

## **Informed Consent in Dentistry and use of Dental Amalgam as a Restorative Material: Suggestions for Managing the Ethical Considerations**

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## Abstract

Dental amalgam has long been used as a durable and cost-effective restorative material. However, global concerns over mercury exposure and environmental safety have triggered calls for a phase-down, particularly under the Minamata Convention. In this evolving context, ethical and legal issues surrounding informed consent require urgent attention. This review used a desk-based methodology, sourcing literature from peer-reviewed journals and official publications via Mendeley, Google Scholar, and NCBI.

**Theoretical framework:** It is grounded in biomedical ethics—especially autonomy and informed consent—and international public health policy.

**Key findings:** Amalgam remains common in Africa and low-resource settings. Informed consent practices are often inadequate, with patients receiving limited information about risks or alternatives. While agencies like WHO and FDA deem amalgam generally safe, concerns remain for vulnerable groups.

**Key recommendations:** Standardized consent protocols, ethics-focused training, and patient education tools are recommended to support shared decision-making and ethical compliance.

**Keywords:** *Dental amalgam use, Informed consent, Ethical considerations, Guidelines, Amalgam safety*

## Problem statement

The consent process in restorative clinical dentistry has largely been on the basis of verbal and implied consent. However, the problem arises when a material such as dental amalgam, with ongoing debates for and against its use, remains a material of choice in many situations, especially in resource-constrained communities and many developed countries. The importance of the debate about whether dental amalgam is safe for continued use appears to have been rekindled in recent years, putting pressure on dental professionals both in developed and developing countries to give patients an opportunity to choose whether they want dental amalgam to be used as the restorative material for their dental restoration(s) (Soler et al., 2002). Of equal importance is the ethical dilemma of whether it is practical to request informed consent for routine dental restorations using dental amalgam considering that it has been used for many decades, and in some situations, the exorbitant cost of alternatives is beyond many communities, especially in resource-poor settings. A review of the literature on the ethical arguments for and against dental amalgam use was carried out, with special emphasis on the

applicability and limitations of the informed consent process. Furthermore, this paper investigated the current regulations and guidelines related to how dental amalgam is used, ethical issues, and the obligations of oral health professionals when using dental amalgam. It concludes by giving recommendations regarding the applicability of the informed consent principles of patient autonomy, beneficence, non-maleficence, and justice. A prototype informed consent form is also suggested.

## **Methodology**

A descriptive analysis of the literature on dental amalgam use and ethics was conducted. A search of the literature was carried out electronically using Mendeley, Google Scholar, Chrome, and other common search engines to extract relevant articles published in peer-reviewed journals. Various keywords and their combinations were used for the literature search including informed consent, dental amalgam use, dentistry, current guidelines on amalgam, ethical considerations, dental profession, dental treatment procedures, among others. The articles were collated, summarized, and analyzed to derive emerging themes for this paper. Ethical clearance to carry out this study was obtained from the Health Research and Ethics Committee of Stellenbosch University.

## **Background**

Dental amalgam is defined as “any alloy of mercury with another metal or other metals” (Webster’s New World Dictionary, 1972). It is one of the most frequently used materials for restoring and preserving decayed teeth (Ramesh et al., 2010). Dental amalgam has been used successfully for more than a century since the 1800s. As a consequence of this long use, its quality has steadily improved over the years. Over the centuries, it has grown to be one of the most trusted and reliable materials for restoring teeth, constituting over 70% of restorations performed by dentists worldwide. Although dental amalgam remains widely used in low-resource settings due to its affordability, longevity, and ease of placement, concerns persist regarding its unaesthetic metallic appearance and mercury content, prompting regulatory scrutiny (WHO, 2021; FDI World Dental Federation, 2021; Lynch, 2019). While composite resins and glass ionomer cements offer mercury-free alternatives, they remain more technique-sensitive and costlier, with no universally accepted substitute matching amalgam’s performance in high-load posterior

restorations in underserved areas (Ramos et al., 2021; Canadian Agency for Drugs and Technologies in Health [CADTH], 2018). According to the World Dental Federation (FDI), “The combination of reliable long-term performance in load bearing situations and its low cost is unmatched by other dental restorative materials. This is despite much research devoted to the development of other dental restorative materials (Ramos et al., 2021; Mjör & Toffenetti, 2000; Ferracane, 2011). Dental amalgam as a direct filling material has wide indications for use, ease of handling, and good physical properties. Although advancements in restorative materials have led to the development of mercury free alternatives, these materials are generally more expensive, technique sensitive, and require strict moisture control—conditions not always achievable in low-resource settings (FDI World Dental Federation, 2021; WHO, 2021; Lynch, 2019). It is for these reasons, along with the continued affordability, durability, and clinical reliability of amalgam in high-load restorations, that its complete global phase-out has not yet been feasible (Ramos et al., 2021). Developments around dental amalgam in recent years Since the first use of dental amalgam over 150 years ago, intermittent controversy has surrounded it. The debates and controversies have centered on the inclusion of mercury

