

The Safety of Dental Amalgam

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Health Canada

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I. Background

■ 1. Concerns over amalgam safety

Dental amalgam has been used in North America for more than 150 years, yet there have been recurrent concerns over its safety. In 1845, the American Society of Dental Surgeons adopted a resolution requiring its members not to use amalgam because mercury, the major component, was known to be extremely toxic. However, membership in the Society declined and it disappeared in 1856.

Public anxiety over amalgam safety has recurred periodically since then. In 1991, the American Dental Association conducted a survey which showed that more than half of the respondents believed that dental amalgam could cause health problems. Twenty percent of respondents had considered having their amalgam fillings removed because of health concerns, or had already had them removed.

The current concern has been prompted by a number of factors. Starting in 1987, the Federal Public Health Office of Germany issued a series of recommendations against the use of amalgam in certain situations, primarily in pregnant women, children, and people with kidney disease.

Sweden has begun a plan to phase out the use of amalgam. As of July 1, 1995, Sweden

has not allowed its use for patients under the age of 20 and, according to present plans, amalgam will be banned entirely after 1997.

In December 1990, the CBS television news show "60 Minutes" broadcast a program on dental amalgam which raised a great deal of public concern. One of the scientists interviewed on this program was Dr. Murray Vimy of the University of Calgary who had done a research experiment in which he had placed radioactively labelled amalgam fillings in the teeth of sheep. The results showed that the mercury quickly appeared in the body organs of the sheep, especially the kidneys. Dr. Vimy reported that the kidney function of the sheep had been impaired by as much as 60 percent.

In 1994, the BBC television series "Panorama" produced a program on amalgam entitled "Poison in Your Mouth," which added to the public's perception that amalgam is hazardous. Numerous newspaper and magazine articles have also contributed to the debate.

In response to public concern and to numerous inquiries as to Canada's position on the safety of amalgam, the Medical Devices Bureau of Health Canada began a study of the issue in 1992 with the aim of developing a statement on dental amalgam.

■ ■ 2. Regulatory status of amalgam in Canada

Dental amalgam and other dental filling materials are classed as medical devices under the Medical Devices Regulations of the *Food and Drugs Act*. The authority of the Act applies only to the sale of medical devices and not to their use by health care professionals.

In 1982, amendments to the regulations were passed requiring pre-market review by the Health Protection Branch of safety and efficacy data for all devices designed to be implanted in the body for more than 30 days. However, dental amalgam and most other dental materials currently in use were exempt from these requirements because they had been on the market prior to the enactment of the regulations. (A similar situation exists in the United States, where regulations were established in 1976.)

In January 1994, dental filling materials were explicitly excluded from the list of devices subject to pre-market review under the Medical Devices Regulations.

Even though dental materials are not subject to pre-market review, they are subject to the general safety provisions of the *Food and Drugs Act* and Medical Devices Regulations. The Branch has the authority to regulate the sale of such materials if there is a safety concern. To date, no regulatory measures have been invoked with regard to amalgam.

■ ■ 3. Mercury release from amalgam and its absorption by the body

Mercury is released from amalgam in several ways. Mercury vapour is continuously evolved from the filling surface and this release is stimulated by chewing, tooth brushing or bruxism (grinding the teeth). The process continues as long as the filling is in the tooth. The vapour can be inhaled or dissolved in saliva and swallowed. Mercury particles are also released from the filling surface through wear or corrosion and are swallowed. A third route of exposure is through mercury particles embedded in the gums or other soft tissue of the mouth during the removal of old fillings. The most significant route of exposure is believed to be inhalation of vapour.

A fraction of the inhaled mercury vapour is absorbed by the lungs and retained by the body. The mercury accumulates in all body organs and tissues, but principally in the kidney, with lower amounts in the brain, lung, liver, gastrointestinal tract and exocrine glands. Elemental mercury in the blood can cross the placenta and the blood–brain barrier.

A number of clinical studies have shown that the levels of mercury in body fluids and organs correlate with the number of occlusal amalgam surfaces in the mouth and the total number of amalgam surfaces. Furthermore, mercury levels in blood and urine have been shown to decrease after the amalgam fillings have been removed.

