



Accelerating the Phase Down of Dental Amalgam

A presentation by the ***American Dental Association***,
the ***FDI World Dental Federation*** &
the ***International Association for Dental Research***

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Progress Phasing Down The Use of Dental Amalgam on National Scales

Mr. Enzo Bondioni
Executive Director,
FDI World Dental Federation

What is Dental Amalgam?



Image source: [Wikimedia Commons](#)

- Dental amalgam is a **filling material for teeth** prepared by mixing mercury with dental amalgam alloy ([ISO 1942:2020](#))
- Used for > 150 years as a **safe, easy to use, durable and cost-effective restorative material for caries**
- **Mercury-free alternatives** exist, but **cannot be considered full replacements** of dental amalgam for all clinical cases yet
- Phase out before the availability of safe, effective, and affordable alternatives, in resource-limited settings, will **impact the provision of quality treatment** and lead to an **increase in teeth extractions**
- **Comprehensive phase-down of the use of dental amalgam is needed**

Untreated caries in permanent teeth are the most prevalent disease worldwide (affecting 2.03 billion people)

Minamata Convention & Dental Amalgam



Mercury-added products	Provisions
Dental amalgam	<p>Measures to be taken by a Party to phase down the use of dental amalgam shall take into account the Party's domestic circumstances and relevant international guidance and shall include two or more of the measures from the following list:</p> <ul style="list-style-type: none">(i) Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration;(ii) Setting national objectives aiming at minimizing its use;(iii) Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration;(iv) Promoting research and development of quality mercury-free materials for dental restoration;(v) Encouraging representative professional organizations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and on promoting best management practices;(vi) Discouraging insurance policies and programmes that favour dental amalgam use over mercury-free dental restoration;(vii) Encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration;(viii) Restricting the use of dental amalgam to its encapsulated form;(ix) Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.

The Minamata Convention regulates the use of dental amalgam through a phase-down approach given public health implications

- Article 4 on **Mercury-added products**
 - Para 3: “Each Party shall take measures for the mercury-added products listed in **Part II of Annex A** in accordance with the provisions set out therein.”
 - Para 8: “**No later than five years** after the date of entry into force of the Convention, the Conference of the Parties shall **review Annex A and may consider amendments** to that Annex in accordance with Article 27.”
 - Para 9: “In reviewing Annex A pursuant to paragraph 8, the Conference of the Parties shall **take into account** at least: [...] (c) The **availability** to the Parties of **mercury-free alternatives that are technically and economically feasible, taking into account the environmental and human health risks and benefits.**”

In countries where advanced alternatives are fully safe, accessible, and affordable, phase out can be considered. This cannot be imposed as a one-size-fits-all solution on all Convention Parties as they adapt phase-down strategies to their national contexts.

Dental Amalgam at COP4.2

Two amendment proposals affecting Annex A, Part II at COP4.2:

- By EU Member States, complements current language, restricts phase-down approach by 2024 based on EU regulation 2017/852 of 17 May 2017
- By the Africa region (led by Botswana, Burkina Faso & Madagascar), replaces current language, asking phase-out by 2029

The African proposal leaves out the emphasis on prevention, coverage and research into alternatives, and waste management >>>>

Road map for actions by Parties to phase down dental amalgam: 2021-2029/ Measures to be taken by a Party to phase down the use of dental amalgam towards a phase out in 2029

1. By 1 January 2023, each Party to the Minamata Convention on Mercury shall issue a communication recommending that only non-mercury dental filling materials be used in children and in women of childbearing age.
2. By 1 January 2025, each Party to the Minamata Convention on Mercury shall set out a national plan concerning the measures it intends to implement to phase out the use of dental amalgam. Parties shall make their national plans publicly available on the internet and shall transmit them to the Secretariat.
3. By 1 January 2027, the manufacture and import of amalgam shall cease. To account for exceptions and accommodate the transition to mercury-free dentistry, Parties may permit domestic sales inside their country for two more years.
4. By 1 January 2029, domestic sales of amalgam inside countries, as stipulated in point 3 above shall also cease.

