DELIVER

REPORT ON FINDINGS

from in-depth analysis of regulatory determinants and payment reforms

This report is published as deliverable under the DELIVER project. The DELIVER project received funding from the European Union's HORIZON Europe research and innovation program under grant agreement 101057077: https://cordis. europa.eu/project/id/101057077.

DELIVER (Deliberative ImproVement of oRal care quality), is a multinational project funded under the EU's Horizon Europe Program. The project aims to enhance the quality of oral care through deliberative dialogue and action involving citizens, patients, providers, payers and policymakers.

Report on regulatory determinants and payment reforms

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DELIVER

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Annexes

Number	Title
Annex A	Analysis coverage, quality provenance, yardstick and consequences 7.1
Annex B	Professional registration, aptitude and language test
Annex C	Guideline for Oral Guidelines

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[1] Foundation Lygature.
[2] Ministry of Health Malta.
[3] Foundation Lygature.
[4] Foundation Lygature.
[5] Academic Centre for Dentistry VU-ACTA.
[6] Heidelberg University.

Table Content

Executive summary

Historically, the healthcare legislative frameworks and determinants relating to healthcare products, services, professional training, medical records, healthcare quality and reimbursement were developed and adopted nationally.
Gradually, European legislation was introduced establishing principles for the free movement of goods, persons and services.
European citizens increasingly cross European borders and are using cross-border services, including healthcare services, digitally or in the respective host state.

Initially, European directives were used as a common legislation framework within the European Union (EU). In the last decade, an increasing number of regulations governing the quality of instruments, medicinal products, healthcare technology and patient records have been adopted to create more unity in effect and interpretation in all Member States of the European Union. European scientific associations, in multiple healthcare disciplines, were formed with the mission to improve quality of care in their specialism or discipline, fostering excellence in scientific research, education and healthcare.

While Member States have and use their statutory freedom to organize the healthcare system and allocate budget to their healthcare system based on national legislation and policy, the playing field for quality, scientific insights on innovation, cooperation, patient-centredness, implementation of ethical principles for government policies and access to healthcare are mostly driven by international and European regulatory determinants including ethical principles, guidelines, briefings, standards and recommendations.
Member States of the European Union are all represented, directly and indirectly, in international bodies, associations and entities that focus on research, standards, guidelines and recommendations developed by their members, Member States or their bodies, associations or healthcare providers, and are all committed to these regulatory determinants and instruments. They can access knowledge developed and made available by international and European entities, in which they are represented, to jointly and effectively achieve cost-efficient qualitative indicators for oral care.

Member States of the European Union are facing the reality of oral diseases affecting 466 million people in the European Region. Member States of the European Union are facing the reality of cross-border healthcare and the consequences of neglected diseases.
All Member States can collaborate effectively to share data and develop guidelines for improvement of population based integrated oral care including prevention.

The Deliver project aims to enhance the quality of oral care for the whole population, including vulnerable groups and disabled persons, through deliberative dialogue and action involving citizens, patients, providers, payers and policymakers. The Deliver project is financially supported by the EU.
This report, in addition to the report Deliver 7.1, analyses the common perspective and regulatory determinants internationally and within the European Union and formulates conclusions, recommendations and a regulatory determinants toolkit to establish oral care

quality improvement instruments and prevention policy efficiently and adequately based on joint scientific insights and enlarged data sets to support population-based accessibility to qualitative and essential oral care, adequate, targeted and population based prevention and payment reforms.

Methodology

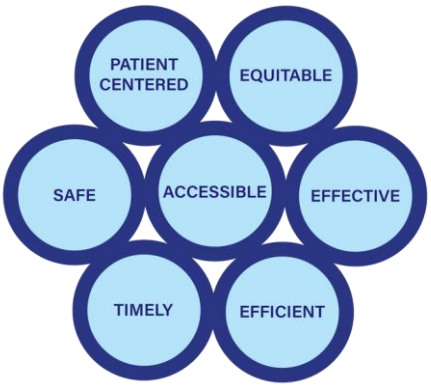
The research is based on mapping and analysing existing and emerging international regulatory determinants, including quality principles, standards, guidelines, ethical principles and the applicable relevant legislative framework in the European Union. The research is furthermore based on mapping relevant stakeholders that can contribute to the mission of the project principles and regulatory determinants toolkit.

In the concluding paragraphs, the outcome of this analysis is plotted against the practice level, professional level, instruments, treatment level, prevention and digitalisation, population based, including vulnerable groups and disabled persons.

Qualitative desk research into regulatory determinants, has been conducted nationally, using the completed questionnaires and the report published (WP 7.1 DELIVER project)[7], internationally and within the context of the European Union. The research entailes policy, relevant stakeholders and regulatory determinants to support, develop and monitor (improvement of) oral care quality following the line of scope, yardstick and consequences on two geographic levels.
Qualitative research was conducted on relevant stakeholders and (governmental) bodies to explore and analyse reports, guidelines, statements, publications, papers, jurisprudence and the regulatory framework of the European Union.

The structure of the research and report is descriptive and exploratory.
The research followed the domains of oral care quality as set out as depicted in the following graphic.[8]

Figure:



[7] Van Veen, E. B., Dorenbos, E.M., Van Ardenne, O., & Listl, S. (2023-2024). *Report findings from a cross-country expert survey on a regulatory basis for quality improvement of oral health care*.
[8] Righolt, A. J., Walji, M. F., Feine, J. S., Williams, D. M., Kalenderian, E., & Listl, S. (2019). An International Working Definition for Quality of Oral Healthcare. *JDR Clinical & Translational Research*, *5*(2), 238008441987544. https://doi.org/10.1177/2380084419875442

The seven domains relate to:
a. The practice (building and organization of the practice) and accessibility;
b. the facilities/instruments;
c. the professionals and;
d. the care (prevention, treatment, interdisciplinary alignment) provided to a person and the community.
Prevention is explored on the international and an European level as an element of public health.

Definitions

Body	The definition as formulated in the Open Data Directive, i.e., the State, regional or local authorities, bodies governed by public law or associations formed by one or more such authorities or one or more such bodies governed by public law. Bodies governed by public law mean bodies that: are established for the specific purpose of meeting needs in the general interest, not having an industrial or commercial character; have legal personality; and are financed for the most part by the State.[9]
Directive	A directive is an EU legislative instrument that sets out a goal that EU Member States must achieve. The Member States must transpose in national regulation to reach these goals (European Union).
European legislation	We refer to the term "European legislation" as all types of legal acts that achieve the aims set out in EU treaties. This definition will thus entail the following instruments: regulations, directives, decisions, recommendations, and opinions.
National law	A broadly defined set of rules, norms and regulatory mechanisms *as constituted* by the individual Member States, including the corpus of laws as enacted directly by the legislature as defined in the constitution and forming a subset of regulation.
Guidelines	Clinical guidelines developed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options, following a transparent methodology to translate best evidence into clinical practice for improved patient outcomes. Additionally, evidence-based CPGs are a key aspect of patient-centred care.[10]
Oral Care Quality	The definition of oral care quality as developed in the context of the DELIVER project, in terms of equitability, accessibility, patient-centeredness, patient safety, effectiveness, efficiency, and timeliness.[11]
Patient and Public Involvement	Research carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' 'them'.[12]

[9] Directive 2019/1024.
[10] GRADE Working Group. (n.d.). *Welcome to the GRADE working group*. Gradeworkinggroup. https://www.gradeworkinggroup.org/; American Academy of Family Physicians (AAFP). (n.d.). *Clinical Recommendations. aafp.* https://www.aafp.org/family-physician/patient-care/clinical-recommendations.html; and WHO. (2014). *WHO handbook for guideline development, 2nd edition*. ISBN 978 92 4 154896 0. https://www.who.int/publications/i/item/9789241548960
[11] Righolt, A. J., Walji, M. F., Feine, J. S., Williams, D. M., Kalenderian, E., & Listl, S. (2019). An International Working Definition for Quality of Oral Healthcare. *JDR Clinical & Translational Research*, *5*(2), 238008441987544. https://doi.org/10.1177/2380084419875442
[12] HSE. (n.d.). *Patient and Public Involvement in Research (PPI)*. hseresearch. https://hseresearch.ie/patient-and-public-involvement-in-research/

Primary care	We rely, for the sake of consistency, on the "working definition" applied for the survey developed for WP 7.1 for which the three levels of care have been categorized: primary, secondary, and tertiary care. Primary oral care has been defined as the first point of contact between patients/consumers and healthcare providers.
Regulation	A binding legislative act, which must be applied in its entirety across the EU.[13]
Standards	A set of specific, concise statements and related measures derived from evidence-based guidance and produced collaboratively. Each standard contains statements that describe priority areas for improvement .[14]

Abbreviations

AI	Artificial Intelligence
CPG	Clinical Practice Guideline
CRC	Convention on the rights of the child
DELIVER	DELiberative ImproVEment of oRal care quality project
EHDS	European Health Data Space
EU	European Union
FDI	FDI World Dentist Federation
GOHP	Global Oral Health Program
GRADE	Grading Recommendations Assessment, Development and Evaluation
EU	European Union
ICESCR	International covenant on economic, social & cultural rights
NCD	Non-Communicable Diseases
PPI	Patient and public involvement
PREMS	Patient reported experience measures
PROMS	Patient reported outcome measures
QI	Quality Indicator
SDG	Sustainable Development Goals
SitA	Situational Awareness
UHC	Universal Health Coverage

[13] European Union. (2023). *Types of legislation*. european-union.europa. https://european-union.europa.eu/institutions-law-budget/law/types-legislation_en

[14] NICE. (2017). *Oral and dental health*. nice. https://www.nice.org.uk/guidance/conditions-and-diseases/oral-and-dental-health

1. INTRODUCTION

Oral diseases and conditions are affecting an estimated 3.5 billion people worldwide with an ever-increasing burden on low- and middle-income countries.[15] Oral diseases affect 466 million people in the European Region[16] and form the third most expensive type of disease to treat in the EU and disproportionally affect vulnerable groups. Many EU citizens do not have access to quality oral care without financial hardship.[17]
Oral health share risk factors with other Non-Communicable Diseases. The health burden of oral diseases is high.[18] Oral health is not sufficiently integrated in primary care.[19] Thematic analysis of evidence in developing countries has led to the conclusion that eleven determinants may result in inequality in oral and dental health services in developing countries including personal characteristics, health status, health needs and health behaviours, social, economic, cultural and environmental factors, as well as insurance, policies and practices and provided related factors.[20]
Moreover, oral health inequalities remain one of the most under-addressed issues in public health. The burden of population-based oral diseases affects disproportionately the disadvantaged population and is not addressed adequately.[21]

The DELIVER project aims to enhance the quality of oral care through deliberative dialogue and action involving citizens, patients, providers, payers and policymakers.

Figure:

WP 2: Quality indicators and monitoring framework.
WP 3: Quality improvement on practice level.
WP 4: Quality improvement on community level.
WP 5: Quality improvement on policy level.
WP 6: Governance/regulation of oral care quality.

[15] WHO. (2022). *Global oral health status report: towards universal health coverage for oral health by 2030*. Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications/i/item/9789240061484
[16] WHO. (2022). *Global oral health status report: towards universal health coverage for oral health by 2030*. Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/publications/i/item/9789240061484
[17] Jevdjevic, M., & Listl, S. (2024). Global, Regional, and Country-Level Economic Impacts of Oral Conditions in 2019. *Journal of Dental Research*, *104*(1), 220345241281698. https://doi.org/10.1177/00220345241281698 and Listl, S., Grytten, J. I., & Birch, S. (2019). What is health economics? *Community Dental Health*, *36*(4), 262–274. https://doi.org/10.1922/CDH_4581Listl13
[18] WHO (adopted by the World Health Assembly in 2023). (2024). *Global Strategy and Action Plan on Oral Health 2023-2030.* Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/022cde3b-a0d8-440e-8b5e-7ab5a90f89e6/content
[19] Patro S.K. (2024). Editorial: Integration of oral health care within the healthcare system. *Frontiers in Oral Health 2024. https://doi.org/10.3389/froh.2024.1387141*
[20] Bastani, P., Mohammadpour, M., Mehraliain, G., Delavari, S. & Edirippulige, S. (2021). What makes inequality in the area of dental and oral health in developing countries? A scoping review. *Cost Effectiveness and Resource Allocation, 19(1)*. https://doi.org/10.1186/s12962-021-00309-0
[21] Serban, S., & Conway, D. (2025). Sugar tax impacts oral health and the need to go further upstream. *British Dental Journal 238,* pp. 642-643. *https://doi.org/10.1038/s41415-025-8637-z* and Kingdon, J.W. (2013). *Agendas, Alternatives, and Public Policies, Updated Edition. Pearson New International Edition. 2nd edition*. ISBN: 978-1-292-05387-5.

WP 7: Regulatory determinants on the international and European level and toolkit.
WP 8: Knowledge transfer

2. JOINT VISION QUESTIONNAIRES AND REPORT 7.1[22]

A questionnaire was designed with the objective to gain insight on:

1. National healthcare regulations for oral healthcare and quality along the lines of provenance of quality and quality indicators, the yardstick and consequences in seven Member States;
2. The organization of the healthcare system and stakeholders including the way oral care is funded in seven Member States;
3. Differences and similarities between the healthcare systems of seven Member States.

The questions were similar in all questionnaires. The questions were based on elements of practice and treatment following the working definition of oral care quality as proposed.
Experts in the field of oral care completed the questionnaires (100% response rate).
The completed questionnaires were discussed during a webinar with experts on September 7, 2023.
The answers and discussions reflected similarities between the healthcare systems.
However, not quite surprisingly, (even more) divergence became evident in legislative structure, responsible bodies and entities involved in oral care quality (development, monitoring and consequences of non-compliance and reimbursement for oral care services).[23]

2.1 Dissimilarities and consequences

Although similarity was established in the collective funding systems for children and young adults,[24] the similarity was to the extent that cut-off ages as well as the comprehensiveness of the coverage differ. An important difference was established in coverage for those above the cut-off age.
The quality of equipment is mostly determined by EU regulations, differences are limited to additional norms.[25] By contrast, quality in terms of competence in using these possibly high-risk devices is not particularly evident.
Regulated transparency (mandatory or not) for oral care is limited,[26] while clinical practice

[22] Van Veen, E. B., Dorenbos, E.M., Van Ardenne, O., & Listl, S. (2023-2024). *Report findings from a cross-country expert survey on a regulatory basis for quality improvement of oral health care*.
[23] Van Veen, E. B., Dorenbos, E.M., Van Ardenne, O., & Listl, S. (2023-2024). *Report findings from a cross-country expert survey on a regulatory basis for quality improvement of oral health care,* p.13.
[24] Van Veen, E. B., Dorenbos, E.M., Van Ardenne, O., & Listl, S. (2023-2024). *Report findings from a cross-country expert survey on a regulatory basis for quality improvement of oral health care,* p.18.
[25] Van Veen, E. B., Dorenbos, E.M., Van Ardenne, O., & Listl, S. (2023-2024). *Report findings from a cross-country expert survey on a regulatory basis for quality improvement of oral health care,* p. 25.
[26] Van Veen, E. B., Dorenbos, E.M., Van Ardenne, O., & Listl, S. (2023-2024). *Report findings from a cross-country expert survey on a regulatory basis for quality improvement of oral health care,* p. 27.

guidelines are limited in several Member States.[27]
As a result of differences in definitions and procedures, certification and accreditation vary.[28]
Furthermore, quality standards may originate from medical associations or from other bodies.[29]
Clinical practice guidelines may be voluntary or mandatory.[30] The typology of dental auxiliary professions seems to differ between the countries.[31]

The dissimilarities stem from a strong national context as well as anomalous funding and payment systems, especially for adults. As indicated, coverage for children or young adults show more similarities although age limits differ. This difference, between adults and children, may be explained by various ethical treaties. These treaties are explained in more detail in Chapters 3 and 4.
The differences between coverage, provenance, yardstick and consequences are shown in **Annex A**.
Although the position of vulnerable groups and persons with disabilities is not specifically included in the questionnaires used for the 7.1 report, the safeguards and principles for equity are addressed in the context of ethical treaties and declarations further detailed in Chapters 3 and 4.

2.2 Similarities in the reality

EU Member States are all confronted with the reality of oral diseases: they form the third most expensive type of disease to treat in the EU and disproportionally affect vulnerable groups while many EU citizens do not have access to quality oral care without financial hardship.[32]
The divergences observed do not correspond with the common reality of the consequences of oral diseases, nor with the cross-border care in EU transborder regions, and neither with a growing flow of dental tourism, EU student programs, transborder secondary long term stays of EU citizens, digital services, the existence and possibilities of EU consortiums for research on treatment and quality, EU clinical trials and the strong cooperation of healthcare professionals within European scientific associations.
All citizens in the EU need transparency, consistency, trust in professionals and their professional trainings and specialisms and, above all, clarity on quality of transborder treatments and the financial consequences thereof.

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[27] Van Veen, E. B., Dorenbos, E.M., Van Ardenne, O., & Listl, S. (2023-2024). *Report findings from a cross-country expert survey on a regulatory basis for quality improvement of oral health care,* p. 28.
[28] Van Veen, E. B., Dorenbos, E.M., Van Ardenne, O., & Listl, S. (2023-2024). *Report findings from a cross-country expert survey on a regulatory basis for quality improvement of oral health care,* p. 31.
[29] Van Veen, E. B., Dorenbos, E.M., Van Ardenne, O., & Listl, S. (2023-2024). *Report findings from a cross-country expert survey on a regulatory basis for quality improvement of oral health care,* p. 25.
[30] Van Veen, E. B., Dorenbos, E.M., Van Ardenne, O., & Listl, S. (2023-2024). Report findings from a cross-country expert survey on a regulatory basis for quality improvement of oral health care, pp. 6,19,20 & 27.
[31] Van Veen, E. B., Dorenbos, E.M., Van Ardenne, O., & Listl, S. (2023-2024). *Report findings from a cross-country expert survey on a regulatory basis for quality improvement of oral health care,* p. 20.
[32] Jevdjevic, M., & Listl, S. (2024). Global, Regional, and Country-Level Economic Impacts of Oral Conditions in 2019. *Journal of Dental Research*, *104*(1), 220345241281698. https://doi.org/10.1177/00220345241281698 and Listl, S., Grytten, J. I., & Birch, S. (2019). What is health economics? *Community Dental Health*, *36*(4), pp. 262–274. https://doi.org/10.1922/CDH_4581Listl13

Travelling citizens cannot take the (complex and from general healthcare deviating) regulatory oral healthcare context of their home country with them.
The differences are striking against the backdrop of increasing collaboration of Member States healthcare professionals in multiple health disciplines (more than 40 medical and health associations and multiple organizations within the EU (see chapter 4)) to develop and share knowledge on treatments, innovation and quality of care and the increasing EU quality standards for the instruments and mechanism used by all healthcare professionals (MDR, IVDR, AI, EHDS, NIS 2 see further chapter 4). [33]
The differences may be explainable. Medical guidelines are based on a systematic review of scientific evidence, either nationally or internationally. At the same time, scientific research relies on relevant and solid data. Evidence may be based on the whole population or an accurate representation thereof. Limited coverage resulting in limited access to oral care may result in non-representative treatment data. Results of research based on non-representative data may complicate the development of adequate population-based guidelines and standards, the development of policy for workforce planning, public prevention policies and standards for integrated care.[34]

Limited oral care coverage may have hampered a solid whole population and community-based oral care approach for prevention policy and population-based guidelines, standards and the various measures for valuing health status and coverage such as quality-adjusted life year (QALY) and the quality-adjusted tooth year (QATY).[35]

A national policy aimed at accessibility of patient-centred oral care entails population based, rather than limited insurance covered based, data.
Well-defined healthcare services, population and community standards based on reliable data and scientific insights form a key element for adequate healthcare contracting, healthcare policy and informed consent of the patient and the payer (either a public entity, the insurer or, again, the patient).
Since the information analysed is based on information from seven, and not all Member States, the pressing question remains:

"How many more dissimilarities are there in the other 20 Member States?"

All Member States of the EU do, however, share a common commitment on international and European levels, and it is likely that all Member States do face the reality of the consequences of sidelined oral care in their care systems.
The EU Member States are, as Members of the WHO, all committed to the same regulatory

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[33] CPME Medecins Europeens European Doctors. (n.d.) *European Medical Organisations. cpme.* https://www.cpme.eu/about/partnerships/european-medical-organisations
[34] Brouwers M.C., Kho M.E., Browman G.P., Burgers J.S., Cluzeau F., Feder G., Fervers B., Graham I.D., Grimshaw J., Hanna S.E., Littlejohns P., Makarski J., Zitzelsberger L., for the AGREE Next Steps Consortium. (2023). *AGREE II: Advancing guideline development, reporting and evaluation in healthcare*. CMAJ 2010;182:E839-842. https://evidence-impact.org/storage/93/The-Appraisal-of-Guidelines-for-Research-&-Evaluation-Instrument-II-(AGREE-II).pdf
[35] Davidson, T. (2022). Measuring Effectiveness for Use in Economic Evaluations in Oral Health. *Introduction to Economic Evaluation in Oral Health Care. Pp. 53-65. https://doi.org/10.1007/978-3-030-96289-0_4*

determinants including WHO resolutions, recommendations, guidelines and briefings. Their associations and standard bodies are represented in the same standard committees on international and EU levels.
EU Member States are represented in various associations on international and EU level and are all committed to the same Human Right Treaties.

Most of all, all Member States must implement EU directives on healthcare professionals and cross-border care in their national regulatory systems and must respect EU regulations on healthcare products and product safety, Health Technology Assessment, AI, services and health records and secondary use of data.

3. INTERNATIONAL LEVEL, FRAMEWORK AND REGULATORY DETERMINANTS

The key actor on the international level supporting health policy, recommendations and guidelines, is the United Nations (UN) established in 1945 and built on the support and expertise of 194 Member States.

3.1 Introduction UN

The purposes and principles of the UN are laid down in its Constitution that articulates the right to health.
The UN adopted seventeen Sustainable Development Goals (SDGs) as a universal call for action for all countries to end poverty, protect the planet, and ensure that by 2030, all people enjoy peace and prosperity. The third goal, good health and well-being, was included as good health and wellbeing are essential to sustainable development. In the wake of this endeavour, the supporting factor of Universal Health Coverage was launched.[36]
WHO publishes world health statistics reports, monitors Sustainable Development Goals and launch WHO programmes.
In order to speed up movement towards the SDG, the Health for All Policies (H4APP) was launched and supported by Directive 2019/1024 The Global Network for Health in All Policies (GNHiAP), initiated by several countries during the 70th WHA Assembly, on 24 May 2017.

3.1.1 Universal Health Coverage Framework (UHC) 2030

The Universal Health Framework 2030 is a multi-stakeholder international platform.
Its mission is to accelerate sustainable progress towards universal health coverage detailed as coverage of the full continuum of essential health services, from health promotion, to prevention, treatment, rehabilitation and palliative care across the life course.
The UHC 2030's 2024–2027 Strategic Framework describes how UHC 2030 operates and adds value, on the path towards the next United Nations high-level meeting on UHC in 2027, and in the last stretch before the 2030 milestone for the SDGs.[37] Universality, equity and the right to health are the starting points of the UHC Framework 2030 and key to expanding population coverage.
Nonetheless, more than half of the world's population cannot access essential health services, and each year 100 million people are pushed into extreme poverty because of out-of-pocket

[36] United Nations (UN). (n.d.). *Homepage. un*. https://www.un.org/en/
[37] UHC2030. (2024). *Homepage.* uhc2023. https://www.uhc2030.org/

healthcare costs.[38]

Universal Health Coverage Framework 2030 defines two targets when following its mission between 2024 and 2027:
1. The importance of aligning work, in particular for international funding,
2. Action to support alignment with one national plan and government systems for public financial management and exchange of information on their actions.[39]

3.1.2 The WHO organization and constitution

"... dental diseases are the most prevalent NCDs globally and, although great improvements in prevention and treatment of dental diseases have occurred in the past decades, problems still persist, causing pain, anxiety, functional limitation (including poor school attendance and performance in children) and social handicap through tooth loss. The treatment of dental diseases is expensive, consuming 5–10% of health-care budgets in industrialized countries, and would exceed the entire financial resources available for the health care of children in most lower income countries" .[40]

The WHO is founded by the Constitution of the WHO, as a special agency with the objective of attainment of the highest possible level of health for all people.
The Constitution is, as explained in the recitals thereof, based on nine principles.

Membership in the WHO is open to all states. At present 194 Member States joined as member including all EU Member States.
The mission and work of the WHO is to translate global health initiatives into regional plans to address and respond to the specific needs. The areas of work are communicable diseases, health security and emergencies, and noncommunicable diseases.
The work of the WHO is carried out by:

a. The Executive Board;
b. The Secretariat;
c. The World Health Assembly.[41]

The World Health Assembly (WHA) is composed of delegates representing its Members (the Member States). Its functions are formulated in the Constitution.[42]

[38] Abodunrin O.R., Olagunju M.T., Alade, O.T., & Foláyan M.O. (2023). Relationships between Oral Health and the Sustainable Development Goals: A Scoping Review. *BioMed, 3(4)*, pp. 460–470. https://doi.org/10.3390/biomed3040037
[39] UHC2030. (2024). *Homepage*. uhc2023. https://www.uhc2030.org/
[40] WHO. (2015). *Sixty-eighth World Health Assembly: Follow-up to the 2014 high-level meeting of the United Nations General Assembly to undertake a comprehensive review and assessment of the progress achieved in the prevention and control of noncommunicable diseases (WHA68/11)*. https://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_11-en.pdf
[41] Article 9 WHO Constitution.
[42] Article 18 jo. article 23 WHO Constitution.

The WHA has authority to make recommendations to its members with respect to any matter within the competence of the WHO.[43]
The policy, recommendations and decisions are the result of the collective will and commitment of its members (Member States).
WHO may invite academic institutions in WHO meetings to participate in consultations, hearings or other meetings and facilitate expert meetings,[44] and designate collaborating centres.[45]
Although being non-binding, the resolutions of the WHO carry considerable weight for its members, and consequently the Member States of the EU, as they are all represented in the decisions on policy, reports and recommendations of the WHO.

3.1.3 WHO Resolutions and Action plans related to Oral Health

"… guide Member States to develop ambitious national responses to promote oral health, reduce oral diseases, other oral conditions and oral health inequalities, make progress on the path to universal oral health coverage for their populations, and consider the development of targets and indicators, based on national situations, building on the guidance to be provided by the WHO global action plan on oral health, to prioritize efforts and assess the progress made by 2030".[46]

The WHA has adopted several resolutions relating to oral care and oral care policy noting the urgent current state of oral health, the prevalence thereof, while expressing concern about the effect of poor oral health on the quality of life.

Figure:

Name Resolution	**number**	**Year**	**Recalled**
Global oral health action plan (GOHAP)	WHA 76(9)	2023/2024	No
Global Strategy on oral health	WHA 75(11)	2022	No
Resolution Oral health	WHA 74.5	2021	No
Related:			
Global Strategy for Health Workforce 2030, a broader concept of universal access to health	WHA 67.24	2022	No
Primary health care	WHA 72.2	2019	Yes
Oral health Action plan for promotion and integrated disease prevention	WHA 60.17	2006	Yes

[43] Article 23 WHO Constitution.
[44] Annex I WHO Constitution.
[45] Article 41 & 44 WHO Constitution.

[46] World Health Assembly, seventy-fourth. (2021). *The WHA74.5 resolution.* https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R5-en.pdf and WHO. (2020). *Stronger collaboration, better health: 2020 progress report on the Global Action Plan for Healthy Lives and Wellbeing for All*. Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/6eff6afe-bd02-451a-b424-b5b5f5fac6e2/content

Cancer prevention and control	WHA 58.22	2005	No
Global strategy on diet, physical activity and health	WHA 57.17	2004	No
Global strategy on prevention and control of noncommunicable diseases	WHA 53.17	2000	No

In resolution WHA74.5 (2021), the Seventy-fourth World Health Assembly requested the Director-General to:

1. Develop in consultation with Member States, a strategy on tackling oral diseases, aligned with the Global action plan for the prevention and control of noncommunicable diseases 2013–2030, and
2. Translate this global strategy, by 2023, into an action plan for public oral health, including a framework for tracking progress with clear measurable targets to be achieved by 2030, encompassing control of tobacco use, betel quid and areca nut chewing, and alcohol use and community dentistry, health promotion and education, prevention and basic curative care – providing as a basis for a healthy mouth, where no one is left behind.[47]

Resolution WHA74.5 (2021) contains six principles as guidelines.

