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Phase-Down of Amalgam Use in Dentistry: A Perspective For its Effective Control and Management

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Abstract

Mercury pollution of the environment and its negative impacts on the health of humans had been recognized many years ago by the world community; and the contribution of dental amalgam, which contains about 50% of mercury by weight, to mercury pollution is well established. Ten percent (10%) of 300 - 400 metric tons of world's consumption of mercury is by dental profession in the form of dental amalgam fillings. The Minamata Treaty or Convention, on control and reduction of mercury pollution, provides for amalgam phase-down over a given time-line as part of the process of total elimination of mercury use in restorative dentistry. The amalgam phase-down approach is based on the fact that outright ban on the use of dental amalgam by nations of the world may be impossible because of individual nation's peculiarities. Therefore, the purpose of this article is to review mercury pollution of the environment and discuss the challenges as well as developing a National Strategic Plan (NSP) in managing amalgam phase-down process.

Keywords: Amalgam; Mercury; Pollution; Strategy; Phase-Down; Treaty

Introduction

I will stand upon my watch and station myself on the towers; I will look to see what he will say to me, and what answer I am to give to this complaint. Then, the Lord replied: write down the vision and make it plain on tablets so that he that reads it may run with it. For the vision is for an appointed time, but at the end it shall speak, and not lie. Though it may tarry, wait for it, because it will surely come to pass; and it will not tarry [1]. This scriptural quotation is given in order to capture and lay the foundation for the introductory aspect of this discourse. The first statement of this quotation can be regarded as the collective voice of the dental profession, while pondering, on how to respond to the complaint of the international community against mercury and its compounds such as dental amalgam. The complaint which the international community has against dental amalgam, which contains about 50% of mercury by weight, is that mercury, as one of the major constituents of dental amalgam, has been recognized as a notorious and dangerous chemical with negative effects on the environment and on the health of the people all over the world.

This recognition of the negative impacts of mercury on people's health and the environment led to the adoption and signing [2] by over 87 nations of the world on the 10th October, 2013 at Minamata, Japan. This treaty is the vision of the international community; and it is to control and reduce mercury pollution and its attendant

negative impacts on the environment and on the health of the people around the world. This vision is for an appointed time (within a time frame). Though it may be delayed because of the recognition, by the international community, that dental amalgam cannot be banned outright by all nations of the world owing to individual nation's peculiarities. However, the vision will speak at the end. Nonetheless, a moratorium of about ten years has been given to all nations to phase-down amalgam use; and this moratorium may delay the final exit of dental amalgam as a restorative material but its final exist will surely come to pass. The purpose of this article is to discuss the challenges and possible national strategies concerning phase-down of amalgam use in dentistry. This discourse will be treated under three broad headings namely:

Background Information

What Is Mercury?: Mercury is a naturally occurring metal. It is a potent neurotoxicant that negatively impacts human health and the environment around the world. It occurs as cinnabar (Hgs) in rocks and soils. It is very mobile and persistent; and it can easily make its way into the atmosphere, soil, ground water and surface waters of local, regional and more distant areas. It is a silvery-white liquid, which is highly soluble in water, freezes at -38.830C and boils at 3570C. It is the only metal which is liquid at standard room temperature [3].

Risks to Humans: Exposure to mercury can result into acute or chronic poising. Acute exposure to elemental mercury levels of 1.1 - 44micogram/m3 for 4 - 8 hours can lead to: chest pain, dyspnea, cough, haemoptysis, impaired pulmonary functions, and interstitial pneumonitis while acute exposure to mercury vapor can lead to: psychotic reactions such as delirium, hallucination and suicidal tendency. Other symptoms of occupational exposure include: erethism, irritability, fatigue, insomnia, loss of memory, depression and vivid dreams. Chronic exposure to mercury can lead to sleep disturbance, tremors and impaired cognitive skills. Fetuses and children are particularly vulnerable to mercury exposure [4-9].

Key Sources of Mercury Emissions: Mercury can be released into the environment naturally through weathering and erosion of rocks and soils, volcanic eruptions, forest fires and presence of trace amount in coal. Human activities which cause releases of mercury into the environment include coal mining, coal burning (coal fired power plants), oil powered plants, artisanal and small scale gold mining, cement production, dental amalgam (production, use, removal and waste management), mercury production mainly for batteries, pig iron and steel production, waste disposal (including municipal and hazardous waste, crematoria, sewage sludge, incinerators) and non-ferrous metal production - typically smelter [4-9]. These emissions cause pollution of the environment (air, water, soil, fish, plants, animals and humans) [4-10].

