Recommendations About the Use of Dental Amalgam in Certain High-Risk Populations: FDA Safety Communication

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The U.S. Food and Drug Administration (FDA) is providing recommendations about the use of dental amalgam (/medical-devices/dental-devices/dental-amalgam) in certain groups of people who may be at greater risk to the potential adverse health effects of mercury exposure, to include:

- Pregnant women and their developing fetuses;
- Women who are planning to become pregnant;
- Nursing women and their newborns and infants;
- Children, especially those younger than six years of age;
- People with pre-existing neurological disease;
- People with impaired kidney function; and
- People with known heightened sensitivity (allergy) to mercury or other components of dental amalgam.

For over 20 years, the FDA has been reviewing, considering and holding public discussions regarding the scientific literature and other evidence on the safety of dental amalgam. Key among our findings are the uncertainties about the acceptable reference exposure levels for mercury vapor (gas), the potential for mercury to convert to other mercury compounds in the body, and whether the degree of accumulation of mercury from dental amalgam results in negative (adverse) health outcomes. The FDA held a meeting of our Dental Products Panel of the Medical Devices Advisory Committee in December 2010 (https://wayback.archive-it.org/7993/20170403223455/https:/www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommi (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and a meeting of our Immunology Devices Panel in November 2019 (/advisory-committees/advisory-committee-calendar/november-13-14-2019-immunology-devices-panel-medical-devices-advisory-committee-meeting-announcement) to discuss these uncertainties. Elemental mercury used in dental amalgam is known to cause adverse health effects, particularly when the extent of exposure is high, in individuals who have reduced ability to remove mercury from their bodies, and in individuals who are sensitive to mercury. Although the majority of evidence suggests exposure to mercury from dental amalgam does not lead to negative health effects in the general population, little to no information is known about the effect this exposure may have on members of the specific groups listed above who may be at greater risk to potential negative health effects of mercury exposure. Accordingly, the FDA recommends that non-mercury restorations (/medical-devices/dental-amalgam/alternatives-dental-amalgam) (fillings) such as composite resins and glass ionomer cements be used, when possible and appropriate, in people who may be at higher risk for adverse health effects from mercury exposure.

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). Removing intact amalgam fillings may result in a temporary increase in exposure of mercury vapor released during the removal process in addition to the potential loss of healthy tooth structure.

At this time, the FDA does not find the available evidence supports a complete ban of the use of dental amalgam (https://beta.regulations.gov/document/FDA-2008-N-0163-0250). 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. In addition, a ban on amalgam may result in deferred or no treatment and have unintended health implications,especially in communities where there might be limited availability of alternative materials.

Recommendations for Patients and Caregivers About the Use of Dental Amalgam

- Be aware the following groups of people may be at greater risk for potential negative effects of mercury vapor (gas) released from dental amalgam fillings:
    - Pregnant women and their developing fetuses;
    - Women who are planning to become pregnant;
    - Nursing women and their newborns and infants;
    - Children, especially those younger than six years of age;
    - People with pre-existing neurological disease;
    - People with impaired kidney function;
    - People with known heightened sensitivity (allergy) to mercury or other components of dental amalgam.

If you are an individual in one of these groups, the FDA recommends that alternative, non-mercury materials such as composite resins or glass ionomer cements be used when possible and appropriate.

- Be aware the durability of any tooth restoration (filling) depends on many factors besides dental filling material. To help your teeth and fillings last as long as possible, you should maintain a healthy diet, proper oral hygiene, and regular dental checkups.
- You should discuss treatment options, including the associated benefits and risks of using detal amalgam or an alternative non-mercury filling material, with your dentist. View the FDA's informational brochure (/media/142415/download) for patients and talk with your dentist if you have additional questions.

Recommendations for Dental Health Care Providers About the Use of Dental Amalgam

- Review the above **Recommendations for Patients and Caregivers About the Use of Dental Amalgam** and discuss the risks and benefits of using dental amalgam and other restorative materials with your patients to allow them to make informed choices regarding their treatment options. We encourage you to share the FDA's informational brochure with your patients prior to any consent to treatment.
- When discussing dental amalgam, avoid using the term "silver filling," as this may imply the filling is made solely from silver and does not accurately convey the mercury component of this restorative material.
- When using amalgam:
  - Use encapsulated amalgam and avoid bulk elemental mercury to minimize the risk of occupational exposure.
  - Avoid placing amalgam in direct contact with other fixed or removable metallic devices in the mouth.
  - Use mercury hygiene best practices (https://www.ada.org/~/media/ADA/Member%20Center/Files/topics_amalgamwaste_brochure.ashxx) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to minimize the patient's and your exposure to mercury vapor. Use amalgam separators (https://www.epa.gov/eg/dental-effluent-guidelines) to prevent mercury-containing dental amalgam waste from being released into the environment.

