

# **Dental Amalgam and Alternative Direct Restorative Materials**

**Editors**

**I.A. Mjör and G.N. Pakhomov**

**Oral Health  
Division of Noncommunicable Diseases  
World Health Organization**



**Geneva  
1997**

© World Health Organization, 1997

This document is not issued to the general public and all rights are reserved by the World Health Organization (WHO). The document may not be reviewed, abstracted, quoted, reproduced or translated, in part or in whole, without the prior written consent of WHO. No part of this document may be stored in a retrieval system or transmitted in any form or by any means – electronic, mechanical or other – without the prior written permission of WHO.

The views expressed in documents by named authors are solely the responsibility of those authors.

---

# WHO Consultation on Dental Amalgam and its Alternatives Geneva, 3-7 March 1997

## List of Participants

**Dr A. Berglund**

University of Umea, Umea, Sweden

**Dr N.S. Braveman**

National Institute of Dental Research, Bethesda,  
MD, USA

**Dr I.R. Cooper**

Department of Health, London, England

**Professor N.R. Gjerdet**

University of Bergen, Bergen, Norway

**Dr A. Hensten-Pettersen**

Scandinavian Institute of Dental Materials,  
Haslum, Norway

**Dr E.D. Jacobson**

Food and Drug Administration, Rockville, MD,  
USA (*Vice-Chairman*)

**Dr D.M. Meyer**

American Dental Association, Chicago, IL, USA

**Professor I.A. Mjör**

College of Dentistry  
University of Florida, Gainesville, FL, USA  
FDI World Dental Federation  
London, UK (*Chairman*)

**Professor M. Nakata**

Kyushu University, Fukuoka, Japan

**Professor E. Reich**

University of Saarland, Homburg, Germany  
(*Rapporteur*)

**Dr A. Schedle**

University of Vienna, Vienna, Austria

**Dr E. Widström**

National Research and Development Centre for  
Welfare and Health, Helsinki, Finland

**Professor G. Zeilig**

Association Dentaire Française, Paris, France

## Secretariat

**Professor D. Bratthall**

WHO Collaborating Centre, Lund University,  
Malmö, Sweden

**Dr T.W. Cutress**

University of Otago, Wellington, New Zealand  
(*Temporary Adviser*) (*Rapporteur*)

**Dr S.A. Hussein**

Regional Adviser, Oral Health, WHO Regional  
Office for the Eastern Mediterranean

**Dr M.I. Mikheev**

Chief, Occupational Health

**Dr G.N. Pakhomov**

Responsible Officer, Oral Health (*Secretary*)

**Mrs J.S. Infirri**

Technical Officer, Oral Health

**Dr S.J. Thorpe**

Regional Adviser, Oral Health, WHO Regional  
Office for Africa

**Dr M.M. Younes**

Chief, Assessment of Risk and Methodologies



## Acknowledgements

---

In part, the editing of the proceedings from the  
WHO Consultation on  
Assessing the Risks and Benefits to Health Oral Care and the  
Environment using Dental Amalgam and its replacement,  
Geneva, 3-7 March 1997,  
has been supported by NIDR/NIH grant 2P50 DE 09307-08.

Excellent secretarial assistance by  
Mr T. Abare and Mrs C. Shaw is gratefully acknowledged.