Dental Amalgams as a Major Contributor to Mercury Pollution: The total world consumption of mercury is between 300-400 metric tons. Ten per cent (10%) of the total world consumption is by the dental profession in the form of amalgam fillings [11-15].

Uses of Amalgam in Dentistry: Amalgam is mainly used in operative dentistry for filling of posterior primary and permanent teeth. It is indicated for large cavities in posterior teeth without pulpal involvement. It is cheap, easy to manipulate, long clinical life span, less prone to secondary caries and less sensitive to technique during placement. However, it does not bond to tooth substance, it cannot be used in anterior region of the dental arch because of its unpleasant color, it discolors the tooth substance and its cavity preparation is more destructive of sound tooth tissue as compared with tooth colored materials such as composite resins and glass ionomer cements [12, 13].

Alternatives to Amalgam: Alternative direct restorative materials such as composite resins, GIC, and Compomers can be used for restoration of carious and non-carious cavities involving anterior and posterior teeth based on specific selection criteria and indications. These are tooth-colored materials with less destruction of sound tooth tissue during cavity preparation [12,13]. GIC and Compomers bond chemically and micro-mechanically to tooth tissue while composite resins can bond to tooth tissue by means of micro-mechanical interlocking mechanism using acid etch technique. These materials can be used for restoration of small and medium-sized carious cavities in both anterior and posterior regions of the dental arches. However, their manipulation, during operative procedure, is technique sensitive. They are expensive, time-consuming; discolor with use, prone to marginal leakage and secondary caries as well as post-operative pain or sensitivity in

respect of composite resins. Restorations of composite resins have been found to leach various substances and ions, but the amounts released do not reach levels associated with adverse health outcomes. However, it must be noted that no material is completely innocuous; and all materials exhibit varying degrees of side-effects on humans based on the degree of toxicity and individuals idiosyncrasy [12,13].

Challenges That May Militate Against Amalgam Phase-Down

National Challenges: Challenges that may militate against smooth process of amalgam phase-down cannot be separated from the myriad of challenges being experienced by different nations of the world. Dental amalgam phase-down should be seen as a national issue which must be treated or handled in context of economic, social, political and moral challenges. There are variations in the challenges affecting the different nations of the world. However, these challenges can be summarized under the following major headings:

- I. Weak Economy: This is characterized by:
- a. dependence on monoculture e.g. petroleum as the main source of revenue generation;
- b. import driven or import dependent;
- c. weak national currency;
- d. unstable market;
- e. predatory-parasitic and non-symbiotic economic investments by multinational companies which are being aided by local neo-colonial masters- (a new phenomenon of neo-colonialism);
- f. poor budgetary allocations to key sectors such as education, health and agriculture;
- g. infrastructural collapse/decay as evidenced by: poor transportation systems (poor roads and water ways as well as poor air services);
- h. collapse of health sector (inadequate equipment and instruments, consumables);
- i. frequent strikes by health workers, inadequate number of health workers etc.;
- j. epileptic power (electricity) supply to homes, offices and industries; and
- k. weakened security, social, educational, economic and commercial institutions
- **II. Corrupt Practices:** This is the greatest cankerworm that eats into the social, economic, political, moral and security fabrics of any nation; and its colossal negative impacts on growth and development can be felt in every aspect of life in any afflicted nations. It can be seen and perceived as:
- a. high levels of inflation of contracts' values in government and private cycles;

- b. outright stealing, embezzlement, misapplication and misappropriation of funds;
- c. diversion and conversion of public funds into private or individual hands.
- d. non implementation of awarded contracts;
- e. poor standards of execution of projects; and
- f. employment or placement or appointment of unqualified and incompetent persons in positions of authority, for selfish reasons, to the detriment of the general populace.

III. Pervasive poverty and hunger: This is characterized by:

- a. poor feeding (unbalanced diet);
- b. poor salaries and wages;
- c. non-payment of salaries and wages for months by some federal ministries and parastatals as well as by some states;
- d. little or no income to be spent on medical and dental treatments;
- e. poor accommodation and homelessness;
- f. joblessness on the part of able-bodied people;
- g. lack of opportunity for employment;
- h. thuggery by jobless people; and
- i. environmental filthiness.