Potential Adverse Health Effects of Mercury Exposure from Dental Amalgam

Dental amalgam (/medical-devices/dental-devices/dental-amalgam) is a type of dental restorative material that is a mixture of elemental mercury and an alloy primarily composed of silver, tin, and copper, and is used to restore the missing structure and surfaces of a decayed tooth. It releases small amounts of mercury in the form of a vapor (gas), depending on the number and age of existing fillings as well as some dietary and chewing habits. Inhaling mercury vapors may be harmful, especially at doses considered higher than those typically seen from use of dental amalgam. Mercury vapor release is highest when placement or removal of the filling occurs. The levels of mercury vapors may also temporarily increase when chewing, brushing, or teeth grinding over the tooth with the amalgam filling. The mercury vapors are primarily absorbed by the body through inhalation to the lungs. The body eliminates some of the absorbed mercury, but small amounts distributed through the bloodstream may collect in certain tissues, including the brain and kidneys, or in the case of pregnant women, in the blood going to the fetus through the umbilical cord.

Mercury is a known toxicant to the nervous system and long-term exposure to ***high*** mercury doses, such as may occur in some occupational settings, may be associated with signs or symptoms (https://www.atsdr.cdc.gov/sites/toxzine/mercury_toxzine.html) such as:

- Mood disorders (for example, anxiety, depression, irritability)
- Sleep difficulties or disturbances
- Fatigue (feeling tired)
- Memory troubles or disturbances
- Tremors (shaking of extremities)
- Difficulties with coordination
- Visual changes
- Changes in hearing
- Kidney damage

The concentrations of mercury vapor released from dental amalgam are low compared to those typically associated with clinical signs of toxicity. Over more than two decades, the FDA and other public health agencies have conducted numerous reviews of scientific data related to potential health effects of dental amalgam. These reviews have generally arrived at the same conclusion that 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, including those signs and symptoms listed above as well as some neurodegenerative diseases such as multiple sclerosis, Alzheimer's disease, and Parkinson's disease.

Although the weight of available evidence does not show that exposure to mercury from dental amalgam leads to adverse health effects in the general population, some caution should be exercised when interpreting conclusions made from review of the scientific literature for reasons including, but not limited to, the following:

- Conflicting or contradictory findings from different studies that may have affected the certainty in reaching the determination on dental amalgam exposure.
- Exposure to additional amounts of mercury from other environmental and/or dietary sources (such as fish) and recent evidence regarding the body's ability to convert one form of mercury into another, which have raised uncertainties regarding the attribution of mercury exposure sources in a given individual.
- Limitations in study design and execution, including lack of control groups, small sample sizes, single-source data, limited duration of follow-up, and underpowering for evaluation of less common outcomes.

There are also uncertainties regarding the levels of exposure to mercury vapor from dental amalgam, and what level of exposure is considered safe for greater risk individuals. Levels of exposure do not necessarily fall consistently within a narrow range, but are dependent on size, number, and age of the fillings, and stresses applied to the filling, such as chewing and brushing. Current estimates of continuous, exposure to mercury from dental amalgam and other sources over a lifetime that are likely to be without risks of harmful effects in the general population and greater risk groups, vary considerably. Taken together, these uncertainties present challenges with regard to defining a specific threshold of toxicity for chronic, low-level mercury exposure from dental amalgam and other sources, particularly for sensitive groups.

There is limited data regarding health outcomes in groups of patients who may be more susceptible or sensitive to the direct neurological effects of mercury (such as developing fetuses and children, and individuals with neurological disorders), or those with an impaired ability to excrete mercury (such as those with kidney dysfunction). Therefore, there is greater uncertainty and concern about the potential risks to these individuals.

Use of Amalgam versus Resin-Based Composites

Dental amalgam has advantages over resin-based composites in certain limited clinical situations. This includes use in high caries risk patients, for large fillings in posterior (back) teeth where biting forces are high, and where moisture can present a problem for certain placement such as near the gumline. For esthetic reasons and others concerning mercury use and disposal, the use of dental amalgam has seen a significant decline over the last decade. Other filling materials (/medical-devices/dental-amalgam/alternatives-dental-amalgam) such as resin-based composites and glass ionomers have become more widely used. The durability of these resin-based materials has improved, although its longevity does not equal that of amalgam, especially for large restorations with higher biting forces, wear, or stress.

Resin-based composite materials (/medical-devices/dental-amalgam/alternatives-dental-amalgam) have important advantages. Namely, they are color-matched to the surrounding tooth structure for better esthetics and do not contain heavy metals, and their placement typically requires the removal of less healthy tooth structure compared to dental amalgam. Resin-based materials disadvantages include shrinkage that can lead to marginal gaps, hypersensitivity to unreacted methacrylate components as well as clinical limitations regarding placement and longevity. Resin-based composites also generally require more time and cost for placement.

If a patient is concerned about mercury exposure from dental amalgam or falls into one of the high risk populations listed above, the use of alternative materials should be strongly considered.

FDA Actions

The FDA will continue to keep the public informed if significant new information about dental amalgam becomes available.

Additional Resources

- FDA's Dental Amalgam Website (/medical-devices/dental-devices/dental-amalgam)
- FDA's Informational Brochure - Information for Patients About Dental Amalgam Fillings (/media/142415/download)

Reporting Problems with Your Dental Amalgam

If you think you have had an allergic or other reaction attributable to dental amalgam, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home). When submitting a report, detailed information regarding the signs and symptoms of the adverse event and the timing of the events relative to the placement of the material would be useful to FDA's evaluation.

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.