However, it must be emphasized that blood and urine mercury levels attributable to amalgam do not approach the level recognized as the onset of clinical mercurialism (mercury poisoning): that level is taken to be 100 µg of mercury per gram of creatinine in urine.

Therefore, it is our conclusion that although amalgam contributes detectable amounts of mercury to the body, these levels do not approach those recognized to cause illness.

■ ■ 4. Adverse health effects attributed to amalgam

Mercury vapour is known to be toxic, but most clinical information on its toxicity comes from studies of industrial workers exposed for long periods of time to high vapour concentrations in factories. There are relatively few clinical studies of the effects of mercury vapour at low levels, or of disease prevalence in amalgam-bearers compared to people without amalgam.

The first signs of mercury vapour toxicity are subtle effects on the central nervous system (CNS), seen as changes in nerve conduction, EEG patterns, psychomotor function and cognitive function. As the exposure increases, the effects become more severe and include tremor, ataxia, loss of memory, insomnia, depression, irritability, personality changes, weight loss, psychological distress and gingivitis. Adverse effects on kidney function begin at

exposure levels of about 50 µg of mercury per gram of creatinine in urine, or about half of the level taken to indicate mercurialism.

A number of hypotheses have suggested that mercury contributes to various diseases, among them Alzheimer's disease, amyotrophic lateral sclerosis, multiple sclerosis and Parkinson's disease.

However, reviews of the clinical evidence indicate that the existing data do not support these hypotheses.

Amalgam is known to cause allergic hypersensitivity in a small fraction (estimated at 2% to 3%) of the population. However, clinical verification of hypersensitivity is difficult; not all individuals who react positively to a skin test for mercury allergy will suffer allergic symptoms when amalgam fillings are placed in their teeth. Tests on individuals who suffered from symptoms they themselves ascribed to mercury did not show that they had elevated mercury levels in body fluids, nor did they have levels of mercury vapour in their mouths higher than an asymptomatic control group.

There have been a few cases reported in the literature in which individuals who suffered from chronic ill-health experienced dramatic improvements after their amalgam fillings were removed. The small number of cases and the lack of controlled studies make it difficult to establish a cause-and-effect relationship in such cases.

Because mercury can cross the placental barrier, some dental schools advise against placing or removing amalgam fillings if the patient is pregnant since the release of mercury vapour is higher during these procedures. Since mercury can compromise kidney function at sub-clinical levels, it is considered advisable to reduce mercury exposure as much as possible in persons whose kidney function is already impaired by disease or other causes.

■ ■ 5. Environmental concerns and policies regarding mercury

Because of the toxicity of mercury and its compounds, many countries, including Canada, have introduced measures to reduce or eliminate mercury in many products, and to control its emission into the environment.

The total amount of mercury waste entering the environment from dental use is declining. However, in some countries dental waste is contributing an increasing fraction of the total mercury effluent because of aggressive programs to reduce mercury waste from other sources. In Sweden, the use of amalgam in private dental practice for tooth restorations in adults dropped from 59 percent in 1985 to 29 percent in 1991. Even so, the Swedish Environmental Protection Agency estimated in 1992 that one third of the mercury in sewage sludge came from dental services. This was one of the factors leading to Sweden's proposal to end the use of dental amalgam by 1997.

It is a recognized principle in the risk management of toxic metals that exposure to them should be reduced as far as possible, provided this can be done at an acceptable cost. A Government of Canada report entitled *Regulatory Framework for Risk Management of Mercury in Canada* describes federal legislation, regulations and guidelines to control or reduce mercury in air, water, waste effluent, marine disposal, dump sites, consumer products, pest control products and industrial exposure.

The Canada/Ontario Agreement has placed mercury on a list of toxic materials targeted for eventual elimination. Under Canada's Environmental Choice Guidelines, the use of mercury in batteries has recently been eliminated, and the paint industry has voluntarily stopped using mercury compounds in interior house paints. The *Hazardous Products Act* prohibits the use of mercury compounds in any paints or finishes on children's toys. Mercury compounds are not allowed as fungicides in seed dressings. It is estimated that between 1982 and 1991, 17.6 percent of the mercury used in Canada was for dental work.