Figure:

Principle 1: A public health approach to oral health	A public health approach to oral health strives to provide the maximum oral health benefit for the largest number of people by targeting the most prevalent and/or severe oral diseases and conditions.
Principle 2: Integration of oral health in primary health care	Primary health care is the cornerstone of strengthening health systems because it improves the performance of health systems, resulting in better health outcomes. Integration of basic oral health services with other noncommunicable disease services in primary health care is an essential component of universal health coverage.
Principle 3: A new oral health workforce model to respond to population needs	Universal oral health coverage can only be achieved by reforming the health, education and resource planning systems to ensure the oral health workforce is of adequate size and skills mix to provide essential oral health care. This requires reassessing the roles and competencies of mid-level oral health care providers and community oral health workers based on the new WHO Global competency framework for universal health coverage.[48]
Principle 4: People-centred oral health care	People-centred oral health care consciously seeks and engages the perspectives of individuals, families and communities, including people affected by oral diseases and conditions. In this approach, people are seen as participants as well as beneficiaries of trusted oral health systems that respond to their needs and preferences in humane and holistic ways. People-centred oral health care actively fosters oral health literacy, shared decision-making and self-management.
Principle 5: Tailored oral health across the life course	The effects may vary and accumulate over time and have complex consequences in later life, particularly in relation to other noncommunicable diseases. These patterns highlight why tailored, age-appropriate oral health strategies need to be integrated within relevant health programmes across

[47] World Health Assembly, seventy-fourth. (2021). *The WHA74.5 resolution*. https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R5-en.pdf

[48] WHO. (2022). *Global Compentency and Outcomes Framework for Universal Health Coverage*. Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/08a5370c-0d2f-4529-a80a-ab9dd1fd6694/content

	the life course, including pre-natal, infant, child, adolescent, working adult and older adult programmes.
Principle 6: Optimizing digital technologies for oral health	Digital technologies can be used strategically for oral health at different levels, including improving oral health literacy, implementing oral health e-training and provider-to-provider telehealth, and increasing early detection, surveillance and referral for oral diseases and conditions within primary care.

The Global Competency and Outcomes Framework for UHC, referred to in Principle 3 of Resolution WHA 74.5, identifies the health worker competencies towards the achievement of UHC organized within six domains: people-centredness, decision-making, communication, collaboration, evidence-informed practice and personal conduct. The Framework for UHC is based on the premise that quality of service is critical to achieving UHC. Achieving this quality requires competencies of health workers that enable them to provide health services that are effective, equitable, efficient, integrated, people centred, safe and timely, thus contributing to progress towards UHC within the overall health system.[49]
The concept of "service" ranges from clinical care for individual patients to the public services that protect the health of whole populations. The concept includes services that come from both within and beyond the health sector. Financial risk protection and protection against severe financial difficulties are imperative as these will provide social protection and peace of mind.[50]
The Global Action Plan, adopted a year later, builds on collective commitment to UHC by 2030. The goal of UHC is to ensure that everyone can use the health services they need without risk of financial ruin or impoverishment.[51]
UHC furthermore requires an understanding of the causes of ill health, the possible interventions, who currently has access to these services and who does not, and the extent of financial hardship that is being incurred by paying out-of-pocket.[52]

A significant challenge to the development of UHC should be noted. Even high-income countries are experiencing challenges in the maintenance of current health services in such a way that their inhabitants can afford to use them.[53]
During the WHO Executive Board 154th session, an intervention was made regarding UHC. In

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[49] WHO. (2022). *Global Compentency and Outcomes Framework for Universal Health Coverage*. Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/08a5370c-0d2f-4529-a80a-ab9dd1fd6694/content and World Health Assembly, seventy-fifth. (WHA). (2022). *Consolidated report by the Director-General*. https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Rev1-en.pdf

[50] Saksena, P., Hsu, J., & Evans, D. B. (2014). Financial risk protection and universal health coverage: evidence and measurement challenges. *PLoS medicine*, *11*(9), e1001701. https://doi.org/10.1371/journal.pmed.1001701

[51] WHO (adopted by the World Health Assembly in 2023). (2024). *Global Strategy and Action Plan on Oral Health 2023-2030*. Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/022cde3b-a0d8-440e-8b5e-7ab5a90f89e6/content

[52] Nde, C. J., Raymond, A., Saidu, Y., Cheng, N. I., Nzuobontane, D., Atemnkeng, J. T., & Mbacham, W. F. (2019). Reaching Universal Health Coverage by 2035: Is Cameroon on Track? *Universal Journal of Public Health*, *7*(3), 110–117. https://doi.org/10.13189/ujph.2019.070304

[53] Stuckler, D., Reeves, A., Loopstra, R., Karanikolos, M., & McKee, M. (2017). Austerity and Health: The Impact in the UK and Europe. *European Journal of Public Health*, *27*(4), 18–21. https://doi.org/10.1093/eurpub/ckx167

this report the stagnation of progress in health coverage was noted. This report provided the Executive Board with four calls for action to governments worldwide:

1. Research;
2. Literacy and availability;
3. Promotion of standards;
4. The creation of public-private partnerships to extend healthcare services while simultaneously driving up access and quality.[54]

To reaffirm political commitment by its Members, WHO convened its first WHO global health meeting to accelerate progress towards UHC in November 2024 based on WHA 74.5 preparing the UN High-Level Meeting of the UN Assembly on the prevention and control of noncommunicable diseases in 2025.

A component of the Global Safety Action Plan 2021-2030 is formed by the Patient Safety Rights Charter built on ten patient safety rights to ensure safety in healthcare and reflects a commitment to integrate essential concepts into core principles and practices of patient safety.[55]

Figure:

The rights formulated in the Charter are grouped in multiple defined subjects.

1. The right to timely, effective and appropriate care.
2. Safe healthcare processes and practices.
3. Qualified and competent health workers.
4. Safe medical products and their safe and rational use.
5. Safe and secure healthcare facilities.
6. Dignity, respect, non-discrimination, privacy and confidentiality.
7. Information, education and supported decision making.
8. Access to medical records.
9. Be heard and fair resolution.
10. Patient and family engagement

Member States, of which 27 EU Member States, are committed to these resolutions and underlying principles.

3.1.4 Global Strategy for Health Workforce

"*Health systems can only function with health workers; improving health service coverage and realizing the right to the enjoyment of the highest attainable standard of health is dependent on their availability, accessibility, acceptability and quality*".[56]

[54] WHO Executive Board. (2024). Statement on I*tem 6: Universal Health Coverage*. https://www.wma.net/wp-content/uploads/2024/01/EB154-WMA-statement-UHC-item-6.pdf

[55] WHO. (2024). *Patient Safety Charter. License:* CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/a48952b5-c8d5-4842-9e68-1ef966ffba85/content

[56] WHO. (2016). *Global strategy on human resources for health: Workforce 2030.* ISBN 978 92 4 151113 1. https://iris.who.int/server/api/core/bitstreams/3ef6ee65-42fa-4d2b-9c75-d55b2df17f9a/content

The Global Strategy for Health Workforce 2030, entails a broader concept of universal access to health,[57] shaping the 21st century context for progressive health work force agenda consisting of multiple agenda items including fostering empowered and engaged communities and promoting innovation on the use of evidence.[58]

3.1.5 WHO Competency Framework for Universal Coverage

The goal of the Global Competency Framework for UHC is to guide the standards for education and practice for health workers in primary care to support achievement of the UHC. The competencies specified in this framework, are the requisite competencies for quality in UHC. The Global Competency Framework for Universal Health Coverage[59] identifies the health worker competencies towards the achievement of UHC organized within six domains further detailed in competencies.

Figure:

Domain	Detailed in e.g. the competencies
People-centredness	➢ Places people at the centre of all practice behaviours. 1.0 ➢ Provides the best possible health care that supports an approach to health services that is effective, equitable, efficient, inclusive, integrated, people centred, safe and timely. 1.1 ➢ Adapts practice to the individual, family and community, including their physical, cognitive, cultural, emotional, linguistic, health literacy and sensory needs and other influences on their engagement with health services. 1.2 ➢ Incorporates a holistic approach to health Behaviours. 4.0 ➢ Supports people to challenge or address their economic, environmental, political and social determinants of health. 4.1 ➢ Supports people to manage their health within health system constraints and their determinants of health. 4.2 ➢ Incorporates health promotion and disability, disease and injury prevention into interactions. 4.3 ➢ Supports individuals, caregivers, families and communities to adopt healthy behaviours. 4.4 ➢ Contributes to protecting vulnerable populations. 4.5
Decision-making	➢ Takes an adaptive, collaborative and rigorous approach to decision-making Behaviours 5.1 ➢ Promotes collaborative decision-making 5.2 ➢ Seeks information and evidence from a range of sources when approaching decision-making. 5.3 ➢ Approaches decisions analytically and methodically. 5.4 ➢ Adapts the approach to decision-making that reflects the complexity, urgency and consequences of decisions. 5.5 ➢ Demonstrates critical thinking to reach decisions that are well reasoned, ethical, evidence informed, feasible, timely and based on the best available information.
Communication	

[57]World Health Assembly, sixty-seventh. (2014). *The WHA67.24 resolution.* https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_24-en.pdf

[58] WHO. (2016). *Global strategy on human resources for health: Workforce 2030.* ISBN 978 92 4 151113 1, p.2. https://iris.who.int/server/api/core/bitstreams/3ef6ee65-42fa-4d2b-9c75-d55b2df17f9a/content

[59] WHO. (2022). *Global Compentency and Outcomes Framework for Universal Health Coverage.* Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/08a5370c-0d2f-4529-a80a-ab9dd1fd6694/content

	➢ Manages information sharing and documentation Behaviours. 13.1 ➢ Uses a range of health-related information management tools, including individual health records. 13.2 ➢ Keeps people informed about health risks and relevant aspects of their health care. 13.3 ➢ Shares information with relevant others in a timely manner. 13.4 ➢ Complies with ethical and legal requirements for obtaining, recording, sharing, retaining and destroying information acquired in an occupational capacity.
Collaboration	➢ Engages in collaborative practice Behaviours. 14.1 ➢ Engages with others across cultural, geographical, organizational and sectoral boundaries, and with individuals, caregivers, families and communities, as partners.
Evidence-informed practice	➢ Applies the principles of evidence-informed practice behaviours. 18.1 ➢ Maintains awareness of evidence-informed practice. 18.2 ➢ Integrates current best available evidence into practice. 18.3 ➢ Promotes evidence-informed practice amongst colleagues. 18.4 ➢ Participates in the generation and application of evidence.
Personal conduct	➢ Engages in lifelong learning and reflective practice Behaviours. 23.1 ➢ Seeks and engages in continuous formal and informal learning linked to current and emerging practice responsibilities.

3.*1.6 WHO Guidelines and handbook for guidelines ensuring the appropriate use of evidence*

WHO furthermore develops global guidelines ensuring the appropriate use of evidence. WHO released a Handbook for guideline development for its steering group, guideline development group and external review group and for anyone interested in understanding how WHO develops guidelines. This handbook covers the methods, processes and procedures for producing and supporting standards for WHO guidelines defined in the context of this handbook.[60]

These recommendations are statements designed to help end-users make informed decisions on whether, when and how to undertake specific actions such as clinical interventions, diagnostic tests or public health measures, with the aim of achieving the best possible individual or collective health outcomes. The WHO guidelines Review Committee is tasked to ensure that these guidelines are of a high methodological quality and developed through a transparent, evidence-based decision-making process. The Guidelines Review Committee develops and implements procedures to ensure that WHO guidelines are based on the best available evidence and are produced in ways consistent with internationally accepted best practices.
When developing guidelines, multiple principles are being observed as detailed in the Handbook for guideline development.

Figure:

[60] WHO. (2014). *WHO handbook for guideline development, 2nd edition*. ISBN 978 92 4 154896 0. https://www.who.int/publications/i/item/9789241548960

- Guidelines address an area of uncertainty and an unmet need for guidance.
- Guidelines reflect the core WHO value of "right to health".
- The process of developing guidelines is multidisciplinary and includes all relevant expertise and perspectives, including input from stakeholders.

The handbook further formulates eight entry points for integrating equity, human rights, gender and the social determinants of health into guidelines. The steering group, involved with developing the guidelines, is tasked to carefully, access the probability that the intervention under consideration will have a bearing on equity, human rights, and gender equality, and the likelihood that a systematic review will provide useful data.[61] Reference is made to the Campbell and Cochrane Equity Methods Group where sixteen authors of systematic reviews explicitly describe the potential effect of interventions, not only on the population, but across the social gradient.[62]
The handbook further describes the role of the staff in assessing quality of evidence while referring to the GRADE categorization in the context of intervention studies and possibly in observational studies.

The WHO may, as clarified in the Handbook, produce interim guidelines when WHO is asked to provide guidance where the available data and information are most certainly incomplete, especially if additional data are anticipated in the near future.[63]
Furthermore, the WHO may collaborate with organizations, including national agencies and specialist medical societies.[64] The WHO guidelines Review Committee is tasked to ensure that these guidelines are of a high methodological quality and developed through a transparent, evidence-based decision-making process.

The Guidelines Review Committee develops and implements procedures to ensure that WHO guidelines are based on the best available evidence and are produced in ways consistent with internationally accepted best practices. WHO has not published any recommendations on oral health (yet). The guideline on maternal health does not include oral health related recommendations.[65]

3.1.7 The WHO Council on Economics on Health for all

"governments should stop thinking about health as a discretionary annual expenditure and start

[61] WHO. (2014). *WHO handbook for guideline development, 2nd edition*. ISBN 978 92 4 154896 0, p. 52. https://www.who.int/publications/i/item/9789241548960
[62] WHO. (2014). *WHO handbook for guideline development, 2nd edition*. ISBN 978 92 4 154896 0, p. 53. https://www.who.int/publications/i/item/9789241548960
[63] WHO. (2014). *WHO handbook for guideline development, 2nd edition*. ISBN 978 92 4 154896 0, p. 7. https://www.who.int/publications/i/item/9789241548960,
[64] WHO. (2014). *WHO handbook for guideline development, 2nd edition*. ISBN 978 92 4 154896 0, p. 9. https://www.who.int/publications/i/item/9789241548960

[65] WHO. (2025). *WHO recommendations on maternal health: guidelines approved by the WHO guidelines review committee. Licence:* CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/12fdb499-733d-4614-aafc-88dcbbb3c829/content

viewing it as a vital long-term investment in society and future prosperity".

The WHO Council on Economics on Health for all was established on 13 November 2020 to rethink how value in health and wellbeing is measured, produced, and distributed across the economy. The Council on Economics issued four foundational briefs, that assess the ability of the current global and national health architecture to deliver health for all across the four pillars, followed by a final report.

Figure of Foundational Briefs:

Governing health innovation for the common good	Fixing market failures and charitable efforts are insufficient to deliver vaccine equity. To end the pandemic and build back better, bold change is needed.	Council Brief no 1, 29 November 2021
Financing Health for all: Increase, transform and redirect.	Demanding ambitious goals to catalyse and focus investments and action, and to put priority on financing health as a long-term investment and not a short-term cost.	Council Brief no 2, 26 October 2021
Valuing Health for All	Rethinking and building a hole-of-society approach Centre pieces of a new system of value and measurement, Values for Health for All: 1. Valuing planetary health. 2.Valuing the diverse social foundations and activities that promote equity. 3. Valuing human health and well-being. 4. Building a health for all economy.	Council Brief no 3, March 2022
Strengthening public sector capacity, budgets and dynamic capabilities towards health for all.	Recommendation for four actions and tools. Actions: 1. Governments should stop thinking about health as a discretionary annual expenditure and start viewing it as a vital long-term investment in society and future prosperity. 2. Ministers of finance and economy should see themselves not only as guarantors of macroeconomic stability, but also as active supporters of healthy and equitable societies with strong health systems. 3. There is a need to entrench a learning culture that institutionalizes capacities and prioritizes dynamic capabilities and ultimately sustains them through continuous investment. 4. Governments can take specific actions to build in-house capacity and strengthen dynamic capabilities.	Council Brief no 4, 30 June 2022

The final report provides thirteen recommendations across four interrelated pillars.

Figure:

1. Valuing Health for all.
2. Financing Health for all.
3. Innovating Health for all.
4. Strengthening public capacity for funding Health for all.

The pillar "Valuing Health for all" leads to four recommendations, including the recommendation to use legal and financial commitments to enforce health as a solid right. The pillar Financing Health summarizes three recommendations, including a comprehensive stable approach to funding health for all noting it is more cost effective to prevent than to cure.[66]

3.1.8 Quality instruments: WHO guidelines for health improvement

"…dental diseases are the most prevalent NCDs globally and, although great improvements in prevention and treatment of dental diseases have occurred in the past decades, problems still persist, causing pain, anxiety, functional limitation (including poor school attendance and performance in children) and social handicap through tooth loss. The treatment of dental diseases is expensive, consuming 5–10% of health-care budgets in industrialized countries, and would exceed the entire financial resources available for the health care of children in most lower income countries ".[67]

3.1.9 Guideline sugars intake adults and children

In 2015, the WHO released the guideline "Sugars intake for adults and children"[68] supported by amongst others the WHO regional office Europe. In this guideline the WHO stated that noncommunicable diseases were responsible for 68% of the deaths in 2012. The risk factors of noncommunicable diseases are poor diet, physical inactivity and obesity. A high level of sugars intake is a big concern because of the association with poor dietary quality, obesity and the risk of obesity. As a result, the guideline focuses on the strong recommendation on balanced sugar intake.[69]

3.1.10 Report on Quality of European Member States

[66] WHO Council on the Economics of Health for all. (2023). *Health for all: transforming economics to deliver what matters – final report*. https://cdn.who.int/media/docs/default-source/council-on-the-economics-of-health-for-all/council-eh4a_finalreport_web.pdf
[67] WHO. (2024). *Global Strategy and Action Plan on Oral Health 2023-2030.* Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/022cde3b-a0d8-440e-8b5e-7ab5a90f89e6/content
[68] WHO. (2015). *Guideline : Sugars intake for adults and children.* ISBN 978 92 4 154902 8. https://www.who.int/publications/i/item/9789241549028
[69] WHO. (2015). *Guideline : Sugars intake for adults and children.* ISBN 978 92 4 154902 8. https://www.who.int/publications/i/item/9789241549028

"The need for multidimensional quality improvement frameworks and a whole-system approach to quality of care to ensure sustainable, equitable and high-quality care for all".

The report on quality of care and patient safety in the WHO European countries is based on a multidimensional analysis of quality of care.[70] The findings report critical gaps including limited implementation of national action plans and policies for the quality of care and patient safety, wide variations in indicator outcomes of dimensions of quality of care and patient safety and wide variations in indicator outcome of dimensions of quality of care.[71]

3.1.11 WHO Global oral health meeting 2024

"National oral health roadmaps aligned with the Global oral health action plan 2023–2030".

The first Global oral health meeting, organized by the WHO, was held in 2024 as part of the preparatory process for the 4th UN High Level Meeting of the UN General Assembly on NCDs in 2025.
The aim of the meeting was to accelerate progress towards Universal Health Coverage for oral health by 2030, to reaffirm political commitment by Member States (of the WHO) on resolution WHA 74.5 and to scale up national efforts to prevent and control noncommunicable diseases, with a focus on oral diseases, to achieve Universal Health Coverage for all by 2030.
WHO shifted its focus from providing information and supporting Member States policy to concrete and actional tools.

3.1.12 Global Child Dental Fund[72]

"Good oral health is a fundamental element of good general health. Through the establishment of a global child dental health taskforce, we will share information on evidence-based prevention. We will work to implement appropriate and effective initiatives to improve oral health and to reduce oral health inequalities both within and between nations".[73]

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[70] WHO. (2024). *Patient Safety Charter. License:* CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/a48952b5-c8d5-4842-9e68-1ef966ffba85/content and WHO. (2021). *Global patient safety action plan 2021-2030: towards eliminating avoidable harm in health care.* Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/a28c34c0-089c-4f5d-a0b1-5d9c35a3cd67/content

[71] WHO. (2024). *Patient Safety Charter. License:* CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/a48952b5-c8d5-4842-9e68-1ef966ffba85/content and WHO. (2021). *Global patient safety action plan 2021-2030: towards eliminating avoidable harm in health care.* Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/a28c34c0-089c-4f5d-a0b1-5d9c35a3cd67/content

[72] Bastani, P., Mohammadpour, M., Mehraliain, G., Delavari, S., & Edirippulige, S. (2021). What makes inequality in the area of dental and oral health in developing countries? A scoping review. *Cost Effectiveness and Resource Allocation, 19(1)*. https://doi.org/10.1186/s12962-021-00309-0

[73] General Central Council. *Homepage.* gdc-uk. https://www.gdc-uk.org/

In 2008, the WHO endorsed the mission of the Global Child Dental Fund built on the concerted pan-European and wider global action from 2008 to 2025 to address the pressing problem of poor child oral health.
As a first step, the Declaration on Child Oral Health was signed by multiple Chief Dental Officers and members of Dental Associations.

3.1.13 The WHO consensus dental amalgam 1997

Balancing on the tightrope on weight of evidence suggesting that dental restorative materials including dental amalgams were safe and effective and on the other hand on concerns expressed in relation to the health effects of mercury in amalgam, WHO released a consensus statement on dental amalgam.

3.1.14 The WHO regions

WHO Member States are grouped in six regions. Each region has a regional office. WHO/Europe represents 27 of the 53 countries of the WHO European Region. WHO/Europe cooperates with a wide range of European Commission services, publishes reports to keep health on the agenda based on the indicators included in the WHO European Programme of Work 2020-2025 and allocates its work to address the Universal Health Coverage target in five different areas.

Figure:

1. *Support Member State efforts to put people at the centre of services.*
2. *Support Member State efforts to ensure and enhance financial protection.*
3. *Support Member State efforts to face post-COVID-19 recovery health workforce challenges.*
4. *Support Member State efforts to ensure access for all to medicines, vaccines and health products.*
5. *Support Member State efforts to improve governance and stewardship.*

In its last report "Keeping health on the agenda" of 17 March 2025, WHO/Europe notes a catastrophic (21%) and impoverishing health spending (14%).[74]
This reports addresses policymakers, healthcare providers and communities to work together to create resilient and inclusive health systems. Evidence is described as the key to achieving this.

3.1.15 WHO and Mobile technologies

"Approaches based on new technologies, such as mHealth, can be used to promote oral health as well as to prevent and control oral disease".[75]

[74] WHO. (2025). *European health report 2024: keeping health high on the agenda.* Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/europe/publications/i/item/WHO-EURO-2025-10668-50440-76183

[75] WHO & International Telecommunication Union. (2021). *Mobile technologies for oral health: an implementation guide.* Licence: CC BY-NC-SA 3.0 IGO.
https://iris.who.int/server/api/core/bitstreams/bc31e8fa-b8fb-4609-8055-bebab849aa96/content

In 2021, WHO published a mobile health technology guide for oral health, Mobile technologies for oral health: an implementation guide, to promote the use of mobile technologies to address the burden of modifiable diseases.[76]

The mOralHealth programme was jointly developed by the WHO Global Oral Health Programme and the BHBM (The Be Healthy Be Mobile initiative) to contribute to the achievement of better oral health as part of the 2030 Sustainable Development Agenda.

Figure:

The programme is built on four modules.
1. To improve the oral health literacy of individuals and communities as well as raise awareness of and advocacy for oral health priorities among policymakers, decision-makers, the media and civil society organizations.
2. For e-learning approaches to enhance the knowledge and skills of general health professionals as well as expand awareness of priority oral health interventions for oral health professionals.
3. Information on the potential of early detection by using remote diagnostics tools to improve timely treatment and facilitate access to and improve quality of health care services.
4. Surveillance in the context of oral health surveillance and collection of epidemiological data as well as monitoring of quality patient care and service delivery.

For each module, implementation, target audience, potential technologies, outcomes and impact are inventoried resulting in actionable and concrete approaches for the targeted groups.

3.1.16 WHO standards and classifications

"Meaningful data for prevention, resourcing or evaluation are best produced with a standardised classification that is based on the latest medical and scientific knowledge".[77]

WHO publishes several standards and classifications, including ICD-11, ICF and ICHI for effective knowledge representation and interoperability.[78]

The International Classification of Diseases and related health problems (ICD) is a globally used standardized system initiated by the WHO to support the identification and qualification of diseases for national healthcare policies and national public health systems. The last version, ICD-11 2024, is released in May 2024. The ICD-11 is a tool for countries to count and identify their most pressing health issues. This knowledge can be used to support the design of effective healthcare systems and public health policies. Oral diseases are also being identified and qualified.[79]

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[76] WHO & International Telecommunication Union. (2021). *Mobile technologies for oral health: an implementation guide*. Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/server/api/core/bitstreams/bc31e8fa-b8fb-4609-8055-bebab849aa96/content

[77] WHO(2019). *International Classification of Diseases 11th Revision*. https://www.who.int/standards/classifications/classification-of-diseases

[78] WHO. (n.d.). *WHO Family of International Classifications (FIC)*. *who*. https://www.who.int/standards/classifications

[79] WHO. (2019). *International Classification of Diseases 11th Revision*. https://www.who.int/standards/classifications/classification-of-diseases

3.2 Ethical principles and social rights

"The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health".[80]

Social and human rights are enshrined in several Declarations and Treaties. Parties to these treaties are committed to the principles and obligations, including access rights to health, promulgating from these Declarations and Treaties.

3.2.1 Universal Declaration of Human Rights

"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control".[81]

The Universal Declaration of Human Rights, as a common standard of achievements for all peoples and all nations, was adopted by the UN General Assembly on 10 December 1948, by over 50 states.
Classical fundamental rights are central, concrete and directly formulated.
The right to medical care is formulated indirectly as an element for the adequate standard of living.[82]

The Office of the United Nations High Commissioner for Human Rights was instituted to promote and protect human rights that are guaranteed under international law.[83]
The Office published factsheet no. 13, including the factsheet "the Right to Health" in June 2008. The Office stressed that States have committed themselves to protecting this right through international declarations, domestic legislation and policies, and at international conferences. The factsheet explains the Right to Health and underpins its vision on the obligations for States promulgating therefrom.
The Office furthermore presented an overview of national, regional and international accountability and monitoring mechanisms and multiple elements of the Right to Health.

Figure:

The right to health contains entitlements.	The right to a system of health protection providing equality of opportunity for everyone to enjoy the highest attainable level of health; The right to prevention, treatment and control of diseases and access to essential medicines health.

[80] Article 12 (1) ICESCR.
[81] Article 25.1 UDHR.
[82] Office of the United Nations High Commissioner for Human Rights (OHCHR) and WHO. (2008). *Human Rights, Health and Poverty Reduction Strategies,* pp. 12-15. https://www.ohchr.org/sites/default/files/Documents/Publications/HHR_PovertyReductionsStrategies_WHO_EN.pdf; Article 12 CEDAW; Article 25 UDHR and Article 10(2) ICESCR.
[83] Office of the High Commissioner for Human Rights, (n.d.). *About us. ohchr.* https://www.ohchr.org/en/about-us

Health services, goods and facilities must be provided to all without any discrimination	Non-discrimination is a key principle in human rights and is crucial to the enjoyment of the right to the highest attainable standard of health (see section on non-discrimination below).
All services, goods and facilities must be available, accessible, acceptable and of good quality.	Functioning public health and health-care facilities, goods and services must be available in sufficient quantity within a State. They must be accessible physically (in safe reach for all sections of the population, including children, adolescents, older persons, persons with disabilities and other vulnerable groups) as well as financially and based on non-discrimination. Accessibility also implies the right to seek, receive and impart health-related information in an accessible format (for all, including persons with disabilities), but does not impair the right to have personal health data treated confidentially. The facilities, goods and services should also respect medical ethics and be gender-sensitive and culturally appropriate. In other words, they should be medically and culturally acceptable. Finally, they must be scientifically and medically appropriate and of good quality. This requires trained health professionals, scientifically approved and unexpired drugs and hospital equipment, adequate sanitation and safe drinking water.

The Office describes the context of discrimination and the right to health by pointing out that discrimination is linked to the marginalization of specific population groups and is generally at the root of fundamental structural inequalities in society. This means that non-discrimination and equality imply that States must recognize and provide for the differences and specific needs of groups that generally face health challenges, such as higher mortality rates or vulnerability to specific diseases.[84] The Office furthermore noted that the obligation to ensure non-discrimination, requires specific health standards to be applied to population groups, such as women, children or persons with disabilities.[85]

Above all, the Office presents a handle for implementation: process indicators to assess obligations and outcome indicators for the results of the efforts from the perspective of the population.[86]

3.2.2 International Covenant on Economic, Social and Cultural Rights (ICESR)

[84] Office of the United Nations High Commissioner for Human Rights (OHCHR) and WHO. (2008). *Human Rights, Health and Poverty Reduction Strategies,* p. 7. https://www.ohchr.org/sites/default/files/Documents/Publications/HHR_PovertyReductionsStrategies_WHO_EN.pdf

[85] Office of the United Nations High Commissioner for Human Rights (OHCHR) and WHO. (2008). *Human Rights, Health and Poverty Reduction Strategies,* p. 8. https://www.ohchr.org/sites/default/files/Documents/Publications/HHR_PovertyReductionsStrategies_WHO_EN.pdf

[86] Office of the United Nations High Commissioner for Human Rights (OHCHR). (2006). *Study on the right to truth,* p. 24.

