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International Association for Dental Research Policy and Position Statements on the Safety of Dental Amalgam

Ajiboye, A. S.; Mossey, P. A.; Fox, C. H.

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Title: International Association for Dental Research Policy and Position Statements on the Safety of Dental Amalgam

Authors: A.S. Ajiboye¹, P.A. Mossey², C.H. Fox¹ and IADR Science Information Committee[†]

Affiliations: ¹International Association for Dental Research, Alexandria, VA, USA; ²Department of Orthodontics, University of Dundee, Dundee, UK; [†]see Acknowledgements for the full list of committee members

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Corresponding author: Dr. A. Seun Ajiboye, Director of Science Policy and Government Affairs, International Association for Dental Research, 1619 Duke Street, Alexandria, VA, USA 22314-3406.

Email: sajiboye@iadr.org

During the 97th General Session and Exhibition of the IADR, the IADR Council adopted policy and position statements on the safety of dental amalgam (American Association for Dental Research 2019). The policy development process is overseen by the IADR Science Information Committee (SIC). While recognizing its global audience, the IADR SIC policy development process is identical to that of IADR's American division (AADR) and has been previously described (Ajiboye et al. 2018).

The policy statement on the safety of dental amalgam is a succinct affirmation of the Association's evidence-based assessment, whereas the position statement is a fuller review of the scientific evidence. These statements were timely for the Third Conference of the Parties (COP-3) to the Minamata Convention on Mercury, an international treaty aimed at reducing global mercury pollution caused by human activity. In 2010, the United Nations Environmental Program estimated that dental amalgam contributed 21-32% and 19-13% of overall air and surface water emissions, respectively, in Europe. However, the total contribution of dental amalgam to mercury pollution is unknown and likely varies by region depending on a number of factors, such as other sources of mercury pollution; prevalence of use of dental amalgam compared to other materials; access to dental care and waste management and cremation practices. Emissions from dental amalgam can result from preparation and removal of dental amalgam, disposal, waste, cremation, etc. While it is estimated that mercury emission to air from cremation accounts for ~0.25% of the total, emissions from the other processes associated with use from dental amalgam have not been quantified (UN Environment 2019).

While the treaty requires the phase-out of many mercury-added products (with exceptions for products used for military use, research, religious practices, vaccines and for which there is no suitable alternative), the parties agreed to a phase-down of dental amalgam – Annex A Part II (Minamata Convention on Mercury: Text and Annexes 2017) – since there was not at the time – and is not currently – a replacement material that is as inexpensive, easy to handle and most importantly, durable as dental amalgam. The treaty development process, negotiations and the role of the dental research community were reviewed in Meyer et al (Meyer et al. 2016). IADR is committed to (a) placing

increased emphasis on research into primary prevention and behavior change strategies that will reduce the prevalence of dental caries and (b) promoting research into new dental materials that could one day replace dental amalgam entirely.

In November 2019, the parties considered a proposal to phase out dental amalgam by 2024 except where no alternative is available. IADR worked with FDI World Dental Congress, American Dental Association and International Dental Manufacturers and conducted meetings with U.S. delegates to the conference from the U.S. State Department and Environmental Protection Agency. IADR also submitted a research report to the treaty secretariat that showed that although research on alternative restorative materials was advancing, new materials were still not completely developed and would not be optimal replacements for dental amalgam in all situations for clinical, economic or practical reasons (International Association for Dental Research 2019). Since the adoption of these statements, the U.S. Food and Drug Administration published an updated systematic literature review, which concluded, “Overall, although exposure to elemental mercury at sufficiently high levels, e.g., chlor-alkali workers, is associated with adverse human health effects, the current evidence is insufficient to support a causal association between mercury from dental amalgam and reported adverse health effects. This is consistent with the assessments of other scientific organizations such as the recent [Scientific Committee on Emerging and Newly Identified Health Risk] report which concluded that dental amalgam does not pose a health risk for the general population, and the currently available evidence neither precludes the use of amalgam in dental restorations nor suggests the need for preventive removal of pre-existing amalgam restorations” (U.S. Food and Drug Administration 2019). Further, a recent analysis from the United Kingdom suggests a complete phase down of dental amalgam threatens to widen oral health inequalities (Aggarwal et al. 2019).