### **Position on use of dental amalgam**

Approximately 200 national dental associations and specialist groups are represented by the FDI World Dental Federation (FDI, n.d.). Due to this extensive membership, its official pronouncements and guidance on dental issues are well respected. A process of wide consultation, discussion, and consensus among leading dental experts worldwide feeds into FDI policy formulation. For instance, FDI pronouncements come from its Science Committee and collaborations with organizations such as the World Health Organization (WHO). In 1997, the FDI, in collaboration with the World Health Organization (WHO), issued a consensus statement that “no controlled studies have been published demonstrating systemic adverse effects from amalgam restorations” (FDI & WHO, 1997, p. 2). The statement further reported that “aside from rare instances of local side effects of allergic reactions, the small amount of mercury released from amalgam restorations, especially during placement and removal, has not been shown to cause any adverse health effects” (FDI & WHO, 1997, p. 2). About ten years later, in 2006, the FDI reiterated that “there was no evidence to support an association

between the presence of amalgam restorations and chronic degenerative diseases, kidney disease, autoimmune disease, cognitive function, adverse pregnancy outcomes or any non-specific symptoms” (FDI, 2007).

In 2009, the WHO published guidelines on the “Future Use of Materials for Dental Restorations” (Petersen, Baez, Kwan, & Ogawa, 2009). The report emphasized possible health effects and environmental contamination from mercury in amalgam. Its objectives included assessing scientific evidence on the use of dental restorative materials, including dental amalgam, and implications of alternatives. The term “phase-out” to describe elimination of dental amalgam use was first proposed by the Global Mercury Partnership, an organization formed by the United Nations Environment Programme (UNEP) in collaboration with the WHO. One objective is “to phase out and eventually eliminate mercury in products and to eliminate releases during manufacturing and other industrial processes,” providing an overview of possible implications of reducing mercury emissions globally.

### **Developments around dental amalgam in recent years**

Since the first use of dental amalgam over 150 years ago, intermittent controversy has surrounded it. The debates and controversies have centered on the inclusion of mercury as a component of dental amalgam (Bjørklund, 1989; Hyson, 2006). Mercury—a metal that is liquid at room temperature—is a poisonous substance in its natural form. There are strong views that mercury endangers the health of dental patients, dental professionals, and the environment due to its potential toxic properties. This school of thought lobbies for the complete ban of dental amalgam use in dentistry (Edlich et al., 2007).

However, there is an equally strong view opposing the ban because no scientific, evidence-based findings associate dental amalgam with deleterious health effects. Instead, proponents argue that banning dental amalgam would leave many populations without proper dental care due to the high cost of alternative restorative materials (Spencer, 2000). The controversy has been heightened by the way the topic is reported in journals and media coverage by television and the press (Flanders, 1992). The first official ban of dental amalgam by any country was enacted by Norway in January 2008 through its Norwegian Minister of the Environment and International Development. Norway banned mercury in products, citing environmental dangers (Norwegian Ministry of the Environment, 2007). The ban specified dental filling materials (dental amalgam), measuring instruments, and other products. This was soon

followed by Sweden and Denmark, both of which forbade dentists from using mercury in fillings. No U.S. state has banned dental amalgam use, but a few have enacted informed consent requirements. Edlich et al. (2008) lament the USA's procrastination in banning or limiting dental amalgam use, which he argues is inconsistent with the expected leadership role of the country. Laws on informed consent for patients receiving dental amalgam restorations have only been enacted by four U.S. states: Maine, California, Connecticut, and Vermont.

### **Environmental concerns of mercury**

A more recent term, "phase-down," describes the preferred approach to reducing mercury use by decreasing amalgam use. Proponents argue that a complete ban is premature (Alexander et al., 2014). This recognizes that complete cessation of amalgam use is inappropriate currently and that more needs to be done before suitable alternatives are widely available. The "phase-down" term is preferred over "phase-out."

On January 20, 2013, UNEP's Intergovernmental Negotiating Committee agreed on a treaty determining the future of dental amalgam (UNEP, 2013). This global, legally binding treaty aims to reduce environmental pollution from mercury. Because dental amalgam contributes significantly to this pollution, it is implicated. The treaty states: "Progress must be made in reducing the use of mercury in dentistry; this should be kept under frequent review. The WHO's phase-down approach has been acknowledged as appropriate" (Mackey, Contreras, & Liang, 2014).