■ ■ 6. Use, suitability and safety of alternative materials

The use of amalgam as a filling material is declining worldwide. In 1990, fewer than half of the tooth restorations in the United

States (96 million out of 200 million) used amalgam. This trend, together with a general decline in the incidence of tooth decay, has resulted in a 38 percent decrease in the total amount of amalgam used since 1979.

The major types of alternative materials available are composites, glass ionomers, gold foil, gold alloy, metal-ceramic crowns and gallium alloys.

All of these materials are more expensive than amalgam and most are not as durable in locations where they are subject to wear during chewing. They are also technique-sensitive — that is, the success of the restoration depends to a great extent on the technique used to place it. A dentist may need special training to acquire this technique.

The safety of alternative materials has not been assessed in much more depth than has the safety of amalgam. In Canada and the United States, most dental materials have been exempted from regulations requiring a detailed review of their safety before sale, since they were in use before the regulations came into effect. In the United States, all approvals of dental materials issued since the U.S. regulations were established in 1976 have been granted without a detailed review of safety data because the material was judged to be similar to a product in use before 1976. If the components of a new dental material are conventional and have a long history of safe use in the oral cavity, the USFDA does not require biocompatibility tests.

Most standards for dental materials have addressed only physical characteristics and have not considered biocompatibility or toxicity. Nevertheless, it is well-known that alternative materials contain toxic components and that these are released in small quantities during the setting process. It is therefore possible that alternative materials may also cause adverse health effects, but little information is available on this. Assessments of the components in alternative materials indicate that the release of toxic substances is very low and does not continue indefinitely, as is the case for the release of mercury vapour from amalgam. Therefore, from the stand-point of long-term biocompatibility, alternative materials now in use appear to pose lower risks than amalgam.

■ ■ 7. The Health Canada assessment of mercury exposure and risks from amalgam

Several studies have attempted to estimate the total amount of mercury to which the average person is exposed from various sources, and to calculate the fraction of total exposure and relative risk due to amalgam. Such comparisons are very difficult because mercury occurs in a number of chemical forms which have different routes of intake by the body, different absorption rates, different excretion rates, different threshold effect levels and different adverse effects.

The Health Canada report entitled *Assessment of Mercury Exposure and Risks from Dental Amalgam* was prepared

for the Medical Devices Bureau by Dr. Mark Richardson and released in November 1995. It was the first comprehensive risk assessment in Canada of mercury exposure from dental amalgam.

This study made an estimate of the exposure of the Canadian population to mercury from amalgam, food and the environment. The study did not include laboratory research or clinical investigations. It reviewed the international literature on the health effects of mercury and used sophisticated computer modelling techniques to calculate mercury exposure from amalgam. This calculated exposure was then used in standard risk assessment procedures to estimate a tolerable daily intake level (TDI) for mercury.

The report used a probabilistic model, together with a computer technique called Monte Carlo simulation, to estimate mercury exposure. The model calculated exposures from environmental sources of mercury such as water, soil ingestion, ambient and indoor air, and various kinds of food. It depended on data on the relation between the number of fillings and the concentration of mercury in the urine of amalgam bearers, and the relation between the concentration of mercury in the air and the concentration of mercury in the urine of industrial worker.

Using this model, the report estimated that for Canadians with amalgam-filled teeth, the average daily mercury exposure (the amount of mercury absorbed by the body)

from all sources of mercury ranges from 3.3 µg for toddlers to 9.4 µg for adults aged 20 to 59. Estimates of exposure from amalgam alone ranged from 0.8 µg for toddlers to 3.4 µg for adults aged 20 to 59.

The Monte Carlo simulations indicated that amalgam contributes about 50 percent of the daily mercury exposure of the average Canadian. This makes amalgam the most significant single source of mercury exposure, compared to food, indoor and outdoor air, drinking water and soil.

Some studies have found evidence of slight sub-clinical impairment of cognitive functions, particularly short-term memory, in individuals exposed to fairly low mercury vapour levels. These effects are not easily detected, and the existing data do not allow the calculation of a no-effect threshold level. The report calculated that mercury vapour levels likely to arise from the average number of dental amalgam fillings were 50 to 100 times lower than the levels which gave rise to sub-clinical effects in those studies.

