

Perceptions in the Selection of Dental Restorative Materials

E. Widström

Perceptions in the Selection of Dental Restorative Materials	197
Organisation of dental care in Finland	197
Concerns about health effects of dental restorative materials	197
Occupational health risks	198
Choice of filling material in special situations	199
Health authority recommendations	199
The use of dental amalgam in Finland	200
Factors influencing the selection of restorative materials in dental care	201
Dental health	202
Costs of dental care	202
Conclusion	202
References	202

Perceptions in the Selection of Dental Restorative Materials

Organisation of dental care in Finland

Finland is a sparsely populated Nordic country with a population of 5 million inhabitants and an area of 338 000 km². There is a fairly large tax-financed Public Dental Service (PDS), employing about 2000 salaried dentists. Dental care for children under 19 years is free in the PDS. About 20% of the population lives in rural areas or small towns, where they can use the PDS with subsidized fees. The PDS primarily offers services to children and adults under 41 years (born in 1956 or later). The majority of older adults uses the services of 2500 private dentists. A small proportion of adults (5%) using private services have reimbursements from the Sickness Insurance. The system is very complicated. In addition to 4900 practising dentists there are about 1000 oral hygienists and 350 denturists, which indicate a clear overproduction of dental workforce.

Concerns about health effects of dental restorative materials

Much debate in Scandinavian countries over the past years has focused on patients' concerns about dental restorative materials, especially amalgam fillings. This controversy began in Sweden in the late 1970s. The focus of concern has shifted over time from galvanic currents to allergic and toxic reactions, and amalgam fillings have been blamed for many diseases (Hanson, 1983, Pleva, 1983, Störte-becker, 1986). Although allergic and toxic reactions to amalgam restorations are shown to be extremely rare (Mjör, 1987, Taskinen *et al.*, 1989, Bergman, 1990, Kousa and Fräki 1990) and no positive correlations are found between numbers of amalgam fillings and patient symptoms in large populations (Ahlqvist *et al.*, 1988, Lavstedt and

Sundberg 1989), many individuals associate general symptoms with dental restorations.

In 1989, 99% of the Finnish dentists had faced patient enquiries about the possibility of side-effects of dental restorative materials, and 93% of the questions were about amalgam (Widström and Forss 1991). The situation was similar in the other Nordic countries. In Denmark and Sweden 60% of the dentists had had such patients at least every week; the corresponding figure for Finland and Norway was 40% ($p < 0,001$). The number of patients asking questions was highest in Sweden and lowest in Finland (Widström *et al.*, 1992). Patients' worries were not confined to their amalgam fillings, but included other materials used in dentistry. Many patients also asked their dentists to replace their amalgam fillings solely because of the fear of possible adverse effects of mercury.

In 1990, a questionnaire study was performed among the Finnish, Danish, Norwegian and Swedish dentists to obtain information on dentists' opinions on the safety of the most usual dental restorative materials (Widström, *et al.*, 1993). About 90% of the dentists considered the risks low for gold, ceramic materials, and glass ionomer. For amalgam, there were statistically highly significant differences between Swedish dentists and dentists in other countries ($p < 0,001$), a smaller proportion of the Swedish dentists believing amalgam to be safe. About half of the respondents considered composites to be low-risk materials (Table 1). Ninety-three percent of the Danish, 97% of the Finnish and Norwegian, and 94% of the Swedish respondents reported having amalgam fillings themselves.

Dental Amalgam and Alternative Direct Restorative Materials

Table 1 Dentists' personal assessment of risks of side-effects of various restorative materials expressed as percentages. "Don't know" answers were excluded.

Material	Risk of side-effects										
	Very low, or low						Very high, or high				
	DK	SF	N	S	All countries		DK	SF	N	S	All countries
	(n=267)	(n=449)	(n=354)	(n=640)	Total	P-values					Total
	%	%	%	%			%	%	%	%	
Amalgam	87.3	80.7	80.1	58.6	73.3	<0.001	4.5	2.7	3.1	10.3	5.8
Composite	60.3	50.9	47.7	45.2	49.6	<0.01	9.0	10.6	13.6	13.3	11.9
Glass ionomer	89.2	92.2	83.1	89.0	88.7	<0.01	0.4	1.3	2.6	1.1	1.4
Gold	99.6	98.0	97.2	98.4	98.3	NS	0.4	0.9	2.3	0.5	0.9
Ceramic materials	97.0	94.6	92.5	96.1	95.1	NS	0.8	0.7	2.0	0.8	1.0

Occupational health risks

A small proportion of dentists were worried about amalgam as an occupational risk factor. Marked differences between the countries studied were found (Table 2). It was evident that the Danish

dentists were most concerned, and the Finnish and Norwegian dentists least concerned about this risk (p<0.001).

Table 2 Dentists' answers to the question: "Do you feel unsure about amalgam as an occupational risk factor at your workplace?", expressed as percentages. "Don't know" answers were excluded.

Country	Yes, very much or yes, somewhat	Not at all, or not very much
	%	%
Denmark (n=270)	17.7	61.7
Finland (n=454)	6.9	73.7
Norway (n=361)	4.5	87.2
Sweden (n=647)	10.4	71.5

Perceptions in the Selection of Dental Restorative Materials

A great majority of the dentists in Denmark, Sweden, and Norway, but few in Finland, stated that patients should be able to get their fillings replaced at their own expense when they wished (Table 3). In all countries a greater proportion of the private (62.3%) than of the PDS dentists (49.3%; $p < 0.001$) were of this opinion. Replacement of fillings was found less justifiable if the costs were to be born by

the national insurance systems. The Danish and Swedish dentists seemed to be more liberal in this respect than the Finnish and Norwegian dentists (Table 3). Again, a greater proportion of the private (22.7%) than of the PDS dentists (9.0%; $p < 0.001$) in all countries thought that the patients should be able to get their fillings changed when they wished.

Table 3 Percentages of dentists who believe that a patient's dental fillings should be replaced without oral or medical indications when the patient insists on it.

Country	When the patient pays all the expenses	When governmental subventions are used to cover expenses
	%	%
Denmark (n=262)	62.9	23.8
Finland (n=448)	22.1	5.8
Norway (n=352)	52.4	8.1
Sweden (n=629)	79.2	24.4

Seventy-three percent of the respondents felt that physicians or medical specialists should examine patients who complained of vague symptoms which they associated with dental restorations.

Choice of filling material in special situations

Marked and partly inconsistent differences were found between the Nordic countries in the use of amalgam in various clinical situations (Widström, et al., 1993). In Denmark a great proportion of the dentists (65%) thought that it was acceptable to use amalgam as retrograde root fillings; in Finland it was not considered hazardous to combine gold and amalgam as it was in the other countries. In their answers to the open questions, many Danish, Finnish, and Norwegian dentists commented that they had never heard that it would be contraindicated to use amalgam for pregnant women or in association with gold. The Swedish dentists' restrictive answers to these questions

closely followed the detailed guidelines given by Sweden's National Board of Health and Welfare.

In all countries, private dentists were more likely to use amalgam in various clinical situations than the dentists in the PDS and they were more prone to replace amalgam fillings for aesthetic reasons. Dentists' opinions were not found to be influenced by their sex, age, or place of practice, but rather by their nationality and, within countries, by their service sector, i.e. private or public. This finding underlines the importance of cultural features. In all countries the private practitioners seemed to be more market-orientated and to pay more attention to patients' wishes than PDS dentists.

Health authority recommendations

Since early 1970s only materials tested by NIOM (the Scandinavian Institute of Dental Materials) have been recommended to be used in the dental

care in Finland and in the other Nordic countries. In 1987, the Medical Board recommended an increased use of glass ionomer cements in children and adolescents. Glass ionomer was thought to be biologically more satisfactory than other materials and the need for removal of sound tooth substance was found to be less than when amalgam was used. Similar recommendations have been made in other countries, e.g. in Australia. The research activity on glass ionomer materials has been high in Finland (Forsten and Karjalainen, 1990, Forss and Seppä, 1990, Forsten, 1993). Continuing education of dental personnel has also been active with regards to new materials and treatment methods in cariology.

Due to increasing questions about amalgam, the National Research and Development Centre for Welfare and Health in Finland appointed an Expert Group in 1992 to study recent advances on the materials used in dental care and any unwanted effects caused by such materials in patients, dental staff and the environment. In the evaluation of scientific articles, reports and also other materials, the Expert Group could not find any scientific proof for the statement that amalgam restorations are hazardous to health or that they could cause chronic mercury poisoning. The Expert Group requested the Ministry of the Environment to issue a statement concerning the effects of amalgam on the environment. In its statement, the National Board of Waters and the Environment claimed that the use of dental amalgam is a considerable source of environmental discharges of mercury in Finland and that dental amalgam contributed approximately 20% of the total annual use of mercury. Only 10% of the amalgam in solid waste annually produced by dental clinics, was delivered to appropriate hazardous waste managing system in 1992. Obviously, part of the waste was stored in practices, but at the same time the risk of discharging the amalgam waste with municipal solid waste to landfills was found to have increased. The primary effect of the discharges was the inability to use the sludge with high mercury levels as an agricultural fertilizer which markedly increased the costs of handling it. As a conclusion

the Ministry of the Environment stated that the use of amalgam should be discontinued.

