

**DENTAL AMALGAM AND MERCURY
IN DENTISTRY**

REPORT OF AN NHMRC WORKING PARTY

FEBRUARY 1999

DENTAL AMALGAM AND MERCURY IN DENTISTRY

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SUMMARY, CONCLUSIONS, CONSIDERATIONS AND ADVICE

Summary

The issue of mercury and dental amalgam in dentistry revolves around the proposition that mercury leaching out of dental amalgam fillings may have an adverse effect on health. At high doses mercury is recognised as a neurotoxin capable of producing a variety of neurobehavioural effects. Over recent years studies of individuals exposed to mercury in a variety of occupational settings have suggested the possibility of subtle effects occurring at substantially lower levels of exposure. Despite the apparent consistency of these findings the individual studies are very variable in terms of the strength of the conclusions that can be drawn from them. There is also considerable uncertainty about the relevance of the measured effects and the extent to which they can be attributed to mercury rather than to other characteristics of the individuals involved.

Overseas a number of developments of relevance have taken place; these include:

1. Publication of a highly cited report by Richardson (1995) in Canada, which concluded that the likely daily intake of mercury from dental amalgam fillings encroached substantially on a prudent safety margin between exposure and identified adverse health effects.
2. In Scandinavia and elsewhere in Europe the use of dental amalgam has been discouraged because of environmental concerns (eg Berglund, 1997; Fan et al, 1997).
3. In the UK a panel reviewing the toxicity of mercury concluded that, while there was no evidence of adverse health effects, it was prudent, where clinically reasonable, to avoid its use in pregnant women (COT, 1998).

Within Australia a small number of dentists and doctors have supported, often vocally, claims made about the potential adverse health effects of mercury from dental amalgam. Evidence provided to the Working Party indicated that a small number of dentists attribute one or more of a wide range of symptoms of unknown aetiology to mercury toxicity, and commonly recommend removal of dental amalgam restorations as part of the management of these problems. A very small number of practitioners recommend and/or use various chelating agents as a means of reducing the body burden of mercury.

Evidence provided to the Working Party indicated a number of other relevant points. A major reduction in the prevalence and extent of dental caries in children, changes in the management of dental caries, and the availability of alternative direct restorative materials which can be used in many clinical situations have led to the use of dental amalgam as a restorative material falling sharply in Australia. It is likely that the use of mercury amalgam will decline even further.

The number of restorations is declining in successive cohorts, indicating that the young adult population is likely to be exposed to reducing levels of mercury in the future. Improvements in oral health in middle-aged adults have been less marked and the number of restorations placed has remained reasonably constant. Increased tooth retention has actually increased the number of restorations present and required in older adults.

A substantial range of new restorative materials has now become available at costs which are only marginally greater than that of restorations with mercury amalgam. The duration of survival of restorations with these materials is presently less than that of the mercury amalgams, creating more significant differences in cost:benefit over the long term.

Dental amalgam is therefore still a desirable direct restorative material from a cost and longevity perspective and is the material of choice in certain clinical situations where its properties are superior to alternative materials.

No pivotal study has been published over the past 5 to 10 years providing unequivocal evidence of any hazard from the levels of mercury presently resulting from dental amalgam restorations.

Apart from the Canadian study by Richardson (1995) no other review from any major country has identified any substantial evidence of hazard from mercury from dental amalgam restorations.

Rather than representing an immediate and clear-cut risk to public health, the issue of the public health relevance of dental amalgam restorations revolves, therefore, around the safety margin between the levels of mercury to which humans are likely to be exposed from dental amalgam restorations and the levels at which possible deleterious effects can be identified. Some evidence exists that under certain scenarios (particularly those with multiple dental amalgam restorations) this safety margin is less than the 100-fold margin that is desirable. However, the safety margin is also substantially larger than exists for some other environmental exposures (particularly lead).

To address the concerns raised it has been necessary to investigate the following questions:

1. Has mercury in dental amalgam restorations a necessary role in the future of restorative dentistry?
2. Is mercury from dental amalgam restorations associated with specific illnesses or conditions?
3. What is the estimated exposure to mercury through dental amalgam restorations under various scenarios in subjects of varying age?
4. At what biological levels of mercury (in blood or urine) do credible adverse health effects of mercury exposure become evident?
5. What intakes of mercury are necessary to produce these biological levels?
6. Is there any rationale to require lesser degrees of exposure to any particular "sensitive subgroups"?
7. What is known of the potential long term health effects of substances which might be used as a substitute of mercury?

With regard to these and other questions, the Working Party offers the following conclusions and considerations. Further, in regard to the Terms of Reference, the Working Party puts forward several recommendations for consideration by HAC and NHMRC.

Conclusions

The Working Party concluded that:

- 1.5.1 Dental amalgam has been the main direct restorative material used in dentistry. Other direct restorative materials are available: composite resins and glass ionomers. Several indirect restorative materials are available for use, although at much higher cost.
- 1.5.2 Trends in the prevalence and severity of dental caries in combination with approaches to the management of dental caries and the restoration of teeth are reducing the total number of amalgam restorations placed each year in Australia.

