Accelerating the Phase Down of Dental Amalgam: Progress Continues

A presentation by:

ADA American Dental Association®

FDI World Dental Federation

IADR International Association for Dental, Oral, and Craniofacial Research

idm® Association of International Dental Manufacturers
Progress Phasing Down The Use of Dental Amalgam

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FDI World Dental Federation
About FDI World Dental Federation

- 1M+ Dentists
- 189 Member Associations
- 133 Countries
Political Progress: Phase Down Dental Amalgam

- **August 2017**: Minamata Convention enters into force
- **May 2021**: Oral health Resolution at WHA74
- **Sept 2021**: Dental preparations incl. WHO Essential Medicines List
- **May 2022**: Global Strategy on Oral Health at WHA75
- **April 2023**: GEF7 Project: Phasing down the use of dental amalgam
- **May 2023**: Global Oral Health Action Plan (2023 – 2030) at WHA76
WHO Member States have Adopted the Oral Health Resolution, Strategy and Action Plan

Supporting the phase down of dental amalgam in accordance with the Minamata Convention on Mercury

- Call for **phase-down** of the use of dental amalgam **taking into account domestic circumstances** and relevant international guidance.
- Recognition that a **viable replacement material** should be developed through **focused research**, which is safe, effective, accessible, affordable, and environmentally sound.
- Mandates WHO to develop **technical guidance by 2025** on environmentally friendly and less-invasive dentistry to support countries with implementation, including supporting preventative programmes.
- Recognition that **collaboration** between the ministry of health and the ministry of environment is critical.
Global Oral Health Action Plan (GOHAP) includes Dental Amalgam Targets

Global target 1

**Global target 1.1: National leadership for oral health**

By 2030, 80% of countries have an operational national oral health policy, strategy or action plan and dedicated staff for oral health at the Ministry of Health or other national governmental health agency.

**Global target 1.2: Environmentally sound oral health care**

By 2030, 90% of countries have implemented measures to phasedown the use of dental amalgam as stipulated in the Minamata Convention on Mercury or have phased it out.
GOHAP Supports Implementation of the Convention

Embeds the Minamata Convention dental amalgam provisions in the targets and indicators by which countries will measure progress.

Calls on WHO to in collaboration with the Secretariat of the Minamata Convention on Mercury and UNEP to support implementation of provisions particularly those related to the phase down in use of dental amalgam in the framework of the WHO Global Environment Facility 7 (GEF-7) project.

Accelerate implementation of dental amalgam provisions and strengthen country capacities in the environmentally sound management of associated wastes under the Minamata Convention and relevant future GEF projects.
Breaking Down Silos + Speaking The Same Language = Progress

Ministries of Environment

Phase down of dental amalgam

Ministries of Health
Mechanisms for Accelerating the Phase Down of Dental Amalgam: GEF 7 Project
GEF7 Project: Phasing Down the Use of Dental Amalgam

Aim:
To protect human health and the environment from harmful effects of mercury through implementation of policies and improved practices to phase down the use of dental amalgams.

Phase down of dental amalgam use through improved policies and technical capacity.

1. Improve management of mercury and hazardous waste from dental use.

2. Knowledge management and global awareness.
Accelerating the Phase Down of Dental Amalgam:

What Did FDI Members Tell Us?
Phasing Down Dental Amalgam: Survey on Global Progress 2021

Is your organization aware of the implications on dental amalgam of the Minamata Convention on Mercury? (n=76)

If “Yes”, does your country have a phase-down strategy to reduce the use of dental amalgam in accordance with the Minamata Convention? (n=64)
What Did FDI Members Tell Us?

If “Yes”, which provisions of the Minamata Convention has your country focused on? (n=45)

- Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land: 75.6%
- Setting national objectives aiming at minimizing its use: 73.3%
- 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: 71.1%
- Restricting the use of dental amalgam to its encapsulated form: 68.9%
- Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration: 68.9%
- Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration: 57.8%
- Promoting research and development of quality mercury-free materials for dental restoration: 35.6%
- Encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration: 20.0%
- Discouraging insurance policies and programmes that favour dental amalgam use over mercury-free dental restoration: 15.6%
How Can Implementation be Further Accelerated?
Accelerating Country-level Phase Down Through Effective Partnerships
Six Key Learnings from the Phase Down Approach

- Phase-down approach is working
- We must learn from the GEF7 projects and adapt strategies according to the evidence garnered
- Alternative materials must be safe, accessible and affordable
- More research on alternative materials is needed, including their environmental impact
- Waste management remains the most important action point even in a phase-out scenario
- Emphasis on prevention remains crucial and should be prioritized
Why the *Phase-Down* and not Phase-Out Approach should be Prioritized