As a result of these efforts and those by other countries, the parties agreed to maintain the original provision while encouraging parties to increase phase-down efforts. COP-4 will be held in 2021. In the intervening time, dental associations will work to gather information on the use of dental

amalgam, comparative effectiveness of dental amalgams and alternatives and other information on the progress of implementing the provision.

Policy statement on the Safety of Dental Amalgam

Based on the best available evidence, IADR affirms the safety of dental amalgam for the general population without allergies to amalgam components or severe renal diseases. IADR supports maintaining its availability as the best restorative option when alternatives are less than optimal based on clinical, economic or practical reasons.

IADR supports the phase-down strategy described in the Minamata Convention on Mercury. Consistent with the recommendations of the treaty, IADR emphasizes the need, firstly, for increased oral disease prevention efforts to reduce the need for any kind of restorative material, and secondly, for further research on new biocompatible and environmentally-friendly restorative materials and approaches that are proven to have equal or improved long term clinical longevity and cost effectiveness when compared to amalgam restorations.

Position statement on the Safety of Dental Amalgam

Introduction

IADR affirms the safety of dental amalgam for the general population without allergies to amalgam components or severe renal diseases. IADR supports maintaining its availability as the best restorative option when alternatives are less than optimal based on clinical, economic or practical reasons. The safety of dental amalgam has been investigated and affirmed through independent systematic reviews of the available scientific literature conducted by national and global scientific organizations, including the European Union (EU) Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), World Health Organization (WHO) and the U.S. Food and Drug

Administration (FDA). The last review identified was conducted by SCENIHR and summarized studies performed up to 2014. This position statement considers evidence identified in previous reviews and after 2014 regarding the safety of dental amalgam for use in general and vulnerable populations and by dental health providers.

The composition and clinical effectiveness of dental amalgams

Dental amalgam is an alloy of metals that comprises approximately 50% mercury and silver, tin, copper and other metals. Dental amalgam was the first durable dental material that could be placed directly into teeth with dental caries and has been in use for over 150 years. Liquid mercury gives dental amalgam its malleability, enabling the dentist to shape and place the material into the tooth before it hardens (Ferracane 2001). Dental amalgam is less expensive (CADTH 2018) and easier to place compared to the most popular alternative material – tooth-colored composite resin. Currently, the use of amalgam varies country-by-country and is driven by clinical, economic and practical reasons (Eltahlah et al. 2018). Composite resin fillings in permanent teeth in the back of the mouth are twice as likely to fail and carry a higher risk of secondary tooth decay compared to amalgam fillings, especially in children. Secondary decay occurs in the tooth after the restoration is placed and is the most common reason that restorations fail (Bernardo et al. 2007; CADTH 2018; Rasines Alcaraz et al. 2014; Soncini et al. 2007).

No established links between amalgam and systemic diseases

Many health-related concerns surrounding the safety of using mercury-containing materials in the mouth have arisen. However, the totality of available evidence is not sufficient to suggest a systemic health risk associated with dental amalgam use in the general population. This is the position of both the FDI World Dental Federation (FDI) and World Health Organization (WHO), which consider the use of dental amalgam to be safe, with risk related only to local irritations and not to systemic adverse health effects (WHO Consensus Statement on Dental Amalgam 1997). The U.S. FDA found insufficient

evidence for a link between mercury exposure from dental amalgam and adverse systemic health effects, including in vulnerable populations. The FDA reviewed data on children and pregnant and breastfeeding women and available studies on a variety of diseases, including multiple sclerosis, Alzheimer's Disease, and other neurological diseases; low birth weight; and cardiovascular disease (National Center for Toxicological Research and U.S. Food and Drug Administration 2009). Likewise, after reviewing several adverse health effects on neurological, immunological, and reproductive systems in the general population, SCENIHR concluded that dental amalgam fillings were not linked to systemic diseases in the general population (Scientific Committee on Emerging and Newly Identified Health Risks 2015).

