



## BRAZILIAN MINISTRY OF HEALTH

### **Mercury-free alternatives to dental amalgam and additional measures implemented nationally for the decrease in the use of the product**

#### ***ANNEX A: Mercury-added products/Part II: Products subject to Article 4, paragraph 3***

*Measures to be taken by a Party to phase down the use of dental amalgam shall take into account the Party's domestic circumstances and relevant international guidance and shall include two or more of the measures from the following list:*

- 1. Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration;***
- 2. Setting national objectives aiming at minimizing its use;***
- 3. Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration;***
- 4. Promoting research and development of development of quality mercury-free materials for dental restoration;***
- 5. Encouraging representative professional organizations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and on promoting best management practices;***
- 6. Discouraging insurance policies and programmes that favour dental amalgam use over mercury-free dental restoration;***
- 7. Encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration;***
- 8. Restricting the use of dental amalgam to its encapsulated form;***
- 9. Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.***

# MEASURES TO BE TAKEN BY BRAZIL FOR THE DECREASE IN THE USE OF DENTAL AMALGAM

## INTRODUCTION

Dental amalgam is an alloy composed mainly of silver (Ag), tin (Sn), and mercury (Hg), and other metals may be added to it. The percentage of mercury in the alloy ranges from 43% to 54%. Dental amalgam has physical and mechanical characteristics that make it one of the most resistant restoring materials in dentistry nowadays.

In oral health, all dental materials used have their pros and cons, and the choice of material to be used depends on the singularity of each patient, situation, and condition of the dental structure and on the availability of technology, infrastructure, and supplies.

The Brazilian Ministry of Health advocates that restoring techniques should be less invasive and less and less necessary and discourages the use of therapeutic techniques that promote a sharper deterioration of a healthy dental structure. It applies to the use of dental amalgam.

The Ministry of Health understands that the use of silver amalgam in certain specific situations is still necessary.

By virtue of the prevalence of dental caries in Brazil and of the economic impact that discontinuing the use of dental amalgam would create on the Unified Health System (SUS), it is considered that its gradual decrease should occur by (i) promoting actions of prevention and control, such as fluoridation of supply water, and investment in oral health in Primary Health Care and (ii) improving new materials (resin and ionomer) for the restoration of extensive carious lesions, so that their use is gradually decreased as the lesion is controlled and new technologies support the treatment.

It is known that the exposure to mercury creates a more direct impact on the health of the worker who manipulates it, however, the additional risk to the health of whoever has the amalgam should not be disregarded. Its incorrect disposal also provokes discussions about its impact on the environment. It is worth mentioning that there are several sources of human exposure to mercury and, in this regard, it is important to acknowledge that dental amalgam and mercury are not synonyms.<sup>1</sup>

Pursuant to the Minamata Convention on Mercury, Brazil has shown a decrease in the use of dental amalgam due to the changes inherent in the best performances of other dental materials and in the health-related increment of technological evolution, that is, as new dental materials improve, those used in the past are suppressed from day-to-day practice.

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<sup>1</sup> “Most of the mercury in the environment results from human activity, particularly from coal-fired power stations, residential heating systems and waste incinerators. Mercury is also present as a result of mining for mercury, gold (where mercury is used to form an amalgam before being burnt off), and other metals, such as copper, zinc and silver, as well as from refining operations.” (WHO, 2007) - [https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUK Ewj7v9O23qLrAhXRkGhf2TDvQQFjABegQIAxAB&url=https%3A%2F%2Fwww.who.int%2Fipcs%2Ffeatures%2Fmercury.pdf%3Fua%3D1&usg=AOvVaw0d\\_D1dGcfAaW3Bbu-TAj7p](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUK Ewj7v9O23qLrAhXRkGhf2TDvQQFjABegQIAxAB&url=https%3A%2F%2Fwww.who.int%2Fipcs%2Ffeatures%2Fmercury.pdf%3Fua%3D1&usg=AOvVaw0d_D1dGcfAaW3Bbu-TAj7p)