The Expert Group concluded in its recommendation that the use of amalgam should be reduced for environmental reasons. Amalgam should only be used when other restorative materials cannot be used. There was, however, no reason for routine removal of well-functioning old amalgam fillings. In February 1994, after several hearings, the Expert Group's recommendation was approved by the Ministry of Social Affairs and Health at a high political level.

Recently, the government has decided that amalgam filters will become mandatory at every dental clinic from 1 July 1998. Separation efficiency of 95% is required.

The use of dental amalgam in Finland

There is rather little information available on the use of different materials by the dental profession. In the early 1990s the companies selling mercury estimated about 1.0-1.5 tons to be used by the Finnish dentists. Today the sale is markedly lower.

In 1992 the Research and Development Centre for Welfare and Health conducted a study both in the PDS and in the private sector to obtain information on the use of different restorative materials in dental treatment. A questionnaire was sent to 25-30% of the health centres and 30% of the private practitioners. The dentists were asked to record information for each of the fillings they placed during a given period. Answers were received from 855 dentists on 9,886 fillings which was considered to be giving a representative sample (Widström and Forss 1994).

Glass ionomer cement was the most common filling material in the restorations inserted for patients under the age of 17 years (Table 4). Amalgam was used in 15% of the fillings.

Perceptions in the Selection of Dental Restorative Materials

Table 4. Percentage distribution of materials used in fillings placed in children and adolescents.
D=deciduous teeth, P=permanent teeth.

Age of patient		Amalgam	Glass ionomer	Composite
years	n	%	%	%
0 - 6	272 *	4	95	1
7 - 11	1157			
D		7	91	2
P		16	56	28
12 - 16	976			
D		7	91	2
P		26	43	31

* Only three fillings in permanent teeth.

In adults, PDS dentists used amalgam in 30% of fillings and private practitioners in 28%. For the youngest and oldest patients health centre dentists tended to select amalgam more seldom than private practitioners. In all age groups, glass ionomer was more often used by PDS dentists whereas private practitioners selected composite. Gold and ceramic materials were used only in 22 restorations in total (Widström and Forss, 1994).

In 1994, twenty-one percent of the private practitioners claimed that they did not use amalgam any more (Widström et al., 1995). It is generally known that patients prefer other materials and the relatively new law (1993) on patients' rights gives them the possibility to claim which material should be used.

Due to the relatively rapid changes in the choice of filling materials, a new survey was conducted among private practitioners in January 1997 in order to obtain information on clinicians' experiences on possible side-effects, the longevity and costs caused by the changed routines. Preliminary results from this survey were presented at the WHO Consultation in Geneva.

Factors influencing the selection of restorative materials in dental care

Until recently, about 80% of all the restorations placed were of dental amalgam (Forss and Widström, 1996). At present, there seem to be large differences among countries in the use of restorative materials. In many countries, amalgam is still the most commonly used restorative material. Whereas in other countries, such as Sweden (Jönsson and Karlsson, 1994) and Finland, the use of amalgam is clearly decreasing. Improved dental health and the introduction of minimal preparation techniques are the most important reasons for this decrease, but the ongoing debate about the possible detrimental effects of amalgam on general health, as well as environmental concerns, have probably also had an influence.

The results of a recent study (Forss and Widström 1996) indicated that private practitioners sought the opinions of their adult patients regarding the selection of restorative material more frequently

(26% of restorative treatments) than their colleagues working in the public sector (11%; $p < 0.001$). The frequency of resin composite restorations increased and that of amalgam and glass ionomer restorations decreased when patients' opinions were sought.

In both health care sectors the replacements of restorations were commonly performed using resin composite as a restorative material. Most of the resin composite restorations were replaced using the same material. The fact that in the treatment of teeth previously restored with amalgam, the replacement material was often a different material, reflects the rapid change in clinical practice. The results also indicate that patients' opinions have a strong influence on the selection of restorative materials.

Dental health

According to national statistics, the dental health of children and young people has steadily improved since the 1970s. DMFT for 12-year-olds was 1.2 and for 18-year-olds 4.7. The need for restorations has also decreased in young adults treated in the PDS.

Costs of dental care

The percentage of GNP spent on dental care in Finland is about 0.5% and at the same level as in Denmark, but considerably lower than in Germany and in Sweden. The total cost of dental care was estimated to be FIM 2 800 000 000 (USD 537 000 000) in 1995 and 66% are financed by the patients. Of the total costs of the PDS, salaries comprised 77% and materials 7%.

Recently, overproduction of dentists has been connected with supplier induced demand in dentistry, e.g., in Sweden (Jönsson and Karlsson, 1994). It has also been suggested, that third party payments increase costs. For patients in Finland and in most European countries, composite fillings are more expensive than amalgam fillings.

However, inadequate information is available on the total costs of dental care as result of the marked changes in the selection of restorative materials.

Conclusion

In Finland it is generally accepted that amalgam fillings in the near future will be part of the history.

It can be concluded, that the present use of amalgam is infrequent in children and adolescents in Finland. Also in adults, amalgam seems to be increasingly replaced by other filling materials. The consequences of the present pattern of the filling material selection are unknown. Based on the present knowledge of the long-term survival of glass ionomer and composite fillings, the number of re-restorations may increase in the future. Due to the fact that subventioned dental care is mainly offered to the age groups younger than 40 years with relatively good dental health, the costs of the changing practice have drawn little attention.

References

- Ahlgqvist M, Bengtsson C, Furunes B et al (1988) Number of amalgam tooth fillings in relation to subjectively experienced symptoms in a study of Swedish women. *Community Dentistry and Oral Epidemiology*, 16:227-231.
- Bergman M (1990) Side-effects of amalgam and its alternatives: local, systemic and environmental. *International Dental Journal*, 40:4-10.
- Forss H, Seppä L (1990) Prevention of enamel demineralization adjacent to glass ionomer filling materials. *Scandinavian Journal of Dental Research*, 98:173-178.
- Forss H, Widström E (1996) Factors influencing the selection of restorative materials in dental care in Finland. *Journal of Dentistry*, 24:257-262.

- Forsten L (1993) Clinical experience with glass-ionomer for proximal fillings. *Acta Odontologica Scandinavica*, **51**:195-200.
- Forsten L, Karjalainen S (1990) Glass-ionomers in proximal cavities of primary molars. *Scandinavia Journal of Dental Research*, **98**:70-73.
- Hanson M (1983) Amalgam - hazards in your teeth. *Orthomolecular Psychiatry*, **12**:194-201.
- Jönsson B, Karlsson G (1994) *Tandvården I en ekonomisk analys*. Stockholm: SNS Förlag.
- Kousa M, Fräki J (1990) Metalliallergia hammashoidossa. *Suomen Hammaslääkärilehti*, **37**:758-764.
- Lavstedt S, Sundberg H (1989) Medicinska diagnoser och sjukdomssymtom relaterade till amalgamfyllningar. *Tandläkartidningen*, **81**:81-88.
- Mjör I (1987) Utgör dentale materialer et toksigologiskt problem? *Tandlaegebladet*, **91**:4 57-465.
- Pleva J (1983) Mercury poisoning from dental amalgam. *Orthomolecular Psychiatry*, **12**: 184-193.
- Störtebecker P (1986) *Kvicksilverförgiftning från tandamalgam - en fruktansvärd risk för människans hjärna*. Täby: Störtebecker Foundation for Research, 1986.
- Taskinen H, Kinnunen E, Riihimäki V (1989) A possible case of mercury-related toxicity resulting from the grinding of old amalgam restorations. *Scandinavian Journal of Work and Environmental Health*, **15**: 302-304.
- Widström E, Birn H, Haugejorden O, Sundberg H (1992) Fear of amalgam: dentists' experiences in the Nordic countries. *International Dental Journal*, **42**: 65-70.
- Widström E, Forss H (1991) Safety of dental restorative materials: a survey of dentists' attitudes. *Proceedings of the Finnish Dental Society*, **87**: 351-357.
- Widström E, Forss H (1994) Selection of restorative materials in dental treatment of children and adults in public and private dental care in Finland. *Swedish Dental Journal*, **18**: 1-7.
- Widström E, Haugejorden O, Sundberg H, Birn H (1993) Nordic dentists opinions on the safety of amalgam and other dental restorative materials. *Scandinavian Journal of Dental Research*, **101**: 238-242.
- Widström E, Pöyry M, Masalin K, Suominen-Taipale L (1995) Yksityissektorilla säästetään protetiikasta. *Suomen Hammaslääkärilehti*, **2**: 902-906.