" The States Parties to the present Covenant recognize the right of everyone to the enjoyment the highest attainable standard of physical and mental health".[87]

The ICESCR, adopted by the United Nations General Assembly on 16 December 1966, builds on the rights in the Universal Declaration of Human Rights. Together, the Universal Declaration and the Covenants form the International Bill of Human Rights. The ICESCR has been ratified by all Member States of the EU.
The handbook "Human Right for All: International Covenant on Economic, Social and Cultural Rights", has been developed as a practical guide for implementation.[88]
Access to healthcare is considered a human right. The WHO based its Availability, Accessibility, Acceptability and Quality (AAAQ) framework on the human rights perspective.[89]

3.2.3 United Nations Convention on the Rights of Persons with Disabilities, adopted on 13 December 2006 (UN CRPD)

"*States Parties have to ensure that private entities that offer facilities and services which are open or provided to the public, take into account all aspects of accessibility for persons with disabilities;"*

This Convention aims to promote, protect, and ensure the full and equal enjoyment of human rights by all persons with disabilities. The convention establishes human rights principles for persons with disabilities, covering civil, political, economic, social, and cultural rights, and is based on eight principles, including accessibility.

States parties must ensure that private entities that offer facilities and services, which are open or provided to the public, consider all aspects of accessibility for persons with disabilities. Nonetheless, persons with disabilities still face barriers even in all aspects of the health system.[90]

Although this premise is relevant for accessibility, equity, patient-centeredness, communication and informed consent, no practice-based guidelines and standards for hearing and/or visual impairment have been developed. Nor are there any websites explaining and building knowledge on oral health treatments and prevention for persons with disabilities and marginalized groups.
The CRPD has been enacted in multiple EU jurisdictions and creates a concrete yardstick. That means that the States that have enacted this Convention, have the obligation to make sure persons with a disability can enjoy equal rights.

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[87] Article 12 ICESR.
[88] Office of the United Nations High Commissioner for Human Rights (OHCHR). (2015). *Human Rights for All: International Covenant on Economic, Social and Cultural Rights.*
[89] Campbell J., Dussault G., Buchan J., Pozo-Martin F., Guerra Arias M., Leone C., Siyam A., Cometto G. (Geneva, Global Health Workforce Alliance and WHO. (2013). *A universal truth: no health without a workforce*.
https://www.researchgate.net/publication/270561476_A_Universal_Truth_No_Health_Without_a_Workforce. https://www.ifhhro.org/topics/aaaq-framework/
[90] WHO. (2023). *Disability: Key facts*. https://www.who.int/news-room/fact-sheets/detail/disability-and-health

3.2.4 The Committee on the Rights of Persons with Disabilities (UN CRPD)

The Committee on the Rights of Persons with Disabilities is formed by independent experts. The CRPD monitors implementation of the Convention by individual States and provides recommendations to support the implementation of the provisions enshrined in the Convention. The CRPD developed and adopted Guidelines on the right to liberty and security of persons with disabilities and prepares reports for the implementation of the Convention. The structure provides for regional offices with the primary function to advance human rights.[91]

3.*2.5 The United Nations Convention on the Rights of the Child (CRC)*

"States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right to access such health care services".[92]

This most widely ratified human rights treaty, adopted by a vast majority of the world's leaders in 1989, is available in full text and a child friendly text.[93] Article 24 formulates a strong and full commitment related to health.
Although the words chosen realized broad commitment of States Parties to the ICESR and CRC, they do not create a concrete yardstick for citizens to hold their governments accountable for not providing adequate coverage for all treatments, nor for full accessibility to oral care services timely. States Parties have an obligation to respect the right to health and refrain from interfering with the enjoyment of the right to health. They are committed to ensuring access to health in their national healthcare system.

Children worldwide suffer from caries while caries is largely preventable as the risk factors are known.[94] The right to health not only includes the provision. The right extends to both the provision and the underlying factors including food and circumstances.[95] Preventive measures in terms of targeted policies are consequently key to prevent further growing disease burden. Human rights law may be a powerful tool in informing and initiating adequate public health and prevention policies.[96]

3.2.6 Declaration of Alma-Ata

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[91] Office of the High Commissioner for Human Rights. (n.d.). *Committee on the rights of persons with disabilities*. ohchr. https://www.ohchr.org/en/treaty-bodies/crpd
[92] Article 24 CRC.
[93] UNICEF. (1989). *Convention on the Right of the Child*. Unicef. https://www.unicef.org/child-rights-convention
[94] Mollet S.D., Manton D.J., Wollgast, J., & Toebes B. (2024). A right to health-based approach to dental caries: towards a comprehensive control strategy. *Caries Research*, *58*(4), p.1. https://doi.org/10.1159/000538459
[95] Mollet S.D., Manton D.J., Wollgast, J., & Toebes B. (2024). A right to health-based approach to dental caries: towards a comprehensive control strategy. *Caries Research*, *58*(4), p. 4. https://doi.org/10.1159/000538459
[96] Mollet S.D., Manton D.J., Wollgast, J., & Toebes B. (2024). A right to health-based approach to dental caries: towards a comprehensive control strategy. *Caries Research*, *58*(4), p. 2. https://doi.org/10.1159/000538459

"Primary care addresses the main health problems in the community, providing promotive, preventive, curative and rehabilitative services accordingly".[97]

The Declaration of Alma-Ata promulgating from the International Conference on Primary Health Care Meeting (1978), reaffirms that health as a state of complete physical, mental and social well-being is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector. It identifies primary healthcare as the key to the attainment of the goal of health.
"Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work and constitutes the first element of a continuing health care process."[98]

Health for All as primary healthcare addresses the main health problems in the community, providing promotive, preventive, curative and rehabilitative services accordingly.[99]

3.2.7. Convention on the Elimination of All Forms of Racial Discrimination

The 1965 International Convention on the Elimination of All Forms of Racial Discrimination contains a stronger commitment in relation to accessibility for all. States must prohibit and eliminate racial discrimination in public health and medical care. People must be able to enjoy equal rights and be treated equally before the law when it comes to public health and medical care.[100]

3.3 International Organizations

Multiple international bodies and associations support quality of health including healthcare instruments and processes. Member States of the EU are represented in these entities and support their mission either directly or through their bodies or associations.

3.3.1 International organization for Standardization (ISO)

ISO is a network of 173 national standard bodies that develop standards based on international expert views for products and processes. ISO has published multiple standards on the

[97] Article VII Declaration of Alma-Ata.

[98] Article VI Declaration of Alma-Ata.
[99] Article VI Declaration of Alma-Ata.
[100] Article 5 (e) (iv) International Convention on the Elimination of All Forms of Racial Discrimination.

organization of a dental practice, the instruments, and treatment.[101]

Figure:

Dentistry information system on the location of dental equipment in the working area of the oral health care provider	*4073*	*2009*
Graphical symbols for dental instruments	*21531*	*2009 and confirmed in 2020*
Vocabulary for dental implants systems and related procedure	*16443*	*2014 reviewed and confirmed in 2019*
Quality Management system	*9001*	*2015*
Integrated dental floss and handles	*28158*	*2018*
Health informatics	*27269*	*2021*
International Patient Summary	*27269*	*2021*
Clinical laboratory testing and in vitro medical devices requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy	*17593*	*2022*

3.3.2 Guidelines International Network (G-I-N)

"As a major player on the global healthcare quality stage, G-I-N facilitates networking, promotes excellence, and helps our members create high quality clinical practice guidelines that foster safe and effective patient care. Its mission is to lead strengthen and support collaboration in guidelines development, adaptation and implementation".[102]

G-I-N, established in 2002, acts as a network and connector for developing guidelines. G-I-N is built on 116 organizational members and 105 individual members from 47 countries supporting the common goal of improving healthcare, through using evidence and implementing evidence-based guidelines. The (G-I-N) mission is to lead, strengthen, and support collaboration in guideline development, adaptation and implementation. G-I-N has developed a guideline library.

[101] ISO. (n.d.) *Health*. iso. https://www.iso.org/sectors/health
[102] GIN. (n.d.). *Homepage*. *g*-i-n. https://g-i-n.net/

3.3.3 International dental organization

The FDI World Dental Federation (FDI), established in Switzerland, is a global organization rooted in its commitment to representing the interests of its 200 members, national dentist organizations in approximately 130 countries across five regions globally, and to supporting their national efforts to raise awareness for oral health. To this end, FDI promotes best practices in the sector through knowledge exchange approaches, leads global advocacy focused on oral health to promote political action in all countries, and builds capacity through grants, awards, and a development fund.
FDI transforms this commitment into active engagement with the WHO, by delivering statements made in consultation with the FDI Vision 2020 Task Team to influence global policies and commitments on oral health and other United Nations agencies, health organizations, governments, and global partners to ensure that oral health is recognized as an essential component of general health and well-being.[103]

The FDI provides expertise to the principal Technical Committee for dentistry (ISO/TC106).

The FDI further aims to build capacity through grants, awards, and a development fund.[104] FDI supports continuous education through its Global Continuing Education Program and alignment.
The FDI has initiated several programs for amongst others AMR and tooth decay and released a consensus on tooth brushing.
The FDI's current advocacy strategy entitled "Securing oral health for all" mainly focuses on oral health being essential to general health and well-being and better oral health through UHC. which is imperative for the successful delivery of the UN SDGs.
In 2020, FDI published an advocacy guide: Promoting Oral Health for Refugees.[105]

FDI's advocacy strategy positions oral health as being essential to general health and well-being and an important goal to support its strategy.[106]
FDI works with the NCD strategic Alliance and is a member of the World Health Professions Alliance.

3.3.4 NCD strategic Alliance

The NCD network consists of over 400 civil society organizations (CSOs), national and regional NCD alliances, and other global and national NGOs, scientific and professional associations,

[103] FDI World Dental Federation. (2020). *Advocacy strategy*. fdi. Www.fdiworlddental.org. https://www.fdiworlddental.org/advocacy-strategy
[104] FDI World Dental Federation. (2022). *FDI world dental federation constitution*. https://fdiworlddental.org/sites/default/files/2022-02/2022-FDI_Constitution.pdf
[105] FDI World Dental Federation. (2020). *Advocacy strategy*. fdi. Www.fdiworlddental.org. https://www.fdiworlddental.org/advocacy-strategy
[106] Glick, M., Greenberg, M.S., Lockhart, P.B. and Challacombe, S.J. (2021). Introduction to Oral Medicine and Oral Diagnosis. *Burket's Oral Medicine (Wiley)*, pp. 1-18. DOI:10.1002/9781119597797. https://onlinelibrary.wiley.com/doi/book/10.1002/9781119597797?msockid=06b147e05b626e1e2e2951ac5a356fbc

and academic and research institutions. Its mission is to unite civil society and drive action on noncommunicable disease (NCD) prevention and care by strengthening and uniting the civil society network to stimulate accountability, NCD prevention and control. NCD Alliance highlighted several key points for achieving this mission.[107]

Figure:

- *National leadership and clearly defined governance structures are essential for navigating the evolving challenges and landscapes in oral health.*
- *Integrating oral health into broader health frameworks helps optimize resources and unlock new funding opportunities.*
- *Collaboration and community engagement are crucial for creating sustainable, widely accepted, and impactful oral health initiatives that meet diverse needs.*

3.3.5 The World Medical Association parallel vision and mission, Declaration of Helsinki

The World Medical Association (WMA) ensures the independence of physicians while also providing the highest possible standards of ethical behaviour and care by physicians. The associations currently consists of 115 National Medical Associations. Its mission is "to serve humanity by endeavouring to achieve the highest international standards in Medical education, medical science, medical art and medical ethics, and healthcare for all people in the world". The WMA is a member of the WHO Executive Board.
The WMA furthermore supports the comprehensive nature of primary healthcare for all ages (compromising preventive care) and a person-centric (rather than community-centric approach), affordable and of high quality.[108]
The WMA developed the Declaration of Helsinki as a statement of ethical principles for medical research involving humans amended in 2024.[109]

3.3.6 World Health Profession Alliance (WHPA)

Formed in 1999, the WHPA unites global organizations representing dentists, pharmacists, nurses, physiotherapists and physicians.
WHPA presents a united voice for the health professions, including dentists, and promotes interprofessional collaboration.[110]

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[107] NCD Alliance. (2021). *NCD Alliance Strategy 2021-2026: Accelerating action on NCDs to promote health, protect rights and save lives.* https://ncdalliance.org/sites/default/files/resource_files/ncda_strategy_2021-2026_final.pdf
[108] World Medical Association. (2024). Statement on I*tem 6: Universal Health Coverage.* https://www.wma.net/wp-content/uploads/2024/01/EB154-WMA-statement-UHC-item-6.pdf
[109] World Medical Association (WMA) General Assembly. (1964). *Declaration of Helsinki. wma.* https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/#:~:text=The%20World%20Medical%20Association%20developed%20the%20Declaration%20of,unethical%20medical%20research%20during%20the%20Second%20World%20War. and World Medical Association. (2024). Statement on I*tem 6: Universal Health Coverage.* https://www.wma.net/wp-content/uploads/2024/01/EB154-WMA-statement-UHC-item-6.pdf
[110] World Health Professions Alliance (WHPA). (n.d.). *About. w*hpa. https://www.whpa.org/about

3.3.7 The Council for International Organizations of Medical Sciences (CIOMS)

CIOMS was founded under the auspices of the WHO and the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1949.
The CIOMS Guidelines have been written in collaboration with the WHO.
The aim of the guidelines (several versions) is to provide internationally vetted ethical principles and detailed commentary on how universal ethical principles should be applied, with particular attention to conducting research (mostly involving human subjects) in low-resource settings.

The Working Group, tasked with the development of the 2016 edition, decided to broaden the scope of the 2002 guidelines from "biomedical research" to "health-related research". The Working Group also acknowledged that there is no clear distinction between the ethics of social science research, behavioural studies, public health surveillance, and the ethics of other research activities.[111]

3.3.8 The World Federation of Public Health Associations (WFPHA)

"Enhancing health systems to implement universal health coverage, promote equity, and providing a flexible framework adaptable to different health and income settings achieve sustainable health outcomes"

> The World Federation of Public Health Associations (WFPHA), founded in 1967, unites 130 member organizations and five million public health professionals to address health inequities, promote evidence-based policies, and foster global collaboration.[112] Almost all EU Member States are represented. Its mission is to address health inequities, promote evidence-based policies, and foster global collaboration. As a result, the association can be seen as a global organization dedicated to global health advocacy. WFPHA developed, together with the WHO, the "Global charter for the Public's health".[113]

The components of the Charter are guided by the key values of public health including equity, ensuring health access as a fundamental human right, inclusivity, promoting diverse participation in public health, justice upholding fairness in health service delivery and solidarity, fostering collective responsibility for global health.
The Charter Objectives include a shared understanding of public health services and the roles that support them.

3.3.9 World Organization of Family Doctors (WONCA) standardizations.

WONCA develops International Classification Standards for Primary Care. The third editions (ICP-3) support the shift from a medical perspective to a person-centred perspective in primary

[111] Council for International Organizations of Medical Sciences (CIOMS).(n.d.). *Homepage*. cioms. https://cioms.ch/
[112] World Federation of Public Health Associations (WFPHA). (n.d.). *Homepage*. wfpha. https://www.wfpha.org/
[113] World Federation of Public Health Associations (WFPHA). (2024). *WFPHA Global Charter for the Public's Health*. https://www.wfpha.org/the-global-charter-for-the-publics-health/

care.[114]

3.3.10 The Organization for Economic Co-operation and Development (OECD)

"Disadvantaged people with low levels of education and income face a double disadvantage: they fall ill and develop more chronic diseases earlier in life, and, once sick, they experience worse health outcomes compared to those with chronic conditions but who are better off in terms of education or income".

The Organization for Economic Co-operation and Development (OECD) is an international network of Member and associated Countries (of which most EU Member States) that supports shaping policies that foster prosperity and opportunity, underpinned by equality and well-being.[115] The European Union participates in the OECD as well. The policy reports include health.

The report "Does Healthcare Deliver?"[116] is based on Patient-Reported Indicator Surveys (PaRIS) developed in cooperation with multiple countries. The indicators outcomes and self-reported experiences of primary care cover patients aged 45 years and older who live with chronic diseases and how it effects their lives. The cornerstone of what patients valued most is tailored as the three T`s: Time, Tailored care and Trouble-free care.[117] Digital tools are crucial in improving communication, reducing errors, and enhancing care co-ordination. Double disadvantage of people with lower income was noted.[118] The report reflects positive outcomes of people-centred care[119] and highlights the critical need to expand and improve the deployment of digital technologies in primary care to elevate overall care experiences.[120] Nonetheless, both digital and printed, tailored to diverse literacy levels and cultural contexts, materials are needed. The authors published several recommendations to policy makers:[121]

Figure:

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[114] ten Napel H., van Boven K., Olagundoye O.A., van der Haring E., Verbeke M., Härkönen M., van Althuis T., Augusto D.K., Laurent L., Schrans D., van Weel C., Schers H. Improving Primary Health Care Data With ICPC-3: From a Medical to a Person-Centered Perspective. *Ann Fam Med. 2022 Jul-Aug;20(4*), pp. 358-361. https://pubmed.ncbi.nlm.nih.gov/35879074/

[115] Organisation for Economic Co-operation and Development (OECD). (2025). *Does Healthcare Deliver? Results from the Patient-Reported Indicator Surveys (PaRIS).* https://doi.org/10.1787/c8af05a5-en

[116] Organisation for Economic Co-operation and Development (OECD). (2025). *Does Healthcare Deliver? Results from the Patient-Reported Indicator Surveys (PaRIS).* https://doi.org/10.1787/c8af05a5-en

[117] Organisation for Economic Co-operation and Development (OECD). (2025). *Does Healthcare Deliver? Results from the Patient-Reported Indicator Surveys (PaRIS),* p. 16. https://doi.org/10.1787/c8af05a5-en

[118] Organisation for Economic Co-operation and Development (OECD). (2025). *Does Healthcare Deliver? Results from the Patient-Reported Indicator Surveys (PaRIS),* p. 29. https://doi.org/10.1787/c8af05a5-en

[119] Organisation for Economic Co-operation and Development (OECD). (2025). *Does Healthcare Deliver? Results from the Patient-Reported Indicator Surveys (PaRIS),* p. 132. https://doi.org/10.1787/c8af05a5-en,

[120] Organisation for Economic Co-operation and Development (OECD). (2025). *Does Healthcare Deliver? Results from the Patient-Reported Indicator Surveys (PaRIS),* p. 130. https://doi.org/10.1787/c8af05a5-en,

[121] Organisation for Economic Co-operation and Development (OECD). (2025). *Does Healthcare Deliver? Results from the Patient-Reported Indicator Surveys (PaRIS),* pp. 163 & 190. https://doi.org/10.1787/c8af05a5-en,

- *Improve access to health information and empower patients through shared decision-making.*
- *Strengthen the use and communication of care plans and enhance interoperability of electronic health records to improve continuity of care.*
- *Invest in digital health literacy and expand patients' access to digital tools in primary care.*
- *Gender inequalities in health are persistent and ask for a targeted policy approach including explicit target setting.*
- *Targeted policy interventions should address socio-economic inequalities in outcomes and experiences.*

3.3.11 European Partnership hosted by the WHO: the European Observatory on Health Systems and Policies

"VHI is a complex and challenging policy instrument and state intervention, even in heavily regulated markets, is not necessarily sufficient to ensure VHI policies are accessible, affordable and provide good financial protection".[122]

The European Observatory on Health Systems and Policies supports Europe's decision-makers by identifying, generating and sharing evidence on health systems in bridging the gap between academia and policy.[123] The European Health Observatory was created in 1998 as a partnership hosted by WHO/Europe. The European Observatory on Health Systems and Policies supports Europe's decision-makers by identifying and sharing evidence on health systems bridging the gap between academia and policy. It brings together international organizations, national and regional governments to support European health policy and promote evidence-informed policy making. To achieve this mission, the European Health Observatory bases its activities on four functions: Country monitoring, Analysis, Performance assessment and Knowledge brokering.

To this end, multiple reports, policy briefs and observations have been published including on the use of evidence-based tools, such as Health Technology Assessment and Key Themes supporting health system transformation.[124]

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[122] European Observatory on Health Systems and Policy. (2016). *Voluntary health insurance in Europe: Role and regulation*. ISBN 978 92 890 5038 *8* https://iris.who.int/server/api/core/bitstreams/aa0116d1-9f49-4392-bbdb-34efa028d985/content

[123] European Observatory on Health Systems and Policies. (n.d.). *Homepage*. eurohealthobservatory. https://eurohealthobservatory.who.int/

[124] Mauer N, Scarpetti G, Wismar M. *A public debate on the future health priorities of the European Union: Outcomes, insights and ideas for action*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies; 2024. Licence: CC BY-NC-SA 3.0 IGO, p. 46. https://eurohealthobservatory.who.int/publications/m/a-public-debate-on-the-future-health-priorities-of-the-european-union-outcomes-insights-and-ideas-for-action and European Observatory on Health Systems and Policy (2005). *Health technology assessment: an introduction to objectives, role of evidence, and structure in Europe,* p. 2. https://iris.who.int/server/api/core/bitstreams/1e3a18c7-8e15-49bd-856f-5cde1179679f/content

The European Observatory published the study on Voluntary Health Insurance (VHI).[125]

In its Briefing paper "Addressing the determinants of health through in and for All Policies", the European Observatory on Health Systems and Policies introduces the concept of Health in (HiAP) and for All Policies (H4AP). [126]
Health for All Policies (H4AP) is, following this concept, an effective and efficient way to improve health.

The European Observatory regularly publishes policy briefs including on improving reach and access to health promotion and preventive services for vulnerable children and adolescents.[127] The organization recommends three key pathways to Policymakers to improve health promotion and preventive services for children and adolescents.

Figure:

1. Strategic collaboration across health, social and educational sectors is vital in tackling the underlying determinants of health which cannot be addressed by one sector alone.
2. Developing robust data collection and the infrastructure to share data facilitates work across sectors.
3. Supporting targeted interventions with tailored outreach initiatives can overcome access barriers.

3.3.12 International Consortium for Health Outcomes Measurement (ICHOM)

"*standardise and drive the global adoption of patient centred outcome measurement as the benchmark of health and quality*".[128]

Founded in 2012 by multiple stakeholders, ICHOM creates a worldwide network to improve health outcomes through standardized value-based healthcare (VBHC) while putting the patient with lived experience at the centre to ensure real-world relevance and address health

[125] European Observatory on Health Systems and Policy. (2016). *Voluntary health insurance in Europe: Role and regulation*. ISBN 978 92 890 5038 *8* https://iris.who.int/server/api/core/bitstreams/aa0116d1-9f49-4392-bbdb-34efa028d985/content
[126] WHO as the host organization for the European Observatory on Health Systems and Policies. (2024). *Health for all policies. License: CC BY-NC-SA 3.0 IGO.*
[127] Eriksen A, De Bock F, Alayli A, Boode K, Durvy B, Gaspar T, Kosola S, Saxena S, van Ginneken E. Imp*roving reach and access to health promotion and preventive services for vulnerable children and adolescents: experiences from five European countries.* Copenhagen: European Observatory on Health Systems and Policies, WHO Regional Office for Europe; 2025. Licence: CC BY-NC-SA 3.0 IGO. https://pubmed.ncbi.nlm.nih.gov/40966369/
[128] International Consortium for Health Outcomes Measurement. (n.d.). *Homepage*. ichom. https://www.ichom.org/

equity.
ICHOM has published 48 standard sets grouped in medical disease areas and patient population including adult oral health. The documentation represents the outcomes that matter most divided in the containers: caries and periodontal disease, symptoms and physiological functions and psychosocial status.

3.3.13 International Association Dental, Oral, and Craniofacial Research (IADR)

"Oral health for the world through discovery and dissemination".[129]

IADR, established in the USA, supports dental, oral, and craniofacial research.
Its mission is to drive dental, oral, and craniofacial research for health and well-being worldwide. IADR strives to create an engaging environment that empowers its members to institute practices and behaviours that promote diversity, equity, inclusion, accessibility and belonging (DEIAB).
IADR provides for online access to multiple publication in the field of its mission.

Figure:

Diversity	The recognition, respect, and value of the range of individual characteristics and experiences that influence personal perspectives and the proportionate representation across all dimensions of human difference.
Equity	The consistent and systematic, fair, and just treatment of all individuals and the dedication to eliminate barriers to fair treatment for underrepresented groups through systemic changes.
Inclusion	The recognition, appreciation, and use of the talents and skills of all backgrounds by creating a welcoming environment through the proactive identification and removal of the barriers that impede the success of all.
Accessibility	The design and development of information, programs, environment, and services so that all people can fully and independently use them. It ensures a level playing field for people by addressing physical and nonphysical barriers.
Belonging	The creation of an environment where everyone is treated and feels like a full member of the community and can thrive.

3.3.14 Organization for Caries Research (ORCA)

[129] International Association Dental, Oral and Craniofacial Research. (n.d.). *About IADR.* iadr. https://www.iadr.org/about-iadr.

"a future where evidence-based prevention and management of dental caries and tooth hard tissue disorders lead".[130]

Founded in 1953 as an international scientific organization based in Europe, ORCA bringsscientists together in the field of cariology. ORCA has published several monographs and consensus statements in the field of caries research including the consensus report on clinical recommendations for caries diagnosis.[131]

3.3.15 Global Self-Care Federation and FIP Association

"Health literacy is a foundational pre-requisite to responsible self-care which makes two-way communication between the individual and their healthcare professional an essential element of effective self-care". [132]

The Global Self-Care Federation represents associations and manufacturers in the self-care industry. The Federation, based in Switzerland, focuses on evidence-based solutions that improve health outcomes and increase healthcare system optimizations. Good oral health practices form an integral component of FIP's selfcare priority program.[133]

FIP Selfcare Association, affiliated with the Global Self-Care Federation, established in The Hague, the Netherlands, builds further on the role of the pharmacist, as an important accessible healthcare provider for citizens, in achieving good oral care.[134] Good oral health practices form an integral component of FIP's self-care priority programme including advice, promotion and managing common oral health symptoms.

Figure:

1. Providing advice on oral hygiene.

2. Promoting oral health and providing advice on dental products.

3.Managing common oral health symptoms and particularly in high-risk populations, such as people living with diabetes and other NCDs.

4.Identifying red-flag symptoms and referring patients to dentists.

5.Dispensing and providing advice on the use of prescription and non-prescription medicines for oral health conditions or with oral health effects.

6.Conducting medicines use reviews linked to oral health.

[130] Organization for Caries Research (ORCA). (2024). *ORCA-EFCD consensus report on clinical recommendation for caries diagnosis. Paper I: caries lesion detection and depth assessment.* doi:10.1007/s00784-024-05597-3. https://link.springer.com/article/10.1007/s00784-024-05597-3
[131] Organization for Caries Research (ORCA). (2024). *ORCA-EFCD consensus report on clinical recommendation for caries diagnosis. Paper I: caries lesion detection and depth assessment.* doi:10.1007/s00784-024-05597-3. https://link.springer.com/article/10.1007/s00784-024-05597-3
[132] Global Self-Care Federation. (n.d.). *Self-care: Home*. selfcare.fip. https://selfcare.fip.org/
[133] Global Self-Care Federation. (n.d.). *Self-care: Home*. selfcare.fip. https://selfcare.fip.org/
[134] Global Self-Care Federation. (n.d.). *Self-care: Home*. selfcare.fip. https://selfcare.fip.org/

7.Managing common conditions such as xerostomia, oral candidiasis, halitosis, tooth sensitivity, gum inflammation or bleeding, mouth ulcers, or cold sores.

8.Contributing optimal antibiotic use in dental practice.

9.Oral health campaigns/awareness days.