**Amalgam Phase Down: The Perspective of the Nigerian Dental Association**

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Introduction

- Amalgam has been in use for more than two centuries and has a long history of being a safe, durable and affordable restorative dental material. Until recent years when resin composites and other adhesive restorative dental materials become more available and predictable in their performance, amalgam comprised 70% of restorations placed to restore carious teeth.[1]

- The decline in the use of amalgam is motivated first by the increasing demand for aesthetic restorations by patients and secondly by the phase-down of amalgam consequent on the Minamata Convention on Mercury.
The Minamata Convention on Mercury

- The Minamata Convention on Mercury is committed to a world-wide reduction and ultimate cessation of production and use of mercury-containing products i.e. ban or phase-out.[2]
- Nigeria signed the Convention on 10, October 2013 and ratified it on 01, February 2018. 128 countries are signatories and 147 countries are parties to it. The Convention came into force on 16, August 2017.
Amalgam Phase Down announced at FDI 2017
Dental Amalgam Phase-Down

• Dental amalgam is the only mercury-added product that is subject to a phase-down by the Minamata Convention.[2]

• Dental amalgam has been the primary material for restorations in the treatment of dental caries, a disease that affects 90% of people world-wide and so it not surprising that much attention is being paid to this material.[1]
Continued Use of Amalgam

- Despite the controversies surrounding amalgam and the planned suspension or stoppage of amalgam use, it is still in clinical use in a number of countries, including Nigeria.[3]

- This is because of its high strength, ability to withstand high masticatory forces, its ease of use, low technique sensitivity and its erstwhile low cost.

- As the phase-down of amalgam is progressing, amalgam has become less available and more costly to obtain in countries, like Nigeria, where it is not produced.
Use of Adhesive Materials

- Adhesive materials are more technique sensitive and require fully functional dental units and uninterrupted electricity for good success.
- Many developing countries are resource-challenged and suffer lack of technical support for the maintenance of dental units even when they are purchased brand new. Unstable electricity power supply seems to compound the problem as the chairs easy get run down due to power fluctuations and outages. This also makes fundamental accessories such as suction machines unavailable, thus, impacting negatively on the placement of adhesive restorations.[4]
Challenges in the Event of Amalgam Phase-out

• Dental caries seems to be on the decline world-wide due to the universal use of fluorides, fluoride-added products and other caries preventive protocols.

• However, in developing countries there is still the issue of late presentation of patients having very large carious lesions. Such large cavities may be out of the scope of Minimal Intervention Dentistry (MID) and they require restorations that can withstand the heavy masticatory loads in the face of hard and fibrous diets.

• The question is: Are the mercury-free alternative restorative materials as tough and resilient as amalgam?
Recommendations

• Amalgam phase-down should be observed for a long time to come in developing countries to allow for education of more dentists and dental students on the use of mercury-free alternatives.

• National Oral Health policies should be put in place which encourage mandatory periodic dental check-ups among students and staff in pre-primary, primary, secondary and tertiary institutions, workplaces and every organization.

• Caries prevention, oral health education and promotion should be intensified in developing countries and indeed all nations.
Recommendations

• More research is need to determine the efficacy and effectiveness of mercury-free restorative materials.

• Dental Schools curricula should be modified to pay more attention to the techniques required for successful placement of adhesive restorations as the protocol for their placement differs from the protocol for amalgam.

• Local research should be encouraged in developing countries to develop new restorative dental materials that are mercury-free and robust enough to serve within the context of the limited resources and infrastructure. [5]
Conclusion

• Amalgam phase-out may be inevitable but the developing countries and indeed all countries need to be assured that the mercury-free alternatives are user-friendly and are as good as or better than amalgam.
Thank You for Listening

References
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: Resin Composites

- Longevity
  - Has improved, but …

Meta-Analysis

<table>
<thead>
<tr>
<th>Risk Ratio</th>
<th>IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amalgam</td>
</tr>
<tr>
<td>10</td>
<td>Composite Resin</td>
</tr>
</tbody>
</table>

In favor of amalgam

In favor of Resin composites

Moraschini et al., J Dent 2015.

Especially in large defects and lacking good oral hygiene

Opdam et al. J Dent Res 2010

RCM: Secondary tooth decay
Still Existing Problems: Resin Composites

- Complex technique
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***

**Schwendicke et al, J Dent Res, 2018
***Aggarwal VR, BMC Health Serv Res, 2019
Cost Effective Alternatives?

- High viscosity Glass ionomer cements (GIC)
  - **Technique:**
    - dry operation field – cavity conditioner – material application – finish
      (WHO briefing note for ART)
  - **Problem**
    - low mechanical strength**
    - about 20% less than modified GIC***
      - Class II

* Dorri et al, 2017, Cochrane Database, ** Lohbauer et al., 2020, ***Ilie et al., 2012

ART = Atraumatic restorative treatment
- in developing countries
- Mainly for Class I
- Generally inferior to RCM*
Cost Effective Alternatives?