Lack of Engagement with the Health Sector



Key challenge remains the lack of engagement with the health sector and taking into consideration public health implications

Says: “Despite the strong presence of WHO Member States among the Parties to the Minamata Convention and despite progress made in implementing relevant measures, this review of [Minamata Initial Assessment] MIA reports raises concern about the extent of engagement of ministries of health in the MIA process and therefore in the implementation of the health-related articles of the Convention. Health ministries did not appear to have been involved in preparing about half the reports, and, in many cases, the role of health ministries in implementing the health-related articles was not yet defined.”

Link: <https://www.who.int/publications/i/item/9789240041011>

Five Key Arguments

Any review of Annex A, Part II beyond reinforcing the current phase-down approach (for instance, by establishing a deadline for Convention Parties to adopt all the current provisions) would be premature, having undesired public health implications. **WHY?**

The phase-down approach is working

Emphasis on prevention remains crucial

More research on alternative materials is needed, including their environmental impact

Alternative materials must be accessible and affordable

Waste management remains the most important action point even in a phase-out scenario



Research Advancements into Amalgam Alternatives

Gottfried Schmalz, Ph.D.
Professor of Operative Dentistry;
Department of Operative Dentistry and Periodontology,
University Hospital Regensburg

Present Research Advancements

- Direct restoratives
 - Resin Composite materials
 - Glass ionomer cements
 - Combinations
- (Indirect restoratives)
 - Crowns
 - Inlays/partial crowns



Still Existing Problems: Longevity?

- Direct restoratives
 - Resin Composite materials
 - Glass ionomer cements



RCM: Secondary tooth decay



GIC: fracture

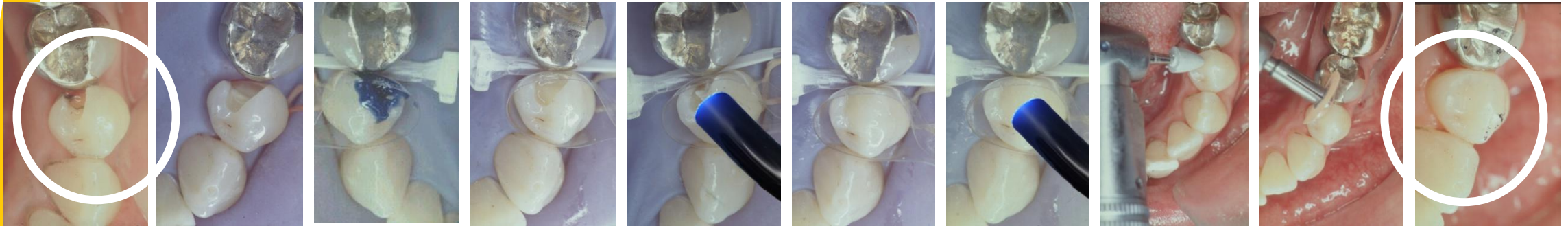
Table 1 Survival of composite restorations, overall, with respect to time to re-intervention, compared with other restorations

Type of treatment	Survival (%) at					n
	1 year	5 years	10 years	15 years		
Amalgam	91	66	51	41	7,292,564	
Composite resin	87	59	43	34	3,504,225	
Glass ionomer	84	53	37	28	1,592,566	
Crown	93	77	63	53	1,202,005	

Dental practice data

Still Existing Problems: Technique?

- Direct restoratives
 - Resin Composite materials



Complex technique

- Glass ionomer cements



Atraumatic restorative treatment

- Especially in developing countries
- For Class I
- Generally inferior to RCM*

* Dorri et al, 2017, Cochrane Database of Systematic Reviews

Still Existing Problems: Costs?