---



# List of Contents

WHO Consultation on Dental Amalgam and its Alternatives

Geneva, 3-7 March 1997

List of Participants .....	i
Acknowledgements .....	iii
List of Contents .....	v
Executive Summary .....	vii
Consensus Statement on Dental Amalgam .....	ix
Research Agenda .....	xiii
Risks and Benefits of Direct Restorative Materials as Alternatives to Amalgam, E. Reich .....	1
Direct Restorative Dental Materials in Oral Health Care - Amalgam, Composites and Glass Ionomers, P. Kosella, J.S. Infirri, G.N. Pakhomov .....	17
Toxic and Allergenic Risks Due to Dental Biomaterials, M. Golberg and G. Zeilig .....	35
Mercury Exposure from Dental Amalgam Fillings: Absorbed Dose and the Potential for Adverse Health Effects, J.R. Mackert Jr. and A. Berglund .....	45
Dental Amalgam and Human Health, Current Situation - A New Zealand Review, T.W. Cutress .....	61
Evaluation of Toxic Effects of Resin Based Restorative Materials, A. Schedle, J.E. Dahl, W. Parzefall, W. Aberer, A. Hensten-Pettersen .....	73
Prevention and Policy of Avoiding Environmental Contamination of Mercury from Oral Care, Including Amalgam Waste Management Issues, D.M. Meyer .....	93
Occupational Health Problems Associated with Dental Materials, A. Henston-Pettersen .....	99
Dental Amalgam. A Report With Reference to The Medical Devices Directive 93/42/EEC from an Ad Hoc Working Group Mandated by the European Commission, I.R. Cooper .....	105
Reporting of Adverse Reactions to Dental Biomaterials Criteria and Preliminary Results from the Norwegian Registry, N.R. Gjerdet .....	139
The Use and Safety of Dental Amalgam: An Overview of Research and a Proposed Research Agenda, N.S. Braveman .....	149
Summaries of Six Review Papers, T.W. Cutress, A. Berglund .....	171
The Use of Dental Amalgam in Sweden, A. Berglund .....	183

*List of contents*

---

Perceptions in the Selection of Dental Restorative Materials, E. Widström .....	195
Dental Amalgam: Utilization Trends, Alternative Therapies and National Policy, D. Jacobson and C. Eccleston .....	205
Policy of the United Kingdom on the Use of Dental Amalgam, I.R. Cooper .....	217
Dental Amalgam and Human Health, Current Situation - A New Zealand Review, T.W. Cutress .....	223
Update of Amalgam use in Japan, M. Nakata .....	237
Policy and Situation in Germany With Respect to Dental Amalgam, E. Reich .....	233
The Use of Dental Amalgam in Africa, S.J. Thorpe .....	239
National Policies on Amalgam Use in Eastern Mediterranean Region, S.A. Hussein .....	243

## Executive Summary

This non-serial publication by the WHO Oral Health Programme is based on specially prepared working papers and presentations made at the WHO Consultation on assessing the risks and benefits to health, oral care and the environment using dental amalgam and its alternatives. Some of the material was made available to the participants prior to the meeting, including detailed reviews of scientific literature related to dental amalgam and other direct restorative materials. Single reprints and abstracts of publications were also at hand and some were circulated prior to the meeting. All these documents formed the basis for detailed discussions which were initiated by reviewing the 1995 WHO/FDI Consensus Statement on Dental Amalgam. The names and addresses of the participants and their affiliations is attached in Annex 1.

In his opening statement, Dr N.P. Napalkov, Assistant Director-General, on behalf of Dr Hiroshi Nakajima, Director-General of WHO, requested participants to review and update the WHO/FDI Consensus Statement on Dental Amalgam, to prepare a proposal for a research project on assessing the risks and benefits of dental amalgam use, and alternative restorative materials, and to identify the possibility of establishing a network between national and international groups and individuals for global monitoring of all issues related to the use of dental restorative materials. In fact, the idea to organize this meeting was made in 1995 when WHO started to receive numerous requests from WHO Member States, organizations and individuals on various aspects related to the use of dental amalgam following the distribution of the WHO/FDI Consensus Statement on Dental Amalgam. The FDI World Dental Federation, which is a non-governmental organization in official relations with WHO, was invited to contribute. After approval by the FDI Council, a joint WHO/FDI Consensus Statement was then distributed in the form of a *note verbale* by the Director-General of WHO to all WHO Member States on 25 October 1995.

To provide more information to the Member States, WHO/ORH was requested to review again the WHO/FDI Consensus Statement and if necessary draft a relevant document on dental amalgam use, taking into account the benefits, but also risks for individual, occupational, and environmental health of restorative materials. The project was thoroughly scrutinized by the WHO Programmes on Environmental Health and Occupational Health.