One of the most important aspects of the study was that it calculated a Tolerable Daily Intake (TDI) for mercury and related that TDI to the estimated mercury exposure from amalgam. Such a calculation had not previously been attempted for mercury vapour.

The concept of a TDI is often used in setting guidelines to limit exposure to hazardous substances from industrial or environmental sources. A TDI for a

substance is the level to which people could be exposed continuously over their lifetime without suffering any harmful effects.

A TDI calculation is usually based on observed adverse effects at high exposure levels, usually in industrial settings. To extrapolate these observations down to a level at which we can be confident that there will be no harmful effects, a number of estimates and assumptions must be made. Furthermore, accepted principles of risk assessment state that if there are uncertainties in the available data, safety factors must be applied in order to err on the side of caution.

Before releasing the study, Health Canada asked a group of international experts in risk assessment, toxicology and public health policy to review it and comment on its methodology and conclusions. The peer reviewers were scientists from Canadian and U.S. universities, research centres and government regulatory agencies.

The peer reviewers generally agreed that the methodology of the study was sound but expressed concerns over the available data. Some reviewers were doubtful that a reliable numerical estimate for a TDI could be determined because of the number of assumptions which had to be made, and the lack of accurate data for many of the factors in the assessment model. They doubted that probabilistic estimation techniques could compensate for the lack of precise data.

Since several reviewers believed that the clinical study used in the first draft of the report was not suitable for this purpose, Dr. Richardson repeated his analysis using a different study by Fawer and co-workers. That study measured a C.N.S. effect in men who were exposed to mercury vapour in a factory. The “end point,” or physiological effect selected for observation, was a slight tremor of the forearm, which is the most sensitive end point identified in human studies of mercury toxicity. This forearm tremor is classed as a “sub-clinical effect” — that is, an effect which is not considered to be an illness.

Because of uncertainties in the data, Dr. Richardson applied a safety factor of 100 to derive a proposed TDI for mercury vapour of about 1 µg/day for a 70 kg adult. His comparison of this TDI with the quantities of mercury absorbed daily by individuals with amalgam fillings indicated that four amalgam fillings should cause no observable adverse health effects in adults during a lifetime of exposure. However, Canadian adults with an average number of fillings (7) might exceed this limit.

The meaning of this TDI has been widely misunderstood. Many people have assumed that it sets a maximum level above which illness will result. However, because of the conservative safety factor used, and the sub-clinical effect on which the calculation was based, exposures several times greater than the TDI would probably not produce any harmful effects.

Since this study was the first of its kind for dental amalgam and had generated a great deal of public interest, since some of the reviewers' concerns related to questions of judgment, and since the study had been extensively revised in response to the reviewers' suggestions, the Department decided to make the study available for public review and comment. After this review, the Department decided that it would not use the calculated TDI as the basis for safety recommendations. The reasons for this decision are discussed further in Section 8.

■ ■ 8. The Health Canada stakeholder committee and its recommendations

In order to obtain views on all aspects of the amalgam question, the Medical Devices Bureau convened a committee representing the groups with major interests in the issue: provincial health ministries, the Canadian Dental Association, manufacturers of dental materials, academic researchers, dentists, environmental and patient advocacy groups, and individuals.

The committee was asked to review and comment on the Health Canada assessment report and to give advice on other aspects of the issue which it felt were important. Two meetings of the committee were held. At the first meeting, Dr. Richardson presented his study and answered questions on the report. At the second meeting, committee members made presentations on the amalgam issue and the assessment study.

The committee discussed the assessment study at some length. Many of the comments were similar to those made by the peer reviewers. Some of these were that too many assumptions had to be made, and that the choice of a safety factor of 100 was largely a matter of judgment and arguments could have been made for choosing a larger or a smaller factor.

New comments related to the suitability of the research paper by Fawer and co-workers as the basis for establishing a TDI for mercury vapour. The major criticisms of the Fawer study were that the sample size was small, the experiment provided no dose-response data, the hand tremors were subtle and difficult to measure, and the researchers did not know the previous exposure history of the subjects, which might have been a factor in the severity of the tremors. The comment was also made that other risk assessment agencies did not consider hand tremor to be an appropriate end point for measuring C.N.S. changes in adults.

