability and future use. Alternatively, there may be security or privacy reasons for deleting the data. Further details can be found in the reference document of this section [DEL04](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7BC68833D1-9B31-4E8E-8A4A-3939D7DEA56F%7D&file=DEL04.docx&action=default) “*AI software lifecycle specification”* (identification of standards and best practices that are relevant for the AI for health software life cycle).

* What happens with the data after the benchmarking (e.g., will they be deleted, stored for transparency, or published)?
* What happens to the submitted AI models after the benchmarking?
* Could the results be reproduced?
* Are there legal or compliance requirements to respond to data deletion requests?
  + 1. **Benchmarking version [X]**

This section includes all technological and operational details of the benchmarking process for the benchmarking version [X].

*Topic driver: Provide details of previous benchmarking versions here using the same subsection structure as above.*

* 1. **Subtopic [B]**

*Topic driver: If there are subtopics in your topic group, please provide the details about the benchmarking of the second subtopic [B] here using the same subsection structure as above (please refer to earlier comments – in red fonts - concerning subtopics).*

1. **Overall discussion of the benchmarking**

This section discusses the overall insights gained from benchmarking work in this topic group. This should not be confused with the discussion of the results of a concrete benchmarking run (e.g., in 4.2.11).

* What is the overall outcome of the benchmarking thus far?
* Have there been important lessons?
* Are there any field implementation success stories?
* Are there any insights showing how the benchmarking results correspond to, for instance, clinical evaluation?
* Are there any insights showing the impact (e.g., health economic effects) of using AI systems that were selected based on the benchmarking?
* Was there any feedback from users of the AI system that provides insights on the effectiveness of benchmarking?
  + Did the AI system perform as predicted relative to the baselines?
  + Did other important factors prevent the use of the AI system despite a good benchmarking performance (e.g., usability, access, explainability, trust, and quality of service)?
* Were there instances of the benchmarking not meeting the expectations (or helping) the stakeholders? What was learned (and changed) as a result?
* What was learned from executing the benchmarking process and methodology (e.g., technical architecture, data acquisition, benchmarking process, benchmarking results, and legal/contractual framing)?

1. **Regulatory considerations (PI: @tannejohannes@gmail.com)**

*Topic Driver: This section reflects the requirements of the working group on* [***Regulatory considerations on AI for health (WG-RC)***](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/wg/SitePages/WG-RC.aspx) *and their various deliverables. It is* ***NOT requested to re-produce regulatory frameworks****, but to show the regulatory frameworks that have to be applied in the context of your AIs and their benchmarking (****2 pages max****).*

For AI-based technologies in healthcare, regulation is not only crucial to ensure the safety of patients and users, but also to accomplish market acceptance of these devices. This is challenging because there is a lack of universally accepted regulatory policies and guidelines for AI-based medical devices. To ensure that the benchmarking procedures and validation principles of FG-AI4H are secure and relevant for regulators and other stakeholders, the working group on *“*[*Regulatory considerations on AI for health”* *(WG-RC)*](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/wg/SitePages/WG-RC.aspx) compiled the requirements that consider these challenges.

The deliverables with relevance for regulatory considerations are [DEL02](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7BF2F46A99-7457-4BC8-81A3-0E1E63D6072A%7D&file=DEL02.docx&action=default) *“AI4H regulatory considerations”* (which provides an educational overview of some key regulatory considerations), [DEL02\_1](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B6AF7C004-8BCE-4151-9F44-45F041A1EB1D%7D&file=DEL02_1.docx&action=default) *“Mapping of IMDRF essential principles to AI for health software”,* and[DEL02\_2](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7B1ED0D4D1-876C-4A0F-AEF7-06D3F445F5E6%7D&file=DEL02_2.docx&action=default) *“Guidelines for AI based medical device (AI-MD): Regulatory requirements”* (which provides a checklist to understand expectations of regulators, promotes step-by-step implementation of safety and effectiveness of AI-based medical devices, and compensates for the lack of a harmonized standard). [DEL04](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7BC68833D1-9B31-4E8E-8A4A-3939D7DEA56F%7D&file=DEL04.docx&action=default) identifies standards and best practices that are relevant for the “*AI software lifecycle specification*.*”* The following sections discuss how the different regulatory aspects relate to the TG-Dental.