Dental Amalgam: Utilization Trends, Alternative Therapies and National Policy

E.D. Jacobson and R.C. Eccleston

Dental Amalgam: Utilization Trends, Alternative Therapies and National Policy	207
Introduction	207
Amalgam utilization trends	208
Amalgam versus alternative direct metallic materials	209
Consumer and health professional attitudes toward amalgam	209
Amalgam-related research	210
Summary	210
References	211
 Annex A Update Statement by the US Public Health Service on the Safety of Dental Amalgam	 213
Annex B Selected Characteristics of Posterior Restorative Materials	215

Dental Amalgam: Utilization Trends, Alternative Therapies and National Policy

Introduction

The United States Public Health Service (USPHS) issued a comprehensive report on the risk management of dental amalgam in 1993 (USPHS 1993). The conclusion of the report was that "... it is inappropriate at this time to recommend any restrictions on the use of dental amalgam..." In 1995, the USPHS revisited the issue and reaffirmed its earlier position, stating that "... there exist no scientifically compelling reasons either to discontinue or curtail the clinical use of dental amalgam or to recommend removal of existing amalgam fillings absent clear evidence of allergy or intolerance in individual patients." (USPHS, 1995; see also Appendix A).

Since then, others have intensively examined the issue of amalgam safety. Just last year, for example, the government of Canada released its findings and policy recommendations (Health Canada, 1996). Over this next year, it is expected that the results of similar assessments by the European Union, the Canadian province of Quebec and New Zealand will be unveiled. The USPHS also intends to prepare an overview of the knowledge that has been gained in the four years since its 1993 report. As part of the overview, the USPHS will re-review the implications, if any, of new scientific information for the policy relating to the use of dental amalgam that is currently in effect in the United States.

In addition to risk-benefit assessments of dental amalgam performed by individual nations, information about the relative safety and clinical benefits of dental amalgam use has been openly shared at a major international forum. This occurred in Berlin, Germany in December 1994, where senior government health officials from nine European nations, Canada and the United States exchanged information about their national policies regarding dental amalgam and the scientific

socioeconomic, political, cultural, environmental and other considerations that provided the underpinning for the dental practice policies pertaining to amalgam and non-amalgam restorative materials.

Initiated by the United States Public Health Service (USPHS), this meeting was enlightening in at least two respects. First, there was remarkable consensus on the current body of scientific evidence and the conclusion that no clear-cut human health hazard can be attributed to dental amalgam. Therefore, while other factors may influence national decision-making as it relates to the recommended use of amalgam in dental restorative procedures, current-day science does not support the proposition advanced by some individuals that amalgam should be banned or supplanted by the use of alternative biomaterials. It should also underscored that the toxicological properties and possible effects on human health for non-amalgam materials are less well established than for dental amalgam.

Second, present concerns about the potential for low-incidence effects among certain sub-populations cannot be totally discounted. Given that amalgam is, by most accounts, still widely used, vigorous pursuit of scientific answers is imperative.

The meeting in Berlin proved so worthwhile, the attendees unanimously voted to reconvene at a later time in order to maintain the important international dialogue that had begun in order to periodically assess the state of science and facilitate a cross-fertilization of opinions and ideas regarding how best to communicate risks and benefits of amalgam and its replacements to our respective publics. Thus, a second international meeting, with even broader national representation, is planned for later in 1997 or early 1998 in Stockholm, Sweden.

Taken as a whole, these national and international assessments and scientific exchange activities are providing a highly useful understanding of what the current body of scientific evidence says about the level of risk at mercury exposure levels normally attributable to amalgam restorations. Through these efforts, health professionals and consumers should be better able to put these risks into perspective when contrasted to the benefits of amalgam, and to understand the advantages and draw-backs of alternative restorative materials now on the market.

This paper will touch on four issues relevant to the perspective of the USPHS on dental amalgam. The first is the trend in amalgam utilization in the United States. The second is a comparison of amalgam with other commercially available metallic dental restorative products. The third is the prevailing attitudes among US consumers and health professionals regarding the amalgam controversy. And fourth relates to research, both ongoing and in the future.

Amalgam utilization trends

At the time the USPHS report was prepared, available data showed that in 1990, 200 million dental restorative procedures were performed in the United States. Of these, dental amalgam procedures accounted for roughly 96 million, a 38 percent decrease in the number of such procedures performed in 1979. This reduction was due to a declining incidence of caries, particularly in children, and anecdotal evidence suggests that this downward trend is continuing. The overall decline is the result of a combination of factors, including the widespread use of water fluoridation systems; the availability of fluoride-containing toothpastes, rinses and gels; wider use of dental sealants; and greater public awareness of the need for and access to dental care.

Besides the reduction in caries, anecdotal reports also point to a reduction in the size of the average lesion and a decline in rampant caries. These

advances in oral health care, including more conservative cavity preparations and adhesive preparations, are also reducing both the need for and amount of dental amalgam. While no national demographic data are presently available from 1990 onward, there are clear indications that amalgam use continues to diminish.

For example, a recently completed study by researchers at the University of Michigan, which tracked changes in dental health and treatments among 750 000 residents of the state of Michigan with dental insurance over a 15-year period (1980-1995), shows substantial improvements in oral health and a corresponding reduction in restorative care (Ecklund et al., 1997). In addition, pediatric dentists are relying more on composites than amalgam to treat their patients (Braveman, 1997).

Despite these trends, dental amalgam, because of its cost-effectiveness, will remain an option for millions of Americans for the foreseeable future. Also, because people are retaining functional dentitions far longer over their lifespans, a need remains for a broad array of restorative materials.

If future scientific studies were to compellingly show a health hazard -- and this would most likely relate to one or more discrete groups of patients -- the US Food and Drug Administration would take appropriate action to safeguard those at risk. Quality science is the key. Actions taken against a product by the FDA must be judicious and science-based, because the ramifications can be serious for both manufacturers and consumers.

Because some percentage of dental procedures in the United States will continue to involve the use of dental amalgam for the foreseeable future, the USPHS has made a firm commitment to remain vigilant with respect to the science. At the same time, the development of alternative materials is being aggressively pursued, including the development of biomaterials that are reasonably competitive from the standpoint of cost and clinical utility, as a means to further reduce the reliance on dental amalgam.

Of highest priority, of course, is the conservation of healthy teeth through the use of available preventive therapies, thereby limiting the use of any restorative material: "The best restoration is the one that is never needed." When teeth can be kept sound, there are no concerns over longevity, toxicity or the aesthetics of restorative materials.

Amalgam versus alternative direct metallic materials

The table appended to this paper (Appendix B), which was excerpted from the 1993 USPHS report on dental amalgam, highlights the advantages and disadvantages of six different types of restorative materials and the trade-offs of each one. It is realized that this table is somewhat incomplete and to some extent outdated, but it provides a useful overview of the pros and cons of some of the most commonly used dental restorations.

In addition, a gallium-based product known by the commercial name "Galloy" was given US marketing clearance in 1996. Based on clinical testing, this product appears to have physical properties and biocompatibility characteristics equivalent to amalgam. It is also relatively non-toxic, has less marginal leakage than amalgam and is comparatively priced.

However, the major drawback of this product is its proclivity to expand in a moist environment, meaning that the use of rubber dams and longer setting times are necessary to prevent material expansion and cracking of remaining tooth structure. It is also prone to tarnishing and thus requires periodic polishing.

Consumer and health professional attitudes toward amalgam

A relatively recent barometer of attitudes about amalgam was the results of focus group testing among consumers and health care practitioners

conducted in 1995 by the US Centers for Disease Control and Prevention (CDC) (Macro International, 1995). Five focus groups were held with consumers, three for dental practitioners and one for non-dental medical professionals for the purpose of determining if a national educational initiative concerning amalgam was necessary or desirable. The findings were as follows:

- In general, consumer awareness of potential amalgam risks is low. Of the consumers surveyed, most were unaware of any health risk related to mercury in amalgam and they were not greatly concerned upon learning about the issue. They identified dental health professionals as their preferred source for dental health information. Many of the consumers polled felt that a large-scale educational campaign on the potential risks of amalgam would be unduly alarming to the general public. Their preferred method of delivery was through educational brochures distributed in dental offices.
- Dentists, dental hygienists and non-dental medical professionals said they have encountered very little inquiry about the potential risks of dental amalgam. The majority of questions and information requests, they reported, have occurred within a short period after a media story appears on the topic. Health professionals recommended the disclosure of information to avoid future media sensationalism and to give the public the opportunity to better understand the issues.

The professionals further agreed that there is a need for further research prior to the development of an educational program. In their view, current research study results are not regarded as conclusive and therefore are seen as lacking in credibility.

Thus, the CDC study tends to validate other experiences in terms of the impact of media stories. For a short time after a story appears, there is a flurry of consumer inquiries and, occasionally, a

few spin-off reports in other media outlets. After this, interest subsides.