3.4 Conclusions:

"Healthcare data has the potential to transform our understanding of health, disease and outcomes, yet it is currently scattered across multiple institutions and countries, stored in different formats, and subject to different rules. This makes it very difficult to fully utilize this data to benefit patients".[135]

Multiple organizations on the international level (provenance) support and contribute to the development of multiple regulatory determinants for improvement of oral health quality in the broadest sense: the quality of instruments, healthcare policy, guidance documents, tools, standards and recommendations (yardstick),

These organizations represent the vision and knowledge of their members, mostly states, their bodies and their associations.
The EU Member States, their bodies and associations are represented in most of these organizations and committed to incorporate universal healthcare goals, ethical treaties and resolutions in their national policy and can use actionable tools in their healthcare policy, planning of workforce and development of guidelines and standards.
Strictly construed, these instruments for improving quality do not directly constitute concrete mandatory regulatory determinants. However, they do establish a strong common commitment and provide the basis for a national regulatory framework and prevention policy (consequences).
Every state weighs up interests and possibilities in various policy areas. This does, however, raise the question if and/or how, during this process, widely supported international instruments are considered, weighed and used in a transparent manner. Recommendations and international standards for implementing the principle of equity, accessibility, patient centredness, cost- effectiveness and for improving quality of health (mostly leading to cost-efficiency) should, following the commitment of the Member States, be weighed transparently.
In deviation from the UN and WHO goal of Universal Health Coverage, many EU citizens do not have access to quality oral care without financial hardship. Oral diseases are among the main drivers of catastrophic health expenditures in the EU and particularly affect poorer and marginalized groups. For those who do not have access to affordable oral care, this poses serious public health threats as the exacerbation of oral diseases can lead to infections, emergency hospital admissions, or even death. Despite vast and multilateral damage to society, the 2021 WHO Oral Health Resolution highlights that oral healthcare has been a dramatically neglected area in health policy for many years. A low sense of urgency for quality

[135] Innovative Health Innovation (IHI). (n.d.). *European Health Data and Evidence Network.* ihi.europa. https://www.ihi.europa.eu/projects-results/project-factsheets/ehden

improvement persists in policy and practice and, therefore, the threats to oral care quality and safety are vast.
It is quite possible that during the years of shaping healthcare policy, regulatory instruments, prevention tools, workforce planning and coverage systems, governments and stakeholders have overlooked the crucial element of accessibility and affordability, and in the wake of that, the crucial policy tool for population based reliable data.
And therein lies the challenge for each Member State of the EU: developing policies and guidelines to achieve adequate coverage, full accessibility, equity and integrated primary care while available data originate from a limited access to oral healthcare.

The baseline formulated in the reports of the European Observatory entails another vital fundament for developing policy: the extent of the right to access of services is not absolute. The focus may be on care that matches the population's needs as closely as possible. However, the European Observatory on Health Systems and Policies further explains that this needs-based focus entails decisions that use robust data collection and sharing infrastructures [136]
Nonetheless, the right to prevention and relevant information in relation thereto may be absolute. Prevention policy should focus on the entire population and may be targeted for different population groups
Member States of the WHO, including the Member States of the EU, all bear the same responsibilities arising from the regulatory determinants (including WHO resolutions, principles, standards, policy briefings, ethical treaties, guidelines) and have access to the same quality instruments, scientific insights and recommendations developed by multiple bodies and associations on the international level.
The coordination for effectively implementing these responsibilities lies to a significant extent in the cooperation between the Member States that are also Member States of the European Union.

4. EUROPEAN LEVEL AND FRAMEWORK AND REGULATORY DETERMINANTS

4.1 Introduction:

"Oral health is a central component of general health. Although most oral diseases can be prevented by health promotion strategies and routine access to primary oral health care, about half of the European population suffers from some form of caries (tooth decay) or periodontitis (gum diseases)".[137]

[136] Eriksen A, De Bock F, Alayli A, Boode K, Durvy B, Gaspar T, Kosola S, Saxena S, van Ginneken E. Imp*roving reach and access to health promotion and preventive services for vulnerable children and adolescents: experiences from five European countries.* Copenhagen: European Observatory on Health Systems and Policies, WHO Regional Office for Europe; 2025. Licence: CC BY-NC-SA 3.0 IGO. https://pubmed.ncbi.nlm.nih.gov/40966369/
[137] Winkelmann, J., van Ginneken, E., & Gomez Rossi, J. (2022). Oral Health Care in Europe: Financing, Access and Provision. *European Journal of Public Health*, *32*(Supplement_3), p. 2. https://doi.org/10.1093/eurpub/ckac129.372

Oral diseases and conditions (dental caries, periodontal diseases, tooth loss, oral/pharyngeal cancers) not only affect over 3.5 billion people worldwide. They are the third most expensive diseases to treat in the EU. It is estimated that oral diseases accounted for € 90 billion direct costs in 28 Member States (in 2018) ranking third behind diabetes and heart diseases while being preventable.[138]
Twenty-seven countries Members of the WHO have accepted the Constitution of the WHO and are committed to the resolutions adopted in the WHA, individually and collectively. All Member States of the European Union are represented in ISO, WMA, FDI and multiple organizations on the international level that support quality improvement of care including oral care.

4.1.1 Bridge from international level to the European level: WHO Regional Office

"address the preventable burden of non-communicable diseases
ensure a solid evidence base for health policy making".[139]

WHO Regional Office for Europe and its Office on Quality of Care and Patient Safety in Athens, has conducted, for the first time, a region-wide assessment of the quality of healthcare and patient safety in the 53 Member States in the WHO European Region and presented the cross-sectional analysis of quality of care and patient safety in the WHO European Region. This report is based on an analysis of macro-level data from international sources and the results of a WHO survey conducted in 53 Member States.
The report states that only one in three countries in the Region has implemented a national action plan on quality of care and/or patient safety, which WHO determines to be a key indicator of whether a country can provide good quality of care to its patients.[140] The need for electronic health records for an effective uptake of quality improvement was noted. Nonetheless, only 70% of the countries implemented EHRs.
Only 13% reported having guidelines for quality and safety in telehealth.[141] The conclusions are built on forty-six indicators grouped into governance and health system functions and six dimensions of quality of care and population health outcomes including effectiveness, efficiency, centeredness, safety, equity, and equitable access to high-quality care for all.[142]
Multiple actions are recommended to move forward. Developing and enforcing standards and

[138] Winkelmann, J., van Ginneken, E., & Gomez Rossi, J. (2022). Oral Health Care in Europe: Financing, Access and Provision. *European Journal of Public Health*, *32*(Supplement_3), p. 2. https://doi.org/10.1093/eurpub/ckac129.372
[139] WHO Regional Office for Europe. (2024). *Taking the pulse of quality of care and patient safety in the WHO European Region: Multidimensional analysis and future prospects*. Licence (CC BY-NC-SA 3.0 IGO. https://splsportugal.com/wp-content/uploads/2023/07/9789289061568-eng.pdf
[140] WHO. (2025). *European health report 2024: keeping health high on the agenda*. Licence: CC BY-NC-SA 3.0 IGO, p. IX. https://www.who.int/europe/publications/i/item/WHO-EURO-2025-10668-50440-76183
[141] WHO. (2025). *European health report 2024: keeping health high on the agenda*. Licence: CC BY-NC-SA 3.0 IGO, p. XI. https://www.who.int/europe/publications/i/item/WHO-EURO-2025-10668-50440-76183
[142] WHO Regional Office for Europe. (2024). *Taking the pulse of quality of care and patient safety in the WHO European Region: Multidimensional analysis and future prospects*. Licence (CC BY-NC-SA 3.0 IGO, pp. XI & XIII. https://splsportugal.com/wp-content/uploads/2023/07/9789289061568-eng.pdf,

guidelines are key.[143] A regulatory framework to support an efficient and continuous development of scientific guidelines on which practice based standards supports development, adoption by stakeholders and practice-based implementation of standards is recommended.

Figure:

1.Comprises integrated quality planning, quality control, and quality improvement activities.

2. Invest in the development of national action plans and policies for quality of care and patient safety.

3. Develop a harmonized set of indicators for measuring and continuously improving quality of care, including measures that matter most to patients.

4. Ensure patient and public representation in national health governance.

5. Establish clear, evidence-based standards for all care settings.

6. Redesign models of care around the needs and preferences of patients.

7. Invest in a Health Care Work Force with the capacity and capability to meet the demands and needs of the population for high-quality care.

8. Invest in robust public budgeting for quality of care and reconfigure payments to incentivize value in health service delivery.

9. Develop comprehensive and multi-stakeholder-led biotechnology sector policies to address quality and affordability for patients and health-care systems.

10. Invest in digital health solutions that support quality of care.

Standards are mentioned as vital instruments for insurance coverage and equity-oriented policies and practices towards the progressive realization of UHC (pricing policy decisions). National systems can, in this way, generate evidence based on properly disaggregated data for the development of equity-oriented policies and practices towards the progressive realization of UHC.[144]

4.1.2 The European Union: protect, support, improve and strengthen

> *"Health is an investment, and the Programme should have this concept at its core. Keeping people healthy and active longer and empowering them to take an active role in managing their health by improving their health literacy will have positive effects on health, health inequalities and inequities, access to sexual and reproductive healthcare, quality of life, workers' health, productivity, competitiveness and inclusiveness, while reducing pressures on national healthcare systems and national budgets. The Programme should also support actions to*

[143] WHO. (2025). *European health report 2024: keeping health high on the agenda.* Licence: CC BY-NC-SA 3.0 IGO, p. 45. https://www.who.int/europe/publications/i/item/WHO-EURO-2025-10668-50440-76183

[144] WHO. (2025). *European health report 2024: keeping health high on the agenda.* Licence: CC BY-NC-SA 3.0 IGO, p. XII. https://www.who.int/europe/publications/i/item/WHO-EURO-2025-10668-50440-76183

reduce inequalities in the provision of healthcare, in particular in rural and remote areas, including in the outermost regions, for the purposes of achieving inclusive growth. The Commission has committed to helping Member States to reach the sustainable development targets set in the UN resolution of 25 September 2015 entitled 'Transforming our world: the 2030 Agenda for Sustainable Development (the 'UN 2030 Agenda'), in particular Sustainable Development Goal 'Ensure healthy lives and promote well-being for all at all ages'. The Programme should therefore contribute to the actions towards reaching those targets".[145]

The EU and EU Member States financially support the WHO.
The EU-WHO collaborate in partnership. This partnership continues to evolve and to tackle emerging health challenges.[146]

Figure:

EU policies and actions in public health aim to:
- *protect and improve the health of EU citizens.*
- *support the modernization of health infrastructure.*
- *improve the efficiency of Europe's health systems.*
- *strengthen preparedness and response measures to cross-border health threats.*

The EU adopts laws and recommendations to protect people, covering, for example, health products and patients' rights.
The EU sets several priorities shaping the political agenda until 2029.[147]

This chapter analyses how the EU, although a partner and not a member of the WHO, and stakeholders operating on the European level, can support the commitment and responsibilities of the Member States of the EU to implement the international regulatory determinants, resolutions, recommendations, common frameworks, guidelines, standards ethical values and tools, for improvement of the quality of oral care on the European level.

4.1.3 Functioning and competences of the EU related to healthcare

"Even though the EC has limited powers in relation to health care services, it exerts considerable influence on the way they are organized by Member States".[148]

Historically, the legal context within Europe did not give any explicit competence to the community institutions in the field of health. Two cases, concerning medical goods and non-emergency care services in another Member State reimbursed by the national home system,

[145] Regulation (EU) 2021/522 and Regulation (EU) No. 282/2014.
[146] WHO. (n.d.). *The EU and WHO: partners for global health.* who.int. https://www.who.int/europe/about-us/partnerships/the-eu-and-who-partners-for-global-health
[147] European Union. (2024). *European priorities 2024-2029.* european.union. *https://european-union.europa.eu/priorities-and-actions/eu-priorities/european-union-priorities-2024-2029_en*
[148] McKee M., Mossialos E., Baeten R. (2003). *The Impact of EU Law on Healthcare Systems*. ISBN: 9789052011066, pp. 58-59. https://academic.oup.com/eurpub/article/16/4/451/644318

created the pathway for obtaining non-emergency social healthcare in another Member State, though leaving several questions unanswered.[149]

Cross-border healthcare within the EU was launched.
Coordination between Member States was needed.

The Treaty on the Functioning of the European Union (TFEU) organizes the functioning of the Union and determines areas of competence and exclusive competences.[150]
The TFEU confers exclusive and shared (with the Member States) competences in specific areas to the Union[151] including economic, social and territorial cohesion[152] consumer protection[153] and defined common safety concerns in public health matters.[154]
In certain areas, the Union has furthermore competence to carry out actions to support, coordinate or supplement the actions of the Member States, without thereby superseding their competence in these areas, e.g. in protection and improvement of human health.[155]
The Union may, furthermore, take initiatives to ensure coordination of Member States' social policies.[156]
However, when performing these tasks, the Union shall consider requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health.[157]

The Union must implement a vocational training policy and drive vocational training and support and supplement the actions of the Member States while respecting their responsibilities for the content and organisation of vocational training.[158]
The European Parliament and the Council may issue directives for the mutual recognition of diplomas, certificates and other evidence of formal qualifications and for the coordination of the provisions laid down by law, regulation or administrative action in Member States.[159] Within the framework of provisions, restrictions on freedom to provide cross border services within the Union shall be prohibited.[160]

[149] CJEU 28 April 1998, Case C-120/95, ECLI:EU:C:1998:167 (Decker) and CJEU 28 April 1998, Case C-158/96, ECLI:EU:C:1998:171 (Kohll)

[150] Article 1 TFEU.
[151] Article 2(1) and (2) TFEU.
[152] Article 4 (2)(b) TFEU.
[153] Article 4(2)(f) TFEU.
[154] Article 4 (2)(k) TFEU.
[155] Article 6(a) TFEU.
[156] Article 5 (3) TFEU.
[157] Article 9 TFEU.
[158] Article 166 TFEU.
[159] Article 53 TFEU.
[160] Article 56 TFEU.

The European Research Area was launched in 2000 to foster circulation of scientific knowledge, research and technology and to strengthen its scientific and technological bases.[161]

Figure:

The European Research Area (ERA) was launched in 2000 with the aim to:
1. prioritise investments and reforms in research and innovation, to support the digital and green transition and Europe's recovery.
2. improve access to excellent research and innovation for researchers across the EU.
3.translate results into the economy to ensure market uptake of research output and Europe's competitive leadership in technology.
4.make progress on the free circulation of knowledge, researchers and technology through stronger cooperation with EU countries.

4.1.4 EU oral health policy and action: balancing on the tightrope to ensure a high level of human health protection while respecting defined autonomy of Member States

"The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organization of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed".

The EU role in health policy and healthcare, commitment and interaction with Member States is cemented in article 168 of the consolidated version of the Treaty on the Functioning of the European Union, TFEU:[162]

Figure:

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.
Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.
The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their actions. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

[161] Article 179 TFEU.
[162] Part three & Title XIV TFEU.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programs in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organization of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organizations in the sphere of public health.
[-]
5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article

7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

The dividing line between what the EU should ensure, initiate, encourage and delegate related to oral health protection, prevention and care and what the EU should leave to the autonomy of the Member States runs through the words:

"respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. "

This last provision in the overall description of an ambitious role of the EU in healthcare for all EU citizens, ensures that the primary control over national health policy and allocation of funds remain in the hands of the Member States, even if the EU would

support the Member States financially in achieving the ambitious goals set by this article 168.[163]

All Member States are committed to the same regulatory determinants on the international level and committed to EU regulations and responsible for the implementation of Directives in their national regulations and may not raise barriers to the principles on which these directives and regulations are based.
Figure:

- Their definitions of health policy should largely correspond to each other.
- Their ethical values are largely based on the same ethical treaties.
- Their citizens travel cross border and may address or need care in a host Member State.
- Their scientific associations participate in the same European scientific associations.
- Their technical standard bodies are represented in the same European institutions.
- These Member States all fall under the scope of Directives and Regulations addressing quality of healthcare products, services and registration of professionals.

All Member States are committed to EU regulations and responsible for the implementation of Directives in their national regulations and may not raise barriers to the principles on which these directives and regulations are based. The policies between the EU and Member States may differ to the extent, however, that the TFEU prevails.

'Different health policies should not however, constitute barriers to the free movement of electronic health data in the context of cross-border healthcare, for example telemedicine and online pharmacy services". [164]

The EU may initiate coordination between the Member States in particular aiming at the establishment of guidelines and indicators and the organization of exchange of best practice and the preparation of the necessary elements for periodic monitoring and evaluation.
The EU bases public health policy on a shared, between the EU and its Member States, basis in a complementary role.
Article 168 TFEU creates and supports roles for the EU to support coordination between the Member States in their mission to improve quality of oral care.

Figure:

1. A complementary role for policies directed to improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health and drugs-related health damage, including information and prevention.
2. An encouraging/cooperating role for cooperation between the Member States and, if necessary,

[163] de Ruijter, A., Hervey, T., & Prainsack, B. (2024). Solidarity and trust in European Union health governance: three ways forward. *The Lancet Regional Health - Europe*, *46*, 01047. https://doi.org/10.1016/j.lanepe.2024.101047
[164] Recital 28 EHDS.

and more in concrete, lends support to their action, to improve the complementarity of their health services in cross-border areas.
3. An Initiating role to promote coordination between the Member States in particular initiatives aiming at the establishment of guidelines and indicators, the organization of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation.
4. A Delegating role related to recommendations to the Council of the European Union.

The EU can, in its initiating role, set the agenda for its policies and actions.
The EU may set and prioritize its policies, while supporting and translating WHO goals, mission and resolutions for the EU.[165] The EU may support, encourage, coordinate or supplement the actions of the Member States when setting the agenda and translating WHO resolutions into their national policies and legislation and carry out actions thereto (including in areas of protection and improvement of human health, and education, vocational training, youth and sport).[166]
The EU is furthermore specifically tasked with implementing a vocational training policy which shall support and supplement the action of the Member States.[167]

The EU seems to balance on the tightrope of Member States responsibilities when available evidence and assessment on the clinical added value is at play.

'*Scientific analysis supporting clinical assessment itself includes consideration of the degree of certainty of the relative effects, taking into account the strengths and limitations of the available evidence. The outcome thereof will not affect the discretion of Member States to carry out assessments on the clinical added value of the health technologies concerned or predetermine subsequent decisions on pricing and reimbursement of health technologies, including the fixing of criteria for such pricing and reimbursement decisions*".[168]

The EU may initiate coordination between the Member States in particular aiming at the establishment of guidelines and indicators and the organization of exchange of best practice and the preparation of the necessary elements for periodic monitoring and evaluation.
It follows that the EU can coordinate, complement and support particularly in areas where there is a common (for all the Member States) challenge or a common response needs to be found.
The EU monitors the achievement of the advancement of the UN 17 Sustainable Development Goals based on 102 indicators. This shows that unmet medical needs have increased since 2018.[169]

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[165] Brooks E., De Ruijter A., Greer S.L. & Rozenblum S. (2022). EU health policy in the aftermath of COVID-19: neofunctionalism and crisis-driven integration. *Journal of European Public Policy 30(4),* pp. 1-19. License: CC BY-NC-ND 4.0. https://www.researchgate.net/publication/365324541_EU_health_policy_in_the_aftermath_of_COVID-19_neofunctionalism_and_crisis-driven_integration
[166] Article 6(e) TFEU.
[167] Article 166 TFEU.
[168] Recital 14 Regulation (EU) 2021/2282.
[169] European Statistical Office. (2025). *Europe Sustainable Development Report 2025 (with indicators).* https://sdg-transformation-center-sdsn.hub.arcgis.com/datasets/sdsn::europe-sustainable-development-report-2025-with-indicators/about

The EU bases public health policy on a shared, between the EU and its Member states, competence in a complementary role.

Figure:

'While Member States define and deliver their national health services and medical care, the EU seeks to complement national policies by means of its health strategy to:

- *prevent illness/disease by promoting healthier lifestyles.*
- *facilitate access to better and safer healthcare.*
- *contribute to innovative, efficient and sustainable health systems.*
- *deal with cross-border threats.*
- *keep people healthy throughout their lifetimes.*
- *harness new technologies and practices."*[170]

Coordination on public health issues is a necessary consequence of the free movement of people, services and goods in the internal market. EU cooperation in the field of public health issues serves to tackle common health challenges resulting for example from antimicrobial resistance, preventable chronic diseases and an aging population.[171]

Figure:

Coordination/cooperation public health issues	Free movement of services and goods in the internal market.
Initiating and Coordination	Establishment of guidelines and indicators and the organization of exchange of best practice and the preparation of the necessary elements for periodic monitoring and evaluation.
Complementary role	Health policy general.
Shared vision	Public health policy.
Coordinate, complement and support	Common (for all the Member States) challenge or response need.
Encourage, Coordinate or Supplement	The actions of the Member States when setting the agenda and translating WHO resolutions into their national policies and legislation and carry out actions thereto.

4.1.5 EU 4Health action plan 2021-2027: a vision for a healthier Europe

"EU4Health is a clear message that public health is a priority for the EU, and it is one of the main instruments to pave the way to a European Health Union".[172]

[170] Regulation (EU) 2021/522.
[171] European Council. (n.d.). *What is the EU's role in health policy.* consilium.europe. https://www.consilium.europa.eu/en/policies/eu-health-policy/ - role
[172] European Commission. (2021-2027). *EU4Health Programme.* health.ec.europe. https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en and Regulation (EU) 2021/522.

The EU4Health program aims to contribute to the long-term health challenges by building stronger, more resilient and more accessible health systems.
The program represents multiple areas of intervention, including strengthening health systems, reinforcing health data, digital tools and services, digital transformation of healthcare, enhancing access to healthcare, developing and implementing EU health legislation and evidence-based decision making and integrated work among national health systems.

4.2 EU Institutions, and their roles to protect, support, improve, and strengthen

EU operates through several institutions.[173]

Figure:

The European Parliament (EP)	The EP exercises legislative and budgetary functions, jointly with the Council. It shall furthermore exercise political control and consultation. It may adopt and initiate resolutions to address the CEU /Member States.
The European Council (EC)	The EC provides the Union with the necessary impetus for its development and defines the general political directions and priorities thereof. Its main role is to determine the EU`s political direction.
The Council of the European Union (CEU)	The CEU exercises legislative and budgetary functions, jointly with the EP and carries policymaking and coordinating functions.
The European Commission (ECOM)	The ECOM promotes the general interest of the Union and takes appropriate initiatives to that end. It also oversees the application of Union law under the control of the CJEU.
The Court of Justice of the European Union (CJEU) (other institutions and bodies)	The CJEU ensures the observance of the interpretation and application of the treaties.
The Court of Auditors (ECA) (other institutions and bodies)	The ECA may play an important role in assessing regulations including those relating to healthcare.
European Centre for Disease Prevention and Control (ECDC) (decentralized agency)	The ECDC helps prepare EU governments in stopping the spread of infectious diseases.
European Centre for the Development of Vocational Training (Cedevop) (decentralized agency)	Cedevop operates as a forum allowing organisations to share ideas and debate how best to improve vocational education and training in Europe. Helps European, national and regional policymakers take informed decisions on vocational education and training provision.
European Training Foundation (ETF)	Supports 29 partner countries in reforming their education and training systems.
European Union Agency of Fundamental Rights (FRA)	Provides independent and evidence- based advice to EU and national decision makers on fundamental rights.
Eurostat	The statistical office of the European Union. Produces European statistics in partnership with National Statistical Institutes and other national authorities in the EU Member States.

4.2.1 The European Commission (ECOM)

"From a health system perspective, low-value care encompasses overuse, misuse and underuse of

[173] Article 13 TFEU.

healthcare services (for example, prevention, diagnostics, treatment, medication). Overuse and/or misuse comprise the delivery of harmful, ineffective, inappropriate, or not cost-effective healthcare services. Underuse refers to healthcare services not provided or used despite being necessary. Low-value care can lead to negative consequences for patients, their caregivers, the healthcare workforce, the health system as a whole and the wider environment".[174]

ECOM launched the Healthier together-EU non-communicable diseases (NCD) initiative that covers the 2022-2027 period and was initiated in a meeting with the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on 14 December 2021 (SGPP) . The aim of this initiative was to support Member States in identifying Non-Communicable Diseases and in implementing effective policies and actions.
The initiative includes five strands. Though these strands do not address oral health directly, they all include a health equity dimension and indirectly support the reduction of health inequalities. The initiative furthermore promotes a holistic and coordinated approach to the prevention of care, better knowledge and data, screening and early detection.
The factsheet lists possible concrete actions including implementing comprehensive public health policies, transferring good practices, developing guidelines and rolling out innovative approaches and launching projects.

In parallel, in May 2022, the 75th World Health Assembly adopted the WHO Global Strategy on Oral Health, recognizing that oral conditions are major public health problems.

ECOM initiates legislative proposals to the Parliament. Impact assessments may be carried out on initiatives expected to have significant economic, social or environmental impacts.[175]
In 2014, ECOM set up an Expert Group on Health Systems Performance Assessment (HSPA) to provide European Union (EU) countries with a forum to exchange experiences in this field and to support national policymakers by identifying tools and methodologies to develop HSPA.
"Value-based healthcare with a focus on low-value care" was selected as a priority topic for 2023-2024. ECOM published its report "Identifying, measuring and reducing low-value care in the context of health system performance assessment 2025", on February 12, 2025.[176]
Value was defined as:

"outcomes that matter most to patients / costs for the complete patient pathway"

Based on this definition, value-based healthcare (VBHC) was proposed as a guiding principle for healthcare reform in various countries as it strives for the best use of limited resources for

[174] European Commission. (2025). Identifying, measuring and reducing low-value care in the context of health system performance assessment. doi: 10.2875/7231733. https://health.ec.europa.eu/document/download/1adc2134-5753-4ffb-a6d5-ab8d224874c6_en?filename=hspa_low-value-care_report_en.pdf

[175] European Commission. (n.d.). *About the European Commission*. commission.europa.eu. https://commission.europa.eu/about_en

[176] European Commission. (2025). Identifying, measuring and reducing low-value care in the context of health system performance assessment. doi: 10.2875/7231733. https://health.ec.europa.eu/document/download/1adc2134-5753-4ffb-a6d5-ab8d224874c6_en?filename=hspa_low-value-care_report_en.pdf

the maximum benefit of individuals and society.[177]

HSPA key findings include types of low-value care, indicators, methodologic obstacles, and implementation of strategies.[178]

Figure:

- *Types of low-value care: Five types of cover overuse and misuse, two types of cover underuse, and two types of cover unwarranted variation, which can signal either underuse or overuse of healthcare. Identifying which part of the observed variation constitutes underuse or overuse, especially in the presence of differing patient preferences and needs, is crucial for designing efforts to combat low-value care.*
- *Indicators for identifying low-value care within HSPA are used in multiple countries covering prevention, diagnostics, treatment and medication as well as other areas. Simultaneously, a lack of indicators for specific areas (for example, mental healthcare, and end-of-life care) was identified.*
- *The main methodological obstacles in measuring low-value care identified in the survey relate particularly to data access and data quality.*
- *The implementation of strategies to reduce low-value care varies between the countries from multicomponent approaches to single measures such as guidelines, financial adjustments for purchasing agencies or health care providers, or auditing and quality transparency. Further solutions for reducing the use of low-value care were proposed in the survey and complemented with findings from the literature. These findings support the implementation and further development of multicomponent strategies tailored to the needs of individual countries.*

Low value care, inefficiencies and even waste have been explored against the backdrop of increasing healthcare expenditures and the overall aim to deliver high-quality and efficient healthcare in a person-centred way.[179]
Addressing low-value care can reduce out-of-pocket payments for individuals and thus financial hardship (for example, impoverishing health spending).[180]
Reducing out-of- pocket payments is an important endeavour towards achieving universal

[177] European Commission. (2025). Identifying, measuring and reducing low-value care in the context of health system performance assessment. doi: 10.2875/7231733, p. 10. https://health.ec.europa.eu/document/download/1adc2134-5753-4ffb-a6d5-ab8d224874c6_en?filename=hspa_low-value-care_report_en.pdf
[178] European Commission. (2025). Identifying, measuring and reducing low-value care in the context of health system performance assessment. doi: 10.2875/7231733. https://health.ec.europa.eu/document/download/1adc2134-5753-4ffb-a6d5-ab8d224874c6_en?filename=hspa_low-value-care_report_en.pdf
[179] European Commission. (2025). Identifying, measuring and reducing low-value care in the context of health system performance assessment. doi: 10.2875/7231733. https://health.ec.europa.eu/document/download/1adc2134-5753-4ffb-a6d5-ab8d224874c6_en?filename=hspa_low-value-care_report_en.pdf;

[180] Liu T., Zhu Z., Thompson M.P., McCullough J.S., Hou H., Chang C., Mark Fendrick A., Ellimotiil C. (2024). *Primary Care Practice Telehealth Use and Low-Value Care Services.* *https://doi.org/10.1001/jamanetworkopen.2024.45436*

health coverage.
Unwarranted variation, variation that is not explained by different needs, is included in the framework for low-value care as well.[181]

The ECOM furthermore supports a stronger European Health Union in which all EU countries respond together to health crises and work together to improve prevention, treatment, and aftercare for diseases.[182]

The ECOM policies address the 17 SDGs. Regarding SDG 3, ensure healthy lives and promote well-being for all at all ages, the policies are directed at complementing Member States' action through legislation and other initiatives such as public health and health systems.[183]
The EU Global Health Strategy, adopted in November 2022, sets three priorities to deal with global health challenges.[184]

Figure:

- *Deliver better health and well-being of people across the life course.*
- *Strengthen health systems and advance universal health coverage.*
- *Prevent and combat health threats, including pandemics, applying a One Health approach.*

These priorities include investing in health infrastructure, strengthening health workforce capacity, health technologies and promoting digital health solutions. A seamless, secure, and interconnected healthcare ecosystem is considered a key element in multiple initiatives as it empowers individuals, healthcare professionals, and researchers to access and share health data and drive better health decisions.[185]

4.2.2 European Parliament (EP)

"Will the Directorate-General for Health and Food Safety (DG SANTE) act as a coordinating body to support Member States in the national implementation of the WHO Strategy?"