## SUMMARY CHART

- Pursuant to the principles of the Unified Health System, Brazil has a universal, free oral health care model that includes actions of promotion, prevention, surveillance, treatment, and oral rehabilitation.
- The Brazilian Health System also promotes actions of continuing education, funds research institutions to carry out studies on minimally invasive techniques, minimal intervention dentistry, early treatment and handling of dental caries, in addition to providing oral health care in the scope of the Primary Health Care (APS).
- Nationally, there are rules and regulations for fluoridation of supply water and fluoride toothpastes. There are also recommendations regarding the use of other therapeutic techniques using fluorides, all within the scope of health promotion and prevention.
- The country conducts, every ten years, the “National Survey of Oral Health Situation” in order to guide the decisions related to the National Oral Health Policy (PNSB).
- Brazil has prohibited the non-encapsulated form of dental amalgam through national laws and regulations and has rules about the disposal of dental amalgam governed by the Brazilian Health Surveillance Agency – ANVISA.

Below, the Ministry of Health highlights the main actions related to measures “**1, 2, 3, 4, 8, and 9**” taken in order to decrease the use of dental amalgam, according to the provisions in part II of Annex A of the Convention and pursuant to its mandate in the health care sector.

### **1. Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental filling.**

The National Oral Health Policy (2004) forms part of the Unified Health System (SUS), which provides universal, free access to the entire population in Brazilian territory. The main objectives of the PNSB is the offer of oral health care to all people and access to oral health care by all people, based on the doctrinal principles of the SUS related to universalization, equity, integrity, decentralization, and popular participation.

Brazil emphasizes the actions of promotion and prevention for the decrease in the need for filling and/or the decrease in the prevalence of extensive cavitated lesions, as well as the need for restoring retreatment.

The Ministry of Health recommends the promotion of a healthy diet, aiming at the decrease in the excessive and frequent consumption of sugar (sucrose); the carrying out

of supervised dental brushing; the fluoridation of supply water,<sup>2</sup> monitoring and examinations of oral situation; as well as the use of materials that prevent the occurrence of more severe lesions, such as the use of fluoride varnishes, sealants, and fluoride gel.

Regarding the handling of dental caries, the SUS recommends to the population the right monitoring, promotion of self-care, healthy diet, and personal hygiene habits, so that the disease does not manifest clinically or that the intervention occurs in early stages, with a reduced need for filling and/or decrease in the prevalence of extensive cavitated lesions, as well as a decrease in the need for surgical-restoring treatment.

Brazil has 27,136 oral health care teams (eSB) that compose the family health care teams, with an estimated coverage of 43.63% in the scope of the APS (July/2020). In the basic health care facilities (UBS), the population subject to them<sup>3</sup> receives health care provided by eSB teams that perform functions of health promotion and oral diagnosis, treatment, and rehabilitation.

Schools and community centers are included in the field of action of the oral health care teams. The eSB teams have competences with the population under their sanitary responsibility such as health promotion, prevention and educational practices. It is recommended that they are approached timely for the identification of risk factors and the health-disease process. The Guidelines of the National Oral Health Policy establish that health promotion and prevention shall be priorities. Every ten years, a national survey of the oral health situation is conducted, within the scope of epidemiological surveillance.

Additionally, the Ministry of Health in 2020 recommended early intervention and oral health education since the gestational period, promoting Prenatal Dental Care (PNO). The health education that is recommended through the PNO aims at promoting a healthy gestation, with the adequacy of the oral environment and health education, recommending a healthy diet to pregnant women, with the lowest consumption possible of sucrose and sanitation of the teeth, reducing the chances of dental caries in the mother during this important stage.

The recommendation of the PNO, also in the field of health education, is that pregnant women breastfeed exclusively until the sixth (6<sup>th</sup>) month, and that, after the first teeth of the baby erupt, a fluoride toothpaste is used to brush them and manufactured or artificially-sweetened products are avoided, as recommended in the Food Guide for

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<sup>2</sup> With respect to fluorides, important allies to avoid the need for restoration, the Ministry of Health has strict rules related to concentration in a content suitable for human health, and it recommends its proper concentration described in Ordinance No. 2914 of December 12, 2012, on Water Potability for human consumption, which refers to Ordinance No. 635/GM/MS of January 30, 1976. Such ordinance provides for the Maximum Amount Allowed (VMP) in the Table of Annex VII, which is 1.5 ppmF. The other recommendations of use for fluorides are listed in a guide with an approach on the many different therapeutic techniques related to fluorides, in proper concentrations (*Guia de recomendações de uso de fluoretos* [Guide with recommendations of use for fluorides], 2009).

