

Indian Health Service Division of Oral Health

Plan to **Phase Down** the Use of Dental Amalgam among American Indians/Alaska Natives

2010 - 2030 (or until dental amalgam is phased out in the U.S.)



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PURPOSE:

The purpose of this plan is to provide IHS, tribal, and urban dental program staff of the intent of the Division of Oral Health to phase down the use of dental amalgam for American Indian/Alaska Native patients over the next few decades, and to inform external stakeholders of this change.

BACKGROUND:

In 2013, the Minimata Convention on Mercury was signed by 147 Parties, including the U.S. On September 24, 2020, the FDA provided guidance about the use of dental amalgam in certain groups of people who may be at higher risk to potential adverse health effects of mercury exposure, to include:

- 1. Women who are pregnant or planning to become pregnant. Placement of new amalgam fillings in a pregnant mother may result in high, transient spikes of mercury exposure to the mother and fetus. Some studies have shown a relationship between the number of amalgam fillings a mother has and mercury levels in umbilical cord blood. Results from these studies did not identify any certain associations with harmful health effects; however, the data is very limited.
- 2. **Nursing mothers.** The amount of mercury in breast milk is typically very low. Some studies have reported a relationship between the number of amalgam fillings a mother has and the amount of mercury in breast milk. The very few, limited studies that have been conducted to evaluate possible harm to infants and children exposed to dental amalgam mercury as a result of breast-feeding did not identify any definite associations with harmful health effects.
- 3. Children, especially those under the age of six. Clinical studies in children ages six and older have not found a definite connection between the use of dental amalgam and harmful health effects. Studies on children under the age of six are very limited. The developing neurological systems of children may be especially sensitive to exposure to mercury vapor.
- 4. People who are more sensitive to mercury or other components of dental amalgam. Some people may have an allergy or sensitivity to mercury or other components (e.g., silver, copper, tin or zinc) of dental amalgam and may report or experience health effects, including allergic reactions and oral ulcers, as well as more generalized symptoms, after placement of an amalgam filling.
- 5. **People with neurological impairment or kidney dysfunction.** Studies show mercury is localized in certain tissues of the body including the brain and kidneys. Very limited clinical information is available about possible health effects of mercury vapor exposure on individuals who already have kidney and/or neurological impairments.

Two key points in the FDA Safety Communication included the following:

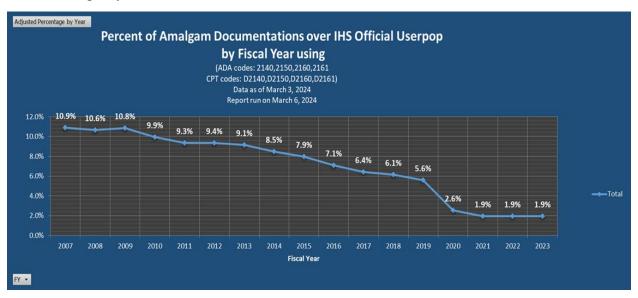
1. "The FDA **does not** recommend anyone remove or replace existing amalgam fillings in good condition unless it is considered medically necessary by a health care professional (for example, a documented hypersensitivity to the amalgam material)."

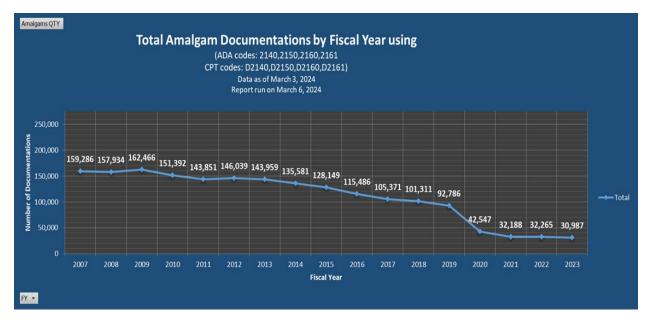


2. "The FDA **does not** find the available evidence supports a <u>complete ban of the use of dental amalgam</u>. The weight of the existing evidence does not show that exposure to mercury from dental amalgam leads to adverse health effects in the general population, and its longevity is better than that of alternatives, especially for large restorations."

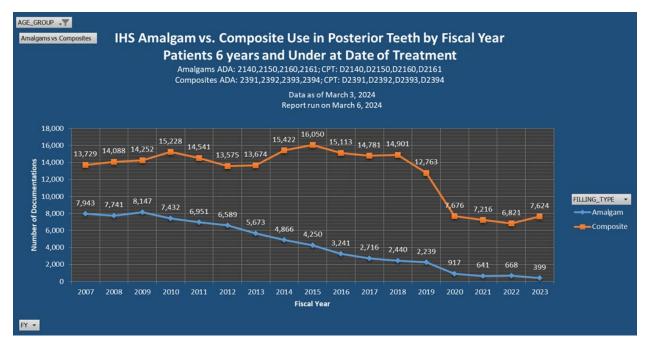
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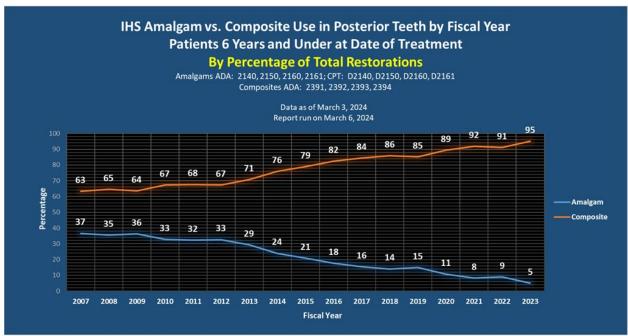
Since 2007, the Indian Health Service has tracked the use of dental amalgam and alternative restorations for American Indian/Alaska Native patients utilizing IHS, tribal, and IHS-funded urban dental programs. The following tables show the steady decline in the use of dental amalgam across the Agency, as of March 3, 2024.