The committee adopted the following statement on the assessment report:

The amalgam risk assessment was done in a careful and conscientious manner with methods generally appropriate for this type of risk assessment. However, given the poor quantifications of exposure in the key toxicological studies used, it is inappropriate to conclude that a TDI set using this approach represents a distinction between health and disease. In any further risk assessments (when sufficient data become

available), the committee believes that significant adverse effects on the central nervous system (or other body systems) would be the appropriate end points.

Health Canada accepted this position and has decided that the setting of a TDI for mercury from amalgam will not be part of the Department's position statement.

The committee approved eight other recommendations:

1 The evidence does not exist to warrant the wholesale removal of amalgam fillings **[passed unanimously]**.

2 The medical and dental practitioners should be alert to the fact that some individuals have sensitivities to amalgam and to the needs of these individuals. All individuals have the right to participate in the selection of the materials that will be placed in their mouth **[passed 18-1]**.

3 Some patients may have concerns that they have adverse systemic effects due to amalgam fillings. Although removal of existing amalgam fillings may, in some individuals, have positive effects, at this time substantial experimental evidence does not exist to confirm those positive effects. Individuals considering such an action should thoroughly discuss the issue with their physician and dentist **[passed 17-2]**.

4 Although there is no evidence that dental amalgams contribute to immunological, neurological or kidney disease in human populations, there is some evidence that mercury exposure from all sources is of more significance to individuals with those problems than to the general population. Dentists and physicians should be aware of these concerns in their choice of dental materials for these patients **[passed 12-6 with 1 absentee]**.

5 It is recommended that a public and professional information package be prepared to make the public more capable, in collaboration with their health care providers, of making informed dental health choices **[passed unanimously]**.

6 The public should be aware that it is the responsibility of the dentist to obtain and update a patient's health history. It is also the responsibility of patients to notify their dentist of any changes in their health status **[passed unanimously]**.

7 Dentists are to be encouraged to decrease the use of amalgam and other restorative materials through the use of diagnostic and preventive treatment strategies based on tooth structure preservation **[passed 15-3 with 1 absentee]**.

8 The committee strongly recommends that funding be made available to support research on the use of dental amalgam or alternatives so that any concerns and questions surrounding their safety can be addressed. This funding should be a joint effort of industry, the dental profession and government **[passed 13-5 with 1 absentee]**.

A report containing a summary of the discussion, the recommendations and dissenting opinions was submitted by the moderator of the meeting, Dr. D. Wayne Taylor of McMaster University on March 1, 1996. Under the terms of reference of the committee, its recommendations are not binding on the Department, although they were taken into careful consideration.

■ ■ 9. Regulatory actions and recommendations in other countries

A number of countries have made official recommendations on the use of amalgam. An important aspect of all of these recommendations is the conclusion that there is no clinical evidence to suggest that amalgam is causing illness in the general population. The major positions are summarized here.

Sweden

In 1988, the Swedish National Board of Health and Welfare published a report on amalgam which made the following points:

There is no data that amalgam causes poisoning.

Amalgam is an unsuitable dental filling material from a toxicological point of view.

Treatment of pregnant women with amalgam should be avoided as far as possible.

Use of amalgam should be gradually decreased.

Alternatives should be used as far as possible.

Patients who have developed contact allergies should have their existing fillings replaced.

In 1992, the Swedish parliament approved a general plan to phase out mercury from all sources, including amalgam. The Swedish National Board of Health and Welfare issued the following proposals for a step-wise reduction in the use of dental amalgam:

After July 1, 1993, discontinue use of amalgam in children's temporary teeth;

After July 1, 1995, discontinue use of amalgam in permanent teeth of patients up to the age of 19.

The Board recognized that using alternative materials would result in higher costs, but pointed out that use of amalgam in people under 20 was already very low. The recommendation went into effect July 1, 1995.

In 1994, Sweden further proposed to cease using amalgam entirely by 1997. A final decision on the implementation of this ban is still pending.

Germany

The Federal Public Health Office of Germany stated in 1992 that:

No reasonable suspicion that amalgam fillings are hazardous to one's health can be established from a medical point of view.