• Modified Glass ionomer cements (GIC) with coating
  
  • **Technique**
    dry operation field – cavity conditioner – material application – finish - Coating – light curing
  
  • **Problem**
  better than high-viscous GICs still low mechanical strength**
  Class II

Resin Coating
- Methyl-Methacrylate
- Light curing needed
- Increased costs
- Limited clinical evidence

* Dorri et al, 2017, Cochrane Database, ** Lohbauer et al., 2020
Cost Effective Alternatives?

• Resin modified Glass ionomer cements
  • **Technique**
    dry operation field – cavity conditioner/adhesive – material application – finish
  • **Problem**
    better than high-viscous GICs
    still low mechanical strength**

Classical indication
  - Decidous teeth

* Dorri et al, 2017, Cochrane Database, ** Lohbauer et al., 2020
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.”
  • Bisphenol-A release***

*Journal of Dental Research 2020
**https://www.fdiworlddental.org/policy-statements
*** European Commission 2015, 2023
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)
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)
    • Alkasites: resin composites with alkaline fillers/with primer (Theerarath T, Sriarj W. Clin Oral Investig. 2022)
  • Glass ionomer cements
    • Modified composition: „Glass hybrids“ (Schwendicke et al., J Dent 2021)
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
  • Presently, new general amalgam 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 for a world-wide scenario, but …
• **Support in research certainly accelerates the Phase Down of dental amalgam**
Public Health Lens – Continued Action and Investment

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Director of Science Policy,
International Association for Dental, Oral, and Craniofacial Research
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

<table>
<thead>
<tr>
<th>Condition</th>
<th>1990 (millions)</th>
<th>2015 (millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Untreated Caries Permanent</td>
<td>1,739</td>
<td>2,521</td>
</tr>
<tr>
<td>Untreated Caries Deciduous</td>
<td>555</td>
<td>576</td>
</tr>
<tr>
<td>Severe Periodontitis</td>
<td>307</td>
<td>538</td>
</tr>
<tr>
<td>Total Tooth Loss</td>
<td>157</td>
<td>276</td>
</tr>
<tr>
<td>Other Oral Conditions</td>
<td>89</td>
<td>134</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>2,513</strong></td>
<td><strong>3,522</strong></td>
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<table>
<thead>
<tr>
<th>1990 rank</th>
<th></th>
<th>2019 rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Oral disorders</td>
<td>1 Oral disorders</td>
<td>1 Oral disorders</td>
</tr>
<tr>
<td>2 Headache disorders</td>
<td>2 Headache disorders</td>
<td>2 Headache disorders</td>
</tr>
<tr>
<td>3 Tuberculosis</td>
<td>3 Hemoglobinopathies</td>
<td>3 Hemoglobinopathies</td>
</tr>
<tr>
<td>4 Intestinal nematode</td>
<td>4 Tuberculosis</td>
<td>4 Tuberculosis</td>
</tr>
<tr>
<td>5 Hemoglobinopathies</td>
<td>5 Cirrhosis</td>
<td>5 Cirrhosis</td>
</tr>
<tr>
<td>6 Gynecological diseases</td>
<td>6 Gynecological diseases</td>
<td>6 Gynecological diseases</td>
</tr>
<tr>
<td>7 Cirrhosis</td>
<td>7 Age-related hearing loss</td>
<td>7 Age-related hearing loss</td>
</tr>
<tr>
<td>8 Vitamin A deficiency</td>
<td>8 STIs</td>
<td>8 STIs</td>
</tr>
<tr>
<td>9 Dietary iron deficiency</td>
<td>9 Dietary iron deficiency</td>
<td>9 Dietary iron deficiency</td>
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<tr>
<td>10 Age-related hearing loss</td>
<td>10 Intestinal nematode</td>
<td>10 Intestinal nematode</td>
</tr>
<tr>
<td>11 STIs</td>
<td>11 Upper digestive diseases</td>
<td>11 Upper digestive diseases</td>
</tr>
<tr>
<td>12 Upper digestive diseases</td>
<td>12 Blindness and vision loss</td>
<td>12 Blindness and vision loss</td>
</tr>
<tr>
<td>13 Low back pain</td>
<td>13 Chronic kidney disease</td>
<td>13 Chronic kidney disease</td>
</tr>
<tr>
<td>14 Other skin diseases</td>
<td>14 Other skin diseases</td>
<td>14 Other skin diseases</td>
</tr>
<tr>
<td>15 Blindness and vision loss</td>
<td>15 Fungal skin diseases</td>
<td>15 Fungal skin diseases</td>
</tr>
<tr>
<td>16 Fungal skin diseases</td>
<td>16 Low back pain</td>
<td>16 Low back pain</td>
</tr>
<tr>
<td>17 Chronic kidney disease</td>
<td>17 Osteoarthritis</td>
<td>17 Osteoarthritis</td>
</tr>
<tr>
<td>18 Endo/metab/blood/immune</td>
<td>18 Endo/metab/blood/immune</td>
<td>18 Endo/metab/blood/immune</td>
</tr>
<tr>
<td>19 Falls</td>
<td>19 Vitamin A deficiency</td>
<td>19 Vitamin A deficiency</td>
</tr>
<tr>
<td>20 Other neoplasms</td>
<td>20 Falls</td>
<td>20 Falls</td>
</tr>
<tr>
<td>21 Osteoarthritis</td>
<td>21 Diabetes</td>
<td>21 Diabetes</td>
</tr>
<tr>
<td>23 Other neoplasms</td>
<td></td>
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</tr>
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https://vizhub.healthdata.org/gbd-compare/
Global Environment Facility (GEF) -7 Project