What this may suggest is that the vast majority of consumers are not overly concerned by such periodic news stories. This may be true because even the most radical stories do not establish a causal link between amalgam and adverse health effects among patients with amalgam restorations.

Every day, consumers are bombarded with reports of health risks, like cancer, from an endless list of sources. Unless definite conclusions are drawn, most consumers tend to "tune out" reports based on speculation, theoretical extrapolations and anecdotal experience.

There are, however, a few individuals and organizations with a strong interest in pursuing government controls. A case in point is in the state of California, where in 1993 an environmental advocacy group notified amalgam manufacturers of their obligation under a state law (known as Proposition 65) to post health warnings in dental offices. Such warnings would alert consumers to the use of dental amalgam and the potential for birth defects and reproductive harm resulting from its use. The dental device manufacturing industry challenged the action and a court overturned the original order. The back-and-forth saga continued when a Federal appeals court last August reinstated the original ruling. And just this past January, the US Supreme Court refused to hear the industry's appeal.

Amalgam-related research

In deference to the report from the US National Institute of Dental Research (NIDR), which is presented elsewhere in this volume and provides a very complete description of the research in the United States, only a few general points need to be made here.

In order to resolve the amalgam issue, more definitive study data are needed, especially data

from well-controlled clinical trials. Given the probability that, at most, the mercury from dental amalgam may induce subtle, low-incidence phenomena, current uncertainties simply will not be overcome by extrapolating from cellular and animal studies.

For example, since the 1993 US report on amalgam, USPHS agencies have sponsored two scientific conferences to look at ongoing cellular, mechanistic, developmental, neurological, immunological and other relevant endpoint studies. At one conference, it was reported that highly distinctive changes have been observed in urinary porphyrin excretion patterns (Woods, 1996). This observation was based on mercury-induced alterations in renal hemebiosynthesis following exposure of experimental animals to methyl mercury in drinking water and exposure at occupational levels of humans to elemental mercury vapour. Although thought-provoking, it is not known whether these indicators will serve as sensitive and specific biomarkers of subclinical mercury exposure effects in humans.

Researchers also reported that studies involving laboratory animals have shown motor and cognitive deficits following exposure to mercury (Newland, 1996). While these results have been validated, the same researchers conceded that current test batteries for intellectual function, memory, coordination and hand tremor are not sufficiently sensitive to determine a true lowest observed adverse effect level (LOAEL) in a human population.

Summary

The presence of mercury in dental amalgam does not appear to present a public health problem; nevertheless, it is a source of concern for many people from both a public health as well as an environmental perspective. How soon this emotionally-charged issue can be resolved is uncertain. Therefore, it is crucial to continue to monitor the safety and effectiveness of all dental restorative materials.

References

- Braveman NS (1997) Personal communication.
- Eklund SA, Pittman JL, Smith RC (1997) Trends in dental care among insured Americans: 1980-1995. *Journal of the American Dental Association*, 128;171-178.
- Health Canada (1996) *The safety of dental amalgam*. (Copies can be obtained from Health and Welfare Canada, Medical Devices Bureau, Tunney's Pasture, Ottawa, Ontario K1J 0L2, Canada).
- Macro International (1995) Focus group report: assessing risk communication needs related to dental restorative materials.
- Newland MC (1996) Behavioral endpoints to identify neurotoxic effects of mercury vapour in animals. Presentation to Mercury Vapor Toxicology Update Workshop sponsored by DHHS Environmental Health Policy Committee, Subcommittee on Dental Amalgam, Bethesda, Maryland, June 28, 1996.
- United States Public Health Service (1993) *Dental Amalgam: A Scientific Review and Recommended Public Health Service Strategy for Research, Education and Regulation*. (Copies can be obtained from the Center for Devices and Radiological Health, US Food and Drug Administration, 9200 Corporate Blvd.(HFZ-1), Rockville, MD 20850, USA).
- United States Public Health Service (1995) *Update Statement by the United States Public Health Service on the Safety of Dental Amalgam*. (Copies can be obtained from the Center for Devices and Radiological Health, US Food and Drug Administration, 9200 Corporate Blvd. (HFZ-1), Rockville, MD 20850, USA).
- Woods JS (1996) Altered renal porphyrin metabolism as a specific biomarker of mercury exposure and effects. Presentation to Mercury Vapor Toxicology Update Workshop sponsored by DHHS Environmental Health Policy Committee, Subcommittee on Dental Amalgam, Bethesda, Maryland, June 28, 1996.

Update statement by the U.S. Public Health Service on the Safety of Dental Amalgam

The U.S. Public Health Service (PHS) continues to maintain a strong interest in the promotion of effective health strategies to foster the oral health of Americans and to ensure high quality dental care services. The PHS continues to believe that the primary oral health goal is to preserve healthy, functional and natural tooth structure for as long as possible. Every effort should be made to prevent initial carious lesions through personal, professional and community-based hygiene measures.

In January 1993, the PHS released a comprehensive report on the risks and benefits of dental amalgam, which recommended that the use of amalgam in dental practice should continue given the absence of scientific proof of a human health hazard for patients with amalgam restorations. In addition, the report outlined a risk management program designed to enhance risk quantification, risk communication and regulatory oversight of amalgam. The multi-agency program is being coordinated by an interagency Subcommittee on Dental Amalgam, formed in 1994 by the Assistant Secretary for Health under the aegis of a PHS Environmental Health Policy Committee (EHPC).

This ongoing program consists of a broad range of basic and applied research studies directed at amalgam safety, development of alternative restorative materials and improved dental practices relating to caries treatment and amalgam use. A risk-benefit educational program for dental professionals and patients and ingredient labelling requirements for various dental products – including amalgam – are now under development. An

international scientific exchange forum on amalgam safety is also under consideration.

To ensure that the PHS remains broadly versed on the dental amalgam issue, members of the Subcommittee met in Berlin, Germany on December 15, 1994 with senior government health officials from nine European nations and Canada. The meeting focused on the policies of individual countries regarding amalgam use, as well as their scientific basis and legal standing.

Participants at the meeting generally agreed that the scientific literature has not revealed evidence of adverse health effects from exposure to dental amalgam for the vast majority of people. Nevertheless, policy differences do exist.

Countries implementing or contemplating restrictions on amalgam use are doing so based on environmental concerns or as a preventive action against theoretically possible adverse health effects. Efforts are underway to continue the dialogue begun in Berlin.

Based upon information obtained from international policy-makers and scientists, in addition to the continued absence of evidence of a human health hazard for patients associated with dental amalgam, the EHPC on January 30, 1995 unanimously agreed to reaffirm the January 1993 PHS policy regarding amalgam restorations.

The PHS recognizes that the use of dental filling materials will remain an integral part of dental treatment for the foreseeable future. Therefore, the

PHS reiterates its earlier conclusion that there exist no scientifically compelling reasons either to discontinue or to curtail the clinical use of dental amalgam or to recommend removal of existing amalgam fillings absent clear evidence of allergy or intolerance in individual patients.

Through the Subcommittee on Dental Amalgam, the Public Health Service will continue to monitor closely all relevant research and amalgam policy

activities to ensure the currency and appropriateness of its policy on this issue. In addition, the PHS will continue to encourage the development and expanded use of effective caries preventive agents and techniques as well as the development of non-mercury containing dental filling materials as alternatives to amalgam.

1 September 1995

Selected Characteristics of Posterior Restorative Materials (from USPHS, 1993)

Critical Parameters in Evaluating Posterior Restorative Materials	AMALGAM	COMPOSITE	GLASS IONOMER	GOLD FOIL	GOLD ALLOY (CAST)	METAL-CERAMIC CROWNS
Median Longevity Estimate ¹	8-12 years	6 to 8 years	No data: ¹ 5 years predicted	No data: 10 to 15 years estimated	12-18 years	12-18 years
Relative Surface Wear	Wears slightly faster than enamel	Excessive wear in stress-bearing situations	Excessive wear in stress-bearing situations	Excessive wear in stress-bearing situations	Wears similar to enamel	Porcelain surface may wear opposing tooth
Resistance to Fracture	Fair to excellent	Poor to excellent	Poor	Fair to good	Excellent	Excellent
Marginal Integrity (leakage)	Fair to excellent Self-sealing through corrosion products	Poor to excellent Polymerization shrinkage can cause poor margins	Poor to excellent	Poor to excellent	Fair to good Depends upon fit and type of luting agent used	Poor to excellent Depends on fit and type of luting agent used
Conservation of Tooth Structure	Good	Excellent	Excellent - if initial restoration, not if replacement	Good	Poor	Poor
Esthetics	Poor	Excellent	Good	Poor	Poor	Excellent
Indications:						
Age range	All ages	All ages	All ages	Adult	Adult	Adult
Occlusal stress	Moderate stress	Low-stress-bearing	Adult - Class V and low-stress primary teeth	Class III and V and crown repair	High-stress areas	High-stress areas
Extent of caries	Incipient to moderate-size cavity	Incipient to moderate-size cavity	Class I and II child incipient to moderate-size cavity	Incipient to moderate-size cavity	Severe tooth destruction	Severe tooth destruction or esthetic considerations
Cost to Patient ²	1X	1.5X	1.4X	4X	8X + gold	8X

¹ Longevity estimates reflect medians from published studies, however, under different clinical situations many restorations will last longer. For materials which have emerged in the last decade and gold foil, estimates are speculative.