- 1.5.3 Altered approaches to cavity preparation, including a philosophy of minimum tooth removal, and the availability of alternative materials are leading to a further movement away from dental amalgam as a direct restorative material.
- 1.5.4 Dental amalgam restorations are now a minority of all restorations provided (28.0% in 1997/98). Total numbers of dental amalgam restorations or surfaces restored with dental amalgam have decreased dramatically in children and young adults and somewhat less in middle-aged adults. This reduces the total number of years that such restorations could be present in a person's lifetime. However, improvements in oral health in middle-aged adults have been less marked and the number of restorations placed has remained reasonably constant. Increased tooth retention has actually increased the number of restorations present and required in older adults.
- 2.2.1 In one large population survey just over a third of adults in the Australian population have expressed a concern about mercury in dental amalgam restorations. However, about half of these, 16.2%, have asked about restorations that don't contain mercury. Few, 5.8%, have avoided or delayed treatment because of mercury in dental amalgams and 4.7% have had restorations replaced because they contain mercury.
- 3.9.1 A limited number of dental, medical and paramedical practitioners attribute a wide range of diseases and symptoms of unknown aetiology to the effects of dental amalgam. A range of factors may contribute to this clinical situation, not the least of which is a desire to assist people who see them as a provider of last resort.
- 3.9.2 The attribution of a range of diseases or symptoms of unknown aetiology to the effects of mercury from dental amalgam showed a number of misconceptions about the relative nature of safety and risk, dose-dependence of toxicity, evaluation of clinical experience and interpretation of diagnostic information.
- 3.9.3 Claims of improvements in health or relief of symptoms upon removal of dental amalgam restorations may be confounded by diet, lifestyle and placebo effects.
- 3.9.4 Some dental practitioners engage in the removal of dental amalgam restorations, following protocols for collection of diagnostic information and clinical procedures for which there is a lack of supportive scientific evidence.
- 4.7.1 Mercury is released at a slow rate from dental amalgams, generally of a few micrograms per person per day among adults, the amount being dependent on many variables including number and shape of fillings, eating habits and bruxism.
- 4.7.2 For the current mean numbers of dental amalgam fillings in Australian children and adults (0.5 and 8.0 respectively), a reasonable estimate of daily mercury absorption per person is about 0.3 μg and 3.5 μg respectively. In comparison, dietary mercury retained in the body is, respectively, about 10-fold and 2-fold higher than these amounts.
- 4.7.3 Attempts have been made to determine the safe level of mercury exposure in humans. The main approach has involved studying people occupationally exposed to mercury in air, and examining a range of subclinical symptoms of neurotoxicity, e.g. hand tremor. While this has been taken further by some risk assessors and combined with safety factors to generate a Tolerable Daily Intake, the Working Party has serious reservations about the quality of data used in such calculations.
- 4.7.4 Of recent studies of exposure to mercury in industry and dental occupational settings, no study was identified which reported clear-cut illness among those exposed to mercury.

- 4.7.5 No studies have been completed which have compared the health outcomes among dental patients with and without dental amalgams to determine whether there may be differences in symptoms associated with mercury neurotoxicity.
- 4.7.6 For the numerous compounds used in alternative restoration materials, it is evident that for most there has been little or no toxicological testing and analysis of release rates from fillings.

Considerations

The Working Party considered that:

- 1.6.1 Dental amalgam is still of benefit in the restoration of teeth in certain locations in the mouth because of its physical properties and technical requirements in terms of techniques. Cost and longevity of dental amalgam restorations in these locations were consequent advantages.
- 2.3.1 Dental providers, their staff and the public all need to be better informed about mercury and dental amalgam in dentistry. Patients have a right to benefit from available scientific knowledge and to participate in clinical decision making.
- 2.3.2 Dentists should provide their patients with appropriate information on risks and benefits of all dental materials to assist them in making an informed choice regarding alternative dental treatments.
- 2.3.3 Dentists should acknowledge patient's autonomy and the exercising of informed consent for all dental treatment.
- 3.10.1 The use of chelation therapy with DMSA and DMPS, for patients with symptoms attributed to mercury from dental amalgam restorations is a matter of concern.
- 4.8.1 Special initiative status be awarded to research projects that address issues of the effectiveness of alternative restorative materials for direct restorations of occlusal and approximal surfaces of permanent teeth, the release of mercury from amalgam restorations, the health-related effects of mercury from dental restorations, and the efficacy of the removal of dental amalgam restorations (singularly or in combination with other interventions).
- 4.8.2 It is desirable to move toward alternative direct restorative materials to dental amalgam. However, the alternative direct restorative materials, which are being increasingly used, have been infrequently studied in terms of their toxicology. Therefore, such toxicological research is a high priority.
- 4.8.3 The quality of data readily available in published reports on the adverse health effects of low levels of mercury is a matter of concern. The concerns including selectivity in the use of studies, multiplicity of exposures, pre-existing conditions and confounding. Further, a number of studies identified with 'suggestive' or positive findings of sub clinical effects are methodologically flawed or have interpretational problems that fail to add to a 'weight-of-evidence'.
- 4.8.4 The potential encroachment of intake of mercury from dental amalgams on the safety margin for the lowest-observed-adverse-effect level is sensitive to the safety factor used. Some published work uses more conservative safety factors than necessary given that the observed adverse effects are minor and subtle.
- 4.8.5 The safety factor between exposure and adverse health effects from mercury could be contrasted with that of other heavy metals, particularly lead.