Nevertheless, the use of amalgam is to be decreased as much as possible in order to reduce the strain on the human body caused by general mercury intake.

As already recommended in 1987 by the Federal Public Health Office, no major dental procedures involving amalgam should be done during pregnancy.

The Office continued to add to the list of contraindications. In 1995, the recommendations advised against using amalgam:

in pregnant women;

in patients with specific forms of kidney disease;

in patients with proven amalgam allergy;

in children under the age of six; and

for specific types of restorative procedures in all patients.

Denmark

Denmark published draft orders in 1989 proposing to discontinue the sale of all products, including dental amalgam, which contain mercury by 1999. However, the orders have apparently not been put into effect.

United States

The U.S. Public Health Service published a major study of amalgam in January 1993. The highlights of the report included the following points:

Use of amalgam is declining; in 1990, amalgam was used in fewer than half of the dental restorative procedures in the U.S.

Amalgam emits mercury vapour, but there is scant evidence that the health of the vast majority of people with amalgam is compromised, nor that removing amalgam fillings has a beneficial effect on health.

The possibility that amalgam, as well as other filling materials, could pose health risks cannot be totally ruled out because of the lack of definitive human studies.

It is inappropriate at this time to recommend any restrictions on the use of dental amalgam.

■ ■ 10. Conclusions

1 Dental amalgam contributes detectable amounts of mercury to the body, and is the largest single source of mercury exposure for average Canadians. However, this exposure is not causing illness in the general population.

2 Current evidence does not indicate that mercury contributes to Alzheimer's disease, amyotrophic lateral sclerosis, multiple sclerosis or Parkinson's disease.

3 Mercury can cross the placental barrier, and can impair kidney function at sub-clinical levels of exposure. Therefore, it is advisable to avoid procedures involving amalgam in pregnant women or individuals with kidney disease.

4 The environmental policies of Canada favour a reduction in the use of mercury in all products. It is prudent to reduce human exposure to mercury where safe and practical alternatives exist.

5 The Health Canada report, *Assessment of Mercury Exposure and Risks from Dental Amalgam* by Dr. Mark Richardson is a useful research study, but currently available clinical data are not reliable enough to permit making a confident estimate of a Tolerable Daily Intake for mercury from amalgam.

6 Evidence does not warrant the removal of existing amalgam fillings from individuals who have no indications of adverse effects.

II. Health Canada Position Statement on Dental Amalgam

Considerations:

1 Although dental amalgam is the single largest source of mercury exposure for average Canadians, current evidence does not indicate that dental amalgam is causing illness in the general population. However, there is a small percentage of the population which is hypersensitive to mercury and can suffer severe health effects from even a low exposure.

2 A total ban on amalgam is not considered justified. Neither is the removal of sound amalgam fillings in patients who have no indication of adverse health effects attributable to mercury exposure.

3 As a general principle, it is advisable to reduce human exposure to heavy metals in our environment, even if there is no clinical evidence of adverse health effects, provided the reduction can be achieved at reasonable cost and without introducing other adverse effects.

Recommendations:

Health Canada advises dentists to take the following measures:

1 Non-mercury filling materials should be considered for restoring the primary teeth of children where the mechanical properties of the material are suitable.

2 Whenever possible, amalgam fillings should not be placed in or removed from the teeth of pregnant women.

3 Amalgam should not be placed in patients with impaired kidney function.

4 In placing and removing amalgam fillings, dentists should use techniques and equipment to minimize the exposure of the patient and the dentist to mercury vapour, and to prevent amalgam waste from being flushed into municipal sewage systems.

5 Dentists should advise individuals who may have allergic hypersensitivity to mercury to avoid the use of amalgam. In patients who have developed hypersensitivity to amalgam, existing amalgam restorations should be replaced with another material where this is recommended by a physician.

6 New amalgam fillings should not be placed in contact with existing metal devices in the mouth such as braces.

7 Dentists should provide their patients with sufficient information to make an informed choice regarding the material used to fill their teeth, including information on the risks and benefits of the material and suitable alternatives.

8 Dentists should acknowledge the patient's right to decline treatment with any dental material.