² Relative cost to patient, in relation to amalgam (1X). There may also be considerable geographic variation.

Policy of the United Kingdom on the Use of Dental Amalgam

I.R. Cooper

Policy of the United Kingdom on the Use of Dental Amalgam	219
Trends in the use of dental amalgam	219
Alternatives to dental amalgam	221
Side-effects of dental amalgam	221
Occupational risk to oral health personnel	221
Environmental concerns	221
Public opinion and the mass media	221
References	222

Policy of the United Kingdom on the Use of Dental Amalgam

The view of the United Kingdom's (UK) Government on concerns expressed recently relating to the safe use of the direct dental filling material, dental amalgam, is currently very straightforward. It reflects the advice which a specialist committee on toxicity of chemicals in food, consumer products and the environment, run under the auspices of the UK Government, gave in 1986 and which subsequently has been set out in replies to the UK Parliament in 1993 and 1994. The advice given to Parliament in 1986 (Hansard, 1986) was:

"Dental amalgams containing mercury have been used for 150 years and we understand that in the United Kingdom some 30 million amalgam restorations are inserted each year. Despite this extensive usage only a very few cases can be recognised as having any reaction to mercury occur each year, and these are due to hyper-sensitivity. Nevertheless, from time to time concern is expressed in some quarters that use of dental amalgam may lead to excessive exposure to mercury and to poisoning.

We have examined the evidence from which such concerns arises. There is some evidence that mercury is released from dental amalgam during the period following insertion and on the removal of the restorations. Some mercury may be released as a result of corrosion but this is likely to be small because of the un-reacted alloy in the finished filling. The development of copper enriched alloys has reduced the potential for corrosion. Vaporisation of mercury from amalgam restorations may possibly occur with prolonged heavy chewing. However long term clinical evidence would seem to suggest the view that substantial amounts of mercury are not released from amalgam fillings.

Theoretical considerations suggest that in extreme cases the amount of mercury released might, were it known to be absorbed, constitute an undesirable although not toxic exposure. However, studies of the concentration of mercury in the blood of people with amalgam restorations indicate to us

that the exposure is in fact of no toxicological significance. It has been suggested also that exposure to mercury from amalgam may be a factor in the development of some chronic diseases, but in our opinion the evidence does not support this contention.

In our opinion the use of dental amalgam is free from the risk of systemic toxicity and only a very few cases of hypersensitivity occur. It is our view that further research in this area would not merit priority."

The Department of Health reviewed the position in 1992 in relation to proposals of the Paris Commission to reduce mercury emissions in the environment. At that time it was considered there was no new evidence to modify the position set out earlier. Department officials continue to monitor and evaluate the results of more recent research from around the World and are deeply involved in the work of an European Economic Area Ad hoc working group, brought together by the European Commission and working to a mandate which very broadly addresses the use of dental amalgam as a medical device under the Medical Devices Directive 93/42/EEC within the EEA Member States. Aspects of the safe use of dental amalgam in humans have been looked at by this Ad hoc working group.

When comparing the UK position with that of the 1995 WHO/FDI consensus statement, the similarities between them are striking and it is difficult to disagree with many of the points the consensus statement makes.

Taking points from the consensus statement mostly in turn, the following addresses the request by the WHO for UK data .

Trends in the use of dental amalgam

Dental amalgam is the most frequently used material for permanently restoring decayed teeth

in the UK. Whilst it is difficult to obtain complete trend data, since this is not collected for some parts of the public and private sectors, there are figures for the five years up to 1995/96 of the dental amalgam restorations in those over 18 years of age, claimed for within the General Dental Services of the National Health Service within England and Wales. This is likely to be the greatest part of the provision of amalgam fillings in these countries.

The overall number of fillings is less than the 30 million quoted above for the UK in the 1986 reply to Parliament and represents a drop in the use of dental amalgam since that time. The trend from 1991/92 to 1995/96 also indicates a fall in each year with respect to claims for amalgam fillings whilst those for non-amalgam fillings (these are direct filling materials of composite resin or glass ionomer) have remained relatively constant during that time.

Table 1 Direct filling restorations claimed for within the General Dental Service of the National Health Service for England and Wales*

	1991/92	1992/3	1993/94	1994/95	1995/96
Amalgams	12 395 314	12 064 600	11 268 052	10 491 657	9 774 763
Non-Amalgams	6 286 872	6 490 611	6 375 329	6 401 479	6 412 285

*Source: Statistics Division of the Department of Health.

All of the above must be viewed against a general backdrop in the UK of a decline in dental caries as shown by national epidemiological surveys carried out since 1968 at ten yearly intervals. For example the proportion of a nationally representative sample of dentate adults with no current decay or unsound teeth in 1968 was 36% (Gray et al., 1970), in 1978 was 41% (Todd et al., 1982) and in 1988, 57%. The mean number of decayed or unsound teeth in adults dropped from 1.9 to 1.1 from 1978 to 1988 (Todd et al.,1991). A further national survey is planned for 1998.

Therefore the amount of dental amalgam being used is likely to continue to fall. This is not only for the reasons stated immediately above but also because in the UK, treatment philosophies have changed in recent years. The complete removal of an amalgam restoration considered to be inadequate is less common, that is the repair of existing restorations to deal with the defective part only is viewed as appropriate treatment. This together with the perception that cavities tend to be smaller than say 25 years ago, partly due to the

abandonment of GV Black's 'extension for prevention' principle and that fewer restorations are being placed, which in turn is due to a more widespread adoption of a policy 'to wait and see' to allow preventive dental decay measures to work, all point to smaller quantities of amalgam being used to fill teeth than previously. The actual amount of mercury used to produce dental amalgam fillings is open to some debate, since precise figures are difficult to gather. One published estimate (Environmental Resources Management, 1996) based on a total of 19 million treatments in the UK is that 19 tonnes, of which 10.5 tonnes are recycled, is used each year. One unpublished estimate for the UK in 1993, based on a total amount of 16 million amalgam fillings placed, is that this represents an annual input equivalent to 9600 kg (9.6 tonnes) of mercury.

On epidemiological grounds there appears to be no reason for the use of dental amalgam not to continue to fall over time, nevertheless it is likely that dental amalgam will remain widely used

unless an alternative is found which will replace it in all respects.

Alternatives to dental amalgam

Turning to point 2 of the WHO/FDI consensus statement, regarding the alternatives to dental amalgam. It is agreed that there is no direct filling material that can fully replace dental amalgam, particularly when considering the mechanical properties required of those fillings placed occlusally in posterior teeth and the ease with which dental amalgam can be placed relatively consistently, under a variety of oral conditions and particularly given the differences in skills of providers.

There are few UK data of the comparative cost-effectiveness of dental amalgam and its replacement. In March 1997 fees for adults within the UK National Health Service for amalgams and non-amalgams are very broadly comparable. Amalgam fees range from £5.70p to £14.70 depending on the number of surfaces, those for composite resin range from £10.65 to £22.65 and for glass ionomer are £9.75. It may be argued that the restoration of teeth using alternative materials to dental amalgam is more time consuming and more technique-sensitive. This may be a factor in the earlier failure than necessary of such restorations. Overall dental amalgam is viewed as being cost-effective and probably more so than replacement by current alternative materials to it.

Side-effects of dental amalgam

The UK view on the side effects of dental amalgam, outlined at the start of this paper, is in line with that made at point 3 of the WHO/FDI consensus statement. They consist of cases of local allergic reactions and are relatively rare. The risk of adverse side effects is therefore low. UK Government policy does not embrace at all a philosophy that general symptoms may be relieved by the replacement of amalgam restorations.

Occupational risk to oral health personnel

Point 4 of the WHO/FDI statement deals with occupational risk to oral health personnel. The UK Health Departments and the British Dental Association, in particular, have produced detailed guidance on the handling of mercury which recognises many of the points in this section (Guidance note EH17,1977; Guidance note MS12,1978; Guidance for the Initial Assessment in Hospitals, 1989; British Dental Association, 1993). In the UK, occupational exposure standards have been set for mercury (Hg) and its compounds, except mercury alkyls, at 0.05mg m^{-3} as a time weighted average exposure over an 8 hour period and 0.15 mg m^{-3} for a ten minute period (EH40/93, 1993). Principally, provided the appropriate guidance is followed regarding the handling of mercury, it is considered that dental personnel are not at particular risk of toxicity from this metal. It may though be necessary for the WHO to address precisely what is meant by phrases in the 1995 consensus statement regarding "approved precapsulated amalgam alloys", "proper mercury hygiene" and "open mixing".