• Objective: to protect the human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds.

• 141 parties, as of April 2023

• Duration – 3 years (1 March 2023 – 28 February 2026)

• Project Areas – Senegal, Thailand, Uruguay, - - Global

• Addresses the whole life cycle of mercury from supply and trade to use, emissions releases and disposal.
Aim: To protect human health and the environment from harmful effects of mercury through implementation of policies and improved practices to phase down the use of dental amalgams.
Project Deliverables

Deliverables
- National assessments and inventory
- 3 case studies (1 per country)
- 3 assessment reports (1 per country)
- 3 sets of national policies (1 per country)
- 3 trainings provided to oral health workforce (1 per country)
- 1 Global technical report

Deliverables
- An assessment tool and protocol developed
- Separators installed and training materials developed
- Dental amalgam waste collected and appropriately disposed of
- National technical reports on best waste management practices of dental amalgam waste (1 per country)
- 1 global guidance

Deliverables
- Technical guidance on environmentally friendly and less-invasive dentistry
- One global database
- Project meetings
- One knowledge hub
- Events/meetings
- Communication products
National Progress in Gradually Reducing the Use of Dental Amalgam

- DoH piloted the waste management in dental facilities
- DoH started to collect data preparing for amended measures

Senegal
Population: 16.4 millions

Thailand
Population: 71.4 millions

Uruguay
Population: 3.4 millions

No existe prohibición de su utilización, sin embargo, sin las condiciones adecuadas de manipulación, descarte y procesamiento último de los desechos contienentes Mercurio, la recomendación es no utilizarla.
Global Environment Facility (GEF) -7 Project

- Accelerate implementation of dental amalgam provisions of the Minamata Convention
- Strengthen country capacities in the environmental sound management of associated wastes under the Minamata Convention
A Global Lens
Global Dental Mercury Usage is Very Small

- SDI estimates annual global mercury use for manufacturing dental amalgam is 12-15 tonnes per year (including all manufacturers of amalgam).
- Proposal by Botswana and Burkina Faso suggests “between 226-322 tonnes of mercury is used for dental amalgam around the world annually.”
Global Amalgam Sales are Rapidly Declining - the Phase Down is Working

- Global amalgam sales
- Does not include local manufactures from China, India, Iran, Malaysia, Greece, Turkey, Spain, Israel

Source: Fastrak Analysis – Key-stone SRL
Includes: Cavex, Coltene, Dentsply, DMG, Ivoclar, Kerr, SDI. (Coltene, Dentsply, Kerr have left the market over the past few years but their sales are in the history)
Global Restorative Sales - $1bn

Source: Fastrak Analysis – Key-stone SRL
Includes: 3M, Cavex, Coltene, Dentsply, DMG, GC, Ivoclar, Kerr, Kulzer, SDI, Shofu, Tokuyama, Ultradent, Voco
Does not include many composite manufacturers that do not report to Keystone
Where is Amalgam Mainly Used

- USA, Canada, Europe, Australia, Middle East
- Estimated amalgam sales into Africa are less than 2% of total sales
- Very little is sold to Africa – none to Burkina Faso or Botswana.
Call To Action: GOHAP

Prioritize oral health research of public health interest: Support research areas of high public health interest in addition to basic health research

Ensure research alignment with national oral health priorities

Invest in research for safe, environmentally sound, mercury-free dental filling materials
Questions and Discussion