The safety of dental amalgam has been confirmed and endorsed by numerous reputable organizations, including the 3rd International Conference on Mercury as a Global Pollutant, the World Health Organization (WHO), FDI World Dental Federation, the European Commission, Health Canada, the UK Committee on Toxicity (COT), the British Dental Health Foundation, the American Dental Association (ADA), the U.S. Food and Drug Administration (FDA), the U.S. Centers for Disease Control and Prevention (CDC), Sweden's National Board of Health and Welfare, the New Zealand Ministry of Health, and the Dental Council of Malaysia (WHO, 1997; ADA, 2020; FDA, 2020; European Commission, 2008).

### ***'Phasing down' of amalgam***

Concerns have been raised about the effect of the phase-down on amalgam, with fears of stigma arising from speculation and fear by the general population. This may have serious implications for health care systems worldwide (IADR, 2010). Therefore, dental amalgam requires careful ethical management, both in its continued use and its gradual phase-down.

### ***To use or not to use amalgam?***

The controversy about the safety of dental amalgam as a restorative material is longstanding (Spencer, 2000). Strong objections to its use are epitomized by Edlich et al. (2007), who claim "it has been well documented that the dental amalgam mixture continually emits mercury vapor during such processes as chewing, brushing, and drinking hot liquids to the detriment of organs such as kidneys, central nervous system, cardiovascular system, and minor effects such as gingival tattoos." They question why the American Dental Association (ADA) has consistently maintained for 150 years that dental amalgam has no deleterious health effects without studies to prove this. Edlich et al. (2007) recommend that the U.S. federal government and states pass laws to protect patients by requiring consent for amalgam use. However, the alleged health effects remain speculative and unproven.

According to Wahl (2001), although mercury-containing dental amalgam has been attacked, literature confirms only the release of small mercury quantities insufficient to cause systemic health problems. Mercury from amalgam cannot be linked to kidney damage, Alzheimer's disease, or multiple sclerosis. Dentists exposed to mercury have not been shown to suffer harmful reproductive or systemic effects. Alternative materials like composite resins have their own concerns, including potential estrogenicity and cytotoxicity from Bis-GMA release (Mackert & Wahl, 2004). All dental materials require careful use according to best practices. Thus, it is logical to balance health concerns with trust that dentists will use best clinical practices.

## Summary

The position on dental amalgam has significantly evolved since earlier endorsements of its safety, particularly due to growing concern about mercury exposure, environmental risks, and the goals of the Minamata Convention on Mercury.

Before 2010 thought on dental amalgam can be referred to as the original position. Dental amalgam was generally viewed as cost effective, durable and safe. This is the position endorsed by major organisations like the World Health Organisation (WHO), American Dental Association (ADA), Food and Drug Administration (FDA) who argued that mercury release from dental amalgam was below toxic levels and not harmful to patients with the exception of very rare allergic reactions. Their views were supported by historical amalgam use accompanied by long term clinical data.

Winds started to shift from around 2013. The period between 2013 and 2020 be referred to as the transitional period. The Minamata Convention on Mercury (2013), a UN treaty signed by over 140 countries (including the US and EU), called for a phase-down of dental amalgam, not due to direct health risks in patients, but due to environmental concerns related to mercury pollution. The focus began shifting from Is amalgam safe? to Should we reduce or eliminate mercury exposure wherever possible? Agencies like the EU Scientific Committee on Health and Environmental Risks (SCHER) and SCENIHR (2008, 2015) confirmed amalgam's safety in most populations but recommended limiting its use in children, pregnant women, and environmentally sensitive settings.

The most current and updated position on dental amalgam use as of July 2025 can be summarized as:

- a. In 2021, the WHO acknowledged amalgam's continued usefulness in low-resource settings but now strongly encourages phase-down. It emphasized investing in alternative mercury-free restorative materials (e.g., composite resins, glass ionomers) and improving health system capacity (World Health Organization, 2021).
- b. In 2020, for the first time, the FDA updated its guidance, recommending limiting the use of dental amalgam in high-risk groups, including pregnant women and developing fetuses, children under 6 years, and people with kidney dysfunction or known hypersensitivity to mercury (U.S. Food and Drug Administration, 2020).



c. Most recently, in 2023, the European Commission announced it is moving toward a complete ban on dental amalgam by 2025, as part of a broader effort to eliminate non-essential mercury uses in the European Union (European Commission, 2023).