Low levels of mercury released from dental amalgam

While it is true that those with dental amalgam fillings generally have higher levels of blood and urine mercury levels, it is important to note that *slight* increases in mercury exposure due to dental amalgam do not rise to a level of concern and are not expected to lead to adverse health effects. The expected exposure to mercury from dental amalgam is well below the EU safety limits established for those occupationally exposed to mercury (Scientific Committee on Emerging and Newly Identified Health Risks 2015). The U.S. Agency for Toxic Substances and Disease Registry (ATSDR) established a minimum risk level (MRL) for chronic inhalation of mercury vapor of approximately 4 micrograms inhaled mercury per day, which is less than people in the U.S. and Canada are exposed to from their amalgam fillings. The MRL is the level of mercury that can be inhaled without the expectation of suffering adverse health effects. Exposure to a higher level of mercury vapor does not necessarily mean the exposed would suffer adverse health effects but that at the MRL, no adverse effect is expected. This value takes into account infants, older people and people with poor health (Agency for Toxic Substance and Disease Registry and Public Health Service 1999). The U.S. Environmental Protection Agency (EPA)

derived a similar risk estimate of 6 micrograms per day (National Center for Environmental Assessment 1995).¹

The amount of mercury released from amalgam restorations is likely dependent on a number of factors including the number of restorations, the surface area of the restorations, chewing and brushing habits and the ages of the restorations (Agency for Toxic Substance and Disease Registry and Public Health Service 1999; National Center for Toxicological Research and U.S. Food and Drug Administration 2009). Urine levels of mercury increase by approximately 1-2 units in adults for every 10 amalgam fillings placed (Dye et al. 2005). Furthermore, the amount of mercury released from amalgam fillings decreases over time (Berdouses et al. 1995; DeRouen et al. 2006; Palkovicova et al. 2008).

Amalgam removal

Some patients have had their amalgam fillings removed out of unfounded health concerns. However, amalgam fillings should not be removed except in the case of an allergic reaction (Agency for Toxic Substance and Disease Registry and Public Health Service 1999; Scientific Committee on Emerging and Newly Identified Health Risks 2015). Patients who had their amalgam fillings removed did not experience a meaningful decrease in blood mercury levels even years after the removal (National Center for Toxicological Research and U.S. Food and Drug Administration 2009). Most studies showed patients did not receive symptomatic relief after removal. In some studies, symptoms did not correlate with the number of amalgam fillings or exposure to mercury, meaning that their symptoms were likely not due to their fillings in the first place. Furthermore, the experience of negative life events made it difficult to attribute symptoms to their amalgam fillings (Agency for Toxic Substances and Disease Registry 2003; Scientific Committee on Emerging and Newly Identified Health Risks 2015).

¹ The MRL derived by ATSDR is for noncancer health effects as is the risk estimate by the U.S. EPA. The EPA assessed potential cancer-causing effects of inhalation of elemental mercury – the type of mercury released by dental amalgam – and did not find enough evidence to draw a conclusion.

Vulnerable populations

There is particular concern around the use of dental amalgam in vulnerable populations, particularly in children and pregnant and breastfeeding women. The systematic reviews performed by the FDA and SCENIHR included studies on these populations. Both the FDA and SCENIHR reviews found that fetal exposure to mercury from dental amalgam correlated with the number of maternal fillings but that exposure decreases after birth even with breastfeeding. Fetal exposure to mercury from maternal dental amalgam restorations is below the “level considered to be hazardous for neurodevelopmental effects in children exposed to [mercury] *in utero*” (Palkovicova et al. 2008); the more time since the mother’s last filling, the less mercury to which the fetus is exposed; and most importantly, has not been linked to adverse health effects in children exposed to mercury from dental amalgam in the womb (National Center for Toxicological Research and U.S. Food and Drug Administration 2009; Scientific Committee on Emerging and Newly Identified Health Risks 2015).