[181] European Commission. (2025). Identifying, measuring and reducing low-value care in the context of health system performance assessment. doi: 10.2875/7231733. https://health.ec.europa.eu/document/download/1adc2134-5753-4ffb-a6d5-ab8d224874c6_en?filename=hspa_low-value-care_report_en.pdf
[182] European Health Union. (n.d.). *What is the European Health Union?* commission.europa.eu. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en
[183] The Council, The European Economic and Social Committee & The Committee of the Regions. (2016). *A new skill agenda for Europe: Working together to strengthen human capital, employability and competitiveness.* eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0381
[184] European Union. (2022). *EU Global Health Strategy: Better Health for All in a Changing World.* doi:10.2875/22652. https://health.ec.europa.eu/document/download/25f21cf5-5776-477f-b08e-d290392fb48a_en?filename=international_ghs-report-2022_en.pdf
[185] European Commission. (2025). Identifying, measuring and reducing low-value care in the context of health system performance assessment. doi: 10.2875/7231733, p. 35. https://health.ec.europa.eu/document/download/1adc2134-5753-4ffb-a6d5-ab8d224874c6_en?filename=hspa_low-value-care_report_en.pdf

EP can drive the legislative agenda at the European level and, indirectly, on the national level. In its Resolution on Equal access to healthcare the EP calls on CEU to initiate multiple actions.[186]

Figure:

6.1 Reduce, where appropriate, the proportion of health expenditure payable by the most disadvantaged patients and take all other necessary measures to ensure that the cost of care does not hinder access to care, including the promotion of increased use of generic drugs.	*6.5. Simplify the administrative procedures required to be able to receive health care.*
6.2. Ensure the accessibility of health care facilities and health professionals throughout the territory by taking appropriate measures, having recourse where appropriate to incentive measures.	*6.6. Introduce measures to combat corruption in the health sector, in close co-operation with the Group of States against Corruption (GRECO).*
6.3. Ensure the accessibility of information on the health system, including vaccination and screening programs, and set up health education programs, while taking account of the specific needs of the different vulnerable groups and of the requirement to reduce language barriers to a minimum.	*6.7. Dissociate their security and immigration policies from health policy, where appropriate by abolishing the obligation on health professionals to report migrants in an irregular situation.*
6.4 Ensure that pregnant women and children, as a particularly vulnerable group, have full access to health care and social protection, irrespective of their status.	

In reaction to the guidance document "Healthier Together non-communicable diseases initiative 2022" of ECOM and the WHO Global Strategy on Oral Health (adopted in the75th World Health Assembly), EP addressed the ECOM with questions.[187]

4.2.3 The court of auditors (ECA)

"The recognition of professional qualifications in the EU – An essential mechanism but used sparsely and inconsistently"

ECA is the external auditor of the EU. Its college is made up of the individual members so assigned by each Member State. Its role is to audit EU's finances.
The court of auditors focuses on multiple topics amongst others Public Health.
The European Court of Auditors has published a special report 10/2024: 'The recognition of professional qualifications in the EU – An essential mechanism but used sparsely and inconsistently.[188]

[186] Council of Europe. (2013). *Parliamentary Assembly*. ISBN: 978-92-871-7744-5. https://book.coe.int/en/parliamentary-assembly-adopted-texts/5808-parliamentary-assembly-adopted-texts-2013-ordinary-session-third-part-24-28-june-2013.html
[187] Clune, D. (2022). *Parliamentary question: The status of oral health in EU health policies.* E-003023/2022: European Parliament. europa.eu. https://www.europarl.europa.eu/doceo/document/E-9-2022-003023_EN.html
[188] European Court of Auditors (ECA). (2024). Special report 10/2024: The recognition of professional qualifications in the EU. In *the European Court of Auditors*. doi: 10.2865/543068. https://www.eca.europa.eu/ECAPublications/SR-2024-10/SR-2024-10_EN.pdf

The Directive on recognition of professional qualifications in the EU was implemented in 2005 and amended in 2013.[189]
The Court of Auditors has examined how effectively the Commission ensured the rights of EU citizens working in regulated professions moving freely between Member States.
The findings in the report include the amendments and new measures.
Citizens and authorities have not, following the findings, made wide use of new measures, such as the European Professional Card, partial access to a profession, or common training principles. Moreover, competent authorities have not considered the alerts in the mandatory Internal Market information System when granting recognition of professional qualifications even in cases as misconduct, ongoing disciplinary measures or criminal convictions. Initiated infringement procedures have been unable to transform weaknesses in the applications in Member States systems and information provided to citizens is generally accessible but often proves to be unreliable and inconsistent.

The recommendations for improvement include to uniform application of the recognition system, to integrate the alert mechanism in the recognition procedure, to initiate an annual update of the lists of qualifications in certain sectors (listed in Annex V to the Directive) where professional recognition may be automatic and a shorter deadline for taking recognition decisions through the automatic system for sectoral professions and reliable and consistent information for citizens.
Dental practitioners rank sixth on the list of total decisions declared by the competent authorities (11,291 decisions) (Commission data extracted in October 2023).
Issues with regard to the dentist and specialized dentist were related to sufficient training duration in years and training hours were required.[190]

4.3. EU Directives and Regulations for and effecting quality of care

The legal framework established by the EU is to ensure harmonization across its Member States in various areas. Member States are committed to the EU regulatory instruments.
The EU legal framework consists of different regulatory determinants and instruments: Regulations, Directives, Decisions, Opinions, Recommendations, Delegated Acts, and Implementing Acts. Regulations apply directly in each Member State while Directives, although binding, are not directly applicable. The Member State should transpose a Directive in national law. Implementation of Directives in the Member States regulatory framework is, consequently, not completely uniform.
The EU Directives and Regulations set quality and safety standards and requirements for the professional, the instruments the professional use, data sharing in cross-border care and common standards and interoperability for healthcare data processed by healthcare professionals.

Figure:

Name regulation	*Reference*	*Content*
European Health Data Space	*Regulation 2025/327*	*Provides for the interoperability of health data*

[189] Directive 2005/36/EC.
[190] Article 23 Directive 2005/36/EC.

		and the primary and secondary use of data related to health.
Artificial intelligence (AI act)	Regulation (EU) 2024/1689	*Regulates harmonised rules on artificial intelligence.*
Regulation on general product safety	*Regulation (EU) 2023/988*	*Regulates the safety of general products and provides for consumer protection and market oversight.*
Health Technology Assessment Regulation	*Regulation (EU) 2021/2282*	*Regulates the evaluation of health technologies.*
Medical Device Regulation	*Regulation (EU) 2017/745*	*Regulates safety and efficacy of medical devices.*
In Vitro Device Regulation	*Regulation (EU) 2017/746*	*Regulates the accuracy and reliability of diagnostic tools and ensures the quality control thereof.*
Directive on ionising radiation	*Directive 2013/59/EURATOM*	*Regulates amongst others the exposure to radiation.*
Medicinal products (Directive and new legislative framework)	*Directive 2011/83/EC, Directive 2009/35/EC. 26.4.2023, on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC, Directive 2009/35/EC*	*Provides for quality requirements for medicinal product development, market authorization all based on a positive benefit-risk balance, safety and efficacy and post authorization monitoring (pharmacovigilance).*
Directive on patients' rights in cross-border healthcare	*Directive 2011/24/EU*	*Regulates access to healthcare in the EU and reimbursement by the home state.*
Regulation Community legal framework for a European Research Infrastructure Consortium (ERIC)	Council Regulation 723/2009	*Regulates the legal form for European Research Infrastructures.*
Directive on the recognition of professional qualifications	Directive 2005/36/EC	*Regulates mutual recognition of formal qualifications of professionals.*

4.3.1 Directive on the recognition of professional qualifications

"All Member States should recognise the profession of dental practitioner as a specific profession distinct from that of medical practitioner, whether or not specialised in odontostomatology. Member States should ensure that the training given to dental practitioners equips them with the skills needed for prevention, d*iagnosis and treatment relating to anomalies and illnesses of the teeth, mouth, jaws and associated tissues. The professional*

activity of the dental practitioner should be carried out by holders of a qualification as dental practitioner set out in this Directive."[191]

Based on Article 47(1) of the TFEU, the issuance of directives for the mutual recognition of diplomas, certificates and other evidence of formal qualifications, this Directive confers the guarantee on persons having acquired their professional qualifications in a Member State to have access to the same profession and pursue it in another Member State with the same rights.[192] However, the facilitation of service provision must be ensured in the context of strict respect for public health and safety and consumer protection. Specific provisions apply for regulated professions having public health or safety implications, which provide cross-frontier services on a temporary or occasional basis.[193]
Nonetheless, the professionals seeking access in another Member State shall be subject to the application of disciplinary rules of the host Member State.[194]

Mechanisms of recognition under the general system are defined in levels based on grouped national education and training schemes into different levels.
The principle of automatic recognition of medical and dental specialities common to at least two Member States shall apply to all specialities recognized on the date of adoption of this Directive, 2005, and consequently twenty years ago, to allow for the characteristics of the qualification system for doctors and dentists.[195]
Generally, a host Member State, must recognize previous pursuit of the activity in another Member State as sufficient proof of knowledge and aptitude if pursuit as listed by the Member State is contingent upon possession of general, commercial or professional knowledge in the host Member State.[196]
Section 4 regulates the dental basic and specialist training.[197]
The training must, more in general, provide the student with the skills necessary for carrying out all activities involving the prevention, diagnosis and treatment of anomalies and diseases of the teeth, mouth, jaws and associated tissues.[198]
The minimum requirements for the programme of studies leading to evidence of formal qualifications in dentistry are listed and shall include defined subjects.[199] One or more of these subjects may be taught in the context of the other disciplines or in conjunction therewith.
Evidence of basic formal qualifications of dental practitioners, dental specialists, orthodontists and oral surgery are listed.[200]

Annex V to Directive 2005/36/EC contains the evidence of formal qualifications of Doctor of Medicine, specialist doctors, nurses responsible for general care, dental practitioners, specialist dental practitioners, veterinary surgeons, midwives, pharmacists and architects.

[191] Recital 22 Directive 2005/36.
[192] Article 4 Directive2005/36/EC.
[193] Recital 6 Directive 2005/36/EC.
[194] Recital 8 Directive 2005/36/EC.
[195] Recital 20 Directive 2005/36/EC.
[196] Article 16 Directive 2005/36/EC.
[197] Article 36, 37 Directive 2005/36/EC.
[198] Article 34 Directive 2005/36/EC.
[199] V.3 Directive 2005/36/EC.
[200] V.3 Directive 2005/36/EC.

In response to several notifications received from Member States related to qualifications and titles, the Commission released a Delegated Decision.[201]

Figure:

Dentist (V.3)	All Member States registered university title as evidence title.
Oral Surgery (V.3.3)	7 Member States did not register evidence title.
Orthodontist	4 Member States did not register evidence title.
Maxillo-facial surgery (categorized separately, as medical specialism)	14 Member States did not register evidence of title.

Annex V paragraph 5 to the Directive, reflects dissimilarities in the formal qualifications of Specialized dentists and oral surgery that may complicate reimbursement of cross-border care and informed decisions of patients. Member States also have different quality criteria, which even more challenges the informed consent of a patient seeking cross-border healthcare.

Figure:

Member State	Dental practitioner	Specialised dentists	Oral surgery
Belgium	yes	yes	no
Czech Republic	yes	no	no
Denmark	yes	yes	yes
Germany	yes	yes	yes
Estonia	yes	yes	no
Greece	yes	yes	yes
Spain	yes	no	no
France	yes	yes	no
Ireland	yes	yes	yes
Italy	yes	yes	yes
Cyprus	yes	yes	yes
Latvia	yes	yes	no
Lithuania	yes	yes	yes
Luxembourg	yes	no	no
Hungary	yes	yes	yes
Malta	yes	yes	yes
Netherlands	yes	yes	yes
Austria	yes	no	no
Poland	yes	yes	yes
Portugal	yes	no	no
Slovenia	yes	yes	yes
Slovakia	yes	no	no

[201] Decision (EU) 2024/1395 of 5 March 2024 amending Annex V of Directive 2005/36/EC of the European Parliament.

Finland	yes	yes	yes
Sweden	yes	yes	yes

The directive does not provide rules for quality enhancing instruments for the professionals such as requirements for reregistration (including criteria for education and minimum volume of treatment), Continuing Professional Development, nor sub-specialism resulting in significant differences in the EU. These rules differ as shown in **Annex B.**

The EU may support vocational training and collaboration between Member States through Centres of Vocational Excellence.[202]

4.3.2 Directive on patients' rights in cross-border healthcare

"The health systems in the Union are a central component of the Union's high levels of social protection and contribute to social cohesion and social justice as well as to sustainable development. They are also part of the wider framework of services of general interest".[203]

To guarantee the fundamental right to transborder care, Directive 2011/24/EU on the application of patients' rights in cross-border healthcare was implemented. The Directive aims to improve the functioning of the internal market and the free movement of goods, persons and services.[204]
This Directive furthermore forms the basis of cross-border cooperation, recognition of prescriptions, and the European Reference Networks (ERNs) (See 4.3.3).[205]

ECOM published Member State data on cross-border patient healthcare following Directive 2011/24/EU.[206]
Patients seeking transborder care seem to involve mostly neighbouring countries.
The cross-border care directive foresees in a national implementation of prior authorization and or prior notification.

Figure:[207]

[202] European Commission. (n.d.). *Policies and activities*. employement-social-affairs.ec.europe. https://employment-social-affairs.ec.europa.eu/policies-and-activities
[203] Directive 2011/24/EU.
[204] Recital 2 Directive 2011/24/EU.
[205] Regulation (EC) No 883/2004 & Regulation (EC) No 987/2009.
[206] European Commission. (2025). *Member State data on cross-border patient healthcare following Directive 2011/24/EU*. doi: 10.2875/0490716. https://health.ec.europa.eu/document/download/1d8edb6b-8149-4a96-862d-3c06b36efb19_en?filename=crossborder_2023_patient-healthcare_data_en.pdf
[207] European Commission. (2025). *Member State data on cross-border patient healthcare following Directive 2011/24/EU*. doi: 10.2875/0490716. https://health.ec.europa.eu/document/download/1d8edb6b-8149-4a96-862d-3c06b36efb19_en?filename=crossborder_2023_patient-healthcare_data_en.pdf

	Prior Notification, optional process for estimation costs (12 Member States)	*Healthcare not subject to prior notification (15)*
Request for reimbursement/prior authorisation	5973 requests for prior authorisation	*449 069 requests for reimbursement*
Reimbursed/authorised	80.9 % (9.2 million) *	*64.9 % (over 101 million)*

Either planned or unplanned, cross border healthcare is reimbursed according to the conditions and reimbursement rates, among the benefits to which the insured person is entitled, that would have been assumed by the Member State of affiliation.[208] However, the patient must advance the costs and apply for reimbursement upon return to the Member State of affiliation.
Above all, the patient must receive information on standards and guidelines, and which healthcare providers are subject to these standards, and relevant information to make an informed choice.

The crucial words "among the benefits to which the insured person is entitled" may entail unexpected financial consequences where deviating standards and guidelines and/or professional competencies of the home state of the person differ from those accepted in the Member State of treatment.
Crucial elements of coverage in the home state lie in the domain of a professional as established in the home state, and secondly, the treatment, possibly as yardstick for a treatment in conformity with science and practice as established in the home state. The answer to the first question is mostly laid down in national law on healthcare providers and their specialism. The answer to the second question is derived from the national (home state) scientific guidelines and standards. However, even if these are not yet provided, e.g. the quality of an innovative treatment, the state of the art in science in the home state prevails.

Consequently, while the Directive follows national guidelines, standards and adequate information to support an informed choice of the patient seeking dental care, the reality for the oral care patient is more complicated if standards and guidelines are not established nor aligned and common scientific guidelines on the European level are lacking.
Common guidelines and scientific insights and alignment of professional titles or at least a table of comparable oral professions and specialism, does not yet provide full coverage in the home countries.[209] Insurers may have deviating coverage policies.

4.3.3 EU Reference networks

European Reference Networks (ERNs) are cross-border networks that bring together centres of expertise and reference to tackle rare, low prevalence and complex diseases and conditions requiring highly specialized healthcare. ERNs enable specialists in Europe to discuss cases of patients affected by rare, low-prevalence and complex diseases, providing advice on the most appropriate diagnosis and the best treatment.

[208] Article 7 Directive 2011/24/EU.
[209] (ECLI:NL:HR:2023:1528)

The networks must be based on voluntary participation by its members, to contribute to the networks' activities in accordance with the legislation of the Member State where the members are established. The network shall be open to new healthcare providers, provided that such healthcare providers fulfil all the required conditions and criteria set, therefore.
In March 2017, 24 European Reference Networks (ERNs) were created under Directive 2011/24/EU, covering clusters of rare, complex and low-prevalence diseases.
There is no ERN for oral care in these selected categories.

The eHealth Network, set up by Directive 2011/24/EU, is the main strategic and governance body at EU level to work towards interoperability of cross-border eHealth services. The Network has the task of producing guidelines on eHealth, as foreseen in the same Directive, and on an interoperability framework for cross border eHealth services.

4.3.4 Directive on ionizing radiation: quality standards for medical exposure to radiation

"A high level of competence and a clear definition of responsibilities and tasks among all professionals involved in medical exposure is fundamental to ensure adequate protection of patients undergoing medical radio diagnostic and radiotherapeutic procedures. This applies to medical doctors, dentists and other health professionals entitled to take clinical responsibility."[210]

The Euratom Treaty provides for the establishment of uniform safety standards to protect the health of workers and of the public.[211] To this end the Euratom Treaty defines "basic standards" for the protection of the health of workers and the public against the dangers arising from ionizing radiation.[212]
Member States may adopt or maintain more stringent measures without prejudice to the free movement of goods and services in the internal market.[213]
The formulated rules apply to undertakings, defined as natural or legal persons who have legal responsibility under national law for carrying out a practice, or for a radiation source (including cases where the owner or holder of a radiation source does not conduct related human activities).[214]
The rules cover training, procedures, information and medical records for (categories of) exposed workers.[215]
The Directive tasks Member States to ensure that any medical exposure takes place under the clinical responsibility of a practitioner entailing that all medical radiological equipment in use is kept under strict surveillance regarding radiation protection and an up-to-date inventory of

[210] Recital 29 Directive 2013/59/EURATOM.
[211] Article 2 Directive 2013/59/EURATOM.
[212] Recital 1 & Article 30 Directive 2013/59/EURATOM.
[213] Recital 5 Directive 2013/59/EURATOM.
[214] Recital 98 Directive 2013/59/EURATOM.
[215] Article 15 & 31 Directive 2013/59/EURATOM.

medical radiological equipment for each medical radiological installation is available to the competent authority.[216]

4.3.5 Transition to regulation for general products

The general product safety regulation enacted in 2023 (regulation (EU) 2023/988) repeals the Directive of 2001 on general product safety.
The objective of the Regulation is to improve the functioning of the internal market while providing for a high level of safety and protection of consumer products.[217]
Products which are designed exclusively for professional use, but which have subsequently migrated to the consumer market, fall under the scope of this Regulation as they could pose risks to the health and safety of consumers when used under reasonably foreseeable conditions.[218]

4.3.6 The General Data Protection Regulation (GDPR)

"...all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services as referred to in Directive 2011/24/EU of the European Parliament and of the Council (1) to that natural person; a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test."[219]

The GDPR (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons regarding the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) has been applicable since 24 May 2018.

Figure:

The Regulation aims to:
1. protect individuals when their data are being processed by the private sector and most of the

[216] Recital 8, 60, 68 & 69 Directive 2013/59/EURATOM.
[217] Article 1 Regulation (EU) 2023/988.
[218] Recital 9 Regulation (EU) 2023/988.
[219] Recital 35 GDPR.

public sector.
2. allow individuals to better control their personal data.

The GDPR not only strengthens individuals' fundamental rights in the digital age, but also stimulates the free movement of personal data and facilitates business by clarifying rules for companies and public bodies in the digital single market.
Other than its predecessor (Directive 95/46/EC), the GDPR significantly reduces the fragmentation in different national systems and unnecessary administrative burdens. The provisions of this Act revolve around the core concepts and definitions of data, personal data, anonymous, controller, processor and the European Data Protection Board.[220]
Personal data are defined as any information relating to an identified or identifiable natural person ('data subject'). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.[221]
Healthcare providers, as controllers, process sensitive types of personal data including medical histories, medical images, diagnoses and/ or test results.[222] Safeguarding this information is of the essence.
The informed consent forms the fundamental basis for the processing of these data. This consent is revocable at any time.

The GDPR is based on the principle of data minimization, whereby the healthcare professional should ensure that only authorized staff has access to patient data to the extent needed for the purpose of their access. The GDPR furthermore entails measures for secure facilities, performance of risk assessments, and protective measures as anonymization and pseudonymization and a data breach response plan to act promptly within the timelines set by the regulation.
The European Data Protection Board releases guidelines, recommendations and best practices.[223]

4.3.7 Medical Device Regulation[224] and the In Vitro Diagnostics Regulation[225]

"The Medical Device Regulation (MDR) is a new regulation that will create a robust, transparent, and sustainable regulatory framework that improves clinical safety and creates fair market

[220] Article 4 GDPR.
[221] Article 4(1) GDPR.
[222] Article 4(7) GDPR.
[223] EDPB. (n.d.). *Guidelines, Recommendations, Best Practices.* edpb.europa.eu. https://www.edpb.europa.eu/our-work-tools/general-guidance/guidelines-recommendations-best-practices_en
[224] REGULATION (EU) 2017/745.
[225] Regulation (EU) 2017/746.

access for manufacturers and healthcare professionals.
Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding medical devices should be introduced, to improve health and safety."[226]

The Medical Device Regulation (MDR) establishes a reinforced legal system for medical devices that supports quality and safety and prioritize transparency and patient access to information when placed on the market and /or put into service.
The Regulation sets common detailed standards for medical devices used by (oral) healthcare professionals, simultaneously allowing a free movement of these devices in the EU.
The structure of the MDR is built on harmonized standards, as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council, as a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as those relating to quality, post marketing surveillance and risk management.

The MDR introduces a single legislative act for all medical devices including implantable medical devices. Sutures, staples, dental fillings, dental braces, tooth crowns, screws, plates, wires, pins, clips and connectors are exempted.
The MDR contains obligations for manufacturers to ensure that patients who are implanted with a device should be given clear and easily accessible essential information allowing the implanted device to be identified and other relevant information about the device, for example indications as to whether or not it is compatible with certain diagnostic devices. Manufactures must provide an "Implant card" containing relevant information (including the Unique Device Identification (UDI) related to the device with which the patient have been implanted.
The MDR introduces the Unique Devices Identification (UDI) system for traceability of devices.[227]

The rules of the IVDR (In Vitro Diagnostic Regulation 2017/746), are aligned with the structure of the MDR. The rules are based on a risk-based classification system (Class A, B, C and D) to ensure the safety and effectiveness of in vitro diagnostics. At present, IVD is used limitedly in the oral healthcare practice.

4.3.8 Regulation on Health Technology Assessment (HTAR):

"In that regard, the joint clinical assessments provided for by this Regulation constitute a

[226] Recital 4 MDR.
[227] Article 27 (1)(a) MDR.

scientific analysis of the relative effects of the health technology as assessed on the health outcomes against the chosen parameters which are based on the assessment scope. The scientific analysis will further include consideration of the degree of certainty of the relative effects, taking into account the strengths and limitations of the available evidence."[228]

The Regulation on health technology assessment ((EU) 2021/2282) has been applicable since 12 January 2025.
The introducing procedural reference and recitals[229] reflect the balancing act promulgating from article 168(7) TFEU and the outcome thereof.

Figure:

" *The outcome of joint clinical assessments should therefore not affect the discretion of Member States to carry out assessments on the clinical added value of the health technologies concerned or predetermine subsequent decisions on pricing and reimbursement of health technologies, including the fixing of criteria for such pricing and reimbursement decisions, which could depend on both clinical and non-clinical considerations individually, or together, and which remain solely a matter of national competence.* "

The HTAR aims to establish a support framework and procedures for cooperation of Member States on health technologies at Union level.
Simultaneously, the regulation entails a mechanism for information, data, analyses and other evidence for joint assessment to be submitted only once at Union Level and common rules and methodologies for the joint clinical assessment of healthcare technologies.
However, the HTAR explicates that Member States' competence, to draw conclusions on the relative effectiveness of health technologies or to make decisions on the use of a health technology in their specific national health context, must be respected. Furthermore, the HTAR may not interfere with the exclusive national competence of Member States, including those for national pricing and reimbursement decisions, or affect any other competences which concern Member States' management and delivery of health services or medical care or the allocation of resources assigned to them.[230]

4.3.9 Artificial Intelligence Act (AI)

"In order to ensure a consistent and high level of protection of public interests as regards health, safety and fundamental rights, common rules for high-risk AI systems should be established. Those rules should be consistent with the Charter, non-discriminatory and in line with the Union's international trade commitments. They should also take into account the European Declaration on Digital Rights and Principles for the Digital Decade and the Ethics

[228] Recital 14 HTAR.
[229] Recital 14 HTAR.
[230] Article 1 HTAR.

guidelines for trustworthy AI of the High-Level Expert Group on Artificial Intelligence (AI HLEG).”[231]

The AI Regulation, laying down harmonized rules for Artificial Intelligence (AI) (Regulation 2024/1689), will becomes effective gradually. The AI Act sets harmonized rules on artificial intelligence to improve the functioning of the internal market by laying down a uniform legal framework to promote the uptake of human centric and trustworthy AI while ensuring a high level of protection of health, safety, fundamental rights and to support innovation.

The AI Act fosters a sufficient level of AI literacy for providers and deployers (users) to ensure appropriate compliance and proper follow-up actions, considering their technical knowledge and the context of the AI-system to be used.[232]
The AI Act follows a risk-based approach as a basis for proportionate and an effective set of binding rules. AI systems identified as high-risk are limited to systems that have a significant harmful impact on the health, safety and fundamental rights of persons.
For the development and assessment of high-risk AI systems, access to high-quality data and a risk-management system is needed.[233]
High-risk systems must be designed and developed in such a way that they can be effectively overseen by natural persons.[234]
Deployers (users) of high-risk systems must take technical and appropriate measures, assign human oversight measures as indicated by the provider, and monitor the operation of the AI system. Deployers (users) of high-risk systems may have to perform a Fundamental Rights Impact Assessment.

4.3.10 European Health Data Space Regulation (EHDS):

"More and more individuals living in the Union cross national borders to work, study, visit relatives or for other reasons.”[235]
“The relevance of different categories of electronic health data for different healthcare scenarios varies. Different categories have also achieved different levels of maturity as regards standardization, and therefore the implementation of mechanisms for their exchange may be more or less complex depending on the category.”[236]

The EHDS was enacted on 6 March 2025 and shall be effective as of 26 March 2027 respecting transition periods. The EHDS is a specific data access system for primary use of health data and secondary use of data for research, innovation, policy making and public health. The EHDS

[231] Recital 7 AI Act.
[232] Article 3 AI Act.
[233] Recital 65 AI Act.
[234] Article 14 AI Act.
[235] Recital 6 Regulation 2025/327 (EHDS).
[236] Recital 25 Regulation 2025/327 (EHDS).

is based on common standards and practices, infrastructures and a governance framework fostering a genuine single market for electronic health record systems, relevant medical devices, high-risk AI-systems and regulator activities.
The regulation was initiated and adopted to facilitate the free movement of personal electronic health data across the EU. The EHDS enables individuals to access, control and share their electronic data cross borders for healthcare delivering when travelling within the EU and to empower them to share those data.
The EHDS lays down common rules and mechanisms for primary use of personal data and secondary use of electronic health data and establishes a cross-border infrastructure enabling the primary use of personal electronic health data across the Union.[237]

The leading principle of the EHDS is that where personal electronic health data are being made available to a healthcare provider or pharmacy by a natural person, or are transmitted by a another controller in the EU in the European Electronic Health Record Exchange Format (EEHRxF), that format should be accepted and the recipient should be able to read the data and use them for the provision of healthcare or for dispensation of prescriptions.[238]
The rules for primary use are, consequently, built on European Health Records (EHR) for the provision of care, including oral care, definitions and implementation of the European Electronic Health Record Exchange Format (EEHRxF), interoperability and patients' rights to support cross-border healthcare.[239]

Healthcare providers, including oral care professionals, must register the relevant personal electronic health data fully or partially under at least the priority categories in an electronic format in an EHR system.[240]
Priority categories of personal electronic health data for primary use are defined.[241] Member States may provide additional categories.
The EHDS enables individuals to access, control and share their electronic data cross borders for healthcare delivery when travelling.