As the preceding graphs indicate, amalgam usage in the IHS has decreased significantly over the past 15 years, coinciding with a large increase in the alternative restorative material, composite resin restorations. In children under 6 years of age, for example, composite restorations outnumbered dental amalgam restorations 6 to 1 in the pre-pandemic year of FY 2019.



PLAN OF ACTION:

Primary prevention of dental caries/tooth decay is the best approach to minimize avoidable dental procedures and potential use of dental amalgam in pediatric populations. To that end, IHS has created multiple initiatives focusing on primary and secondary prevention. These include:

- 1. <u>IHS Early Childhood Caries Collaborative</u>, a multi-disciplinary project designed to prevent early childhood caries in children under 6 years of age through:
 - a. Increasing access to dental care by 25% in AI/AN children through a "first tooth, first exam" motto, utilization of non-dental partners to screen children and refer to IHS, tribal, and urban dental programs for follow-up, and education in AI/AN communities about the importance of primary teeth.
 - b. Increasing the use of topical fluorides, particularly fluoride varnish, by 25% in AI/AN children through utilization of medical partners, education in AI/AN communities, and recommendations to apply fluoride varnish 3-4 times per year in children, especially those classified as high risk for dental caries (tooth decay).
 - c. Increasing the use of dental sealants, including the use of glass ionomer (GI) sealants when moisture control could not be attained, by 25% in AI/AN children through education of providers about GI efficacy and education of AI/AN communities.
 - d. Increasing the use of interim therapeutic restorations by 50% in AI/AN children. These GI fillings are an alternative to dental amalgam placed in primary teeth, usually without anesthesia. We accomplished this through the development of an AI/AN "superhero" named "Mighty Mouth" that we used to educate communities about this type of restorative material.
- 2. National Children's Dental Health Month, held each February and includes multiple educational topics designed to promote prevention of dental disease in children. Topics in the past include limiting sugar-sweetened beverages in sippy cups, first tooth first exam, fluoride varnish, dental sealants, and the importance of primary (baby) teeth.
- 3. <u>Give Kids A Smile Campaign</u>, a new collaboration between the IHS and the American Dental Association beginning in 2020 that promotes prevention and restoration of dental caries with composite resins and/or GI restorative material.
- 4. Annual seed funding in the Oral Health Promotion/Disease Prevention Funding Initiative, that has led to the development of innovations such as fluoride varnish use (IHS was the first federal agency to implement fluoride varnish in 1998), silver diamine fluoride (a dental caries arresting agent that led to the second national protocol developed by the IHS and system-wide implementation starting in 2014), and the use of glass ionomer sealants in primary molars.

As a result of the renewed emphasis on prevention of dental caries, the IHS has seen the first-ever reduction of dental caries in children under the age of 6 years, with a 5% decrease in caries experience and a 14% decrease in untreated decay, according to a 2019 IHS survey data brief.



IHS Division of Oral Health Dental Amalgam Phase-Down Plan, 2010-2040

In addition to primary prevention, the IHS Division of Oral Health has promoted alternatives to the use of dental amalgam including:

- 1. Posterior composites (tooth-colored resins) restorations, which now outnumber posterior amalgams 6 to 1 in children under 6 years of age;
- 2. <u>Glass ionomer restorations</u>, which release fluoride, for which IHS has seen a 200% increase since 2010 in children under 6 years of age;
- 3. The use of stainless steel crowns to cover primary teeth that are decayed; and
- 4. The use of silver diamine fluoride as a secondary prevention technique.

TIMELINE FOR FURTHER ACTION:

Fiscal Year 2024

- Reduce the use of dental amalgam in all patients by 25% by the end of FY 2024, and by 50% in children < 6 years of age, compared to FY 2019 data.
- Provide guidance to IHS, tribal, and urban dental programs to cease the use of dental amalgam on deciduous (primary) teeth.

Fiscal Year 2025

- Conduct a national webinar for IHS dental providers regarding the 2020 FDA Safety Communication and this phase-down plan.
- Further reduce the use of dental amalgam in all patients by 25% by the end of FY 2025, compared to FY 2023 data.

Further Reductions

- Develop policies that reduce the amount of dental amalgam purchased by IHS service units, while also looking at the possibility of developing blanket purchase agreements in the purchase of glass ionomer and composite restorative materials.
- Further reduce the use of dental amalgam in all patients until dental amalgam is phased out in the U.S.