* 1. **Existing applicable regulatory frameworks**

Most of the AI systems that are part of the FG-AI4H benchmarking process can be classified as *software as medical device* (SaMD) and eligible for a multitude of regulatory frameworks that are already in place. In addition, these AI systems often process sensitive personal health information that is controlled by another set of regulatory frameworks. The following section summarizes the most important aspects that AI manufacturers need to address if they are developing AI systems for Dental Diagnostics and Digital Dentistry.

* What existing regulatory frameworks cover the type of AI in this TDD (e.g., MDR, FDA, GDPR, and ISO; maybe the systems in this topic group always require at least “MDR class 2b” or maybe they are not considered a medical device)?
* Are there any aspects to this AI system that require additional specific regulatory considerations?
  1. **Regulatory features to be reported by benchmarking participants**

In most countries, benchmarked AI solutions can only be used legally if they comply with the respective regulatory frameworks for the application context. This section outlines the compliance features and certifications that the benchmarking participants need to provide as part of the metadata. It facilitates a screening of the AI benchmarking results for special requirements (e.g., the prediction of prediabetes in a certain subpopulation in a country compliant to the particular regional regulatory requirements).

* Which certifications and regulatory framework components of the previous section should be part of the metadata (e.g., as a table with structured selection of the points described in the previous section)?
  1. **Regulatory requirements for the benchmarking systems**

The benchmarking system itself needs to comply with regulatory frameworks (e.g., some regulatory frameworks explicitly require that all tools in the quality management are also implemented with a quality management system in place). This section outlines the regulatory requirements for software used for benchmarking in this topic group.

* Which regulatory frameworks apply to the benchmarking system itself?
* Are viable solutions with the necessary certifications already available?
* Could the TG implement such a solution?
  1. **Regulatory approach for the topic group**

*Topic Driver: Please select the points relevant for your type of AI and the corresponding benchmarking systems. If your AIs and your benchmarking are not a medical device, this might be quite short.*

Building on the outlined regulatory requirements, this section describes how the topic group plans to address the relevant points in order to be compliant. The discussion here focuses on the guidance and best practice provided by the [DEL02](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/_layouts/15/WopiFrame.aspx?sourcedoc=%7BF2F46A99-7457-4BC8-81A3-0E1E63D6072A%7D&file=DEL02.docx&action=default) *“AI4H regulatory considerations.”*

* Documentation & Transparency
  + How will the development process of the benchmarking be documented in an effective, transparent, and traceable way?
* Risk management & Lifecycle approach
  + How will the risk management be implemented?
  + How is a life cycle approach throughout development and deployment of the benchmarking system structured?
* Data quality
  + How is the test data quality ensured (e.g., the process of harmonizing data of different sources, standards, and formats into a single dataset may cause bias, missing values, outliers, and errors)?
  + How are the corresponding processes document?
* Intended Use & Analytical and Clinical Validation
  + How are technical and clinical validation steps (as part of the lifecycle) ensured (e.g., as proposed in the IMDRF clinical evaluation framework)?
* Data Protection & Information Privacy
  + How is data privacy in the context of data protection regulations ensured, considering regional differences (e.g., securing large data sets against unauthorized access, collection, storage, management, transport, analysis, and destruction)? This is especially relevant if real patient data is used for the benchmarking.
* Engagement & Collaboration
  + How is stakeholder (regulators, developers, healthcare policymakers) feedback on the benchmarking collected, documented, and implemented?
  1. **Dentition Stages**

The project of teeth identification, can be divided in three separate Phases: **Permanent Dentition; Milk Dentition and Mixed Dentition**.

At this time, only panoramic radiograph from patients with Permanent Dentition shall be included and that’s because it will be an enormous task to identify any teeth and if we try to identify, besides the permanent teeth, the milk teeth and germs too, that shall be very difficult for the training set and the model.