Environmental concerns

The WHO/FDI statement at point 5 deals with environmental concerns and the UK government would find little to disagree with in the statement. In particular there seems to be scant information on the extent to which mercury, derived from dental amalgam, contributes to the contamination of the environment. This seems to be a particularly grey area with very little research activity.

Public opinion and the mass media

Turning to point 6 of the WHO/FDI consensus statement on public opinion and the mass media.

Again we would not differ greatly with most of the statement. In the UK public concerns regarding the safety of dental amalgam, however, are not generally very widespread. Such concerns do tend to increase, for a short while, immediately following mass media coverage. As an example, a BBC television programme first broadcast in the summer of 1994 in the Panorama programme series and entitled 'Poison in the Mouth' dealt solely with the issue of safety of dental amalgam. The Department of Health received about 120 letters from the public and dentists in the four month period following this programme.

Whilst there is little evidence that the dental profession in the UK is engaged in the extensive removal of dental amalgam fillings and their replacement with alternative materials, there is anecdotal evidence that complaints of such a practice, to one defence organisation in the UK, comprises its most frequent complaint. As stated earlier for a variety of reasons the use of direct filling materials used as an alternative to dental amalgam may increase the cost of such care.

References

- Hansard, 1986 House of Commons Official Report: Parliamentary debates, written answers, 23 July 1986, cols 309-310.
- Gray PG, Todd JE, Slack GL and Bulman JS (1970). *Adult Dental Health in England and Wales in 1968*. London HMSO. ISBN 11 700043 4.
- Todd JE, Walker AM, Dodd P (1982) *Adult Dental Health (1978)*. United Kingdom Volume 2. London, HMSO ISBN 0 11 690789 4.
- Todd JE, Lader D (1991). *Adult Dental Health 1988 United Kingdom*. London HMSO ISBN 0-11-691324-X.
- Environmental Resources Management (1996). *Mercury in the UK. Final report for the Department of the Environment*, London.
- Guidance note EH 17 (1977) *Mercury-health and safety precautions*. Health and Safety Executive. London, HMSO. ISBN 011 883176 3.
- Guidance note MS 12 (1978) *Mercury-medical surveillance*. Health and Safety Executive. London, HMSO. ISBN 0 11 883174 7.
- Guidance for the initial assessment in hospitals (1989). *The Control of Substances Hazardous to Health*. Department of Health, London, HMSO. 38-41. ISBN 0 11 321262 3.
- The British Dental Association (1993). *Health and safety law for dental practice. Advice Sheet A3: 24-26*.
- EH40/93 (1993) *Occupational exposure limits 1993*. Health and Safety Executive. London, HMSO. ISBN 0-11-882080-X.

Dental Amalgam Profile - New Zealand

T.W.Cutress

Dental amalgam profile - New Zealand	225
General	225
Perceptions and attitudes to dental amalgam	225
Definition of dental restorations	225
Trends in dental health and care	225
Amalgam usage	225

Dental amalgam profile - New Zealand

General

Until the success of preventive programmes became evident 20 years ago dental caries was endemic in children and adults in New Zealand. Dental amalgam was the principal means of restoring treated teeth. Access of all children to a freely available, comprehensive School Dental Service ensured that most treatment needs in children were met with, consequently, a high prevalence of amalgam fillings from an early age and a need for regular replacement of the amalgams were required throughout adult life.

One legacy of the past caries problem is a high amalgam loading in the adult population (3.7 million) of between 20-40 million individual amalgam restorations. Problems, if any, related to mercury toxicity appear to be confined to a small number of the population. No mercury related health problems have been confirmed in dental care providers although some data are available on higher body mercury burdens of dental personnel compared with non occupational subjects.

Perceptions and attitudes to dental amalgam

The overall prevailing opinion of those involved in dentistry is that amalgam is safe, cost-effective and the most suitable material for load bearing posterior restorations. A small minority of health professionals diagnose and treat some neurological syndromes as chronic mercurialism and hold the opinion that dental amalgam is a hazard to health.

Definition of dental restorations

The Ministry of Health, New Zealand recognises dental restorations as *medical devices* which implies that none of the components of the device are hazardous to human health and are acceptable health remedies.

Trends in dental health and care

The prevalence of caries-free 5 year old children was 14% in 1950 and 55% in 1995; for 12 year old children the levels were 2% in 1977 and 48% in 1994. The national mean number of DMFT teeth for 12 year olds in 1977 and 1994 were 7.0 and 1.4 respectively.

Amalgam usage

The majority of dental practitioners continue to use dental amalgam on a regular basis. Approximately 10-15% of practitioners have declared their practices as mercury-free environments. Dental amalgam remains the principal dental restorative material prescribed for posterior teeth by the School Dental Service. There are signs that both the magnitude of use and dependency on dental amalgam as the material of choice for posterior restorations has slowly changed and that the rate of change is expected to increase over the over the next 5 years. The major factors at play are: increased availability of improved non dental amalgam materials; increased patient awareness of, and requests for, non amalgam restorations; increasing population concerns on environmental and health hazards.

Overall, information from the Dental Supply Companies indicate a 5-7% annual decrease in demand for amalgam products.

Health and Disabilities Commission (NZ Government 1995): recent legislation in New Zealand requires that all health professionals inform patients of relevant health care needs - and options for treatment. This includes the respective advantages and disadvantages of treatment and materials.

Update of Amalgam Use in Japan

M. Nakata

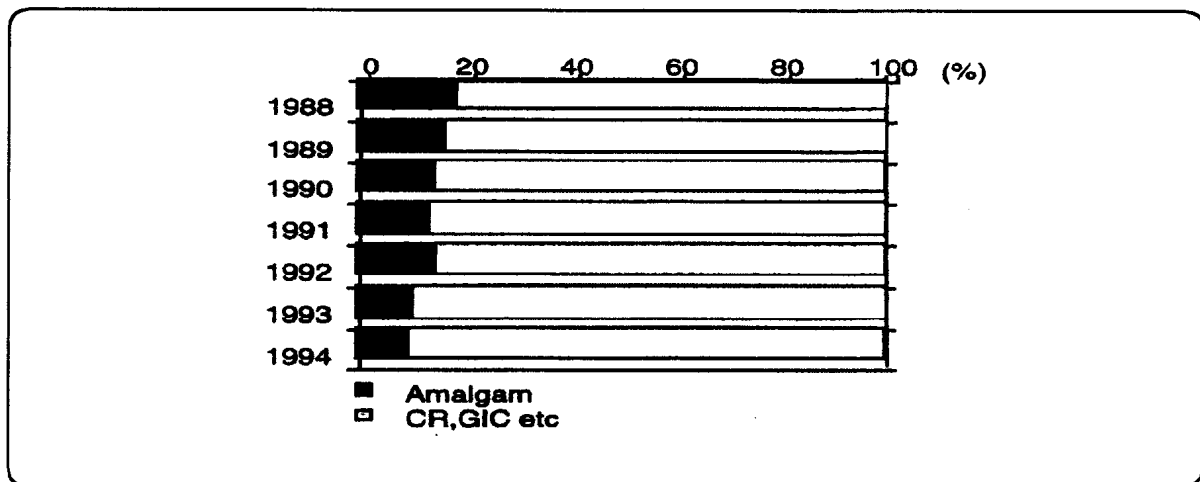
Update of Amalgam Use in Japan	229
The use of restorative materials	229
Amalgam separators	230
References	231

Update of Amalgam Use in Japan

The use of restorative materials

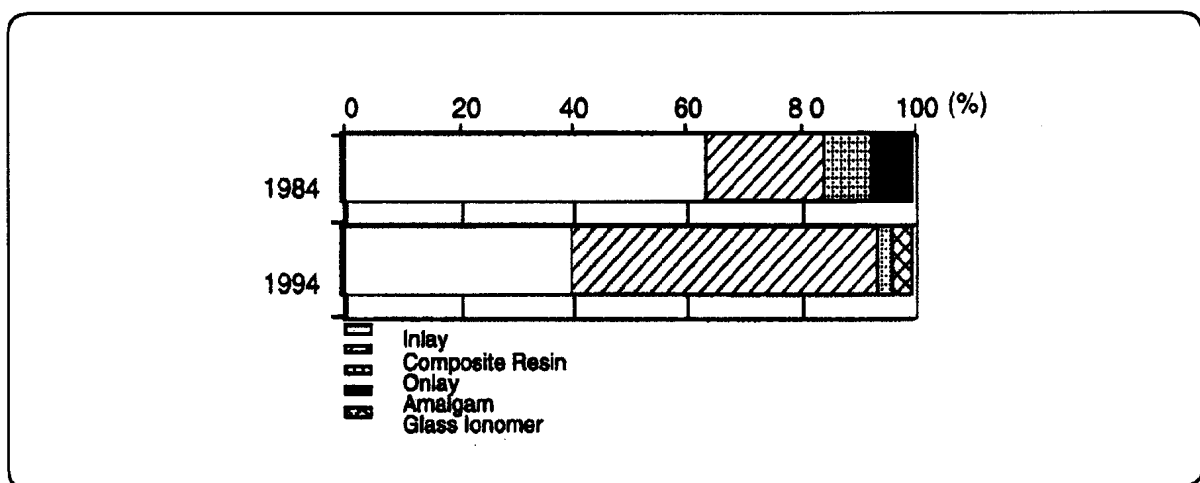
There is no ban or restrictions on amalgam in Japan, but the use of amalgam has decreased in recent years as shown in Figs. 1 and 2.