IV. Weak political structures and political instability as demonstrated by:

- a. frequent policy changes in government;
- b. lack of continuity;
- c. self-centered programmes and projects;
- d. duplication of efforts and functions;
- e. uncoordinated response to national issues;
- f. lack of national interest; and
- g. dangerous compromises based on personal interest.

Professional Challenges

The dental profession and dental professionals also have some challenges that can seriously impede the smooth process of amalgam phase-down; and these challenges must be recognized and dealt with at the initial stages of the development of National Strategic plan for amalgam phase-down.

These challenges include:

- a. resistance to change by dental professionals owing to old beliefs,
- b. convention and practices which have turned some dentists into bigots;

- c. limited number of dental clinics and centers to provide dental services for the teeming population;
- d. inadequate number of dentists and other auxiliary personnel to provide dental services to patients; and
- e. expensive nature of dental profession in terms of training personnel, acquisition of instruments and equipment and provision of dental services to patients.

Developing A National Strategic Plan For Managing The Phase-Down Of Amalgam

The development of a National Strategic Plan (NSP) should put into perspective all the aforementioned myriad of challenges. Therefore, the recognition of these challenges by the stakeholders and the strong will of the stake holders will enable them fashion out an appropriate National Strategic Plan (NSP) based on the nation's peculiar characteristics. Amalgam has served the dental profession for over 150 years and it will still serve the profession for more years to come. However, with the signing of Minamata Treaty and ratification of the Treaty by concerned nations of the world, it is imperative for the concerned nations to put in place strategic plans to phase-down amalgam use over a given period of time in compliance with one of the major provisions of the Minamata Treaty [6-9,11]. The Scandinavian countries had already banned the use of amalgam as a restorative material in dentistry [12,13]. Nonetheless, the treaty provides for a phase-down approach on the use of amalgam as opposed to outright ban so that countries can put up strategic plans to reduce and control amalgam use and its eventual elimination as a restorative material in dentistry.

The proposed National strategic Plan to phase-down amalgam in concerned nations of the world can be discussed under the following six steps:

Establishment of a working or coordinating group;

Gathering baseline data and developing the national overview;

Setting a goal and objectives;

Formulating the implementation strategy;

Assessment or evaluation mechanism; and

Approving or endorsing National Strategic Plan (NSP).

Establishment of A Working Or Coordinating Group: A working group, which will be charged with the responsibility of championing the course and process of the phase-down of amalgam, should be set up. This group will be responsible for drawing up the National Strategic Plan (NSP) based on given terms of reference such as organizing all stakeholders meetings, conferences, workshops, lectures and seminars in order to obtain invaluable information and advice in the formulation, execution and analysis of the Strategic Plan. The stakeholders should include:

- a. environmental organization (having a vested interest in mercury reduction);
- b. academic and research institutions;

- c. legal (can provide legal advice, information on the use of mercury);
- d. representatives from industry and commerce (trade associations and professional bodies may provide additional information or data);
- e. public health and safety groups;
- f. agricultural groups Give information production of food crops;
- g. trade representatives to give information on import/ export and issues related to potential restrictions on trade;
- large scale mining and other industry;
- i. Non-governmental organizations (NGOs) with vested interest in mercury free dentistry;
- j. representatives of Federal and State Ministries;
- k. local government officials and staff;
- l. community leaders;
- m. miners e.g. artisanal small gold miners (ASGM);
- n. international organizations; and
- o. possible funding sources and institutions.

Gathering Baseline Data And Developing The National Overview: Information should be gathered on:

- a. level of consumption of amalgam;
- b. importation of amalgam;
- c. disposal methods of amalgam waste;
- d. level of mercury vapor in various dental clinics and centers all over
- e. the country;
- f. level of consumption of alternatives to amalgam in different dental clinics and centers around the country;
- g. amalgam spills/mercury spills management lines in dental clinics;
- h. current legal issues concerning amalgam use;
- i. economics, such as earnings per capita;
- j. storage of unused amalgam;
- k. types of amalgam formulations being used by dental clinics;
- l. techniques of mixing and insertion of amalgam; and
- m. in-house hygienic practices in dental clinics and centers.