<sup>3</sup> To ensure the coordination of health care, expanding the access and competence of the teams acting in Primary Care, the National Primary Care Policy recommends: i. - That the population subject to each Primary Care team (eAB) and Family Health Care team (eSF) is of 2,000 to 3,500 people, located in its territory, ensuring the principles and guidelines of Primary Care. Link: <http://bvsm.sau.de.gov.br/bvs/sau.delegis/gm/2017/MatrizesConsolidacao/comum/250693.html#:~:text=i.,e%20diretrizes%20da%20Aten%C3%A7%C3%A3o%20B%3%A1sica>.

Children under 2 (2019). The promotion of a healthy diet and oral health care habits since gestation and education of pregnant women in health will have an impact on the life of the children, who will have a better oral health situation, as it aims at reducing the prevalence of early dental caries during childhood, which affects the primary dentition.

Still in the scope of primary health care, the schools, recognized as practice spaces for health education and prevention of lesions, promoted the implementation of the *Programa Saúde na Escola* (PSE) [Health in School Program] (2007). The PSE was created in order to promote integration between education, actions of promotion, prevention, diagnosis, surveillance, and, especially, health education in public schools. In these actions, the students, the pedagogical staff, and the community are involved.

For the indigenous population, the Ministry of Health, through the Special Office for Indigenous Health (SESAI), organized free distribution of oral hygiene materials, composed of toothbrush, dental floss, and fluoride toothpaste. In addition to the development of several activities aimed at promoting the oral health of such populations for about 750,000 indigenous people who live in more than 5,000 villages.

The Ministry of Health recommends the following to the governmental entities:

- Expansion of the oral health coverage through the implantation of oral health care teams in the family health care teams, which must promote actions of promotion and prevention, identification of needs for treatment in early stages, health education, among others.
- Acknowledgement of territory, identification of risk groups and early-stage oral lesions for early intervention.
- Promotion of health education actions in collective environments, such as schools and community centers.
- Promotion of a healthy diet, aiming at reducing the excessive, frequent consumption of sugar (sucrose), risk factor for dental caries.
- Carrying out of supervised dental brushing.
- Fluoridation of supply water, as a collective means for controlling dental caries.
- Oral health surveillance, monitoring, examinations of oral situation, and the right registration of information in the primary care information system.
- Use of materials that prevent the occurrence or promote the staging of caries lesions, avoiding the progression of such injuries to a more severe stage, with the need for restoration.

## **2. Setting national objectives aiming at minimizing its use.**

The Sectoral Plan for Implementation of the Minamata Convention, prepared by a Working Group of the health sector and established by Ministry of Health Ordinance No. 2,197, on July 20, 2018, aims at expanding and strengthening the country's institutional and technical capacities to identify, diagnose, treat, and monitor vulnerable populations; reducing and eliminating risks to human health arising from exposure to mercury and mercury-containing products; in addition to developing a research agenda and increasing the knowledge of the population and health professionals on the risks posed by the exposure to mercury, so that they also become an active part of the process to improve the proper management of this contaminant within the Brazilian territory.

Among the actions addressing dental amalgam contained in this Plan, attention is called to:

- Publication of Resolution No. 173, of September 15, 2017, of the Brazilian Health Surveillance Agency – ANVISA, which prohibited the manufacturing, importation, and sale, as well as the use in health services, of mercury and mercury powder for non-encapsulated amalgam alloy indicated for use in Dentistry become effective on January 1, 2019; It is important to highlight that specific explanatory materials were prepared and the oral health teams were informed about the prohibition of this type of dental amalgam by the Ministry of Health.
- Creation of distinctions between restoring techniques in the information and monitoring system of the Ministry of Health. This action shall allow oral health teams to register the type of filling that shall be used as of 2020. This information shall be useful to verify the use of this dental material and other restoring techniques in the long term.
- Preparation of a diagnosis of the dental amalgam use profile in the country's Basic Health Care Facilities with oral health professionals, which included the preparation and disclosure of an exploratory survey on consumer habits, use, and disposal of amalgam in Brazil.
- Systematic review of the literature available on cost-effective and clinically effective mercury-free alternatives for dental filling, which includes the preparation of a Scientific Review on the safety of dental amalgam and a Scientific Review on the efficiency of dental amalgam and substitute materials.
- Preparation of a Report on the use of amalgam within the scope of the indigenous health care subsystem.