- Direct restoratives
 - Resin Composite materials
 - several studies: Increase of costs*
 - Experiences in Norway: 33 – 50% increase
 - Also for bulk technique**
 - **Reason: Complex technique**
 - **Consequence: if resources are missing: more extractions and more oral health inequalities worldwide*****



*Review: European Commission Scientific Committee on Emerging and Newly Identified Health Risks 2015

**Schwendicke et al, J Dent Res, 2018

*** Aggarwal VR, BMC Health Serv Res, 2019

Still Existing Problems: Safety?

- Amalgam

- International Association for Dental Research 2020 (IADR)*

“On the basis of the best available evidence, the IADR affirms the safety of dental amalgam for the general population without allergies to amalgam components or severe renal diseases.”

- FDI 2021**

“The preponderance of available evidence does not link the presence of amalgam restorations with chronic and degenerative diseases, ...in the general population”

- Alternatives

- EU Scientific Committee on Emerging and Newly Identified Health Risks*** and IADR 2020*

“Non-mercury containing alternatives are not free from any concerns about adverse effects.”

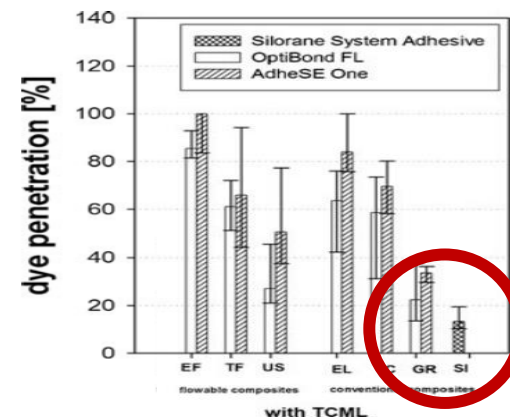
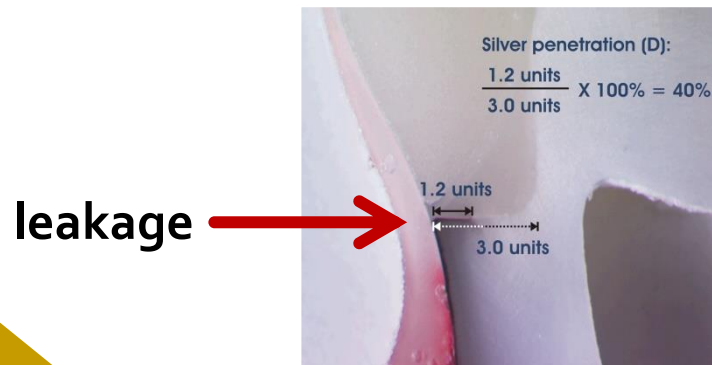
*Journal of Dental Research 2020

** <https://www.fdiworlddental.org/policy-statements>

*** European Commission 2015

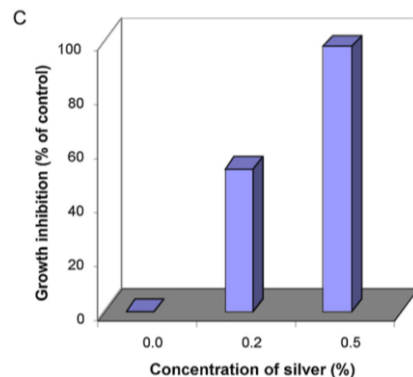
Research Advancements - Under Investigation

- Direct restoratives (selected)
 - Resin Composite materials
 - New resin chemistry: replace degradation prone traditional **resins** by degradation resistant **resins** (Gonzalez-Bonet A, et al, Biomacromolecules. 2015)
 - Better polymerization/reduced shrinkage: use of “**ring-opening**” **molecules** alone and in combination with acrylates (Krifka S,. et al., Clin Oral Investig. 2012; Danso R, et al., Dent Mater. 2018)



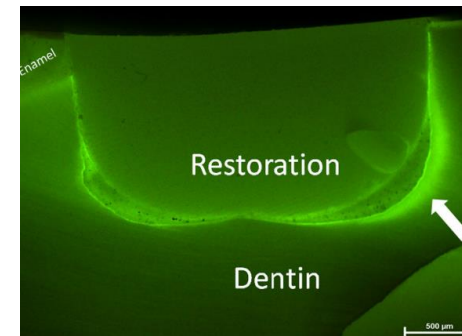
Research advancements - Under Investigation