Figure 1 The share of Amalgam among dental filling materials used in Japan*



* The Ministry of Health and Welfare: Data from the National Insurance System, 1995.

Figure 2 Restoration materials for permanent posterior teeth*



* Y. Hosoya et al: Statistics at the pediatric dental clinic at the Nagasaki University Dental Hospital, Japan, 1996.

It is generally accepted that mercury is hazardous to health. In the past, Japan suffered two bad cases of mercury pollution, in Kumamoto and Niigata, and Minamata disease is well known for the name of its site. The Minamata incident, in which several

persons died after eating fish contaminated with organic mercury, provoked quite a bit of concern about the environment. Subsequent findings revealed that the Minamata problem resulted from local industries dumping not metal mercury, but organic

mercury in the water system. While this incident has little to do with current dental practices, dentists in Japan seem sensitive about the issue. A very low level of mercury is detected in the oral environment as a result of corrosion from amalgam and also in the sewage from dental clinics. The form of this mercury is inorganic. Existing evidence does not point to a serious health risk from mercury as long as the only source is dental amalgam.

As amalgam constitutes a major dental material, it remains an important matter to investigate potential health risks associated with its use. We can not disregard the fact that a small percentage of individuals may show the allergic reactions to dental amalgam (Fujii, 1996), and that inorganic mercury may change its chemical property to organic mercury by interaction with bacteria and chemical materials in water.

As almost all dental facilities in Japan are private, the disadvantages in using amalgam have given an impetus to changing the restorative material from amalgam to resin based materials, which still has a problem with respect to durability but matches cosmetic needs. Another reason is the current national health insurance system which allows the use of metal inlays and composite resin materials. In Japan regular dental treatment is covered by national health insurance, and new materials such as composite resin or glass ionomer have been adopted. This insurance system makes dentists use new materials efficiently and in a timely manner on a very wide basis. Based on this system, dentists in Japan use metal alloys and composite resins for posterior restorations much more than amalgam. Despite the higher costs of composite resin and metal in comparison to amalgam, these alternatives reportedly are gaining popularity.

Amalgam separators

In 1980 the Japan Dental Association consulted with certain dental manufacturers to seek possible efficient amalgam separators for drains on a trial

basis. Trial productions of amalgam separators were able to recover more than 99.8% of the mercury in sewage. Total mercury concentration in sewage, after using amalgam separators manufactured in Japan, ranged from 0.0755 to 0.001 mg/l.

One company in Japan recently developed an extra-oral vacuum aspirator which can remove mercury at the rate of 99.94% with the help of a filter (Suyama *et al.*, 1995). This vacuum device is designed to trap amalgam, drill dust and other floating particles in the patient mouth before they can become airborne in dental clinics. The system uses a four-stage air cleaning mechanism to remove up to 99.97% of all floating dust. Larger resin particles in the air are trapped in the dust filter. The charcoal filter traps amalgam particles, and smaller particles are caught in the Gortex filter. Finally, when the air passes through the biofilter located just inside the air outlet, all remaining dust 0.3 micrometers or larger is removed. Clearly, these amalgam separators are highly efficient in mercury recovery. The mercury recovery rates in these separators are higher than that of other separators which are slated for introduction to the Japan market.

Although we have succeeded in manufacturing such efficient amalgam separators, the total mercury concentration in sewage after using these separators still cannot pass the severe standard of total mercury concentrations in sewage in Japan (less than 0.005 mg/L). The efficiency of amalgam separators can be improved by, for example, using finer filters but the cost performance and size of amalgam separators must be taken into consideration.

Since 1991 ISO TC106 have discussed the standard for amalgam separators installed in dental units. The appointed working group determined that the standard of mercury recovery rate should be more than 95%. Japan has voted against this standard because the requirements are low and far from the Japanese standard. Other countries have taken an opposite stand, each with its own reasons. In this situation, although no government regulation

requires amalgam separators, Japan's dental manufacturers will instal amalgam separators in dental units on request from domestic consumers, and all dental units for export are equipped with a separator. Since the use of amalgam is very limited in Japan, the need for separators is rather low.

The problems in using amalgam separators may be cited as follows:

1. The increased cost of installing the separator in the dental unit.
2. Sewage from dental units is not the only source of amalgam waste from dental clinics. Rather, we must integrate the amalgam collection systems for all amalgam waste in dental clinics.
3. Only a few dental colleges have facilities, including tanks, for storing toxic agents such as heavy metals, which are later treated at a special facility. Furthermore, dental students no longer are required to produce amalgam fillings specifically.

4. Amalgam sediments should be collected in the dental clinic until treated by authorized facilities.

References

Hosoya Y, Kashiwabara Y, Tominaga A, Nishiguchi M, Fukumoto S, Goto G (1996) Clinical study on the restoration of primary teeth. - Comparison with 1984 and 1994- *Japanese Journal of Pediatric Dentistry* **34**: 214-223. (in Japanese with English summary)

Suyama Y, Ozaki T, Takaku S, Fukuzawa Y, Mochizuki H, Ishii T, Yoshida S (1995) Eliminating effects of an air purifier on infectants during dental procedures. *Bulletin of Tokyo Dental College* **36**: 27-31.

Fujii Y (1996) A case of intractable dermatitis which may be caused by allergy of dental amalgam. *Japanese Journal of Conservative Dentistry* **39**: 1255-1258. (in Japanese with English summary)

Policy and Situation in Germany with Respect to Dental Amalgam

E. Reich

Policy and Situation in Germany with Respect to Dental Amalgam	235
Annex 1 Restorative Materials in Dentistry	237
Foreword:	237
Allergy	237
Pregnancy	237

Policy and Situation in Germany with Respect to Dental Amalgam

In the process of legal and financial changes in the German health system reforms are introduced that has considerable effects on dentistry. The dentist can now decide on the material of choice for the patient and is no longer restricted by the legal situation. But the patient has now to pay part (for fillings) or all (for inlays) of the cost for restoration. Dental supply companies estimate that the trend from amalgam towards esthetic materials that was seen in the last two years, has stopped or even partially reversed.

According to new laws the population under 19 years of age today will not get payed anything for prosthetic work. For the older part of the population the prosthetic costs are still covered by the regular insurance companies (Krankenkasse).

The caries prevalence has declined in the last years so that the DMFT for 12 year old children is now in the range of 1.6 to 3.1 with an approximate mean of 2.3. Fissure sealants are widely used in children for up to one third of the molars.

The restrictions in place for amalgam¹ are under revision at the German Federal Health Agency. The restrictions so far for amalgam are:

1. non-use in patients with known allergy to amalgam or its contents
2. non-use in pregnant women
3. non-use in children under 6 years of age

4. non-use in patients with severe kidney diseases
5. non-use in non-stressbearing areas
6. no new amalgam placed in contact with other metallig restorations.

These wide ranging restrictions will be changed presumably towards an individual treatment decision by the dentist for his patient. Restrictions are then evaluated based on the individual's clinical condition. The legal situation will be changed by the new laws of the European Community. According to the reclassification of dental materials as medical devices used in dentistry, and not as medicaments, the legal situation should be similar in the entire EU.

Since the beginning of the 1990's amalgam separators are mandatory in dental practices. Also amalgam capsules and amalgam scrap has to be treated according to special waste management.

¹ Annex 1 Restorative Materials in Dentistry is an unofficial English translation of the Consensus Statement prepared by Professor Dr G. Schmalz, President, Deutsche Gesellschaft für Zahn-, Mund-, und Kieferheilkunde. The official German text has been published in several journals, including the Zahnärztliche Mitteilungen 1997; 87: 1812-1814.

Restorative Materials in Dentistry

Consensus statement of the German Ministry of Health, the German Institute for Drugs and Medical Devices (BfArM), the Federal Dental Chamber, Kassenzahnärztliche Bundesvereinigung¹, the German Scientific Dental Association, the German Association for Operative Dentistry and the German Association of dentists practising naturopathy.