Furthermore, data gathering will be based on: consulting previous data bases to review and analyze current and past project to gain insight into the nature of the issue at national level; conducting surveys and interviews to gather relevant information on

amalgam; and determination of quantity of amalgam consumption from dental clinics and centers over a given period of time. These pieces of information are required as baseline data for monitoring purpose during the period of the phase-down of amalgam.

Setting Goals and Objectives: After gathering all the relevant information, the problems or challenges relating the amalgam phase-down can be succinctly defined. Therefore, goals and objectives can be clearly stated taking into consideration the expected outcomes. The goal of amalgam phase-down is a gradual reduction of amalgam use over a time-line at which it will eventually cease to be used as a restorative material in dentistry. The main objective is to reduce or eliminate mercury emission, arising from amalgam use, into the environment. The specific activities to be performed in order to bring about a reduction or a total elimination of mercury emissions into the environment (arising from amalgam use) can be turned into specific objectives in the National Strategic Plan. The objectives must be specific, measurable, assignable, realistic and time-dependent ("SMART" objectives).

Formulating the Implementation Strategy: This aspect of developing a national strategic plan for amalgam phase-down will be discussed under two sub-headings:

- **A. Constituents Of Strategic Plan Implementation:** The implementation strategy is a major part of the National Strategic Plan and it should contain some fundamental elements namely:
- a. work plan;
- b. outreach plan;
- c. time-line; and
- d. budget
- **a. Work plan:** This is the listing of all the activities to be carried out under the strategic plan; and it is done by the working group in collaboration with all relevant stakeholders. These activities are marked for specific government ministries, agencies and NGOs that are best positioned to implement these activities. Specific activities are tied to specific outcomes for easy evaluation of the implementation process.
- **b. Outreach plan:** This is concerned with dissemination of information nationally, regionally, state-wide and locally by specific government's agencies and institutions on the need to eliminate amalgam use in dentistry because of its negative impacts on human health, owing to mercury emissions. Information should also be disseminated on:
- i. alternatives to amalgam;
- ii. how to improve oral health;
- iii. need and importance of eating balanced diet;
- iv. visiting dentists regularly for check-ups;
- v. oral hygiene education and promotion;
- vi. management of amalgam waste;

- vii. storage of amalgam waste; and
- viii. benefit of drinking fluoridated water.

The dissemination of these pieces of information can be done through talks and discussions in mass media (electronic and print), workshops, seminars, lectures, symposia, conferences and text messages.

- c. Time-Line: The strategic plan must have a beginning and an end. The time-line must also have some reference points or milestones which are attached to evaluation of some specific objectives. The phase-down of amalgam must be activated at a particular time and it must be concluded within a time frame.
- **d. Budget:** The working group must prepare clear and definite budget for the phase-down of amalgam based on definite activities to be carried out during the phase-down period. The budget must be written in the language that can be understood by the finance ministry and other institutions that may provide funds for the project. Budget implementation must be transparent and tied to specific programmes or activities of the National Strategic Plan. Accountability is of utmost importance in order to encourage the funding institutions to do more.
- B. Proposed Activities or Programmes during Amalgam Phase-Down: Specific activities or programmes will be carried out by relevant agencies, institutions or ministries during the phase-down period. These activities can be grouped under two major subheadings namely:
- a. Preventive Activities.
- b. Effective amalgam management activities.
- I. Preventive Activities: The objective of the preventive approach is to reduce the quantity of amalgam consumption based on the principle of source reduction.10Source reduction activities include:
- 1. Legal Activities: Enactment of pollution prevention law by the National Assembly is imperative. This law should cover amalgam phase-down with specific time-line at which amalgam should cease to be used as a restorative material in dentistry in Nigeria. The purpose of this national law is to domesticate Minamata Treaty and enhance compliance with the provisions of the Minamata Treaty. The federal and state ministries of justice as well as other relevant agencies and institutions should create public awareness concerning the existence and provisions of such law. The use, importation, and trade in amalgam should also be banned at the expiration of the timeline of the phase-down; and the ban on amalgam should be given a legal backing.
- 2. Research and Data Collection Activities: There is urgent need to determine the levels of mercury vapor, quantity of amalgam consumption as well as other related amalgam management activities in all the various dental clinics and centers all over the country by researchers so as to form a

baseline data for comparison during the phase-down period. It is also important to have information concerning level of mercury pollution in Nigerian environment because amalgam is a way or contributor to mercury pollution.