- Direct restoratives (selected)
 - Resin Composite materials
 - New adhesives: one step Universal (Josic U., et al., Dent Mater. 2022)
 - Self adhesive materials (Cieplik F., et al., Clin Oral Investig. 2022)
 - Multifunctional (bioactive) materials; e.g. antibacterial (Schmalz/Cieplik, Monogr Oral Sci. 2021)



Nanosilver:
Antibacterial
In vitro

Dental Materials. 2011; 27: 322–328



Nanosilver:
Less secondary caries
In vitro

Krämer N., et al., Clin Oral Investig. 2015

Research Advancements - Challenges

- From bench to bedside
 - Limited predictivity of laboratory (bench) studies
 - Screening methods to select the best candidates
 - Randomized clinical studies (bedside) necessary
 - “Success” of a restoration can be evaluated only after 5/10 years
- Costs
 - So far new alternatives only at higher costs
- Implementation into health care system takes time (training, equipment)

Research Advancements - Conclusions

- New alternative materials have already been developed
- Still, problems exist for: affordability, durability and safety
- Strong research activities are under way
- Due to inherent technical problems, frankly, no reliable indication of a timeline can be given, but ...
- **Support in research certainly accelerates the Phase Down of dental amalgam**



Public Health Lens – Continued Action and Investment

Christopher Fox, Ph.D.
Chief Executive Officer,
International Association for Dental Research

Annex A; Part II Dental Amalgam Provisions

- Measures to be taken by a Party to phase down the use of dental amalgam shall take into account the Party's domestic circumstances and relevant international guidance and shall include two or more of the measures from the following list:
 - Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration;
 - Setting national objectives aiming at minimizing its use;
 - Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration;
 - Promoting research and development of quality mercury-free materials for dental restoration;
 - Encouraging representative professional organizations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and on promoting best management practices;

Annex A; Part II Dental Amalgam Provisions

- Measures to be taken by a Party to phase down the use of dental amalgam shall take into account the Party's domestic circumstances and relevant international guidance and shall include two or more of the measures from the following list: (continued)
 - Discouraging insurance policies, and programmes that favour dental amalgam use over mercury-free dental restoration;
 - Encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration;
 - Restricting the use of dental amalgam to its encapsulated form;
 - Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.

Minamata COP-3 MC-3/2 (2019)