1 July 1997

Foreword:

A conference on amalgam and its alternatives was held between the German Minister of Health, Horst Seehofer, and the German Institute for Drugs and Medical Devices as well as representatives of the professional dental organizations (Federal Dental Chamber, Kassenzahnärztliche Bundesvereinigung), representatives of the scientific dental associations (German Scientific Dental Association, German Association for Operative Dentistry) and the German Association of dentists practising naturopathy. The reason for this meeting was that patients and dentists, as well as the population in general, were increasingly put into a state of uncertainty by partly contradictory statements on amalgam and other dental filling materials². Common points of view on amalgam and its alternatives were elaborated, which are presented in the present consensus statement:

1. Special health care measures for pregnant and nursing women and for allergic patients do not only apply to amalgam, but also to other dental filling materials.

¹ Federal Authority for dentists working in the social insurance system.

² These materials include plastic filling materials as well as dental casting alloys for inlays, dental crowns and bridges.

Allergy

In general, restorative materials are not to be used in those patients where an allergy against a component of the restorative material has been demonstrated.

Pregnancy

An extensive filling therapy, exceeding emergency treatment (e.g., pain, lost filling), should be avoided for pregnant women. No amalgam fillings should be placed in or removed from the mouths of pregnant women, if possible. According to present knowledge, there is no evidence that the exposure of the unborn child to mercury released from the mother's amalgam fillings causes any health damage to the child.

In general, with pregnant women only short-lasting treatments should be performed, as diagnosis and therapy are only possible in a limited way. Glass ionomers, comonomers or similar materials may be used here as alternatives to amalgam.

2. Restrictions concerning the indication of restorative materials in patients with severe renal dysfunctions is primarily directed at the mercury in amalgam.

Severe renal dysfunctions are a relative contra-indication to the use of amalgam. Sufficient publications are available, which describe the kidney as a preferred target organ for mercury intoxication.

3. The dentist is in charge of deciding which restorative material is adequate for children, considering their particular situation.

The special circumstances related to the teeth of children and to the treatment of children should be considered in the course of selecting the appropriate

restorative material. As a treatment with amalgam may lead to an exposure of the organism to mercury, it should be carefully considered for preventive health care reasons if an amalgam therapy is necessary.

The same applies when considering a potential exposure to other restorative materials.

4. According to the present knowledge, regulations in regard to a ranking of restorative materials by the German Institute for Drugs and Medical Devices are not regarded as justified. In individual cases, decisions should be based on the patient's individual situation. Alternatives to amalgam should only be recommended if sufficient knowledge concerning the safety of the alternatives for the individual is available.

The decision, which restorative material is to be used in the individual case, must be based upon the patient's individual situation; this is independent of the amalgam discussion. A general ranking of restorative materials is difficult because different criteria may be applied (e.g., clinical indication, technique of handling materials, material properties, aesthetics, costs, toxicological aspects).

The dentist is responsible for the individual "right of choice" of the material.

Alternatives to amalgam can only be recommended on the basis of a benefit-risk-analysis. The risk assessment for restorative materials on the market is checked considering new information.

Physicians and dentists should take into consideration that individual persons might react sensitively to restorative materials and they should consider the individual needs of these patients. All patients have the right to be involved in the choice of the material.

5. The responsibilities of the German Institute for Drugs and Medical Devices and of the dental organizations are clearly to be distinguished from each other and to be clarified as such. The dentist is responsible for the use of the respective restorative material.

In the process of licensing medical drugs (on the basis of the documentation supplied by the manufacturer), the German Institute for Drugs and Medical Devices is responsible for those products, which are in use until 13 June 1998 according to the relevant German drug legislation (Arzneimittelgesetz). This responsibility covers the indication, contraindication and side-effects of the substances. For products with the CE-sign, according to the Medical Device Directive, the responsibility of the German Institute for Drugs and Medical Devices is restricted to the documentation, evaluation, and the estimate of risks arising from these medical devices (after being placed on the market).

The dentist is responsible for the use of the licensed restorative material or the CE-marked medical device within the range of the given indication and purpose, respectively.

The professional dental organizations (Federal dental Chamber, Kassenzahnärztliche Bundesvereinigung) will, on the basis of scientific information; e.g., by means of recommendations, emphasize points of interest, which the dentists should specifically consider during treatment and which refer to the work as a dentist. These may be:

- pulp/dentin protection
- proper curing
- polishing
- choice of material (e.g. gamma 2-free amalgam).

The Use of Dental Amalgam in Africa

S. J. Thorpe

The Use of Dental Amalgam in Africa	241
Introduction	241
Situation in the African Region	241

The Use of Dental Amalgam in Africa

Introduction

Dental amalgam has been used in oral care for more than a century and a half. Its advantages include the fact that it is cheap and easy to use, less technique sensitive than other filling materials and durable with enough strength and wear resistance. However, the material has a number of disadvantages: it is un-aesthetic and requires the tooth to be cut and shaped with rotating instruments thus removing healthy dental tissue and the resultant cavity is larger than the lesion; it exposes the patient to very small amounts of mercury vapour and particles during placement and removal and to minute quantities of mercury vapour during chewing, although no adverse effects from this exposure have been demonstrated; oral care personnel are exposed to larger quantities of mercury over their working life, thus there is need to monitor their exposure; and some patients have an allergic reaction to metals contained in the amalgam.

Situation in the African Region

In the African Region of WHO dental amalgam is the most extensively used restorative material for repair of decayed posterior teeth mainly because of its advantages.

Neither the WHO Regional Office nor Member States in the African Region have policies in place in respect to the use of dental amalgam and no action is currently proposed that we are aware of. This is probably because the alternatives to dental amalgam, until recently, required some form of light which was often not available or not working routinely. Also the abrasion resistance of alternatives has been poor, particularly under the conditions in the Region.

Questions about the use of amalgam that do arise, do not usually come from patients but oral health care personnel and concern waste disposal.

The WHO Regional Office as well as countries in the Region will support a proposal to launch a Global Research Project on assessing the risks and benefits of using dental amalgam. In a Region where the majority of the people live without reliable electricity, there are very few trained staff, facilities are poor, climatic conditions are different and cost is a major factor, development of restorative methods and inexpensive biomaterials that can withstand local climate, storage and handling limitations will also be most appropriate.

National Policies on Amalgam Use in the Eastern Mediterranean Region

S. A. Hussein

National Policies on Amalgam Use in the Eastern Mediterranean Region (EMR)	245
Background	245
Present situation on amalgam	245
use in EMR	245
Policy on amalgam use in EMR	245
References	246

National Policies on Amalgam Use in the Eastern Mediterranean Region (EMR)

Background

Several national and international organizations have formed committees of experts to examine the question of whether dental amalgam restorations pose a health risk. After conducting indepth analyses, these organizations which include the American Dental Association, US Public Health Service, World Health Organization (WHO), and the Swedish Medical Research Council, have been unanimous in declaring that there is no clear scientific evidence that the mercury released by dental amalgam poses a health risk (CCEHRP, 1993).

Moreover, as a result of cooperation between WHO and FDI and as a response to the worldwide concerns expressed in recent times about dental amalgam, the two organizations have issued a consensus statement on dental amalgam. The statement supports the use of amalgam as a safe and cost-effective restorative material.

Present situation on amalgam use in EMR

In a feedback from several countries of EMR, it was noticed that the primary responsibility for ensuring the safety of materials rests with the Central Government. This role has been mandated to the health protection division of the Ministry of Health.

The following is a summary of the present situation in relation to the use of amalgam:

1. One country has shown concern towards mercury toxicity for dentists and auxiliaries who are regularly exposed to mercury vapour.
2. One country has taken measures since 8 years ago to use capsulated amalgam and amalgamator to reduce exposure to mercury vapour.
3. In one country the Ministry of Education encouraged the use of glass ionomer rather

than amalgam as the dental filling material in school children.

4. Though one Member State stressed the need to prepare strategies and policies in the use of dental amalgam, another Member State has prepared instructions that were given to dentists regarding the use of amalgam in the clinic:
 - all posterior teeth that need fillings to be filled with amalgam
 - all class II permanent teeth fillings to be filled with amalgam
 - class I filling to be filled with composite, depending on the judgment of the dentists
 - all primary teeth should be filled with glass ionomer.

In one country, the health authorities are in favour of the American Dental Association's position on amalgam use. They believe that the use of dental amalgam as a restorative material does not pose a health hazard to the non-allergic patients.

In one country, appropriate steps have been taken to educate the oral health professionals on the risks and symptoms of mercury poisoning as well as the proper ways of amalgam disposal.

Policy on amalgam use in EMR

In the context of the above situation, most Ministries of Health in EMR have no specific policies and positions related to dental amalgam. Even national professional associations such as the country's dental association, have no specific role in formulating related policies.

Most countries stated that there is no written policy regarding the use of dental amalgam. As such amalgam is now widely used in dental practice as it was used 150 years ago.

References

CCEHRP (1993) Dental Amalgam: a scientific review and recommended public health service strategy for research, education, and regulation. Washington, DC,

Public Health Service, Department of Health and Human Services.