Being firmly convinced only the prevention of dental diseases can solve all the problems in relation to the use of restorative materials, it should be emphasized that the complete eradication of dental caries may not be possible in the foreseeable future. Consequently, the approaching problems should be addressed, not only in relation to dental amalgam, but also to composites, glass ionomers and mercury free alloys. Thus, the WHO Consultation was limited to direct restorative materials, that is, materials which are pliable and inserted into the tooth during the same visit as the caries is removed. Indirect restorations usually required two visits to the dental office. They comprise of inlays, onlays and crowns which are prepared from dental casting alloys, ceramics or rarely from resin based materials. These indirect restorations are from 5-8 times more expensive than amalgam restorations.

Referring to requests received from Member States and individuals, it is clear that even by updating the WHO Statement, it will still be difficult to meet all of the needs, since there are many important public health issues related to restorative dental material use which require coordinated global activities, including laboratory and clinical research, effective exchange of information between countries, institutions and individuals. In this connection, participants of the meeting have defined the major need for further research and to establish a global project based on registries of side effects of dental restorative materials. Two such registries have already been initiated by the

## *Executive Summary*

---

Departments of Health and Social Welfare in Norway and Sweden. Other countries are urged to start similar projects and the WHO will coordinate their efforts on a global basis and produce reports as needed.

The participants of the meeting have agreed that the main outcomes of the Consultation should be published as a WHO/Oral Health Programme document. It is believed this material as presented in this publication could assist health authorities

and the public to understand and reflect on the current situation of dental restorative materials. Another reason for the publication of this book is for effective and rapid exchange of information on the topics discussed at the meeting and to prevent misunderstandings or misinterpretations of the results from various research projects or actions undertaken and policies implemented by some Member States in respect of the use of dental materials.

*Gennady Pakhomov and Ivar A. Mjör*

---

# **Consensus Statement on Dental Amalgam\***

**7 March 1997**

**This Consensus Statement was unanimously approved by  
the participants of the WHO Consultation, Geneva, 3-7 March 1997**

Consensus Statement on Dental Amalgam, 7 March 1997 .....	xi
Preamble .....	xi
The use of dental amalgam .....	xi
Safety of dental amalgam .....	xi
Occupational risk to oral health personnel .....	xi
Environmental concerns .....	xi
Public opinion and mass media .....	xii
Research Agenda to Improve Health .....	xiii

\* Unanimously endorsed by the General Assembly of the FDI World Dental Federation, 6 September 1997.



# **Consensus Statement on Dental Amalgam**

## **7 March 1997**

**This Consensus Statement was unanimously approved by  
the participants of the WHO Consultation, Geneva, 3-7 March 1997**

### **Preamble**

Dental caries (tooth decay) is a common oral disease and its prevention is in accord with the main mission of WHO. In spite of great success in the prevention of dental caries, caries in need of restoration still occur. In these cases, diseased tissue should be removed and teeth restored with appropriate material(s). Dental amalgam, a compound of mercury and silver-based alloys, is widely used as a dental restorative material. While the current weight of evidence suggests that dental restorative materials, including dental amalgams, are considered to be safe and effective, concerns have been expressed about the health effects of mercury in amalgam. Following an evaluation of a large amount of sometimes conflicting evidence from diverse sources, the WHO offers the following consensus statements on dental amalgam:

### **The use of dental amalgam**

Dental amalgam is a frequently used material for restoring decayed teeth. It has been used successfully for more than a century and its quality has improved over the years. Amalgam restorations are durable and cost-effective; they are, however, not tooth-coloured. While much research has been devoted to the development of dental restorative materials, there is currently no direct filling material that has the wide indications for use, ease of handling and good physical properties of dental amalgam. The restorative materials currently available as alternatives to dental amalgam significantly increase the cost of dental care.

### **Safety of dental amalgam**

Dental amalgam restorations are considered safe, but components of amalgam and other dental restorative materials may, in rare instances, cause local side-effects or allergic reactions. The small amount of mercury released from amalgam

restorations, especially during placement and removal, has not been shown to cause any other adverse health effects.

Because of concerns over adverse effects of mercury, some patients with or without symptoms, may request the removal of their amalgam restorations. While there has been a number of case studies and informal reports, no controlled studies have been published demonstrating systemic adverse effects from amalgam restorations. At present, there is no scientific evidence showing that general symptoms are relieved by the removal of amalgam restorations. Therefore, after a comprehensive oral examination and appropriate dental treatment, these patients should be considered for referral to other health care professionals for diagnosis and treatment if symptoms persist.