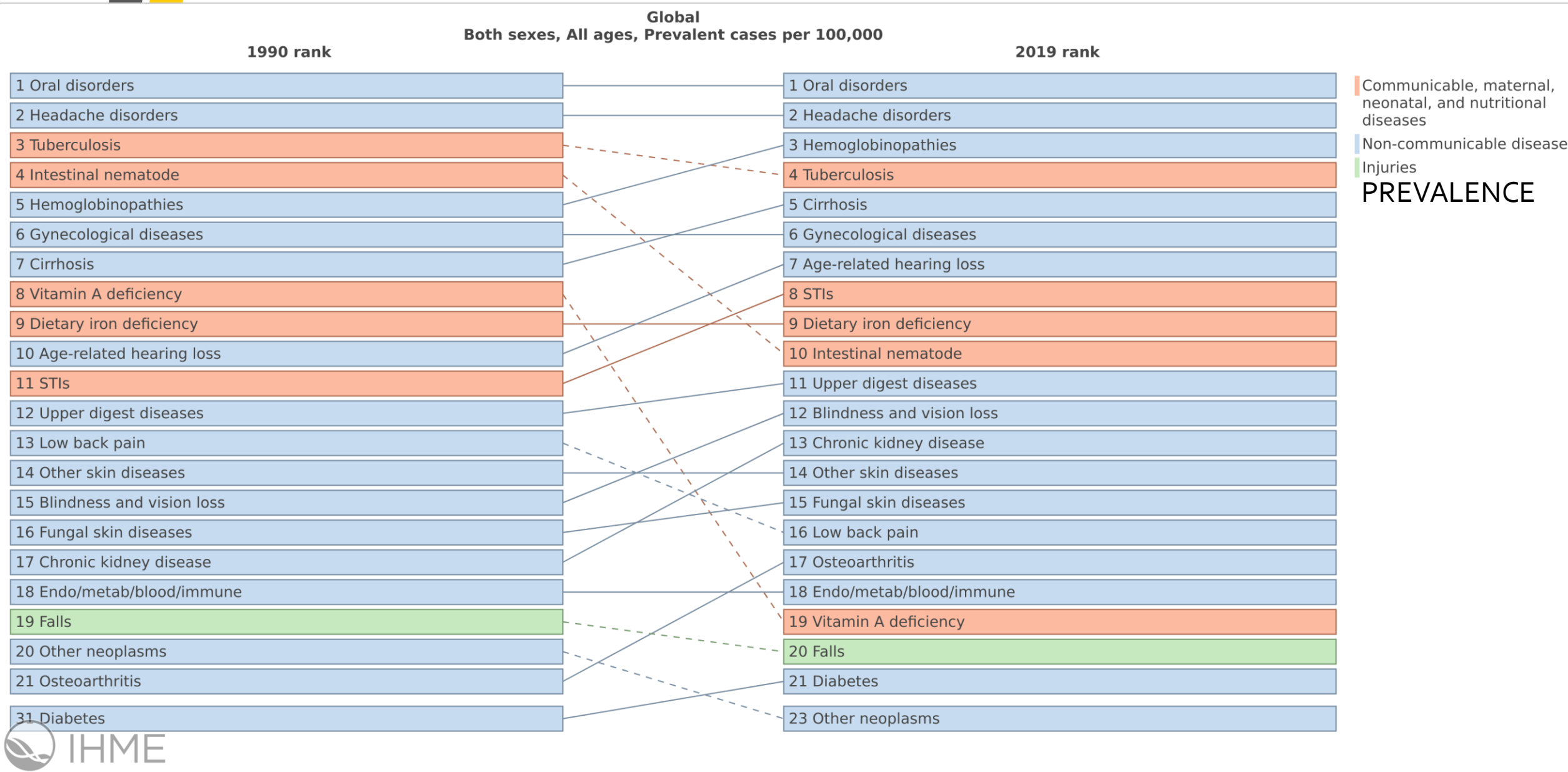
- Decision adopted by the third Conference of the Parties to the Minamata Convention on Mercury:
 - *Encourages* Parties to take more than the two required measures in accordance with Annex A, part II, of the Convention to phase down the use of dental amalgam;

3.5 Billion People

- Global Burden of Disease (GBD) 2015 Study
 - Disability-Adjusted Life Year (DALY) 1990-2015
 - 3.5 Billion People – 48% of World's Population
 - no notable improvement between 1990 and 2017.
 - Due to aging and population growth, burden of oral diseases
 - increasing over 25-year time period
 - Untreated dental caries in permanent teeth is the most prevalent condition - 2.5bil

No. of cases (millions)	1990	2015
Untreated Caries Permanent	1,739	2,521
Untreated Caries Deciduous	555	576
Severe Periodontitis	307	538
Total Tooth Loss	157	276
Other Oral Conditions	89	134
TOTAL	2,513	3,522

Kassebaum, N.J., et al *J Dent Res* 2017



WHO 74th World Health Assembly: Oral Health Resolution 2021

- Adopted Executive Board January 2021 -> WHA May 2021
 - Key concepts in Resolution:
 - Quality of Life, healthy ageing, associations with CVD, diabetes, cancers, pneumonia and premature birth
 - Shared risk factors: Tobacco, harmful use of alcohol, free sugars, poor hygiene
 - Necessity to integrate strategies on oral health into overall Non-Communicable Disease (NCD) policies
 - Efficient workforce models for oral health services
 - Oral health services as part of essential health services to deliver Universal Health Coverage (UHC)

WHA74.5 – Oral Health Resolution

- Sri Lanka, over 40 supporting Member States and the broad coalition of NSAs
- Onward to the Global Strategy 2022 and Global Action Plan 2023 including best buy interventions on oral health as part of NCDs and integrated into UHC!