Two studies are particularly notable. The National Institute of Dental and Craniofacial Research funded two studies in Portugal and the U.S. to determine if there were any adverse health effects in children whose teeth were restored with dental amalgam. Both studies were randomized clinical trials and were conducted over seven and five years, respectively. In each study, over 500 children were randomly assigned to group receiving either amalgam or composite resin fillings. As expected, both studies showed that children with amalgam restorations had higher levels of mercury in their urine compared to children treated with composite resin (Bellinger et al. 2006; DeRouen et al. 2006). In the Portugal study, urinary mercury levels plateaued by the second year of the study and declined throughout the rest of the study. Furthermore, there was no statistical difference between children in the amalgam or composite resin groups in behavioral tests, including memory and attention, at any point during this study. Children whose teeth were restored with composite resin in this study also experienced more failure of their tooth restorations, congruent with previous observations (Bernardo et al. 2007; DeRouen et al. 2006; Soncini et al. 2007). In the study conducted in the U.S., there was also

no statistical difference between children treated with dental amalgam and composite resin in neurological tests, including for IQ and memory, or kidney function (Bellinger et al. 2006).

Since 2014, studies on pregnant women and children showed increased mercury in urine and blood of children and pregnant women with dental amalgam fillings, as expected (Baek et al. 2016; Golding et al. 2016); no statistically significant association between maternal amalgam restorations and stillbirth after accounting for maternal parameters such as age and smoking, among others (Lygre et al. 2016); higher maternal and cord blood in mothers with amalgam restorations but no difference in birth weight, length or head circumference (Bedir Findik et al. 2016) and no increased risk of child mortality or neurological disorders of the sons of female dental staff (Naimi-Akbar et al. 2014; Vähäsarja et al. 2016).

The SCENIHR review did recommend alternative restorative materials for the primary teeth of children and the teeth of pregnant women, but this recommendation was made to comply with the provisions of the Minamata Convention on Mercury to address environmental concerns (see section, “Mercury and the Environment – the Minamata Convention”) (Scientific Committee on Emerging and Newly Identified Health Risks 2015).

It is, however, well recognized that amalgam should not be used in patients with a verified contact allergy to amalgam or its components (Thanyavuthi et al. 2016). Furthermore, the SCENIHR reports draws attention to the fact that amalgams should not be the restoration of choice for patients with severe renal diseases as mercury excretion is impaired in this cohort.

Occupational safety issues and dental amalgams

Another concern is the occupational safety of using dental amalgam. Dental professionals who place dental amalgam are exposed to more mercury than the general population, although exposure should be decreasing due to the use of encapsulated dental amalgam and increased awareness and precautions when handling dental amalgam (National Center for Toxicological Research and U.S. Food

and Drug Administration 2009; Scientific Committee on Emerging and Newly Identified Health Risks 2015). In addition there is a preference for placing tooth-colored materials over dental amalgam (Bakhurji et al. 2019). Indeed, studies of U.S. dentists since 2014 found a substantial decline in mercury exposure from 1976 when the average level exceeded 20 micrograms per liter urine to 2012 when the average was less than 2 micrograms per liter for the reasons described above. On average, dentists were still exposed to more mercury than the general population but only by about 1 microgram per liter (Anglen et al. 2015; Goodrich et al. 2016).

The FDA found too many confounding variables and significant weaknesses in the studies reviewed to draw a conclusion about the neurobehavioral effects of mercury exposure on dental professionals, including the presence of other chemicals used in dental clinics (National Center for Toxicological Research and U.S. Food and Drug Administration 2009). A 2015 study found an association between tremor and urinary mercury levels and cumulative mercury exposure. The study is based on a convenience sample of dentists, so there may be selection bias in that some dentists were perhaps more motivated to participate than others or less able to participate based on health status. Furthermore, the authors did not have access to data on fish consumption of the participants and other possible confounding variables.