### **3. Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental filling.**

The Ministry of Health recommends researching about and enhancing the oral health approach focused on the promotion, prevention, minimal intervention, and maintenance of good health conditions by strengthening the incentives to self-management through tooth brushing and recommending the use of fluoride-containing products both by the population and oral health professionals. The main approach of the Federal Government

is to decrease the demand and need for dental filling of the population, encouraging and fostering oral health promotion and prevention.

Additionally, it is important to mention that the composite resin and glass ionomer are the main mercury-free restoring materials used to treat dental caries.

The Atraumatic Restorative Treatment (ART), recommended by the Ministry of Health (BRAZIL, 2007; 2018) uses only hand instruments and does not require electrical dental equipment and piped water. Among other advantages, it is possible to perform the ART fillings outside the healthcare facilities and in specific populations, such as those geographically isolated. Nevertheless, it is important to emphasize that the restoring material used in this technique (glass ionomer) does not have the same physical and chemical properties and clinical performance as the dental amalgam, and its lifespan is shorter than the amalgam's.

It is worth mentioning that, despite the technological evolution of glass ionomer cements, they show more wear and less resistance to fracture than resin and amalgam, which restricts their indication.

In remote regions of difficult access, where there is no timely dental assistance and reduced availability of dental equipment, as well as for persons in vulnerable situations, the dental amalgam may be the material of choice of oral health professionals, as it is more suitable for those situations.

It is known that the use of dental amalgam requires low technological capacity, while composite resin requires a dental curing light in good conditions of use to provide a good polymerization of the material (process of converting the resin into the plastic/solid state by light). Additionally, an adhesive system with good properties is necessary, allowing the resin to adhere to the dental substrate.

Nonetheless, the Indigenous Health Care Subsystem Report identified that, despite the increase in the total number of fillings carried out between 2015 ( $n = 150,440$ ) and 2018 ( $n = 270,946$ ), factor that may be associated with the increased access to dental services, that, in addition to developing assistance activities, also perform actions directed to prevention of dental caries and other oral health problems.

Despite the fact that the total number of fillings increased, the report identified that there was a decrease in the proportion of amalgam fillings in comparison with other materials. Amalgam fillings represented 10.3% ( $n = 15,565$ ) of the fillings performed in 2015, and this percentage dropped to 9.2% ( $n = 25,008$ ) in 2018. These numbers reflect a reduction trend in the use of the amalgam and an increase in the use of amalgam substitutes over time, with significant regional differences.

It is important to note that among indigenous groups, especially those from the northern region of the country, the consumption of certain ingredients and the way of preparing food may result in a hard and fibrous diet, such as moorhen flour, game meat, *moquém* (meat roasted on embers, wrapped in banana leaf), seeds, coconuts, among others. Additionally, certain ethnic groups use teeth as a working tool to manufacture artifacts and household items, especially when the activity requires cutting and stripping fibers and vines.

Both the diet and the use of teeth in manufacture may be associated with the report that, in certain locations, there are indigenous peoples who show a preference for amalgam fillings over other materials, as they think the amalgam has better performance, more resistance, and longer lifespan.

Finally, we highlight that, according to the Scientific Review (DATS/HAOC/PROADI-SUS/2018), despite being mercury-free materials and despite being the patients' preferred alternative for mimicking the natural appearance of teeth, composite resins include in their formula a series of chemicals that may be released during the life cycle of the filling, from manufacturing to placement, removal, and disposal. These chemicals are mostly monomers and include compounds such as 2-hydroxyethyl methacrylate, triethylene glycol dimethacrylate, or monomers derived from Bisphenol A, according to Mulligan *et al.*, 2018.

The pollution potential of composite resins in the environment reflects the life cycle of the material, as well as the dental amalgam's. Despite the fact that BPA from monomers of the composite resin can be released in certain scenarios, the potential of this release is not well-defined.

#### **4. Promoting research and development of quality mercury-free materials for dental filling**

The Ministry of Health organizes Working Groups and promotes the integration with Health Research and Higher Education Institutions to improve and support continuing education for oral health care professionals in Brazil. In this regard, the most recent publication of the book "*A Saúde Bucal no SUS*" [Oral Health Care in the SUS] (2018) provided updates on the oral health care network, focusing on the APS, recommending minimally invasive techniques for treating dental caries, for example, based on the most recent scientific evidence.