The Commission shall, by 26 March 2027, lay down the technical specifications of the priority categories of health data.[242] In March 2029, key parts of the EHDS Regulation will be applicable, including, for primary use, the exchange of the first group of priority categories of health data (Patient Summaries, ePrescriptions/dispensations) in all EU Member States.
Rules on secondary use will also start to apply for most data categories (e.g. data from electronic health records). In March 2031, the exchange of the second group of priority categories of health data (medical images, lab results, and hospital discharge reports) should be operational in all EU Member States. Rules on secondary use will also start to apply for the remaining data categories (e.g. genomic data).
The regulation stipulates in its recitals that Member States must observe ethical principles.[243]

[237] Article 1 Regulation 2025/327 (EHDS).
[238] Recital 26 Regulation 2025/327 (EHDS).
[239] Article 2 (1)(b) Regulation 2025/327 (EHDS).
[240] Article 13 (1) Regulation 2025/327 (EHDS).
[241] Article 14 (1) Regulation 2025/327 (EHDS).
[242] Article 15 (1) Regulation 2025/327 (EHDS).
[243] Recital 24 Regulation 2025/327 (EHDS).

Recital 28 of the EHDS emphasizes the importance of telemedicine. Telemedicine has the potential to reduce inequalities, reinforce the free movement of Union citizens across borders, and facilitate provision of care in remote regions.[244]
The growing importance of telemedicine, as an important tool that provide patients with access to care and that may tackle inequities, is weighed against the responsibility of Member States for their healthcare policy and regulations on telemedicine, including online pharmacies, and reimbursement for these services in line with their national legislation to the extent, however, that they may not create barriers to the movement of electronic health data in the context of cross-border healthcare.[245]

TEHDAS (Towards the European Health Data Space), was formed in May 2024 and is based on the European Commission's EU4Health Programme. The project TEHDAS is carried out by multiple Member States to create guidelines for secondary use under the EHDS.

4.3.11 Legislative framework medicinal products

"Common standards of quality, safety and efficacy for the authorization of medicinal products constitute a cross-border public health issue that affects all Member States and thus can be regulated effectively only at EU level"[246]

In 1965, the general pharmaceutical legislation was established with the dual objective of safeguarding public health and an internal market for medicines. Over the years, the legislative framework has covered various topics such as quality requirements for product development and market authorization, all based on the fundamental principle that a marketing authorization is granted only to medicines with a positive benefit-risk balance after assessment of their quality, safety and efficacy. An important revision was initiated and adopted on post authorization monitoring (pharmacovigilance) and thereafter falsified medicines.[247]
The transparency Directive (2004/109/EC) regulates procedural aspects of the Member States' pricing and reimbursement decisions excluding the level of price.
The proposal initiated in 2023 (April,4 2023), on the Union code relating to medicinal products for human use and repealing Directive 2001/83/EC and Directive 2009/35/EC, complements and further develops the roles of the Member States and competent authorities of the Member States.

Recently, a proposal for a resolution was initiated by the European Parliament to strengthen the security of supply and ensure the availability of critical medicinal products and of medicinal products of common interest. The proposal was firmly based on article 35 of the Charter of Human Rights which states that the Union should ensure a high level of human health protection in all policies and activities.
The primary objective of the proposal builds further on this yardstick by adjoining the consideration that the availability of safe, efficacious and high-quality medicinal products is considered vital to achieving safeguarding public health across the Union by strengthening the

[244] Recital 28 Regulation 2025/327 (EHDS).
[245] Recital 28 Regulation 2025/327 (EHDS).
[246] Explanatory memorandum on the Union code relating to medicinal products for human use and repealing Directive 2001/83/EC and Directive 2009/35/EC.
[247] Directive 2011/83/EC.

security of supply and ensure the availability of critical medicinal products and of medicinal products of common interest.[248]

4.3.12 NIS2-Directive

"The growing interdependencies are the result of an increasingly cross-border and interdependent network of service provision using key infrastructures across the Union in sectors such as energy, transport, digital infrastructure, drinking water and waste water, health (...), as well as space in so far as the provision of certain services depending on ground-based infrastructures that are owned, managed and operated either by Member States or by private parties is concerned, therefore not covering infrastructures owned, managed or operated by or on behalf of the Union as part of its space programme. Those interdependencies mean that any disruption, even one initially confined to one entity or one sector, can have cascading effects more broadly, potentially resulting in far-reaching and long-lasting negative impacts in the delivery of services across the internal market. The intensified cyberattacks during the COVID-19 pandemic have shown the vulnerability of increasingly interdependent societies in the face of low-probability risks."[249]

Directive 2022/2555, on measures for a high common level of cybersecurity across the Union, sets out common rules to keep Europe safe from cyber threats. It covers 18 important sectors, including healthcare. The idea is that every EU country strengthens its own cybersecurity and works closely with others when cyber incidents happen across borders.

Cybersecurity means protecting computer systems, networks, and data from attacks or misuse. The goal of cybersecurity is to protect network and information systems (NIS), their users, and other affected individuals from cyber incidents and threats. The NIS2 Directive replaces NIS1 (2016). The new version includes more sectors, has clearer rules, and gives governments stronger powers to check and enforce compliance.

Figure:

- Develop a national cybersecurity strategy that includes plans for supply chain security, fixing software weaknesses, and teaching people about cybersecurity.
- Keep an updated list of key service providers (for example, hospitals or energy suppliers) that must follow these rules.
- Report serious cyber incidents quickly and take steps to prevent them from happening again.

NIS2 does not just cover traditional sectors like energy, healthcare, and finance. It includes amongst others online and digital services as well.

[248] European Commission (2025). *Proposal for a regulation of the European parliament and of the council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest.* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC0102, amending Regulation (EU) 2024/795.
[249] Recital 37 NIS-Directive.

Medium and large companies in these areas must take proper cybersecurity measures and inform national authorities about major cyber incidents that could cause serious disruption.

Under NIS2, company leaders are responsible for making sure their organizations follow the rules. This means cybersecurity is no longer just an IT issue, but rather an organizational issue that may be monitored for compliance by bodies authorized to verify compliance and impose penalties.[250]

4.3.13 Standards and data platforms:

"Safe access to healthcare for patients is a basic right nowadays."[251]

European standards are being developed by three officially recognized standard organizations of which the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) supported and formed by standardization bodies of 34 European countries.[252] More than 20 technical committees, dedicated to healthcare, support the development of European Standards setting safety, quality, and performance requirements for medical devices that are put on the European market. The standard organizations have been officially recognized by the European Commission as being responsible for developing and defining voluntary standards at European level.[253]
Their members are national standardisation bodies, governmental bodies and other authorities, including the EC and the European Free Trade Association (AFTA).
CEN cooperates internationally with ISO, while CENELEC cooperates with the International Electrotechnical Commission (IEC).
National Member States may, through their national technical standardization bodies represented in ISO, CEN and or CENELEC support and/or impose security certification obligations for processing personal data and securing technical systems for healthcare providers including ISO-27001 certification and NEN 7510 and NEN 7512 standards for processing personal data.

The CEN International Patient Summary Standard and implementation guidance are the result of the work performed under a Grant Agreement with the European Commission and EFTA (SA/CEN/GROW/EFTA/000/2015-16). The certification activities supported by CEN, include health and safety as well as health and ICT.

CEN furthermore supports standardization activities in several sectors including healthcare, ICT, materials and healthcare products in support of the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR) to ensure a smooth citation of healthcare standards in the Official Journal of the European Union.
The standards published are developed by experts, established by consensus and adopted by

[250] *NIS2 Directive: securing network and information systems*. digital-strategy.ec.europe. https://digital-strategy.ec.europa.eu/en/policies/nis2-directive
[251] CENELEC. (n.d.). *Healthcare*. cencenelec. https://www.cencenelec.eu/areas-of-work/cen-sectors/healthcare/
[252] Regulation (EU) 1025/2012.
[253] CENELEC. *Healthcare*. https://www.cencenelec.eu/areas-of-work/cen-sectors/healthcare/

the Members of CEN and/or CENELEC.
They enable businesses to ensure that their products or services comply with essential requirements that have been set out in European legislation (EU Directives).
Although the standards are not legally enforceable, considerable importance is attributed to their validity.

4.4. Research Infrastructures

The framework containing the procedures and conditions for setting-up European Research Infrastructures at Community level was established in 2009 through the "ERIC Regulation" (Council Regulation (EC) No 723/2009 on the Community legal framework for a European Research Infrastructure Consortium) in order to facilitate the establishment and the operation of large European research infrastructures among several Member States and associated countries. As laid down in the ERIC Regulation, the principal task of an ERIC shall be to establish and operate a research infrastructure. This research infrastructure must contribute to, amongst others, the mobility of knowledge and/or researchers within the European Research Area and contribute to the dissemination and optimization of the results of activities in Community research.

Figure:

The following entities may become members (article 9 ERIC Regulation):

a. Member States (at least three).
b. Associated countries.
c. Third countries other than associated countries.
d. Intergovernmental organizations.

4.5 Digitalization and telemedicine: eHealth Action Plan 2012-2020 and eHealth Network to work closely together

"Information and Communication Technologies (ICT) applied to health and healthcare systems can increase their efficiency, improve quality of life and unlock innovation in health markets"[254]

Multiple initiatives and plans have been initiated to address barriers, improve informed decision making and support telemedicine.

4.5.1 eHealth Action Plan 2012-2020[255]

[254] European Commission. (2012). *EHealth Action Plan 2012-2020*. https://health.ec.europa.eu/document/download/39c9a1ee-6afa-4ab9-a472-ddeac925d14f_en?filename=com_2012_736_en.pdf
[255] European Commission. (2012). *EHealth Action Plan 2012-2020*. https://health.ec.europa.eu/document/download/39c9a1ee-6afa-4ab9-a472-ddeac925d14f_en?filename=com_2012_736_en.pdf

The eHealth Action Plan 2012-2020 – innovative healthcare for the 21st century was launched in 2012, in the context of the Europe 2020 Strategy for smart, sustainable and inclusive growth. Following the eHealth Action plan 2004, the new eHealth Action Plan aimed to address and remove barriers experienced, in line with the objectives of the Europe 2020 Strategy and the Digital Agenda for Europe. This plan pursued various objectives including the description of EU's role and the encouragement to Member States and stakeholders to work together.

eHealth offers benefits such as improving efficiency and effectiveness of systems and their control, and the reduction of expenditures. The plan forms one of the concrete actions to promote free movement of EU citizens within the EU.[256]
The Action Plan encourages national and regional authorities, healthcare and social care professionals, industry, patients, service providers, researchers and EU Institutions to closely work together.[257]
The basis of the eHealth interoperability, required for this cooperation, is the eHealth Network created through Directive 2011/24/EU on patients' rights in cross-border healthcare.

This Action Plan foresees in an explicit role for patients. Enhancing health literacy empowers patients to manage their health and their healthcare more proactively, to prevent poor health and make informed choices.
The EU expresses its coordinating role for the support of Member States, patient organizations and stakeholders to help patients in an effective manner, to benefit from cross-border healthcare.[258]
Health information and knowledge systems serve evidence-based decision-making by patients. To this end, the system should consist of, *inter alia*, the use of existing instruments and, as appropriate, further development of standardized health information and tools for monitoring health, collection and analysis.
The eHealth Network was implemented in 2019 and non-binding Recommendation on a European Electronic Health Record Exchange Format were adopted.[259]

The non-binding Recommendations provide guidance to Member States and facilitate the exchange of good practices concerning the development of different digital health services, such as telemedicine, mHealth, or new technologies in big data and artificial intelligence.[260]
The guidelines provide recommendations for the patient summary including allergies, medical alerts, vaccinations, current problems, pregnancies as well as device and implant information.[261]
Code systems already implemented in eHDSI , ICD and SNOMED CT GPS, are prioritized.

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[256] European Commission. (2012). *EHealth Action Plan 2012-2020,* p. 4. https://health.ec.europa.eu/document/download/39c9a1ee-6afa-4ab9-a472-ddeac925d14f_en?filename=com_2012_736_en.pdf
[257] European Commission. (2012). *EHealth Action Plan 2012-2020,* p. 6. https://health.ec.europa.eu/document/download/39c9a1ee-6afa-4ab9-a472-ddeac925d14f_en?filename=com_2012_736_en.pdf
[258] Consideration 12 Directive 2011/24/EU.
[259] Decision 2019/1765, 22 October 2019, EU 2019/243 .
[260] Article 4(c) Decision 2019/1765.
[261] eHealth Network. (2024). *Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU.* https://health.ec.europa.eu/system/files/2023-10/ehn_guidelines_patientsummary_en.pdf

4.5.2 Telemedicine

"the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients".[262]

Although the roots of telemedicine stretch further back for several decades, the COVID-19 pandemic pushed telemedicine more to the foreground.
Remote healthcare service provision is, by definition, based on technology and telecommunication to bridge the distance between the healthcare provider and the citizen.
Remote healthcare services may be nationally and internationally, either intended or not.
The regulatory framework for the technology applied depends on the intended use of the technology and the specific context.
Technology used for treatment, prevention and monitoring within healthcare is largely subject to a European regulatory framework.

Telemedicine may entail monitoring. The health parameters extend from physiological parameters, such as body temperature, through wearable sensors for biochemical signal detection.
Gradually, this form of medical research may also be applied to skin, eyes, and oral cavities to detect the various parameters in a non-invasive way .
Further development of the technology and research may support improvement of, and access to, oral health services in low population areas, cost effectiveness and access to oral care by vulnerable groups and disabled persons. The technology may improve intercollegiate consultation within the profession and other disciplines as well.[263]

In its accompanying working document on the applicability of the existing EU legal framework to telemedicine services, the Commission clarifies and summarizes the benefits of telemedicine services while explaining legal context and issues.[264]

Figure:

In order to provide telemedicine cross-border within the EU, healthcare professionals first have to look for the responses to the following questions

- *Licensing: Does the telemedicine provider also need to be licensed/registered in the Member State of the patient?*
- *Data Protection: What are the conditions for the legitimate processing of personal data related to health?*
- *Reimbursement: Will the cross-border telemedicine service be reimbursed?*

[262] European Commission. (2012). *EHealth Action Plan 2012-2020,* p. 68. https://health.ec.europa.eu/document/download/39c9a1ee-6afa-4ab9-a472-ddeac925d14f_en?filename=com_2012_736_en.pdf
[263] Li Y., Tang H., Liu y., Qiao Y., Xia H. & Zhou J. (2022). Oral wearable sensors: Health management based on the oral cavity. Biosensors and Bioelectronics (10). https://doi.org/10.1016/j.biosx.2022.100135
[264] European Commission. (2012). *Staff Working Document on the applicability of the existing EU legal framework to telemedicine services: EHealth Action Plan 2012-2020.* https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0414:FIN:EN:PDF

- *Liability: What is the liability regime applicable in case damage arises?*
- *Relevant jurisdiction and applicable law in case of damage: What are the relevant jurisdiction and the law applicable in case damage arises?*

The Working Document fosters support to national administrations and implementing actors, by providing them with clarification on how telemedicine is affected by current EU legislation. The vision is based on a general flow of healthcare services: providing information (websites and telecommunication), treatment and processing of medical data and healthcare records. This vision seems to include targeted prevention, diagnosis, treatment and follow-up as well. Based on this premise, telemedicine falls under the scope of Articles 56 and 57 of the Treaty on the Functioning of the European Union (TFEU) and is subject to the principle of free movement of services.

In contrast, while the health telemedicine service provision should, as a service, be subject to the general freedom regarding the free movement of services[265], the healthcare provider and citizen may be in different jurisdictions, which may bear as a consequence that different rules on quality standards for healthcare services and the healthcare providers apply.[266] The recommendations of the Committee include detailed advice on the accessibility of healthcare providers on the accessibility of their websites.[267]

4.5.4 EU Ethical principles for digital health

"The efficiency of health systems relies to a large extent on the way they are perceived, understood, and trusted, as well as on the accessibility of the services they offer, whilst ensuring respect for human rights.
Improving the health literacy of people and systems has the potential to improve the safety and quality of health care, reduce disparities in health outcomes thereby promoting more prosperous and equitable societies. It is an asset for healthcare, disease prevention and health promotion. It generates a return on social and economic investments which helps to save time, costs, and lives."[268]

In the framework of its Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025), the Council of Europe Steering Committee for Human Rights in the fields of

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[265] Bird & Bird. (2025). *An international overview of the regulatory legislation concerning telemedicine.* https://www.twobirds.com/-/media/new-website-content/insights/pdfs/telemedicine-brochure_may-2025.pdf

[266] WHO Regional Office for Europe. (2024). *Taking the pulse of quality of care and patient safety in the WHO European Region: Multidimensional analysis and future prospects.* Licence (CC BY-NC-SA 3.0 IGO. https://splsportugal.com/wp-content/uploads/2023/07/9789289061568-eng.pdf

[267] WHO. (2025). *European health report 2024: keeping health high on the agenda.* Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/europe/publications/i/item/WHO-EURO-2025-10668-50440-76183

[268] Council of Europe. (2023). *Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025).* https://rm.coe.int/strategic-action-plan-final-e/1680a2c5d2

Biomedicine and Health (CDBIO), initiated a Guide to health literacy for equitable access to healthcare.
This Guide aims to empower the whole population, including those in vulnerable situations, to be more effective in accessing healthcare services and in making appropriate decisions regarding their health. Appropriate decisions need a solid basis of health information provided in such wording and presentation that the whole population understand the health information and know what healthcare services are available and how best to access them.
The Guide presents examples based on actions, tools and good practice including on access to digital spaces to understand and use health services as digital health communication.
Following the Guide, healthcare services should be easy to use and adapted to individual needs.
In Januari 2022, 16 ethical principles, including the principle of health professional-patient confidentiality in the application of digital health, were adopted.[269]

4.6 Organizations in the EU supporting quality of oral care

Multiple bodies and associations within the EU support quality of oral health. Mostly national associations are represented in these entities and support their mission.

4.6.1 Council of European Chief Dental Officers (CECDO)

"There is a need for comprehensive Pan-European activities on establishing standards and guidelines and information should be exchanged. The domains within the guidelines should include a number of core topics such as infection control, radiation safety, patient records and confidentiality and better information exchange between all health care, oral health care workers and the public."[270]

CECDO, inaugurated in The Hague in 1992, is the council of Chief Dental Officers in Europe. Chief Dental Officers are the senior professional officials or civil servants who act as advisers to national governments in Europe on matters related to oral health.
CECDO has delegates from nearly all EU countries and countries from the EEA.
The organization collects data and operates the CECDO database for information relating to Oral Health Workforce, Dental Education, Costs and Oral Health Indicators as well as examples of guidelines, oral health plans and/or strategies relevant to oral health in the European region.
CECDO has published several position papers and reports including the reports on Dental Specialties and Continuing Professional Education.

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[269] Council of Europe. (n.d.). *Access to digital spaces to understand and use health services.* coe.int. https://www.coe.int/en/web/human-rights-and-biomedicine/access-to-digital-spaces-to-understand-and-use-health-services/-/highest_rated_assets/nTmcJLi8P0UU/content/european-union-

[270] he Council of European Chief Dental Officers (CECDO). (2012). *CECDO position paper on public-private mix.* https://cecdo.org/wp-content/uploads/2014/10/CECDO-POSITION-PAPER-ON-PUBLIC-v-PRIVATE-Provision-of-Care_April-2012.pdf and CECDO. (2012). *CECDO position paper on specialization in dentistry*. https://cecdo.org/wp-content/uploads/2014/10/CECDO-position-paper-on-Specialisation-in-Dentistry_April2012.pdf

4.6.2 The Council of European Dentists (CED)

"Dental practices rely on evidence based clinical guidelines and recommendations developed by healthcare professionals."

Established in 1961, CED represents dentists from 30 European countries and promotes the interests of the national dental organizations, dental chambers and their members. The organization strives to defend high standards of oral healthcare and effective patient safety centred professional practice across Europe. Its Working Groups and Task Forces work on issues including oral health promotion, patient safety, infection control, medical devices, dentists' qualifications, mobility of dentists and patients, competition policy and eHealth.[271]
The Council published the extensive CED manual of dental practice for the first time in 1997. The manual, commissioned by CED, was updated regularly up to 2015.[272]
The manual provides information on legal and ethical regulations, dental training requirements, and the healthcare systems across the EU.

4.6.3 Platform for Better Oral Health

"Strong primary care (PC) produces better health outcomes against lower costs and contributes to equity of care"

This multi stakeholder Platform was founded in 2010 to unite experts, professionals and organizations committed to improve oral health across Europe. Its mission is to advance oral health, champion cost-effectiveness, disease prevention and to highlight its role in overall health and tackling inequalities across Europe.[273] The Platform encourages sharing and adoption of best practices in oral health across European countries through its members and partnerships. The Platform considers the exchange of information between members, generating data and evidence key for achieving its mission.
The Platform presented, in 2015, the Oral Health Challenge in Europe and the European Health Report Card, measuring progress towards achieving targets.[274] Key findings covered prevention and investment. In this period, ten years ago, programmes for prevention of oral diseases and promotion of good oral health already existed and appeared to be cost effective. The report emphasises the possibility of establishing evidence-based interventions to cover areas and populations that are neglected by current policies and programmes and a comprehensive strategy to ensure that programmes, such as some of those identified in the overview, are

[271] Council of European Dentists (CED). (2015). CED resolution on standardization. In *cedentists.eu*. https://www.cedentists.eu/wp-content/uploads/2023/09/Document-titleEN-4.pdf and Council of European Dentists (CED). (2015). *Manual of dental practice 2015*. https://www.cedentists.eu/wp-content/uploads/2023/08/EU-Manual-2015.pdf

[272] Kravitz A.S., Bullock A., Cowpe J. & Barnes E. (2015). *Manual of Practice 2015 (Edition 5.1)*. https://www.kavo.co.jp/wp-content/uploads/2024/09/EU_MANUAL_OF_DENTAL_PRACTICE_E5.1.pdf
[273] Oralhealthplatform. (n.d.) *About us.* oralhealthplatform. https://www.oralhealthplatform.eu/about-us/.
[274] Platform for Better Oral Health in Europe. (2015). Platform announces recommendations for EU-wide action on oral health. *British Dental Journal 219, 473.* https://doi.org/10.1038/sj.bdj.2015.872

rolled-out and sustained.

4.6.4 European Patients Forum

"Promoting the principles of meaningful patient involvement in projects, policy and health systems via capacity building activities."[275]

EPF formulates several goals and missions including to promote meaningful, systematic and structured patient involvement in policymaking, research and in shaping healthcare practices that empower patients to be active partners in care and to engage in the digital transformation of healthcare in Europe. Its 78 members represent specific patient groups, active at EU level and national coalitions of patients. EPF supports equity and equitable access to high-quality healthcare for all patients. EPF engages in the digital transformation of healthcare in Europe to support safe, high-quality, more participatory, and person-centred healthcare that brings better outcomes for patients and value for society.

4.6.5 European Patients' Academy on Therapeutic Innovation

The organization aims at enhancing patient involvement by providing information, education, and opportunities for collaboration for patients and researchers throughout all aspects.[276]

4.6.6 European Medical Association (EMA)

Created over 100 years ago, today EMA (in this context the medical association) is represented by associate members of all Member States and multiple non-Member States.
EMA publishes books on general healthcare topics including new strategies to advance (Pre)Diabetes Care, integrated approach and Health care Overview.

The public information does not show involvement of oral health professionals or relationship with oral health.

4.6.7 The International Agency for Research on Cancer (IARC)

"Each year, nearly 390 000 people are diagnosed with oral cancer and 190 000 people die from the disease globally. Oral cancer is the 16th most diagnosed cancer type and the 15th most common cause of cancer death."[277]

The WHO is the parent organization of the International Agency for Research on Cancer (IARC) established in Lyon (France). IARC functions as the specialized cancer agency of the WHO. The objective of IARC is to promote international collaboration in cancer research, including oral health. On the 2025 oral health day, the Oral Cancer Team presented a video on causes,

[275] European Patients' Forum (EPF). (2020). *Strategic Plan 2021-2026,* p. 16. https://www.eu-patient.eu/globalassets/epf-strategic-plan-2021-2026-final.pdf
[276] European Patient's Forum (EPF). (n.d.). *The European Patients' Academy (EUPATI)*. eu-patient. https://www.eu-patient.eu/projects/eupati2/
[277] International Agency for Research on Cancer. (2023). *Cancer Types Teams: Oral Cancer Team (OCT).* iarc.who.int. https://www.iarc.who.int/teams-oct/

burden, and symptoms of oral cancer.
The aim of the Oral Cancer Team is to develop innovative and collaborative research across multidisciplinary themes.

4.6.8 Insurance Europe Federation

"Raise awareness of health risks and health prevention among citizens. Policymakers can launch awareness-raising campaigns to promote routine check-ups and preventative action to support insurability."[278]

Insurance Europe is a European insurance and reinsurance federation. Through its 39 member associations, the national insurance associations, it represents 922,000 employees and 4,900 reinsurance undertakings that account for around 95% of total European premium income.

Insurance Europe publishes statistics and contributes to EC's calls related to health and health development regularly.
The statistics include the role of private insurers in health in terms of extending, complementing and substituting.[279]
In its report "European Insurance in Figures 2020", Insurance Europe notes that the role of private insurers differs significantly across Europe due to differences in the way national healthcare systems are organized and financed. In addition, three systems are distinguished.

Figure:[280]

Supplementary	Offers faster access to treatment, and a wider choice of healthcare providers or enhanced services.
Complementary	Covers excluded charges or services to complement public schemes.
Substitute	Provides cover for people who are not eligible for, or who opt out of, public schemes.

4.6.9 European Public Health Association (EUPHA)

"Public health monitoring is useless without public health reporting. The major aims of public health reporting are to communicate the state of health of a population to 'all who need to know' and to support the preparatory as well as evaluative phases of health policy making and

[278] Insurance Europe. (2024). *Insurance matters: Health*.
https://www.bing.com/insurance+europe+2024+Raise+awareness+of+health+risks+and+health+prevention+among+citizens.++Policymakers+can+launch+awareness-raising+campaigns+to+promote+routine+check-ups+and+preventative+action+to+support+insurability
[279] Insurance Europe. (2020). *European Insurance in Figures: 2020 data*.
https://www.bing.com/insurance+europe+2020+in+figures
[280] Insurance Europe. (2020). *European Insurance in Figures: 2020 data,* p. 27.
https://www.bing.com/insurance+europe+2020+in+figures

health care planning. Therefore, without reporting, public health monitoring cannot adequately influence the policy process."[281]

The mission of EUPHA, established in Utrecht, the Netherlands, is to unite Europe's public health community to exchange expertise, influence policy, and build healthier societies through its members and associated members, institutions and associations across the European Union. Its vision is to foster cross-sector and cross-regional collaboration, to address the complex social, environmental, political, and commercial determinants of health.[282]

EUPHA pursues commitment to narrowing health inequalities with a strong focus on supporting marginalized and vulnerable populations.
The organizational structures facilitate Sections, including for oral health, to bring together researchers, policymakers and practitioners working in the same field for knowledge sharing and capacity building.
The oral health section focuses, among other things, on partnership, SDGs, interdisciplinary collaborations, dissemination of evidence-based knowledge and guidance to professionals and policy makers.[283]

Figure:

1. Strategic collaboration across health, social and educational sectors is vital in tackling the underlying determinants of health which cannot be addressed by one sector alone.