## **Ethics and dental amalgam**

The objectives of ethics in dentistry and medicine are to guide health care professionals on how to act in situations and to safeguard human dignity, promote justice, equality, truth, and trust. Although many moral theories (consequentialism, deontology) can justify informed consent for amalgam use, this paper focuses on principlism due to its popularity and practical application (Beauchamp & Childress, 2013). Notably, the principles of Beauchamp and Childress are *prima facie* and not easily ranked (Gillon, 1985; Meyers, 2003).

### ***Ethical principles in relation to amalgam use***

The principles of clinical ethics serve as aspirational goals for health professionals. They provide guidance but are not absolute. The four main principles are autonomy, non-maleficence, beneficence, and justice, which can overlap and compete for priority.

### ***Patient autonomy***

Autonomy is “the right of an individual to make decisions for themselves. In health care, this means allowing patients to decide about treatment after receiving all necessary information, self-governance or self-rule” (Moodley & Naidoo, 2013). Dentists have an obligation to uphold patients’ rights to self-determination and confidentiality. Most dentists agree that patients must consent to amalgam treatment, but the question remains: is verbal or implied consent enough, or should routine written informed consent be required?

Kakar et al. (2014) argue informed consent is both a legal requirement and moral obligation, representing the patient’s right to participate in clinical decisions. They recommend written consent for invasive, irreversible procedures such as amalgam fillings.

## **Ethical Principles in Dental Amalgam Use**

### ***Non-maleficence***

Dentists must protect patients from harm by maintaining current knowledge and explaining treatments accurately. Continuing education and updated skills are essential. Informed consent ensures amalgam restorations are not seen as trivial.

### ***Beneficence***

Dentists should competently serve patients, respecting their values and preferences. The ADA advises presenting both the benefits and risks of amalgam and alternatives while documenting patient choices (ADA, n.d.). Even if amalgam is the preferred clinical option, patients' wishes to avoid it must be honored, supporting the case for written informed consent.

### ***Justice***

Justice in dentistry encompasses legal, distributive, and rights-based fairness (Moodley & Naidoo, 2013). In resource-limited settings, choices may be restricted, but informed consent ensures fair participation in decision-making for all patients, including underserved communities.

### ***Types of informed consent***

*Implied consent:* Passive cooperation, often undocumented, used for non-invasive procedures (Mirza, 2012).

*Verbal consent:* Spoken agreement, common for routine treatments but not ideal for amalgam use.

*Written informed consent:* Essential for procedures involving risk, including amalgam fillings. It documents details, risks, and alternatives, promoting autonomy (Mirza, 2012).

## ***Veracity***

Dentists must be honest and transparent, building trust and enabling patient participation. Informed consent fosters truthful, factual interactions.

Role of professional dental associations

Professional associations should promote formal consent practices. For instance, the ADA has created brochures to guide discussions on filling materials (ADA, n.d.).

## **Summary**

Though many regulatory authorities support amalgam's safety, public concerns remain. Informed consent is vital for ethical and legal reasons, especially when controversies exist. While all dental materials carry risks, amalgam's history of scrutiny justifies explicit consent. Current trends lean toward verbal consent, but formal processes are necessary (ADA, n.d.).

## **Recommendations**

More studies should explore the desirability and practicality of informed consent in restorative dentistry.

National Dental Associations should provide standardized patient brochures and consent forms on dental fillings.

Suggested example of patient information brochure content: dental filling materials

This brochure provides information on dental filling materials. It is hoped that it will help you to make a decision when choosing the filling (restorative) material best suited for your particular circumstance. It gives the advantages and disadvantages of some of the most commonly used dental filling materials used to restore decayed/rotten teeth. Please note some of the options may not be offered in this practice. In the event that we do not have the option that you chose, we will try to refer you to the nearest dentist who may be offering that treatment.

## ***Prevention of tooth decay***

The following tips can help you prevent the need for dental fillings:

- Brushing your teeth after meals, using a soft to medium toothbrush
- Brushing a fluoride-containing toothpaste
- Flossing between your teeth regularly
- Eating a balanced diet (including fruit, fibrous foods, and less sugary foods)

### ***Choosing a dental filling material***

Your dentist may find out during your dental examination that you need dental fillings. Decayed/Rotten teeth can be filled with a variety of dental filling materials and it is recommended that you have some information about these different materials so that you can be assisted in making an informed choice best suited to your situation. Should you have any questions or concerns about a dental filling material, do not hesitate to raise them with your dentist. Some factors may influence you and your dentist's choice such as:

Patient's oral and general health; the surface of the tooth where filling is located; amount of biting force; duration and number of visits needed to complete the filling procedure; how long lasting the filling should be, expense involved.