This is a holistic and multi-sectorial strategy. It is not an issue to be handled by the dental profession alone. It involves all sectors of a nation's economy. Every sector has roles to play; and all stakeholders must be involved. Time-line must be given for the activities of every stakeholder. A summary of individual stakeholder's activities are highlighted below:

- A. Federal and State Ministries of Health:
- i. generation of enhanced oral health education and promotion policies;
- ii. increase the funding of the dental hospitals and clinics;
- iii. training of more dental personnel;
- iv. provision of adequate facilities in the dental clinics and centers;
- v. banning of the use of dental amalgam in pediatric dentistry;
- vi. formulation of guidelines on amalgam use during the phase-down period; and
- vii. formulation of guidelines on all aspects amalgam waste management.
- B. National and State Assemblies:
- i. enactment or amendment of pollution prevention law,
- ii. including amalgam phase-down, to lay down the legal framework for the implementation of the phase-down of dental amalgam.
- C. Federal and State Ministries of Justice:
- i. activation of the process of implementing any national law concerning amalgam phase-down as well as Minamata Treaty; and
- ii. creation of public awareness of the existence of such law and treaty.
- D. Federal and State Ministries of Communications:
- i. generate enhanced communication policies that will encourage companies in the dissemination of information on the need for mercury free dentistry.
- E. Mass Media Companies:
- i. dissemination of information, as part of public social responsibility,
- ii. on the need for mercury free dentistry, use of alternative restorative materials as opposed to amalgam, benefits of good oral health and oral health education and promotion.
- F. Federal and State Ministries of Finance:

- i. create a special budgetary heading for amalgam phasedown;
- ii. increase budgetary allocations to health, education and agriculture ministries; and
- iii. sponsorship of conferences, lectures, symposia, workshops, seminars on amalgam phase-down and mercury pollution.
- G. Federal and State Ministries of Transportation:
- i. improve road, water and air transportation systems to enable patients to have easy access to dental clinics, centers and hospitals. Improved transport systems provide prompt access to dental clinics and reduce delay in treatment as well as missed appointments.
- H. Federal and State Ministries of Education:
- i. modification and strengthening of undergraduate and postgraduate curricula;
- ii. adequate funding of the dental schools; and
- iii. training of more dental personnel.
- I. Dental Schools:
- i. modification and strengthening of undergraduate and postgraduate Curricula;
- ii. placing more emphasis on the use of alternative restorative materials.
- iii. teaching of alternative restorative materials should precede the
- iv. teaching of amalgam to de-emphasize the use of amalgam;
- v. adequate supply of alternative restorative materials in the treatment and teaching clinics; and
- vi. researching more into the use of alternative restorative materials.
- J. Federal and State Ministries of Agriculture and Water Resources:
- i. generation of enhanced agricultural policies to encourage farmers to produce more food stuffs;
- ii. encourage people to eat balanced diet which is a prerequisite to the development of strong teeth;
- iii. determination of levels of mercury concentrations in different types of fish found in the concerned nations' waters so as to give pieces of advice concerning their consumption;
- iv. supply of fluoridated water into all homes; and
- v. determination of levels of mercury in different water supplies so as to give pieces advice concerning their safety for consumption.
- K. Federal and State Ministries of Information and Culture:

- i. encourage people to eat traditional foods as opposed to complete
- $\begin{tabular}{ll} ii. & dependence on fast foods, refined sugars and soft drinks; \\ and \\ \end{tabular}$
- iii. create public awareness on the negative impacts of mercury on human health.
- L. Federal and State Ministries of Labor and Productivity:
- i. improve on the present minimum wage for Nigerian workers to enable them pay their medical and dental bills as well as feeding on balanced diets.
- M. Federal Ministry of Mines and Power:
- i. generation of enhanced policies that will encourage generation distribution and supply of constant electricity to hospitals and clinics.
- ii. Many dental treatment procedures cannot be done without electricity.
- N. National Agency for Food and Drug Administration and Control (NAFDAC):
- i. provide regulatory role on fluoridation of specific foods such as water, milk, salt etc.;
- ii. enforcement of regulations concerning provision of fluoride in certain foods; and
- iii. determine the optimum concentrations of certain chemicals in foods and drugs.
- O. Local Government Officials and Staff:
- i. creation of awareness during the phase-down of amalgam because they are closer to the people.
- P. Law Enforcement Agencies: Police, Custom, Immigration etc.:
- i. enforcement of laws relating to amalgam phase-down and related environmental pollution issues.
- Q. Federal and State Environmental Protection Agencies:
- i. $\;\;$ regulate and control disposal of amalgam waste during the phase-down period.
- R. Non-Governmental Organizations (NGOs):
- i. creating awareness on the need to have mercury free dentistry in public health by organizing workshops, seminars, conferences, lectures, symposia and health campaigns; and
- ii. rooting for the use of alternative restorative materials, as opposed to amalgam in dentistry.
- S. Federal and State Ministries of Environment:
- provide regulatory standards/guidelines on use, control, reduction, and amalgam waste management by dental clinics and dental centers.