2. Developing robust data collection and the infrastructure to share data facilitates work across sectors.

4. Supporting targeted interventions with tailored outreach initiatives can overcome access barriers.

4.6.10 European Health Policy Platform

Funded through the EU4Health Program 2021-2027, the European Health Policy Platform facilitates discussions, encourages collaboration and host webinars. The platform facilitates access to multiple networks including the Exchange network to exchange good practices and share training materials.[284]

[281] European Public Health Association (EUPHA). (n.d.). *Public health monitoring and reporting (PHMR); what is it and why do we need it?* https://db.eupha.org/section_page.php?one=Public+Health+Monitoring+and+Reporting&two=Aims+of+the+section.
[282] European Public Health Association (EUPHA). (n.d.). *About us.* eupha. https://eupha.org/about-us/
[283] European Public Health Association (EUPHA). (n.d.). *Public health monitoring and reporting (PHMR); what is it and why do we need it?* https://db.eupha.org/section_page.php?one=Public+Health+Monitoring+and+Reporting&two=Aims+of+the+section.
[284] European Commission. (n.d.). *About the Platform.* webgate.ec.europe. https://webgate.ec.europa.eu/hpf/page/show/505.

4.6.11 Platform for better oral care in Europe

"Dedicate funding from EU programmes such as EU4Health and Horizon Europe towards research in oral health."[285]

Founded in 2010, this platform is a multistakeholder initiative uniting professionals and organizations to promote the recognition of oral health as an essential component of overall health and well-being. The initiative has published a position paper indicating links between better oral health and general health.

Figure:

The platform calls on EU Policymakers to drive impact at Member State level:
1. to promote and encourage the adoption of best practices which have successfully improved oral health.
2. to support the implementation of the WHO Global Action Plan on Oral Health 2023-2030.
3. to Facilitate the implementation of integrated healthcare teams and a primary care workforce which can cater to the needs of the population.[286]

[285] Oralhealthplatform. (n.d.) *About us.* oralhealthplatform. https://www.oralhealthplatform.eu/about-us/.
[286] Oralhealthplatform. (n.d.) *About us.* oralhealthplatform. https://www.oralhealthplatform.eu/about-us/.

4.6.12 The European Association of Dental Public Health (EADPH)

"the science and art of preventing oral diseases, promoting oral health and improving the quality of life through the organized efforts of society".

The EADPH, founded in 1996 and established in Germany, is a science-based forum for professionals having an interest in dental public health and community dentistry. Its objective is to promote dental public health.[287]

This objective is achieved, amongst others, by the promotion of effective oral health and oral health strategies within Europe and to support oral health initiatives within the countries. EADPH pursues multiple objectives including to be an advocate on oral health issues and to be supportive of oral health initiatives within countries. To this end EADPH publishes amongst others responses to the WHO draft for a guideline "Sugars intake for adults and children"[288] and the Resolution on control of e-cigarettes (first statement July 18th, 2014, and updated on September 30th, 2019).

4.6.13 European Forum for Primary Care

"To advance networked primary care research in order to improve the health of the population across Europe and beyond."[289]

EFPC, an association established in Utrecht, the Netherlands, was formed in 2005, to improve the health of the population by promoting strong primary care. Its aims include advancing networked primary care and research to improve the health of the population across Europe and beyond.
The organization is built on an Executive board and working groups.
The public information does not reflect that oral care is embedded in the organisation and dissemination instruments.

4.7 EU Ethical principles

"Standards and guidelines should address and include intercultural aspects, disabilities, and intercultural translations and services
to support a more equitable health status in the Union. In the prevention of ill-health (an aspect of pre-distribution), the Union should deploy its considerable regulatory capacities (Box 7)."[290]

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[287] European Association of Dental Public Health (EADPH). (n.d.). *Resources*. eadph. https://www.eadph.org/resources/.
[288] WHO. (2015). *Guideline : Sugars intake for adults and children*. ISBN 978 92 4 154902 8. https://www.who.int/publications/i/item/9789241549028
[289] European Forum for Primary Care (EFPC). (n.d.). *Background*. euprimarycare. https://euprimarycare.org/background/
[290] de Ruijter, A., Hervey, T., & Prainsack, B. (2024). Solidarity and trust in European Union health governance: three ways forward. *The Lancet Regional Health - Europe*, *46*, 01047, p. 5. https://doi.org/10.1016/j.lanepe.2024.101047

Ethical principles within the EU framework are referred to in the recitals of multiple EU regulations and the European Convention of the Human Rights.

4.7.1 The European Convention on Human Rights

"Incomplete coverage of oral care can create inequality if the uncovered part of the reimbursement for prevention and /or treatment forms a reason to forego this care. Multiple barriers may apply including insufficient interpretation and intercultural mediation services, complex and restrictive administrative procedures, economic costs, cultural insensitivity in clinical practices and possibly disabilities preventing a visit to the practice or possibly inadequate adaptation of services to meet the needs of diverse populations. Health policies that ensure the effective exercise of the right to health for all individuals, regardless of their racial or ethnic background are needed."[291]

*The Eu*ropean Convention on Human Rights and Fundamental Freedoms (ECHR), effective as of September 1953), ratified by all the Member States, sets forth fundamental rights and freedoms including the right to life (article 2 ECHR). The Working Group on Social Rights, created in 2003, explored the opportunity of having any new justiciable rights under the supervision system set up by the European Convention on Human Rights. In the context of this right, the Steering Committee for Human Rights (CDDH) released several reports based on expert views.

The right to health was explored. Experts noted that the right to health should cover more than mere medical assistance. By way of example, it was observed that this right could include the right to a healthy environment. Other experts considered that it would be better to formulate the "right to health" as a "right to access to healthcare" or alternatively a "right to healthcare" as health itself can never be guaranteed, not even with the best of healthcare.[292]

More rights are granted by additional protocols to the Convention. The Steering Committee for Human Rights conducts the intergovernmental work such as the legal standards and the processing of relevant jurisprudence of the European Court of Human Rights and produces reports and drafts guidelines and recommendations for the adoption by the Committee of Ministers. It advises and gives its legal expertise to the Committee of Ministers on all questions within its field of competence.

4.7.2 Charter of Fundamental Rights of the European Union (2012/C 326/02)

"Everyone has the right of access to preventive health care and the right to receive help from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."[293]

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[291] Gonzalez-Rabago Y., Lanborena N.& Rodriguez E. (2025). Barriers to healthcare for racialised populations in Europe: a scoping review of reviews. *International Journal for Equity in Health 24 (1).* https://doi.org/10.1186/s12939-025-02577-1

[292] Council of Europe. (2008). *Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research.* https://pubmed.ncbi.nlm.nih.gov/19180986/

[293] Article 35 Charter of Fundamental Rights of the EU.

The Charter of Fundamental Rights (Treaty of Lisbon, 1 December 2009) is built on six fundamental rights. The right of solidarity addresses explicitly Healthcare.[294]
The Charter implements the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community.[295] The right to access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices are explicated.[296]
The Charter addresses the Union as well. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.[297]

4.7.3 EU third action plan on human rights and democracy 2020-2024 (extended to 2027)

" Curb inequalities by combating poverty and social exclusion, and by promoting non-discriminatory access to social services, including quality and affordable health services and inclusive and equitable quality education, including distance learning. Build practitioners' capacity to respond to the specific care needs of all persons in vulnerable situations with no exception of any kind.
Foster health promotion and equal access to preventive health services and the right of everyone to the enjoyment of the highest attainable standard of health, especially in times of crisis with special attention to persons affected by discrimination and marginalisation."[298]

The action plan entails concrete action for the next five years in the field of external relations including protecting and empowering individuals to transform the concrete actions related to healthcare.

4.7.4 Ethical principles for Digital Health: EU action plan on human rights and democracy 2020-2024, eHealth Network:

"supporting health promotion, disease prevention and improved delivery of healthcare through better use of health data and by improving digital skills of patients and healthcare professionals"[299]

Following Article 14 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, the eHealth network was established.
The voluntary network connects national authorities, designated by the Member States. The rules for the establishment, management and functioning of the network are formulated in an implementing Decision of the Commission (Commission Implementing Decision 2019/1765 of 22 October 2019). The eHealth Network may facilitate and provide guidance, including guidance on the exchange of good practices concerning the development of different digital

[294] Article 35 Charter of Fundamental Rights of the EU.
[295] Article 26 Charter of Fundamental Rights of the EU.
[296] Article 35 Charter of Fundamental Rights of the EU.
[297] Article 35 Charter of Fundamental Rights of the EU.
[298] European External Action Service (EEAS). (2020). *EU Action Plan on Human Rights and Democracy 2020-2027, pp. 15-16.* https://www.eeas.europa.eu/sites/default/files/documents/2024/Action-Plan-EN_2020-2027.pdf
[299] Article 14 Directive 2011/24/EC.

health services, such as telemedicine, mHealth, or new technologies in the area of big data and artificial intelligence and supporting health promotion, disease prevention, and improved delivery of healthcare through better use of health data and by improving digital skills of patients and healthcare professionals. The eHealth Network adopted general guidelines for the electronic exchange of health data under the Cross-Border Directive including the definition of a Patient Summary:

"*an identifiable dataset of essential and understandable health information that includes the most important clinical facts required to ensure safe and secure healthcare. This summarised version of the patient's medical data gives health professionals the essential information they need to provide care. Although this dataset is intended to aid health professionals in providing unscheduled care, it can also be used to provide planned medical care (e.g. in the case of citizens movements or cross-organisational care paths)*"[300]

In 2022 the Commission introduced the ethical dimension and ethical principles in digital health to overcome disparities in skills and resources to use online sites and services while digital health communication and healthcare services should be easy to use.

Figure:

1. Placing digital health within a framework of humanist values.
2. Enabling people to manage their own health data digitally.
3. Developing inclusive digital health.
4.Implementing eco-friendly digital health.

Each category is further detailed in four principles.[301]

4.8 Dental Tourism, patient mobility and cross-border care

"Dental tourism isn't a new phenomenon, but recently it has become a buzzword in the contemporary dental landscape, provoking concern from practitioners and policymakers alike."[302]

Patient mobility has not emerged in recent years. Patient mobility is created by multiple, mostly socio-economic factors.[303]

[300] Article 2 Directive 2011/24/EU.
[301] Council of Europe. (n.d.). *Access to digital spaces to understand and use health services.* coe.int. https://www.coe.int/en/web/human-rights-and-biomedicine/access-to-digital-spaces-to-understand-and-use-health-services/-/highest_rated_assets/nTmcJLi8P0UU/content/european-union-
[302] Sellars S. (2025). Dental tourism: What's behind the 'why'?. *BDJ in Practice 38. DOI: https://doi.org/10.1038/s41404-025-3084-8*
[303] Turner L. (2008). Cross-border dental care: 'dental tourism' and patient mobility. *British Dental Journal (204)*, pp. 553–554. https://doi.org/10.1038/sj.bdj.2008.403

The destinations for patients are worldwide and within the EU.[304] The phrase "Dental Tourism" is mostly used for worldwide oral care, might have emerged from the attractive tourist offers associated with this form of transborder care.
Irrespective the quality of professionals, the instruments they use and the treatment the professionals of the praised countries apply, the consequences of complications, medication prescribed, missing data in patients records and possible restorations are borne by the home Member State as most of these consequences will fall under the (mandatory) insurance of the travelling citizen either as urgency care or regular care.
Reported findings on quality and cost effectiveness are not all positive.[305]

4.9 European guideline for oral guidelines to support payments reforms

"In order to be included in the basic package, care must, above all, be effective: evidence must show that care does what it is meant to. This is a statutory requirement. In general, care is automatically included if its effectiveness has been proven."[306]

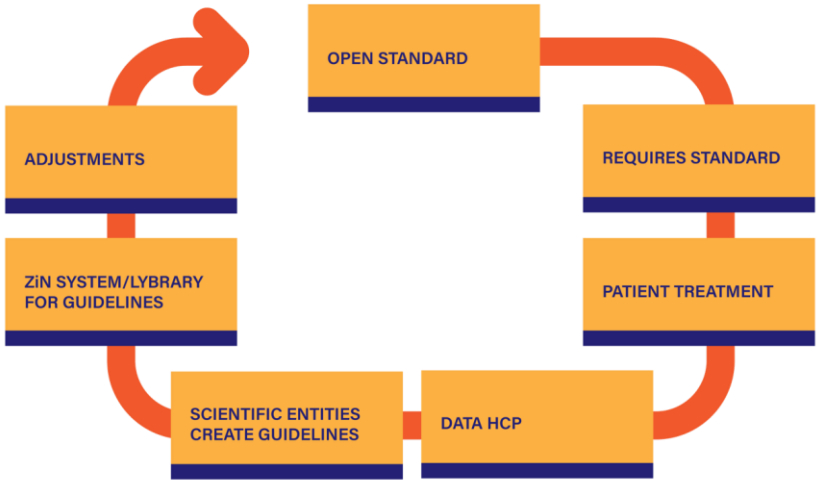
In 2009, the minister of Health of the Netherlands installed the Directing Council for Healthcare (Regieraad Zorg) tasked with the mission to structure, develop and implement healthcare guidelines as a matter of urgency to improve quality, to support insurance companies while simultaneously assuring patient involvement and joint decision making.
An analysis of the gradual and inconsistent development of guidelines at that time concluded that a standard for guideline development, the guideline for guidelines, was needed to support efficient and coordinated development guidelines for multiple disciplines.
This guideline included an explicit paragraph on patient`s involvement and collaboration between the different disciplines in healthcare.
The guideline for guidelines was launched in 2012 and supported rapid and unified development of standards and guidelines with patient involvement during 2012 and 2016 in several disciplines.[307]
This guideline forms the basis of the guideline for oral guidelines, including a section on vulnerable groups and integrated oral care in primary care. The guideline is developed and supported by several DELIVER consortium members (See Annex C).

In 2023, the second approach to support guidelines and standards in the Netherlands was launched and based on the meanwhile implemented Act on the Quality, complaints, and disputes in the care sector (Wkkgz), introduced in 2016 (January 1, 2016). The Wkkgz governs

[304] Dental Tourism Association. (2025). *Global Dental Tourism Guide*. dentaltourismassociation. https://dentaltourismassociation.com/
[305] O'Brien, K. J., Forde, V. M., Mulrooney, M. A., Purcell, E. C., & Flaherty, G. T. (2022). Global status of oral health provision: Identifying the root of the problem. *Public Health Challenges*, *1*(1). https://doi.org/10.1002/puh2.6
[306] National Health Insurance Institute. (n.d.). *Advising on and clarifying the contents of the standard health care benefit package*. english.zorginstituutnederland. https://english.zorginstituutnederland.nl/about-us/working-methods-and-procedures/advising-on-and-clarifying-the-contents-of-the-standard-health-care-benefit-package
[307] Regieraad Kwaliteit van Zorg. (2012). *Richtlijn voor Richtlijnen*. https://www.zorginzicht.nl/binaries/content/assets/zorginzicht/ontwikkeltools-ontwikkelen/Richtlijn+voor+Richtlijnen+derde+herziene+versie.pdf

multiple elements of quality applicable to health institutions and healthcare providers.
The WKKGZ foresees in a quality register for all quality standards and measurement indicators and the criteria for registration of these instruments in the quality register.[308] Whereas the interpretation of medical scientific based professional standards is determined by the professional group itself, quality standards are drawn up jointly by healthcare providers, health insurers and clients.
The Healthcare Institute determines for which forms of care a quality standard or measuring instrument is required, or a quality standard or measuring instrument must be included in the public register.[309]
Before a standard or measuring instrument is listed in the register, a financial evaluation is carried out to measure the financial impact.[310]
This second structured and unified approach for adequate guidelines and standards for all treatments builds on a continuous and population-based data and guideline circle.
The circle starts with data from health records released to scientific associations for guideline development to be further assessed and transformed to standards, evaluated and registered by ZIN. These data have been generated from insured healthcare for the whole population.
ZiN has published multiple manuals and guidelines related to vulnerable groups.[311] The guideline development follows the guideline for guidelines AQUA-leidraad. The national project does not cover primary oral care yet.[312]

Figure of data and guideline circle:



[308] Article 3 Wkkgz.
[309] Article 11a Wkkgz.
[310] Zorginstituut Nederland. (2021). *Toetsingskader kwaliteitsstandaarden en meetinstrumenten (versie 3.0).* https://www.zorginzicht.nl/binaries/content/assets/zorginzicht/algemeen-ondersteuning/toetsingskader-kwaliteitsstandaarden-en-meetinstrumenten-versie-3.0.pdf
[311] Stichting Kind & Ziekenhuis. (2015). *Een kwaliteitsstandaard voor een speciale doelgroep: Beschrijving ontwikkelen criteriasets in de vorm van een stroomschema*. https://www.zorginzicht.nl/binaries/content/assets/zorginzicht/ontwikkeltools-ontwikkelen/Bouwstenen+Beschrijving+ontwikkelen+criteriaset.pdf
[312] Zorginstituut Nederland. (2021). *AQUA-Leidraad*. https://www.zorginzicht.nl/binaries/content/assets/zorginzicht/ontwikkeltools-ontwikkelen/aqua-leidraad.pdf

5. CONCLUSIONS

Oral health coverage entails a healthcare structure for all while respecting individual or population-based needs in terms of availability, affordability, quality, patient-centred and within a reasonable timeframe.
Targeted policy is needed to balance national economic restrictions and interests, healthcare structures, regulations and social rights to achieve affordable, patient-centric, and sustainable access to oral care.

Today's reality is characterized by increasing cross-border care, limited scientific insights into neglected oral care to vulnerable groups and the persons that cannot afford non-mandatory oral care insurance.
The reality of today has overtaken the history of Member States and their policies on which current national regulations for oral care are mostly based.
Member States of the EU are all committed to the same international and European regulatory determinants that support and pave the way to improvement of oral quality and access for all.
These regulatory determinants should be weighed transparently in national healthcare policies to improve population-based quality for oral care on the practice, professional, instrument and treatment level.

Provenance, yardstick and consequences of the practice including prevention:
The right to access oral care includes the right to access to practices and the right to accessible (digital) information related to prevention and treatment.
Practices should be accessible for persons with impairments and information about treatment, alternatives, aftercare and prevention must be understandable, legible and clear for the whole population inclusive vulnerable groups and persons with impairments.

Provenance, yardstick and consequences of the professionals:
The EU regulatory framework addresses the quality of the oral care professionals through a Directive as a regulatory determinant. Deviating national implementation regulations complicate the intended effect of the Cross-Border Healthcare Directive.
The (financial) consequences for the EU citizens may have an important impact if regulations on professional and treatment guidelines do not align.

Furthermore, there seems to be a mismatch between the essence and purpose of the directive cross-border care (non-urgent and regular care), increasing cross-border circulation of patients, the EHDS and the differences in oral care professionals, limited guidelines and standards and differentiated and limited oral health coverage.
The negative consequences can be mitigated if professional titles, specialism, re-registration requirements and treatments are recognizable and comparable for citizens and insurers and if guidelines are developed in joint European cooperation based on population-based data.

Being authorized as a professional does not automatically lead to being competent for all (innovative or more complicated) treatments. Continuous Professional Development is key for all healthcare professionals including oral healthcare professionals. Guidelines are needed and may be developed in a European context to support national decision-making on implementation, transborder patient information and minimum requirements for continuous

quality of the oral professional for the treatments they offer.

Provenance, yardstick and consequences of the instruments and diagnostical products oral care professionals may use:
The EU legislative framework is based on strong, all Member States binding, regulatory determinants for the practice level.
Multiple EU regulations with direct effect regulate the quality of these instruments and in vitro diagnostics.
European directly applicable regulations on general products, medicinal products, radiation, in vitro diagnostics, privacy, AI, cybersecurity and medical devices ensure adequate and common quality and safety requirements within the EU, monitored by notified and public bodies.
Qualifications for the use of devices may be needed and developed on a national basis.
All EU-based oral professionals may verify quality, CE certification and Post Marketing Surveillance information on the EUDAMED platform.

Provenance, yardstick and consequences for treatment
All EU Member States are represented in the WHO and international bodies and associations.
All EU Member States and their institutions are represented in EU bodies that can importantly contribute to achieving access to healthcare for the entire population respecting oral health quality.
Most oral care professionals are represented in, or are members of, international and European platforms and associations that share and disseminate information on population-based oral care, quality improvement and integrated patient-centred primary care.
Guidelines and standards pave the way to patient-centric, integrated primary care, public health, prevention tools, innovations and quality of care and most of all: cost- effectiveness needed for the challenges of today and tomorrow.
Cooperation to improve quality and develop guidelines within the European context has been a reality for multiple medical disciplines for many years. Cooperation for developing guidelines supports national policy making and the development of standards for the practice, professional and treatment level in a cost-effective and efficient way.

Prevention: the role of the EU: complement, support, strengthen and coordinate
It is striking that prevention in the field of oral and general care, while crucial for cost-effectiveness and managing the burden of increasing healthcare expenditure, has a lower priority on the agenda of the EU, EU associations, scientific associations and bodies. EU prevention campaigns are cost-effective, efficient and realize maximum impact as they disseminate the same message to EU citizens throughout the EU wherever they are resided or wherever they travel.
A joint public prevention approach in the form of a joint EU initiative and campaign is not new. This approach has been chosen for alcohol prevention. This joint initiative created a strand of projects and established a Committee on Data Collection, Indicators and Definitions.[313]

Article 168 TFEU addresses the defined tasks and responsibilities of the EU, respecting the responsibilities of the Member States authorities for organizing and financing healthcare.

[313] European Commission. (2009). *Alcohol Measures for Public Health Research Alliance (AMPHORA).* https://cordis.europa.eu/project/id/223059/reporting

The role of the EU, through bodies and organizations, may be legislative and non-legislative in terms of healthcare policy, action plans and setting the EU agenda.
The EU legislative competence might be seen as limited in the context of healthcare, the sector for which autonomy for Member States has been formulated.
However, the reality of today is worded precisely in the paragraph where the responsibilities of Member States are explicitly mentioned. These responsibilities are importantly formed by commitments for each Member State, enshrined in human rights treaties, resolutions, missions, standards and guidelines developed by global and European organizations where Member States, their bodies and organizations are represented.
The obligations and commitment of the EU to complement and support national health policies, to encourage cooperation between Member States and to promote the coordination between their programmes are to be fulfilled in full respect of the responsibilities of Member States for the definition of their health policies and for the organization, management and delivery of health services and medical care.
These responsibilities include their commitment to international determinants: international resolutions, guidelines and recommendations.

Opportunities for efficient oral care quality improvement:
Today's opportunities are characterized by the development of telemedicine, growing collaboration and multiple European associations, organizations and institutes that may contribute to accelerated guideline development, standardization and patient-centric and primary care integrated approaches for improving population based oral care quality.
The step forward to invest in reversing negative trends lies in collaboration between Member States, their associations and bodies, in sharing knowledge, data, scientific insights and coordinating prevention policies based on understandable, clear and unambiguous information to citizens in the EU.
Scientific insights support cost efficiency for instance for the most common treatment: monitoring.[314]
Collaboration is needed to support increasing cross border movements of EU citizens, and in its wake the approaching common data for primary care as foreseen in the European Health Data Space (EHDS), and digitalization of oral health services.
The EU may support and coordinate the collaboration.

Collaboration is mostly needed to bridge possible data bias resulting from limited coverage and financial hardship. The step forward for quality improvement and access for all can only be built on reliable population-based data. Collaboration to create and support a European oral care data infrastructure will foster efficient development of population-based scientific guidelines, respecting rights of disabled persons and vulnerable groups.

Collaboration is needed between the primary care professionals and their associations, including the general healthcare practitioner and pharmacist to improve patient-centred, cost-effective care and integrated population-based guidelines for (innovative) treatments. These

[314] Clarkson J.E., Pitts N.B., Goulao B., Boyers D., Ramsay C.R., Floate R., Braid H.J., Fee P.A., Ord F.S., Worthington H.V., Van der Pol M., Young L., Freeman R., Gouick J., Humphris G.M., Mitchell F.E., McDonald A.M, Norrie J.D., Sim K., Douglas G., Ricketts D. (2023). Risk-based, 6-montly and 24 monthly dental check-ups for adults: the INTERVAL three-arm RCT. *Health Technology Assess 2020(60), pp. 1-138.* https://doi.org/10.3310/hta24600

guidelines support Member States in developing national standards, prevention policies and policies towards adequate coverage instruments and targeted adequate oral care and information for vulnerable groups and disabled persons.

Prevention campaigns and accessible oral health information for persons with visual and hearing impairments may be initiated, supported and coordinated by the EU and multiple European Associations including patient organizations and organizations for public health.

Digitalization, remote monitoring and the EHDS contribute to cost-efficiency, transparency, common standards and guidelines to be addressed in cooperation on the European level.
Digitalization may be supported and coordinated by the EU.
The EHDS is built on common and recognizable treatment registrations and consequently a solid basis for secondary use of these data.
The EU may financially support the development of an oral care Masterfile in the context of the EHDS.

Telemedicine is qualified as an increasingly important tool that can provide patients with access to care and tackle inequities. Digital and other tools can facilitate the provision of care in remote regions.
Irrespective of the responsibilities of Member States under article 168 TFEU, different healthcare policies may not constitute barriers for the free movement of electronic health data in the context of cross-border care.[315]
The EU may support coordination and collaboration and may support synergies within the EU 4-health programme.

6. RECOMMENDATIONS: THE GATEWAY TO EFFICENT QUALITY IMPROVEMENT FOR EU MEMBER STATES

1. Integrate international and EU regulatory determinants, develop the quality oral care improvement toolkit and recommendations, while aligning and collaborating with the relevant stakeholders in the oral health quality domain. (see schedule below). (2026)
2. Classify their scope and the quality domains (see figure below). (2026)
3. Base quality improvement tools including guidelines and information on international and EU common determinants and values, while respecting the common ethical principles and framework (continuously) (2026-).
4. Form an EU based oral care improvement taskforce, "Oral Care Alliance", (representatives of oral care associations, primary care platform, EU and national prevention policy stakeholders, digital healthcare services stakeholders, insurance associations and patient organisations, professional development and registration organisations). (2026)
5. Address and involve international and EU (medical) associations and stakeholders to discuss their involvement in cost-efficient development of scientific guidelines and insights to support quality-of-care tools and common definitions of essential oral care integrated in primary care to support national coverage, standards and reimbursement policies (see figure below). (2026)

[315] Recital Regulation 2025/327 (EHDS).

6. Establish a guideline for oral care guidelines and involve scientific organisations for oral care and primary care, patient representatives and EU bodies tasked with ERN and ERIC infrastructures. (2026)
7. Realize alignment between relevant EU bodies and EU based professional organisations (oral care and primary care) to support an EU based oral care data infrastructure for oral care research and scientific guidelines (professional, treatment, digital care and prevention to support national policies for standards and reimbursement (see figure below). (2026)
8. Collaborate through an EU oral care scientific organisation to develop aligned patient record information to support interoperable exchange of data for oral primary care as foreseen in the EHDS (2026-2028).
9. Address international and EU stakeholders to develop targeted prevention campaigns and to discuss actionable tools and collaboration within the EU when initiating campaigns and a targeted approach to an oral care prevention agenda within the EU (2026-2028).
10. Develop the oral health digital agenda including digital health services, telemedicine, EHDS policy, websites and records and develop guidelines for digital services, prevention and information, population based while respecting persons with impairments. (2026)
11. Address EU bodies and EU stakeholders to (financially) support (digital) instruments for targeted, community based oral prevention, monitoring and oral care aligned with the needs of persons with impairments and vulnerable groups, while involving patient organisations, primary care stakeholders and public health associations to collaborate and develop a joint oral care prevention policy. See figure below. (2026)
12. Develop scientific principles to support a joint vision on oral care professionals, common training, principles for professional development and structured information on oral care professionals and treatment for cross-border care patients.