### ***Direct and indirect dental fillings***

Depending on the method used to place dental fillings, they are divided into 2 main groups: direct and indirect dental fillings. Direct fillings are packed immediately into a prepared tooth cavity while the patient sits in the dental chair while indirect fillings usually require two or more visits. Indirect fillings are manufactured in a dental laboratory upon prescription from a dentist after cavity preparation in the surgery and supply of an impression to the laboratory. Examples of direct fillings are: dental amalgam, composite/white dental fillings. Examples of Indirect dental fillings are: porcelain fused to metal crowns and bridges, zirconium/metal free crowns and bridges, gold or other precious metals inlays, onlays, veneers, crowns and bridges. Inlay, onlays and veneers can fabricated from ceramics or composites as well.

### ***Amalgam: as an example of a direct restoration***

The word amalgam when referring to dental fillings means a mixture of two or more metals in which mercury is a component. Dental amalgam is a mix of approximately 43 percent to 54 percent mercury with other metals, including silver, copper and tin. Dental amalgams have commonly been called “silver fillings” because of their silver colour when they are first placed. Today, amalgam is used most commonly in the back teeth. It is one of the oldest filling materials and has been used (and improved) for more than 150 years. Dental amalgam is the most thoroughly researched and tested filling material. Should you swallow a bit of an amalgam filling, the mercury within it is very poorly absorbed and typically does not enter the bloodstream and is excreted. Scientific research continues on the safety of dental amalgam. Many public and private agencies reconsider this issue on an on-going basis ([www.ada.org](http://www.ada.org)). Occasionally questions have been raised concerning the safety of amalgam fillings but there is no evidence to suggest that it is not safe and to support discontinuation of the material. The following organizations currently approve the use of dental amalgam: World Health Organisation, World Dental Federation and the American Dental Association

Material	Advantages	Disadvantages
<b>Amalgam</b>	Durable, cost-effective, one-visit application, resistant to moisture and recurrent decay	Aesthetic concerns, removal of healthy tooth structure, potential for mercury waste
<b>Glass Ionomer</b>	Releases fluoride, quick placement, good for children and elderly	Not suitable for high-pressure areas, can become rough with age
<b>Composite</b>	Tooth-colored, minimal removal of tooth, no corrosion	Less durable, technique-sensitive, more expensive

Ferracane, J. L. (2011), Mjör, I. A., & Toffenetti, F. (2000), Mount, G. J., & Hume, W. R. (2005), Sakaguchi, R. L., & Powers, J. M. (2012), WHO. (2021).

## Summary of Findings on Informed Consent in Dentistry

Though most dentists understand the importance of informed consent, practice is inconsistent.

- In Uganda, most obtain consent but prefer verbal methods (Nabiryo et al., 2022).
- In India, awareness is high but regular use of consent is limited due to time constraints and perceived simplicity (Chandrashekar et al., 2015).
- In Nigeria, most claimed to obtain consent, but few used formal documentation or understood its components (Ogunbanjo et al., 2014).
- Globally, many dentists rely on informal verbal consent, especially in busy or resource-limited settings (Parsel et al., 2017).

## Suggested Informed Consent form for Dental Amalgam Fillings

### ***Suggested Informed Consent for Dental Amalgam Restorations 1 (Adapted from and by kind permission of Dr Randall Otterholt)***

I, ....., understand that dental amalgam, like other materials, carries certain risks. I acknowledge:

1. *Mercury content:* Although concerns exist, there is no scientific proof of harm.
2. *Sensitivity* may occur during or after the procedure.
3. *Numbness* may result from local anesthesia.
4. *Fracture or loosening* of large fillings may occur.
5. *Need for root canal or extraction* may arise if decay has reached the pulp.
6. *Fragility* of fresh fillings—avoid chewing on them for 24 hours.
7. Amalgam tattoos may form from leftover particles.
8. *Environmental* concerns—residual amalgam waste may contribute to mercury pollution if mismanaged.

I have read the brochure, had an opportunity to ask questions, and received satisfactory answers. I accept potential consequences and understand that no guarantees have been made regarding the outcome. I

have been informed about alternatives such as composite resin, crowns, and inlays. I voluntarily consent to the use of amalgam for my dental treatment.

- Patient Name: \_\_\_\_\_
- Signature: \_\_\_\_\_ Date: \_\_\_\_\_
- Guardian (if applicable): \_\_\_\_\_
- Witness: \_\_\_\_\_
- Dentist: \_\_\_\_\_

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