### **Occupational risk to oral health personnel**

A potential health risk to oral health personnel from mercury exposure exists if working conditions are not properly organized. The application of proper mercury hygienic requirements together with monitoring of mercury vapours in the work environment in dental clinics will significantly reduce mercury exposure.

### **Environmental concerns**

Mercury used in dentistry may contaminate the environment via the disposal of waste products from dental clinics. Equipment is available to collect metallic waste generated during dental amalgam placement and removal. Appropriate collection and recycling technology is also available to reduce mercury pollution of the environment, including pollution from crematoria.

## **Public opinion and mass media**

Today there is considerable exchange of information on dental amalgam around the world. For environmental reasons some countries are restricting all uses of mercury, including dental amalgam. Due to publicity in the mass media, however, the situation in those countries which have undertaken restrictive action is often misinterpreted, leading to numerous inquiries about the safety of dental amalgam and a demand for the removal of amalgam fillings.

The current weight of evidence is that contemporary dental restorative materials, including dental amalgam, are considered to be safe and effective. However, adverse biological reactions to the materials do occasionally occur and they must be treated on an individual basis. The WHO recognizes the importance of the continued monitoring of the safety and effectiveness of all dental restorative materials.

---

# Research Agenda to Improve Health

The participants of the WHO Consultation devoted considerable time to a discussion of a research agenda related to dental restorations. Many attempts were made to reach agreements on a prioritized list of research topics in the area of dental restorations. Since the participants had a diverse and heterogeneous background, these discussions often ended up in general, but also specific, views on operative/conservative dentistry, cariology and preventive dentistry. Apart from one item of global research which was unanimously agreed on, the participants felt that the other research topics outlined should be presented in an unprioritized list.

## The research topic unanimously agreed on was to establish a:

Global registry of biological and adverse health effects for monitoring of dental material related symptoms/diseases in various populations (patients and professionals) including the formation of an international advisory group to establish guidelines and evaluate the collected data.

Rationale:

- as recommended by various international groups;
- in order to accumulate sufficient information to aid in the design, evaluation and improvement of dental device materials;
- to clarify health status in order to reduce health care costs;
- to be responsive to consumer and patient group concerns.

## The other research topics discussed and generally agreed on included:

Research to develop affordable preventive caries programmes, making any restorative material unnecessary, including studies helping to identify

fractions of various populations at high caries risk, for targeted actions.

Rationale:

- as recommended by various international groups;
- best treatment is prevention;
- more efficient and cost-effective prevention;
- all restorative treatments and materials have some degree of risk;
- reduce iatrogenic effects.

Studies to identify special risk groups and individuals highly sensitive to various restorative materials.

Rationale:

- unexplainable symptoms;
- particular health problems.

Development of restoration methods and inexpensive biomaterials that can withstand local climatic, storage and handling limitations.

Rationale:

- easily applied by local health personnel;
- majority of people live without reliable electricity;
- increase shelf-life of materials;
- usable under variable conditions.

Research to develop improved and novel materials, including development of biological materials (biomimetics/tissue engineering) for restorative purposes.

Rationale:

- regenerate tooth tissue;
- eliminate cutting procedure;
- biocompatibility;
- reduce adverse effects.

Develop better diagnostic methods for caries and methods for clinical decision making. Development of criteria regarding the replacement of failed restorations.

## *Research Agenda to Improve Health*

---

**Rationale:**

- as recommended by expert groups;
- best treatment is prevention;
- more efficient and cost-effective prevention;
- all restorative treatments and materials have some degree of risk;
- reduce iatrogenic effects.

Improving methods for minimal intervention in caries management.

**Rationale:**

- save tooth structure;
- low cost;
- efficient.

Improved and affordable methods for recovering and recycling of restorative materials.

**Rationale:**

- prevent pollution;
- recover cost.

Improved methods to make relevant dental material information available, including use of Internet.

**Rationale:**

- need to update oral health personnel;
- education of consumers;
- easy access;
- environmental reasons.

Development of direct filling materials with easy handling characteristics.

**Rationale:**

- easily applied by oral health personnel;
- improved quality;
- reduce cost;
- usable under variable conditions.