RESOLUTIONS

EB148.R1 Oral health¹

The Executive Board,

Having considered the report on oral health: achieving better oral health as part of the universal health coverage and noncommunicable disease agendas towards 2030,²

RECOMMENDS to the Seventy-fourth World Health Assembly the adoption of the following resolution:

The Seventy-fourth World Health Assembly,

Having considered the report by the Director-General on oral health: achieving better oral health as part of the universal health coverage and noncommunicable disease agendas towards 2030;

LEADING THE WORLD TO OPTIMAL ORAL HEALTH



WHO World Health Assembly 74 (WHA74)

Item 13.2 Political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases – Oral health

WHO DG: “Oral Health has been Overlooked for Too Long”



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Seventy-fourth World Health Assembly

WHO and the WHA – an explainer

Media resources

Watch live WHA74 sessions

The sessions can be watched live on 24 May - 1 June 2021. Recordings will be available in the sidebar listing.

UPCOMING: Seventh meeting of Committee A 27.05.2021 14:00 - 17:00 (CEST)

Available languages: [عربي](#) [中文](#) [English](#) [Français](#) [Русский](#) [Español](#)

GUEST EDITORIAL

The Role of Research in the WHO Oral Health Resolution

B. Varenne¹ and C.H. Fox² 

Keywords: global health, United Nations, World Health Organization, non-communicable diseases, dental research, evidence-based practice

On January 21, 2021, the 148th session of the World Health Organization (WHO) Executive Board adopted a comprehensive resolution on Oral Health (WHO 2021a) after carefully considering the WHO Director General's report on *Oral Health: Achieving Better Oral Health as Part of the Universal Health Coverage and Noncommunicable Disease Agendas towards 2030* (WHO 2021b). The adopted Executive Board resolution will now proceed to the 74th WHO World Health Assembly in May 2021. The last time an

document to communicate the value of oral health to all policy makers, including, of interest to International Association for Dental Research (IADR) members, government research funders and private foundations.

The 2021 Resolution notes and builds on the inclusion of oral health in 2 United Nations (UN) political declarations: the UN General Assembly High Level Meeting on the Prevention and Control of Noncommunicable Diseases (UN 2011) and the UN General Assembly High Level Meeting on Universal Health Coverage in 2019 (UN 2019).

The Noncommunicable Disease Political Declaration includes the following paragraph:

tropical diseases, as part of universal health coverage.

These 2 seemingly small mentions of oral health over the past decade set the stage for oral health ascending to the highest level of global health policy discussions.

The resolution also notes the Minamata Convention on Mercury (United Nations Environmental Programme 2013) and the need for focused research to develop viable replacement dental restorative materials to phase down the use of dental amalgam.

The rationale for the need for an oral health resolution will be familiar to readers of the *Journal of Dental Research*, and articles were cited that

- WHO Member States' Commitments:

*“The resolution calls on member states to **integrate oral health within their national policies and, as part of general health, to reorient the traditional curative approach and move toward a preventive and health promotion approach to oral health, develop surveillance and monitoring systems, map and track fluoride in drinking water, and reduce risk factors for oral diseases and strengthen oral health care as part of universal health coverage.**”*

JDR Clinical & Translational Research. 2021;6(2):112-114. doi:[10.1177/2380084421997095](https://doi.org/10.1177/2380084421997095)