So, in Phase One - **Permanent Dentition**, we focus on Permanent teeth identification; in Phase Two - **Milk Dentition,** once we have already been able to identify the permanent teeth, so we can focus on milk teeth identification; and in Phase Three - **Mixed Dentition**, once we have already been able to identify the permanent and the milk teeth, so we can focus on the germs identification.

* 1. **Imaging Acquisition Format**

Regarding the radiographic or tomographic or photographic image acquisition, I suggest to use the International standard DICOM (Digital Imaging and Communications in Medicine) for the communication and management of medical imaging information and related data, from NEMA (National Electrical Manufacturers Association). The use of DICOM is a safety guarantee for the image and the information embedded in the “dcm'' file. It shall be noted that all major x-ray equipment manufacturers in the dental market, such as Instrumentarium, Kavo, Soredex, Carestream Dental, Plameca, Vatech, NewTom and others are already DICOM compatible, directly or indirectly (with a bridge software).

* 1. **Anonymization or Deidentification**

Regarding the anonymization or deidentification of the DCIOM files from each image, it can be used with a free Python Library – Pydicom (<https://pydicom.github.io/> ). It is a very nice tool for that purpose, it can be directed to each of the many DICOM tags (ex. Name, ID, Gender, Date of Birth, Referring Dentist, Modality, etc). After this step, anonymization, the image can be converted to any image file format, such as “jpeg”, “png”, “bmp” or nay other, for the training set or the model. ( \* This is a technical issue that, probably, shall not be pointed out by a dentist like myself, so this is just a mention!)

* 1. **Direct DICOM-to-CNN**

Recently Dr.Salim Kanoun and Wendy Revailler, have developed a Python Library, DICOM-to-CNN (<https://github.com/salimkanoun/Dicom-To-CNN> -<https://dicom-to-cnn.readthedocs.io/en/latest/> ) that allows to process DICOM files directly for training and inference purpose, without the conversion step. (\* This is a technical issue that, probably, shall not be pointed out by a dentist like myself, so this is just a mention!)

1. **References**

*Topic driver: Add the bibliography here.*

*Topic driver: If you include figures in this document, please use the following MS Word format/style (otherwise the figure won’t be included in the table of figures).*

|  |  |  |
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| A |  | B |

Captions for figures use WinWord style "Figure\_No & title"

**Figure 1: Example of a figure**

**Annex A:  
Glossary**

This section lists all the relevant abbreviations, acronyms and uncommon terms used in the document.

|  |  |  |
| --- | --- | --- |
| **Acronym/Term** | **Expansion** | **Comment** |
| TDD | Topic Description Document | Document specifying the standardized benchmarking for a topic on which the FG AI4H Topic Group works. This document is the TDD for the Topic Group Dental Diagnostics and Digital Dentistry (TG-Dental) |
| TG | Topic Group |  |
| WG | Working Group |  |
| FGAI4H | Focus Group on AI for Health |  |
| AI | Artificial intelligence |  |
| ITU | International Telecommunication Union |  |
| WHO | World Health Organization |  |
| DEL | Deliverable |  |
| CfTGP | Call for topic group participation |  |
| AI4H | Artificial intelligence for health |  |
| IMDRF | International Medical Device Regulators Forum |  |
| MDR | Medical Device Regulation |  |
| ISO | International Standardization Organization |  |
| GDPR | General Data Protection Regulation |  |
| FDA | Food and Drug administration |  |
| SaMD | Software as a medical device |  |
| AI-MD | AI based medical device |  |
| LMIC | Low-and middle-income countries |  |
| GDP | Gross domestic product |  |
| API | Application programming interface |  |
| IP | Intellectual property |  |
| PII | Personal identifiable information |  |
| […] |  |  |

**Annex B:  
Declaration of conflict of interests**

In accordance with the ITU transparency rules, this section lists the conflict-of-interest declarations for everyone who contributed to this document. Please see the guidelines in FGEI 4H-F-105 “ToRs for the WG-Experts and call for experts” and the respective forms (Application form & Conflict of interest form).

**Company/Institution/Individual XYZ**

A short explanation of the company’s area of activity and how the work on this document might benefit the company and/or harm competitors. A list of all people who contributed to this document on behalf of this company and any personal interest in this company (e.g., shares).

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