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The safety of dental amalgam and alternative dental restoration materials for patients and users

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The European Commission asked its independent Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to provide a risk assessment on dental amalgam and alternatives such as resin-based composites, glass ionomer cements, ceramics and gold alloys to update the SCENIHR's 2008 Opinion in light of new developments and data.

The updated 2015 Opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users has now been published and evaluates the scientific evidence concerning any possible links between amalgam and amalgam alternatives and allergies, neurological disorders or other adverse health effects.

The SCENIHR found that results from numerous studies looking for links between mercury derived from dental amalgam and various neurological and psychological or psychiatric diseases (including Alzheimer's, Parkinson's, multiple sclerosis and kidney diseases) were inconclusive and contradictory. One difficulty faced in finding a causal relationship between dental amalgam and diseases, is that mercury exposure is usually expressed as the total amount of mercury in body fluids (primarily urine) and there is no differentiation between exposure sources or between organic and inorganic mercury. This issue is relevant due to the different toxicological profile of the two forms. Consumption of fish, which contains essentially but not exclusively methyl mercury, is the leading source of mercury exposure for the general public, followed by dental amalgam, which contains elemental mercury and inorganic mercury. The Opinion does not address the issues of methyl mercury.

After evaluating inorganic mercury in food, the European Food Safety Agency recommended a tolerable weekly intake of inorganic mercury of 4 μg/kg body weight. Tolerable limits for dietary exposures to mercury are relevant to amalgam safety considerations, because inhaled elemental mercury (from dental amalgam) may add to the total body burden of inorganic mercury. Although breath, blood and urine samples from people with amalgam fillings show that their level of exposure is 5–30 times lower than that permitted for occupational exposure, the European Food Safety Agency reported that people with many amalgam fillings still might be exceeding the tolerable weekly intake for inorganic mercury due to this additional inhalation exposure. However, evidence is weak and the data are mainly derived from model-based calculations. Studies on large patient collectives did not show any clear correlation between the number of dental amalgam restorations and negative health effects.

The amount of mercury concentrated in the adult brain is, however, associated with the number of amalgam fillings, and in unborn children, mercury concentration in the kidney (but not the brain) is associated with how many amalgam fillings the mother has. This is a relevant information since, elemental mercury is a well-documented neurotoxicant, especially during early brain development, and inorganic mercury also constitutes a hazard to kidney function.

Mercury accumulates in the central nervous system: the estimated modelled half-life for inorganic mercury in the brain is more than 10 years. Post-mortem studies on the accumulated concentrations in brain tissue show that they sometimes reach values similar to those that cause neurochemical changes in experimental models *in vitro*, but this effect has not been linked convincingly to dental amalgam. Studies in school-age children also showed no convincing amalgam-associated neuropsychological deficits. However, recent studies suggest that some people (independently on age) may have a genetic susceptibility to mercury internal exposure and toxicity.

Less than 0.3% of patients with dental amalgam have a local reaction to dental amalgam, including allergic reactions, but this is usually quickly resolved by removing the amalgam. However it is not necessary nor recommended to remove clinically satisfactory dental amalgam when there have been no signs of adverse reactions. Mercury exposure for both the patient and the dental personnel is highest during the procedure for putting in or removing the dental amalgam, causing a transient increase in the plasma mercury levels. That said, recent studies show that dental personnel do not suffer from adverse effects from the use of dental amalgam, despite the fact that they are exposed to it more than other people.

Alternative materials to amalgam also pose concerns about adverse effects. All dental restorative materials are medical devices in risk class IIa. The certification process does not include examination of the design dossier and the chemical specification does not have to be revealed to the third party. They are chemically complex

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and, it may be difficult to know exactly which is their exact composition. Although manufacturers are required to assess biocompatibility and the risk from unintended side effects, there is a lack of data on relevant exposure and on the toxicity of the constituents of the materials.

Considering the lack of data, it is not possible to provide a scientifically sound statement on the safety of these materials. The only exception was related to BPA from some dental materials. It was considered in depth within the SCENIHR Opinion "The safety of the use of bisphenol A in medical devices" (2015); it was concluded that the BPA release from dental material was associated with only negligible health risks. In the 30 years or so tooth-coloured filling materials alternative to dental amalgam have been increasingly in use: there has been significant advances in the composition of these materials (with reduced bioavailability of harmful components through improved polymerisation processes) and little evidence of clinically significant adverse effects. That said, more people, both patients and dental personnel, have shown allergic reactions to some of these substances than to amalgam.

As with any other medical or pharmaceutical intervention, caution should be exercised when considering pregnant women being treated with these alternative materials, as well as with dental amalgam. There is no evidence that infants or children are at risk of adverse effects arising from the use of alternatives to dental amalgam, but similarly to mercury, genetic polymorphisms may also exist for toxicokinetics of some components in these materials, so some people may be more genetically predisposed toward having adverse reactions to them, just as some studies have suggested is the case for reactions to mercury.

In conclusion, the SCENIHR reports that dental amalgam already in place is not considered a health risk for the general population. Consequently, existing amalgam restorations should not be removed as a preventive measure, also considering the transient peak of exposure associated with the removal event. Dental personnel may be at greater risk to higher mercury exposure from dental amalgam than the general population, although they do not report having any more adverse effects. Information on exposure, toxicity and clinical outcomes for alternative materials is much scarcer than for dental amalgam. There is some evidence that some of the low molecular weight substances used in their preparation are associated with local allergic reactions. There are insufficient data to draw firm conclusions about associations between these alternative materials and neurological or other health disorders.

The SCENIHR concludes that using either amalgam or alternative types of restorative material can be effective and satisfactory in dental restorative treatment. The longevity of restorations of alternative materials in posterior teeth has improved making it more equal to amalgam in performance, but in some cases, like for filling large cavities or treating patients prone to cavities, amalgam remains the better choice.

The choice of material should be based on patient characteristics, and should be an informed decision. . Some things to consider are if the fillings are for primary or permanent teeth, if the patient is pregnant or allergic to mercury or other components of restorative materials, or if they have impaired renal clearance. As a general rule, the relative risks and benefits of any dental treatment need to be weighed carefully.

The use of dental restoration materials impacts not only the patient and the dental personnel, but also the environment; a SCHER opinion specifically devoted to this issue was recently published (2014). The trend toward using adhesive alternatives has resulted in a sustained reduction in the use of dental amalgam in the EU and is seen as positive.

There is clearly a need for further research, in particular in regard to genetic susceptibility related to mercury effects and to the constituents of alternative restorative materials, as well as a need to develop new alternative materials with a high degree of biocompatibility.

The full Opinion may be read online at http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf.

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Transparency document

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