II. Effective Management of Amalgam during the Phase-Down Period: In this write-up, it is impossible to exhaustively outline, in specific terms, the guidelines to be adopted. However, directions or areas of focus can be listed. Effective management of amalgam will cover placement, removal, storage and disposal of amalgam waste as well as amalgam spills/mercury spills' management during the phase-down period [12-15]:

1. Placement of Amalgam

- a. Equipment or technology modification;
- b. Process modification during placement;
- c. Operational changes e.g. improvement of house-keeping and inventory control;
- d. Reformation or re-design of amalgam product; and
- e. Standard guidelines for mercury spills management should be established.
- **2. Removal of Amalgam Restorations:** Standard guidelines must be established for use by dentists.

These guidelines will include:

- a. use of rubber dam;
- b. use of special suction tube;
- c. fast cutting bur to reduce mercury vapor;
- d. use of copious amount of water during cutting;
- e. cutting the amalgam into chunks;
- f. use of safety goggles;
- g. maintenance of clean filtered air in the dental surgery; and
- h. covering the skin in order to avoid contact with mercury and amalgam particles or scraps.
- **3. Storage of Amalgam Waste:** Amalgam waste must be appropriately stored in a sealed container, containing water, prior to disposal as part of medical waste to avoid spills and vaporization.
- **4. Disposal of Amalgam Waste**: Amalgam waste should be disposed of using modern methods as opposed to traditional methods of solid waste disposal.

Assessment Or Evaluation Mechanism

Specific criteria should be established to review, monitor and evaluate process of National Strategic Plan (NSP). Information and data should be collected based on objectives of National Strategic Plan (NSP). Evaluation of quantity of amalgam consumed as well as management of amalgam waste by dental clinics should be carried out at specified reference points within the time-line of the amalgam phase-down. It must be clearly understood that the level of achievement of objectives should be tied to specific reductions in the levels of mercury vapor and amalgam consumption as well as compliance with effective amalgam management guidelines

to reduce mercury emissions. Industrial project evaluation and questionnaires can be used to review, monitor and evaluate National Strategic Plan (NSP) within the time-line.

Approving The National Strategic Plan (Nsp)

This is the act of getting endorsement for the National Strategic Plan (NSP) by all stakeholders. It can be achieved by getting all stakeholders involved at the initial preparation of the National Strategic Plan (NSP) as well as during implementation and evaluation stages of National Strategic Plan (NSP) process. Approval or endorsement can be in the forms of agreement and definite ministerial directives, budgetary allocations from ministries and financial supports from other stakeholders. It must be recognized that obstacles to endorsement can arise as a result of duplication of functions by different institutions, conflicting functions among implementation groups, conflicting interest with respect to priority ordering owing to financial consideration, degree of importance of the National Strategic Plan (NSP) to national growth and development. A clear identification of these obstacles at the beginning of the National Strategic Plan (NSP) process would provide opportunity of resolving those (issues) at the earliest stages of National Strategic Plan (NSP) process.

Conclusion

The phase-down of the use of dental amalgam in restorative dentistry requires a coordinated holistic and multi-sectorial approach by stakeholders. It is an acceptable option as opposed to outright ban on dental amalgam. It is feasible and desirable. Therefore, it should be given a national attention; and a National Strategic Plan (NSP) should be developed and implemented in order to meet the deadline or time-line at which amalgam should cease to be used as a restorative material in dentistry in compliance with the provisions of the Minamata Treaty or Convention.

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