WHO 75th World Health Assembly: Draft Global Strategy on Oral Health

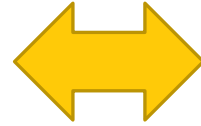
- Key Preventive Approaches for Dental Caries that will Reduce the Need for *Any* Dental Restorative Material
 - National Oral Health Care Systems
 - Funding and Integration
 - Health Workforce Planning
 - Target Social and Commercial Determinants of Health
 - Reduce Intake of Free Sugars
 - Focus on Oral Health Inequities
 - The Use of Fluorides
 - Community-based methods: Water fluoridation
 - Fluoride toothpaste

Need to Integrate and Synergize

UNEP

Minamata Convention on Mercury

- Party to the Convention
- Ministry of the Environment
- Obligates Parties to Phase Down the Use of Dental Amalgam



WHO

WHA 74.5 Oral Health Resolution

- WHO Member States
- Ministry of Health
- Calls on Member States to:
 - Integrate Oral Health into Overall Health
 - Reorient towards a Preventive approach
 - Map and Track Fluoride
 - Reduce Risk Factors
 - Strengthen Oral Health Care as part of Universal Health Coverage



Separators and Waste Management

Elizabeth Shapiro, DDS, JD

Chief of Governance and Strategy Management,

American Dental Association



International Standards for Amalgam Separators

- ISO 11143:2008
- Effectively filter 95% of amalgam waste
- This standard was last reviewed and confirmed in 2016, and remains the most current version.

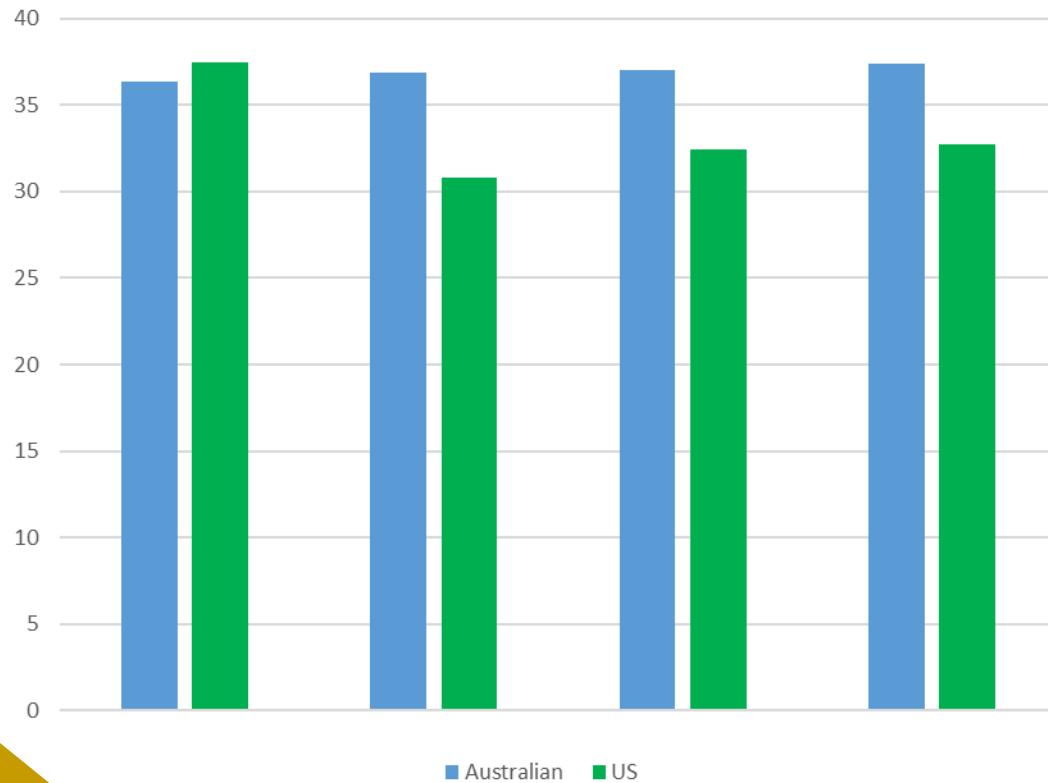


Mandated or Not:

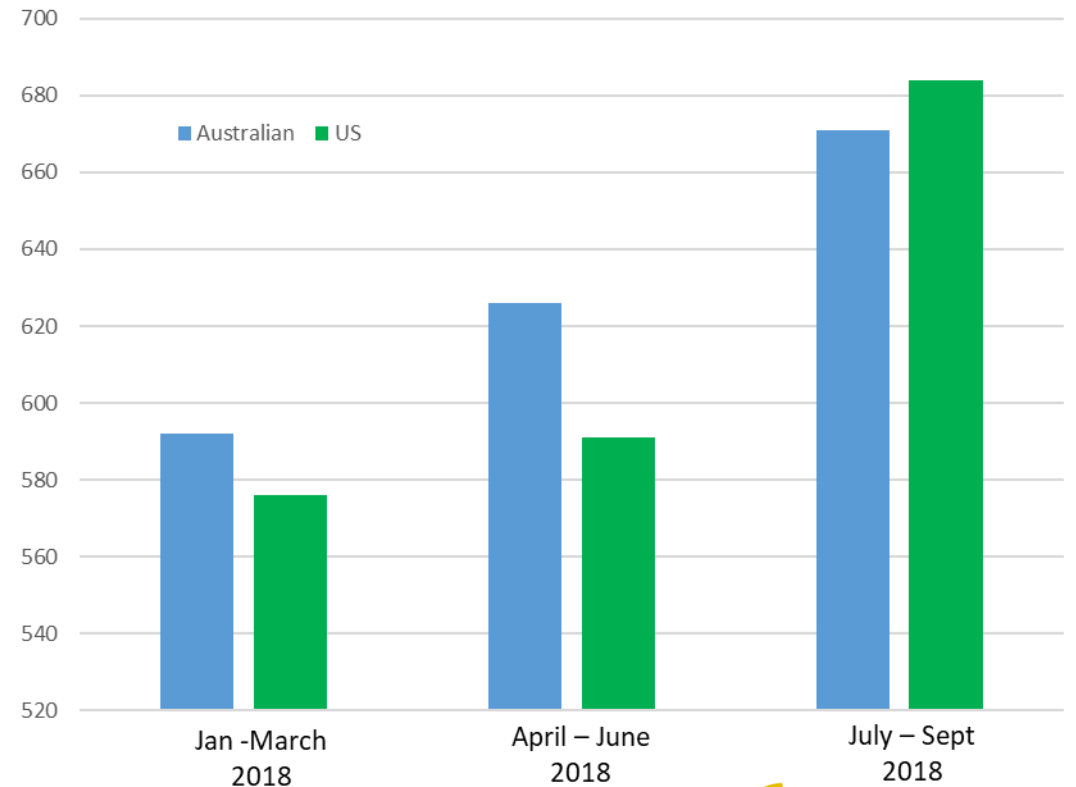
- United States: Environmental Protection Agency (EPA) regulation
 - In effect July 14, 2017
 - Full compliance July 14, 2020
- Australia: ADA began in 2007 addressing dental waste management, with most recent revision Aug 2021—separators “should be installed”
- European Union: Mandatory use of amalgam separators
 - Environmental Management of Dental Materials: Responsible Practice 2013 Update (in part)
 - In support of responsible practice for the reduction of the environmental impact of the use of dental amalgam, dentists should:
 1. Use amalgam separators which respect ISO standards

Consistent and Successful Removal of Amalgam from the Waste Stream

3 mo. measures of kg Hg/kg of amalgam collected



of separators service by one vendor over time



Three Month Snapshot

- Amalgam collected– 1, 099KG
- Mercury recovered– 368KG
- Amalgam Separators serviced– 658
- Despite phase down, dental amalgam will continue to exist and waste will need to be addressed



Beyond Separators?



- Capacity to recycle needed.
- Infrastructure development planned and executed.
- Existing amalgam restorations and other mercury sources exist, and will continue to exist
- Funding sources such as Global Environment Facility (GEF) 7.

Questions and Discussion



Closing Remarks

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