Occupational safety studies have uncovered poor adherence to safety guidelines. The SCENIHR review noted one study that found violations of environmental and personal safety standards in 67% and 45%, respectively, of clinics visited (Ritchie et al. 2004). Some recent studies also revealed violations of occupational safety regulations and indicated the need for more training on the safe use of dental amalgam, properly ventilated dental clinics and oversight (Jamil et al. 2016; Khwaja Mahmood et al. 2016). The study by Khwaja and colleagues also highlighted the fact that there is still a high level of dental amalgam use among dentists in Pakistan, even in children and pregnant women and use can vary dramatically by location (Khwaja Mahmood et al. 2016). The FDI and WHO recommend using proper personal protective equipment and techniques and monitoring of mercury vapor levels in dental clinics

to minimize exposure of dental personnel to mercury vapor (WHO Consensus Statement on Dental Amalgam 1997), which is especially important for dentists who will continue to place high amounts of amalgam fillings. These data also reiterate the need for prevention to reduce the need for amalgam in the first place.

Since 2014, two studies in Taiwan using national insurance claims data on the neurological effects of dental amalgam warrant further investigation. The first study found that women with dental amalgam fillings had a higher overall risk of having Alzheimer's Disease than women without dental amalgam fillings after adjusting for age, location and income (Sun et al. 2015), and the second found that people with dental amalgam fillings had a greater risk of having Parkinson's Disease (Hsu et al. 2016). Neither study include a "pure" control group as the analysis was conducted from claims data, so the authors could not examine patients to ensure control group members had not received fillings before the beginning of the study date. Furthermore, the authors did not account for fish consumption (a source of methyl mercury). It is possible that once these factors are accounted for, the difference between the study and control groups would disappear. In particular, Hsu and colleagues' study on Parkinson's Disease noted that most patients were diagnosed two years after receiving dental treatment and that "it is unlikely that mercury would induce [Parkinson's Disease] in such a short time." The authors concluded that the study was unable to establish a causal association (Hsu et al. 2016).

These recent studies on associations between neurological health effects on dentists and the general population provide important contributions and directions for future studies that should address these limitations and provide more conclusive results but are not on their own sufficient to establish a causal relationship between dental amalgam fillings and Alzheimer's or Parkinson's Disease.

Mercury and the Environment – the Minamata Convention

Over 100 countries have ratified the Minamata Convention on Mercury and agreed to provisions to protect the environment from mercury emission to land, air and water, including phasing

down the use of dental amalgam. IADR agreed to promote research into alternative restorative materials and has been active in this regard. IADR calls on parties to the Convention to invest in research and development to accelerate the clinical use of new restorative dental materials. IADR especially supports the provision for countries to increase oral disease prevention efforts to reduce the need for any kind of restorative material in the first place, as the global pervasiveness of oral diseases will continue to slow the phase-down. According to the treaty, new measures that include the phase-down of amalgam restorations shall be regularly reassessed during the Conference of the Parties to the Convention.

Conclusions

Based on the best available evidence, IADR affirms the safety of dental amalgam for the general population without allergies to amalgam components or severe renal diseases. IADR supports maintaining its availability as the best restorative option when alternatives are less than optimal based on clinical, economic or practical reasons.

IADR supports the phase-down strategy described in the Minamata Convention on Mercury. Consistent with the recommendations of the treaty, IADR emphasizes the need, firstly, for increased oral disease prevention efforts to reduce the need for any kind of restorative material, and secondly, for further research on new biocompatible and environmentally-friendly restorative materials and approaches that are proven to have equal or improved long term clinical longevity and cost effectiveness when compared to amalgam restorations.

Author contributions

A.S. Ajiboye contributed to conception and design; data acquisition, analysis, and interpretation; drafted and critically revised the manuscript. P.A. Mossey, C.H. Fox and the IADR Science Information

Committee contributed to conception and design and critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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