The country conducts, every ten years, the "National Survey of Oral Health Situation" in order to guide the decisions related to the National Oral Health Policy (PNSB).

Two studies have been carried out by a research group of Cochrane Brazil (2020), whose research subjects and main findings were the following:

##### **1 – Study I: Hall Technique**

A technique that indicates the biological sealing of caries in primary molars in which preformed metal crowns (PMCs) are put using the Hall technique. The Hall technique used to insert preformed metal crowns (PMCs) in primary molars is a minimally invasive treatment option, because the caries are not removed, but rather they are sealed by cementing the crowns.

Researchers have concluded that such technique has advantages in comparison with conventional restoration techniques and conventional PMCs, because "it does not require the use of anesthetic, it does not require tooth preparation, or occlusal adjustments, and it

may be implemented in environments away from specialized dental centers and with non-specialized professionals. Additionally, the execution of the technique is simple, it takes less time, and it aims at reducing the child's stress and at facilitating the conduct of the professional".

## 2 – Study II: ART

A technique that indicates the removal of carious tissue using hand instruments and subsequent restoration using glass ionomer, using finger pressure, not requiring light curing polymerization.

Researchers have concluded that the clinical decision must be considered taking into account the possibility of using the ART technique as a clinical option. Given the advantages of the implementation of the ART technique, namely, the fact that it may be used in environments without electrical energy and that it requires simple instrumentation and less local anesthetic, this technology must be studied further. It is argued that the ART technique may have a better performance if it is implemented by trained professionals, who are attentive to the particularities of using the materials. The choice of materials with improved resistance must be considered.

## **8. Restricting the use of dental amalgam to its encapsulated form.**

Brazil has adopted rules restricting the use of silver amalgam to its encapsulated form. The restriction of the use of amalgam only to its encapsulated form was defined by Collegiate Board of Directors' Resolution (RDC) No. 173 of September 18, 2017, of the Brazilian Health Surveillance Agency – ANVISA, which prohibits in the entire national territory the manufacturing, importation, and commercialization, as well as the use in health care services, of non-encapsulated mercury and powder for amalgam alloy indicated for use in Dentistry.

## **9. Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.**

The right way to store traces of amalgam fillings and the right way to dispose of teeth with such fillings are described in ANVISA RDC No. 222/2018, which establishes that the collection of mercury waste resulting from the preparation of dental amalgam may occur in a sturdy, unbreakable container with a large mouth and made of an inert material.

There must be a water line over the waste stored in the container, which shall be sent to be restored or to another form of disposal in compliance with the rules defined by the competent environmental authority. The amalgam fillings being replaced by other materials are a bigger challenge. During their removal, the use of diamond dental burs and drills produces small amalgam granules that are removed from the mouth by suction devices that, on their turn, are disposed of directly into the sewerage system. A potential solution for proper disposal in such cases is the use of separating filters, which are studied and regulated by ANVISA.

## CHALLENGES IN THE IMPLEMENTATION OF ADDITIONAL MEASURES TO REDUCE THE USE OF DENTAL AMALGAM WITHIN THE POST-COVID-19 PANDEMIC CONTEXT.

The Research on the Oral Health Situation of the Brazilian Population (SB BRASIL), which was expected to be carried out in 2020, was postponed due to the current public emergency scenario caused by the Covid-19 pandemic. This study was supposed to assess the current landscape of the distribution of dental caries nationally, based on the DMFT (Decayed, Missing, and Filled Teeth) index.

Due to the Covid-19 pandemic scenario and to the fact that Sars-CoV-2 is transmitted by oral fluids, Brazil has promoted the suspension of elective dental treatments, which worries oral health care managers and professionals regarding the higher demand for dental treatments that is arising at this moment and that will arise in a post-pandemic scenario. In this regard, with the suspension of the elective treatments, suspension of health promotion and prevention practices, early identification of risk groups, and timely intervention for action in early stages of the disease, most likely, the need for restoration and the aggravation of the activity and severity of carious lesions will be noted. This scenario has been under examination in the Federal level, but it should also be considered in the assessment of the removal of therapeutic techniques from the SUS.

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