International and EU regulatory determinants toolkit:

Figure:

INTERNATIONAL	PROVENANCE	YARDSTICK	CONSEQUENCES
DIGITILISATION	1.WHO (World Health Organization)	1.mHealth programme, Be Healthy Be Mobile Initiative four modules; Health Technology guide oral health;	Support, Commitment

	2.OECD (Organization for Economic Co-operation and Development)	2. Improve the deployment of digital technologies tailored to diverse literacy levels	Recommendations
PRACTICE/ (DIGITAL) ACCESSIBILITY	1.UN Convention on the Rights of Persons with Disabilities (CRPD) Committee	1. Guidelines on the right of liberty and security of persons with disabilities.	Support (Strong) Commitment
	2. UN/WHO (World Health Organization)	2. UHC Framework 2024-2027; SDG Global Action Plan 2021-2030; Patient Safety Rights Charter; AAAQ	Strong Commitment/ Commitment
	3. ISO (International Organization for Standardization)	3. Standards for Security (Instruments and Practice)	Strong Commitment/ Implementation
PROFESSIONAL AND RESEARCHERS	1.WHO (World Health Organization)	1.Global Strategy for Health Workforce (domains); Global Competency and Outcomes Framework	(Strong) Commitment
	2. ISO (International Organization for Standardization)	2. ISO Standards	Strong commitment/ implementation
	3.WHPA (World Health Professional Alliance)	3.Inter-professional Collaboration	Strong commitment/support

	4. OECD (Organization Economic Co-Operation and Development)	4. Global Competency Framework.	Recommendation/Support
	5.FDI (World Dental Federation)	5. Global Continuing Education Programme and Alignment	Recommendation/Support
	6. WMA (World Medical Association)	6.Ethical Standards; Declaration Helsinki ; Global Competency Framework; Interprofessional Collaboration	Strong Commitment/ Support
	7.WHPA (World Health Professional Alliance)	7.Interprofessional Collaboration	Commitment/ support
INSTRUMENTS/ PRODUCTS	1. ISO (International organization for standardization)	1. Standards for implants, instruments and products.	(Strong) Commitment/ Possible mandatory under national law
TREATMENT, INTEGRATED CARE, COMMUNITY	1.WHO (World Health Organization)	1. Global Safety Action Plan 2021-2030; Patient safety rights; WHO Guidelines and handbook for Guideline development, eight entry points; WHO Guideline Review committee;	(Strong) Commitment Support

		Guideline Sugars intake adults and Children; Report on quality care and patient safety; Global Consensus Amalgam; Declaration Alma-Ata; International Classification of Diseases related health problems.	
	2.UN CRC (Convention on the Rights of the Child)	2.Highest attainable standard for the Child.	Strong commitment
	3. ISO (International Organization for Standardization)	3.ISO Technical Standards.	Strong commitment General accepted and possibly mandatory standards nationally
	4.G-I-N (Guidelines International Network)	4. Implementing Evidence Based Clinical Guidelines.	Support/ Recommendations
	5.FDI (World Dental Federation	5. Programme AMR; Consensus toothbrushing; Guidelines Ethical Principles	Strong commitment Support
	6.ICHOM (International Consortium for Health Outcomes Measurements)	6.Standards based on Health Outcomes	Support/ Recommendations
	7.IADR (International Association Dental, Oral and Craniofacial Research)	7.Craniofacial research	Support/Commitment

	8.ORCA (Organization for Caries Research)	8.Research and consensus statements on caries	Strong recommendations
	9.Global Self-Care Federation	9.Evicence-based solutions to selfcare	Recommendations/ Support
	10. WMA (World Medical Association)	10. Ethical Principles of medical research; Comprehensive nature of primary care.	Strong Commitment
	11.IARC (International Agency for Craniofacial Research)	11.Dental, oral and craniofacial research	Support
	12.WONCA (World Organization Family Doctors)	12.Standards Primary Care	Strong commitment
	13.OECD (Organization for Economic Co-Operation and Development)	13. People centric care: Time, Tailored and Trouble-free	Recommendations/ Strong Commitment
POLICY/ PREVENTION	1.WHO/WHA (UN) Resolution/guidelines/ Factsheets Office of the United Nations High commissioner for Human Rights	1. Prevention of NCD; Guideline sugar intake for adults and children; Global Oral Health Action Plan; Guiding Principles (six); International Classification of Diseases and related problems. ICD-11 oral diseases; SDG, Global Safety Action Plan 2021-2030;	Strong Commitment/ recommendations

		Factsheet right to health; Elements right to health; WHA 74.5 Guideline; Global Charter for Public's health; Declaration Alma-Ata; Health for all and health problems in the community; Process indicators to assess outcome indicators from the perspective of the population.	
	2.CIOMS (Council for International Organization of Medical Sciences)	2. Guidelines for international vetted ethical Principles	Strong commitment
	3.WFPHA (World Federation of Public Health Associations)	3.Global Charter Public Health	Recommendations
	4.European Observatory hosted by WHO	4.Briefing addressing determinants through Health in and for all Policies (HIAP,H4AP); Policy briefs health promotion and prevention services.	Recommendations/ Support
	5.NCD Strategy Alliance	5.Key points to drive action on non-communicable diseases.	Recommendations Support
	6.Global child Dental Fund	6.Declaration on Child oral health	Strong Commitment

	7.ICESR (International Convention on Economic and Social Rights)	7. Handbook Human Rights.	Recommendations Strong commitment
	8.Un Convention on Rights of Persons with Disabilities and committee on the Rights of persons with Disabilities	8. Guidelines and report implementation.	Strong commitment/ support
	9.United Nations Convention on the Right of the Child to Health	9. Right to Health.	Strong commitment
	10.FDI (World Dental Federation)	10.Guide promoting Oral Health for Refugees.	Support/ recommendations
	11.NCD Strategic Alliance	11.Key points NCD prevention and care.	Recommendations/ Support
	12.OECD (Organization for Economic Co-operation and Development)-	12. Patient Reported indicator of Surveys (PaRIS) and the three T`s.	Recommendations/ Support
	13.IADR (International Dental Oral and Craniofacial Research)	13.DEIAB Principles (Diversity, Equity, Inclusion, Accessibility and Belonging).	Strong commitment
	14.Global Selfcare Federation	14.Role pharmacist in good care practices; Selfcare priority programme.	Recommendations/ support

	15.ICHOM (International Consortium for Health Outcomes Measurement)	15.Realworld relevance and equity.	Recommendations/ support
	16.WMA (World Medical Association)	16. Comprehensive nature of primary care for all ages and a person-centric approach, affordable and of high quality.	Recommendations
COVERAGE/ PAYMENT REFORM	1. WHO (incl Council on Economics Health for all)	1.Universal Health Coverage Framework 2030 Global Health Action Plan; Foundational Briefs and Final Report; Report Keeping health on the agenda: resilient and inclusive health systems.	(Strong) Commitment)
	2.Office of the UN high Commissioner for the Declaration of Human Rights	2.Factsheet right to health; Implementation tool process indicators to access obligations and outcomes	Strong commitment/ support
	3.WHO Europe	3.Keeping health on the agenda of Universal Health Coverage	Recommendations/ Commitment
	4.UN ICESR (International Convention on the Economic and Social Rights)	Handbook Human Rights for all	Support/ Recommendations
	5. European Observatory on Health Systems	5. Study Voluntary Health Insurance; Health technology	Support/Recommendations

	(partnership hosted by WHO)j	assessment; Concept Health in all Policies (HiAP, H4AP).	

Figure:

EU	PROVENANCE	YARDSTICK	CONSEQUENCES
DIGITILISATION AND DIGITAL SERVICES	1. ECOM (European Commission	1.eHealth Action Plan 2012-2020; EU legal framework applicable to telemedicine.	Applicable/ Strong /Commitment
	2.EHDS (European Health Data Space)	2. Standard Patient Record, interoperability; Exchange data primary care; Secondary use data for research.	Applicable (transition period), national implementation specific items
	3.Council of Europe (CEU)	3. European Principles for Digital Rights ; Principles for the Digital Decade; Document on the applicability of the existing European legal framework telemedicine services.	Strong commitment, Support
	4.eHealth Network strategic governance body for e-health services	4. Recommendations on an Electronic Health Record exchange format; Exchange of good practices for development of digital services (telemedicine, mHealth, new technologies in Big Data and artificial Intelligence); Code system	Strong commitment Support for implementation

	5. European Patients Platform	5. Supports Digital transformation in Europe, safe, high quality, more participatory, person-centered	Key stakeholder/ support
	6.eHealth Network (implementation decision 2019/1965)	6.Ethical Principles for Digital Health	Strong commitment/ Support
PRACTICE/ ACCESIBILITY	1.Directive 2013/59/EURATOM	1. Protection of the health of workers and the public, procedures, training, information and medical records.	Strong Commitment, Applicable (Directly or through implementation in national regulatory system) High common level of cyber security.
	2. General Product Safety Regulation (2023/988) Medical Device Regulation (2017/745) In Vitro Diagnostics Regulation (2017/746) AI act (2924/1689) General Data Protection Regulation (GDPR)(2016/679) NIS 2 Directive (2022/2555) Medicinal products (2001/83) And national implementation acts	2.Product safety measures; Monitoring safety; Post Marketing Surveillance; Internal competency; Informed consent forms and transparency and protection of data; Cyber security measures; Internal Instructions; Clarity responsibilities; Reporting; Internal Instructions and monitoring; DPIA and FRIA.	Applicable National implementation acts

	3.European Health Data Space (EHDS (2025/327)/ TEHDAS guidelines	3.Standardization Records based on Patient Exchange format; Interoperability software and treatment classification.	Mandatory/ Guidance
	4. CENELEC/CEN Committee for Electronical Standardization/ Committee for standardization	4. International patient summary standard (CEN); Standards for processing data; Standards electronic devices (CENELEC).	Strong commitment/ Mandatory/ Contractual obligations
	ISO (International Standard Organization)	5. Certification and standards for security and processing data.	Strong commitment and guidance/contractual obligations
PROFESSIONAL	1. Court of Auditors view on Regulation on the recognition of professional qualifications/	1. Recommendations for the improvement of information for citizens, transparency, monitoring.	Recommendations to be transposed in national regulations, a common approach needed to support national authorities.
	2.Directive on the application of patient`s rights in cross -border care/EU reference networks (2011/24	2.Interoperability of cross border eHealth services; Common guidelines; Information sheet on treatment and professional to be implemented; Professional card; Alignment/explanation professional titles to be implemented.	National implementation acts; Improvement needed to support person –centered adequate information and alignment with system .
	3. CECDO (Council of Chief Dental Officers)	3.Data Base for Oral Health Workforce; Reports Dental Specialties and continuing professional education;	Support, Stakeholder for alignment and continuing professional education

	4.EUPHA (European Public Health Association)	4. Interdisciplinary cooperation; Public health stakeholder.	Support, Stakeholder
TREATMENT	1.WHO regional office Europe	1. Recommendation for continuous development of scientific guidelines on which practice-based standards may be built to support adoption by stakeholders.	Strong commitment/ To be transposed in national law/ Applicable. Support
	2. EU research infrastructure (ERIC regulations 723/2009)	2. Operates research infrastructures	Solution for building shared data and scientific insights for Guideline and standard development.
	2.CECDO (Council of Chief Dental Officers)	2.Health Indicators; Examples of guidelines.	Strong commitment; Support guidelines Important Stakeholder
	3.CED (Council of European Dentists)	3.CED manual; Oral health promotion; Patient safety; Infection control; Medical devices; eHealth.	Strong commitment for oral care professionals, Important stakeholder for implementation.
	4.EMA (European Medical Association)	4.Approach integrated care; Healthcare overview.	Commitment Support Strong commitment professionals Stakeholder implementation
	5.EUPHA (European Public Health Association)	5.Dissemination of evidence-based knowledge	Commitment Support/ Stakeholder for prevention policy
	6.IARC (International Agency for	6. International cooperation in research; Data to support guidelines.	Support evidence-based guidelines treatment, prevention and policy

	Research on Cancer)		
	7.Platform for better oral care	7. Facilitates implementation of integrated healthcare teams and primary care workforce; Promotes best practices	Support/ Strong Commitment
POLICY/ PREVENTION	1.WHO regional office Europe	1. 64 indicators grouped into governance and health systems functioning, domains related to quality of care	Commitment/ Strong Commitment
	2. ECOM (European Commission)	2.EU4Health Action Plan 2021-2027, EU areas of intervention; Reinforcing health data and systems; Digital transformation.	Commitment/support
	3.Expert group Health Systems Performance Assessment	3.VHBC (Value Based Healthcare); Indicators for low value care; Data access and data quality; Key findings Health Systems performance Assessment	Support/Commitment
	4. Regulation on Health Technology Assessment (2021/2282)	4.Support framework and procedures for cooperation between Member States for technology assessment	Applicable/ Commitment
	5.European Patient Platform	5.Tools and policy for patient involvement.	Strong commitment/ important stakeholder
	6.European Patient`s Academy on Therapeutic Innovation	6.Enhancing patient involvement, education and collaboration for patients and researchers.	Strong commitment/ Important stakeholder

	7. EUPHA (European Public Health Association)	7. Supports marginalized and vulnerable groups; Interdisciplinary cooperation.	Important Stakeholder
	8.EADPH (European Association of dental health)	8.Promotion of Effective Oral Health and Strategies; Responses to the Resolution on Control of E-cigarettes; Responses to the WHO draft for a guideline "Sugar intake for adults and children".	Strong commitment Important stakeholder
	10.European Forum Primary Care	10.Promotion of strong Primary Care; Advanced Network Primary Care	Support Important stakeholder
	11. European Convention on Human Rights	11.EU third action plan on human rights and democracy	Strong commitment
	12. Platform for Better Oral Health	12.Oral health Challenge in Europe; European Health Report Card	Policy support/strong commitment
COVERAGE/PAYMENT REFORM	1. European Observatory on Health Systems (Partnership hosted by WHO)	1. Health Technology Assessment (needs-based policies); Health Technology Assessment (high-value and low value care).	Recommendations/ Commitment
	2. Insurance Europe Federation	2. Report European Insurance in Figures 2020; Three coverage systems.	Information/ stakeholder

ANNEX A: Analysis coverage, quality provenance, yardstick and consequences

Figure of coverage (cosmetic dentistry excluded):

	NL	DA	SW	PO	UK	GE	MA
Coverage adults	No, private insurance possible, general own risk applies.	15-20% covered. Rest out-of-pocket.	Yes	No, only for people VIH/SIDA, eligible for oral cancer screening and the elderly.	Yes, with co-payment. Free services for pregnant women and mothers with children to 12 months.	Yes, for regular materials and technique. Dental implants covered in specific cases.	Yes.
Coverage minors	Yes	Yes	Yes	Yes, limit is based on the age of the minor.	Yes	Yes	Yes
Age minor	18	21	24	18	18	18	16

Figure of provenance quality instruments:

	NL	DA	SW	PO	UK	GE	MA
Provenance	Dual: Legal framework for general formulations further implemented in guidelines and standards mostly developed by scientific associations within legislative framework (legislation pending)	Dual: Guidelines on essential standards for quality, national body, Danish Patient Safety Authorisation (DPSA).	Legislation: National Dental Care Act sets some requirements for good dental care.	Public Body: The Directorate-General for Health (DGH) issues clinical guidelines, quality standards (Quality Department of the DGH) and recommendations.	Dual: Standards that are developed by different bodies, some guidelines are enshrined in law and some are developed by specialist bodies. The organisations that are mostly involved are the NHS and National Institute for Health and Clinical Excellence (NICE)	Dentists must implement measures to promote the quality of contract medical care [statutory health insurance]. These guidelines are formulated by professional societies such as the German Society of Dentistry and Oral Medicine and the German Society of Periodontology, these guidelines not binding.	Licensing of Private Medical Clinic Regulations and the Regulations under the Public Health Act. The standards for public health are issued by the Superintendent of Public Health.

Figure of the yardstick:

	NL	DA	SW	PO	UK	GE	MA

Guidelines and standards/ recommend ations	Binding clinical guidelines made by a governmental body and professional organisations.	Binding clinical guidelines made by a governmental body.	Voluntary clinical guidelines made by a government al body.	Voluntary clinical guidelines, but can be used for malpractice cases, made by a governmental body and professional organisations.	Binding clinical guidelines made by a governmental body and professional organisations.	Voluntary clinical guidelines, but can be used for malpractice cases, made by professional organisations .	Voluntary clinical guidelines, but can be used for malpractic e cases, made by profession al organisatio ns.

Figure of the consequences:

	NL	DA	SW	PO	UK	GE	MA
Financially	No coverage Fine	No refunds from the government for the dentist.	A dentist can get a fine from the Health and Social Care Inspectorate.	The DGH can give a dentist a fine or a loss of fees.	-	-	-
Professional	Health and Youth Care Inspectorate may give a formal warning or impose financial and operational consequences Disciplinary court may impose various sanctions	DPSA can order a dentist to change procedures or terminate activities.	The Health and Social Care Inspectorate can give a prohibitionary period or even revoke the license of a dentist.	The DGH can give disciplinary sanctions like a warning, censorship, suspension or expulsion	NICE can have dentists removed from the professional registry/revoke the dentists' licence to practice.	The Association of Statutory Health Insurance Dentists can withdraw a dentists' licence to contract with social insurance funds.	The licence to practice as a dentist must be renewed conditional on fulfilment of all qualifications.

Annex B: Professional registration, aptitude and language test

Country	**Initial registration**					Reregistration requirements
	Degree National	**Degree EU/EEA/ Switzerland**	**Aptitude test**	**Language test**	**Other**	
NL	MSc Dentistry (6 years: 3 years BSc, 3 years MSc)	Degree in dentistry (inc. Practical experience)	Language test	Yes, Dutch B2+	no	2080 hours practice in relevant expertise per 5 years
GE	Dentistry university level, 5000 hours,5 years; first aid; one	Professional qualification as a dentist	Yes*, if there is no certificate of conformity/ no proof of	Yes, B2 general and C1 technical	Personal and health suitability.	No, mandatory Continuing Professional Development Non compliance leads

	month nursing service; four week internship; dental exam.		professional experience.			to the revoking of a dentist's license.
DK	MSc Dentistry (5 years: 3 years BSc, 2 years MSc) (Faculty of Health and Medical Sciences University of Copenhagen, 2014)	Degree in dentistry and certificate of conformity	No	No	Certificate of good standing	No
SW	MSc Dentistry (5 years)	Profession certificate in line with EU directive requirements	No	Prove language skills at C1 level in Swedish, Danish or Norwegian.	Not prohibited from pursuing the profession; A Swedish personal identity number.	No
UK*	Bachelor of Dentistry (5 years)	Degree in dentistry and 1600 hours of clinical experience.	Overseas registration exam	IELTS GPA of 7.0	Statement of comparability	No
MA	MSc Dentistry (5 years)	Degree in dentistry	No	No	good conduct	No
PO	MSc Dentistry (5 years)	Degree in dentistry	No	Prove language skills conformant to article 10(6) BOMD and article 48 of law no. 9/2009.	No Criminal record	No

* UK has unilaterally put legislation in place that confirms that EEA-qualified dentists will continue to benefit from quasi-automatic registration arrangements until at least June 2028.

Annex C Guideline for Oral Guidelines

Guideline for Oral Guidelines: criteria for developing and implementing population based, primary care integrated and patient -centric Oral Guidelines

This Guideline for oral guidelines comprises three phases with their own criteria:

- Preparation phase
- Development phase
- Finalization phase

Preparation phase

1. The subject, purpose and target group of a guideline are selected
In principle, any organization can take the initiative to develop guidelines. The choice of the subject is determined by, among other things, the prevalence of the disorder or condition, the burden of suffering, social relevance, and the expectation that a guideline can improve the quality of care. The subject is delimited by indicating what the guideline is and is not about. For effective implementation, the objective of the guideline must be clearly described and clear to the target groups. The latter refers to both healthcare professionals and healthcare users. These target groups are clearly named, so that they can immediately determine whether the guideline is relevant to them.
2. The initiator of the guideline identifies the primarily involved professional organizations and patient/client organizations.
The primarily involved professional organizations are the organizations that together have the most important share in the care of the healthcare user group described in the guideline. The primarily involved patient/client organizations are those organizations that represent the patient/client group(s) that are central to the guideline or that promote their interests. It is advisable to seek coordination with relevant field parties including primary care healthcare providers to promote national cooperation and integrated care, to prevent duplication of work and to standardize guideline methodologies.
3. The primarily involved organizations elect the chair and are responsible for the functioning of the chair
The target groups primarily involved in the subject jointly elect an independent and expert chair. Agreements can be made about delegating responsibilities, decision-making powers and tasks, for example to a supporting organization with specific expertise in the field of guideline development.
4. The primarily involved organizations form the working group and determine the working method
The primarily involved organizations are invited to delegate members to the working group. Based on substantive considerations, the members determine in consultation with the chair which other relevant parties are represented in the working group and what the balance between the parties involved is. If the number of parties becomes too large, a core group can be formed within the working group. It is recommended that all professional organizations involved provide the delegated members with a ‘mandate letter’. This letter specifies the responsibilities, powers, and agreements regarding feedback and consultation.
There are various methods for guideline development. The initial questions can be elaborated jointly, multidisciplinary, or in various monodisciplinary processes (for example via a ‘network guideline’). It is essential that coordination takes place between the participating professional groups and patient/client organization(s). The method of guideline development is explicitly described in the guideline.

5. Content experts and methodological experts are involved in all phases of guideline development.

The content expert is active in the field of the target group involved, has substantive knowledge and practical experience with the subject, and is considered a representative of a professional organization. This also applies to the content expert of the patient/client organization(s) and the primary care organizations. The expertise of the methodological experts includes knowledge of and experience with guideline process guidance, systematic literature research (searching, selecting, assessing and summarizing literature), selection of population-based criteria, including vulnerable groups and disabled persons and clinical epidemiology. Furthermore, the guideline working group includes or is supported by experts with knowledge of and experience in writing and editing texts, developing indicators, and implementing guidelines.

6. The patient/client perspective is part of the guideline
The relationship and communication between healthcare provider and healthcare user in the broadest sense (population based and considering persons with visual or other disabilities) is an important point of attention in every guideline. The specific expertise and experiences of the healthcare user group with regard to the subject of the guideline must be taken into account as much as possible. There are several methods to contribute to this, such as participation in the working group, focus groups, questionnaire research and literature research, or a combination of these. Input from healthcare users is particularly desirable in the problem analysis at the start of the process, in the bottleneck analysis, the formulation of initial questions, the determination of outcome measures, the formulation of recommendations and in the comment phase. Involve at least two representatives of the healthcare user group when developing the guideline. They provide at least one initial question. The relevant professional organizations also ensure that input from the patient's perspective, including persons with visual and other disabilities and vulnerable groups, is sufficiently addressed. This task can be delegated to the initiating organization, the chair, or to methodological experts. The guideline describes how the patient/client perspective, in the broadest sense, has been shaped.

7. The influence of conflicts of interest is limited as much as possible
The guideline procedure is designed in such a way that the financier cannot influence the content of the procedure, the data, or the recommendations. Any conflicts of interest of working group members are recorded in a declaration of interests that all members complete before the working group starts. This may involve commercial, professional, or scientific interests. Examples include being on a payroll, sponsorship, having a financial or commercial interest in a profit-making company, and participation in a scientific study that is part of the selected literature. Agreements are made within the working group on how to deal with interests (conflicts) and who is responsible for solving the problems that may arise. The interests and contact are stated in the guidelines. These agreements are in accordance with national regulations and codes of conduct for research integrity.

Development phase

8. The guideline development starts with a bottleneck analysis.
The bottleneck analysis focuses on both the content and the organization of care. In addition to care providers and care users, other relevant parties (stakeholders), for example representatives of health insurers, (primary) care organizations, social workers, public healthcare institutions, governmental healthcare bodies and institutions must be questioned about bottlenecks and information needed for integrated care. Methods may consist of literature research, questionnaire research, focus groups, and interviews with key figures. The

aim is to obtain as complete an overview as possible of the challenges and opportunities in practice. The inventory of impeding factors for acceptance and implementation of the future guideline forms part of the bottleneck analysis. The working group is responsible for the analysis and prioritization of bottlenecks.

9. Based on the bottleneck analysis, specific initial questions are formulated.
The initial questions may relate to etiology, screening and prevention, diagnosis, instruments, oral care professionals, guidance, prognosis and follow-up, and organization of care. A specific initial question contains population-based intervention and control intervention, and outcome measures. Outcome measures may relate to, among other things, prevalence/incidence of complaints, symptoms, conditions and risk factors, effectiveness, safety (side effects and serious harm), diagnostic accuracy, efficiency (costs, cost-effectiveness, budget impact) and patient/client satisfaction. Outcome measures in (social) functioning (including work), multi- and comorbidity, and quality of life deserve extra attention. (Social) functioning can be mapped with the International Classification of Functioning, Disability and Health (ICF). The working group prioritizes the initial questions and selects the most relevant initial questions for targeted literature research.

10. The literature is systematically summarized and transparently presented by a methodologist and a content expert.
When developing a search strategy, a specifically trained information specialist is preferably involved. Systematic literature summarization by at least two people, independently of each other, increases the reliability of the literature search. When conducting the literature search, collaborate and/or divide tasks with international partners. First, existing (foreign) guidelines are searched for systematic reviews and summaries of evidence. If these are not available, the literature is searched for (observational) studies, recommendations, tools, and opinions. The available evidence is systematically summarized. This includes an exhaustive systematic search strategy, predetermined inclusion and exclusion criteria, and systematic assessment of the quality of the studies, if possible, followed by a quantitative summary of the results (meta-analysis). The method used to summarize the literature is explicitly presented in the guideline. Evidence tables and a grading system that makes the strength of the evidence explicit (for example, GRADE) are preferably used.

11. The methods used to formulate the recommendations are presented transparently.
There is an explicit link between the recommendations and the underlying scientific evidence. When drawing up the recommendations, health benefits, side effects, safety, effectiveness and factors that promote and hinder the application are considered. The method used to reach consensus is explicitly described. Focus groups, open space meetings, and observation methods are useful methods for achieving consensus.

12. The recommendations are specifically formulated
A recommendation describes specifically, and precisely which policy is considered appropriate in certain situations for a well-defined patient group. It is clear which action is recommended and what the goal is. A recommendation is formulated in such a way that it is clear how strongly it should be interpreted. If there is sufficient evidence for the added value of a new intervention compared to an existing intervention, preference is expressed for the new intervention. Acceptance and feasibility of the recommendations are taken into account.

13. An oral care guideline includes considerations of efficiency and cost effectiveness
Insight into the financial consequences of recommendations is necessary to make socially responsible choices when spending resources in healthcare. It is important that major organizational and financial consequences of recommendations are discussed or calculated. If necessary, an economic evaluation, like cost-effectiveness or budget impact analysis or an overview of possible costs and benefits, is carried out. This requires specific expertise in the field of health technology assessment (HTA). In principle, the alternative with the most favorable cost-effectiveness is chosen as preference. Economic considerations in the guideline can be used in policy decisions at local, regional, or national level.

14. An oral guideline includes considerations on knowledge gaps
The literature study shows whether there is sufficient evidence, insufficient evidence, conflicting evidence, or no evidence to answer an initial question. In the last three cases, there is a knowledge gap. Knowledge gaps are described briefly and concisely in the guideline in a separate paragraph, preferably with prioritization (for the research agenda).

15. An oral care guideline text has fixed parts
The guideline text always contains a care-related part and a general part. The scientific evidence is presented in an evidence table, preferably in a fixed format, such as that of the G-I-N Evidence Tables Working Group 7. The relationship between the strength of scientific evidence and the recommendation must be made explicitly, in text and/or symbols.
The general section describes the aim, target group(s), method and development, including authors and a list of all parties involved together with reported interests. This section also contains a summary, suitable for direct consultation in practice and tailored to the needs of healthcare professionals and healthcare users. The guideline indicates who owns the copyright and any user rights of the guideline.

16. Products are delivered that promote the application of the guideline
The guideline development process delivers products that are tailored to the needs of both healthcare professionals and healthcare users, including marginalized groups and persons with visual and hearing impairments. For healthcare professionals, this includes computer applications, training materials, and audit systems. For healthcare users, this includes products such as patient versions of the guideline in laymen language, choice-supporting information and education materials (such as decision aids), avatars, visuals and other products that promote self-management and joint decision-making by healthcare professionals and healthcare users in the care process. The minimum products to be delivered are determined in the initial phase of the development process.

Finalization phase

17. Experts and future users of the guideline are consulted before publication of the guideline.
In the comment round, healthcare professionals and healthcare users, including vulnerable groups and persons with visual and hearing impairments, assess the guideline for content and applicability. This commentary is preferably requested via the relevant scientific and professional associations and patient/client organizations. In addition, comments can be requested from methodological experts who assess the guideline for methodological validity and from representatives of health insurers, healthcare organizations, and institutions. The method of the comment round and the processing of the comments are briefly described in the

guideline. Guidelines can also be assessed during an invitational conference, national public meeting, by means of a questionnaire survey or by a field test with a draft of the guideline.

18. The guideline is approved by at least all primary care professional groups, patient organization(s) and organizations representing marginalized groups and persons with visual and hearing impairments.
Authorization - approval by professional oral care associations on the EU and national level - is a formal ratification of the guideline. This is requested by all associations involved in the development of the guideline. The patient organization(s) are requested to approve at least the bottlenecks they have introduced and elaborated in the guideline. The guideline is published after three months or earlier, but not before all primary professional groups; patient organization(s) and organizations representing marginalized groups and persons with visual and hearing impairment have given their approval.

19. A procedure for revising the guideline is stated
The guideline states the term for revision and responsible persons or organizations for revision. The term can be based on the expected scientific developments.
The guideline describes the procedure for registering unanswered bottlenecks and/or new (scientific) insights that may lead to adapted recommendations. A guideline can be revised in its entirety or only in parts.

20. The primary organizations involved are actively committed to applying the guideline in practice during all phases of guideline development.
A guideline (partly) based on bottlenecks should include points of attention and recommendations for implementation. These describe, among other things, the implementation of tasks and responsibilities of the various healthcare professionals and healthcare organizations involved.