- 4.8.6 There is a need for closer surveillance of the growing literature on the pharmacokinetics of elemental mercury, from the diet and from dental amalgams, especially with regard to the central nervous system and renal function.
- 5.4.1 An emphasis be given to population and personal dental caries preventive measures to reduce the incidence of caries requiring any type of direct restorative treatment.
- 5.4.2 Applications of general public health and environmental health principles dictate that where possible exposure to mercury be reduced where a safe and practical alternative exists.
- 5.4.3 The trend toward the use of alternative direct restorative materials in the deciduous and permanent teeth of children be encouraged as a prudent measure.
- 5.4.4 During pregnancy it is prudent to minimise exposure to all foreign substances including materials used in dental restorations. This indicates that placement or replacement of dental amalgam restorations should be avoided, especially during the first trimester.
- 5.4.5 Since the kidney is a target organ for elemental and inorganic mercury it could be prudent for exposure to mercury to be minimised in persons with kidney disease.
- 5.4.6 Dentists should be aware of the remote possibility of allergic hypersensitivity to mercury from amalgam restorations.
- 5.4.7 The NHMRC guidelines on dental amalgam hygiene be followed to reduce occupational and patient exposure to mercury in dental practices and environmental exposure to mercury from dental amalgam waste.

Advice

The Working Party advises:

1. Dental amalgam continues to be a useful direct restorative material. While low levels of mercury are released and absorbed from dental amalgams, there is no convincing evidence of adverse health effects at these levels with the exception of rare cases of contact hypersensitivity. However, general public and environmental health principles dictate that where possible exposure to mercury from dental amalgams be reduced where a safe and practical alternative exists. This becomes more prudent in special populations, including children, women in pregnancy and persons with existing kidney disease.
2. A risk assessment be undertaken in order establish the safety margins between current intake of mercury from dental amalgam and levels at which adverse health effects are likely. This risk assessment should include:
 - A critical evaluation of studies demonstrating adverse effects of exposure to low levels of mercury.
 - Estimation of the exposure to mercury under various scenarios with changing age, diet and numbers of restored tooth surfaces.
3. The withdrawn NHMRC pamphlet on *Dental Amalgam and Mercury in Dentistry (1992)* and the statement prepared in 1995 but not released (See Appendix A) should not be reinstated. A new pamphlet on Dental Amalgam and Mercury in Dentistry should be written and distributed to health professionals and consumers.

References

- Berglund A. The use of dental amalgam in Sweden. In: Mjör IA and Pakhomov GN (eds). Dental amalgam and alternative direct restorative materials. Geneva: World Health Organization, 1997: 185-193.
- Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment. Statement on the toxicity of dental amalgam. London: Department of Health, 1998.
- Fan PL, Arenholt-Bindslev D, Schmalz G, Halbach S, Berendsen H. Environmental issues in dentistry-mercury. *Int Dent J* 1997; 47:105-9.
- Richardson GM. Assessment of mercury exposure and risks from dental amalgam. Final report. Ottawa: Medical Devices Bureau, Health Canada, 1995.

DENTAL AMALGAM AND MERCURY IN DENTISTRY WORKING PARTY

Background

The Office of the National Health and Medical Research Council (NHMRC) had noted, in 1995, that its pamphlet *Dental Amalgam and Mercury in Dentistry (1992)* 'did not reflect a balanced view of the concerns around the health effects of mercury amalgams'. The pamphlet was subsequently rewritten in 1995, but never reprinted. The draft version is presented in Appendix A. The 1992 pamphlet, which constituted NHMRC's policy statement on the issue of mercury amalgams, was withdrawn in August 1997, due to a reference error. Since the withdrawal NHMRC has been approached to provide an informed position statement on the health effects of dental amalgam and mercury in dentistry. The NHMRC's Health Advisory Committee (HAC) resolved at its December 1997 meeting to establish a Working Party to review its former policy statement in light of available evidence, and to consider the need for a full and systematic review of the scientific evidence available on the health effects of dental amalgam and mercury.

Working Party

The Working Party was formed in May 1998. It comprised:

Professor John Spencer (Chairperson)	Faculty of Dentistry The University of Adelaide
Dr Rob Loblay	Immunology Unit Department of Medicine The University of Sydney
Dr Jim Fitzgerald	Environmental Health Branch South Australian Health Commission
Professor John McNeil	Department of Epidemiology and Preventive Medicine Monash University
Ms Jocelyn Bennett	Australian Complementary Health Association Ross House Melbourne (Consumer Health Forum representative)
Ms Helen Lucas (Technical Secretary)	National Health & Medical Research Council

Terms of Reference

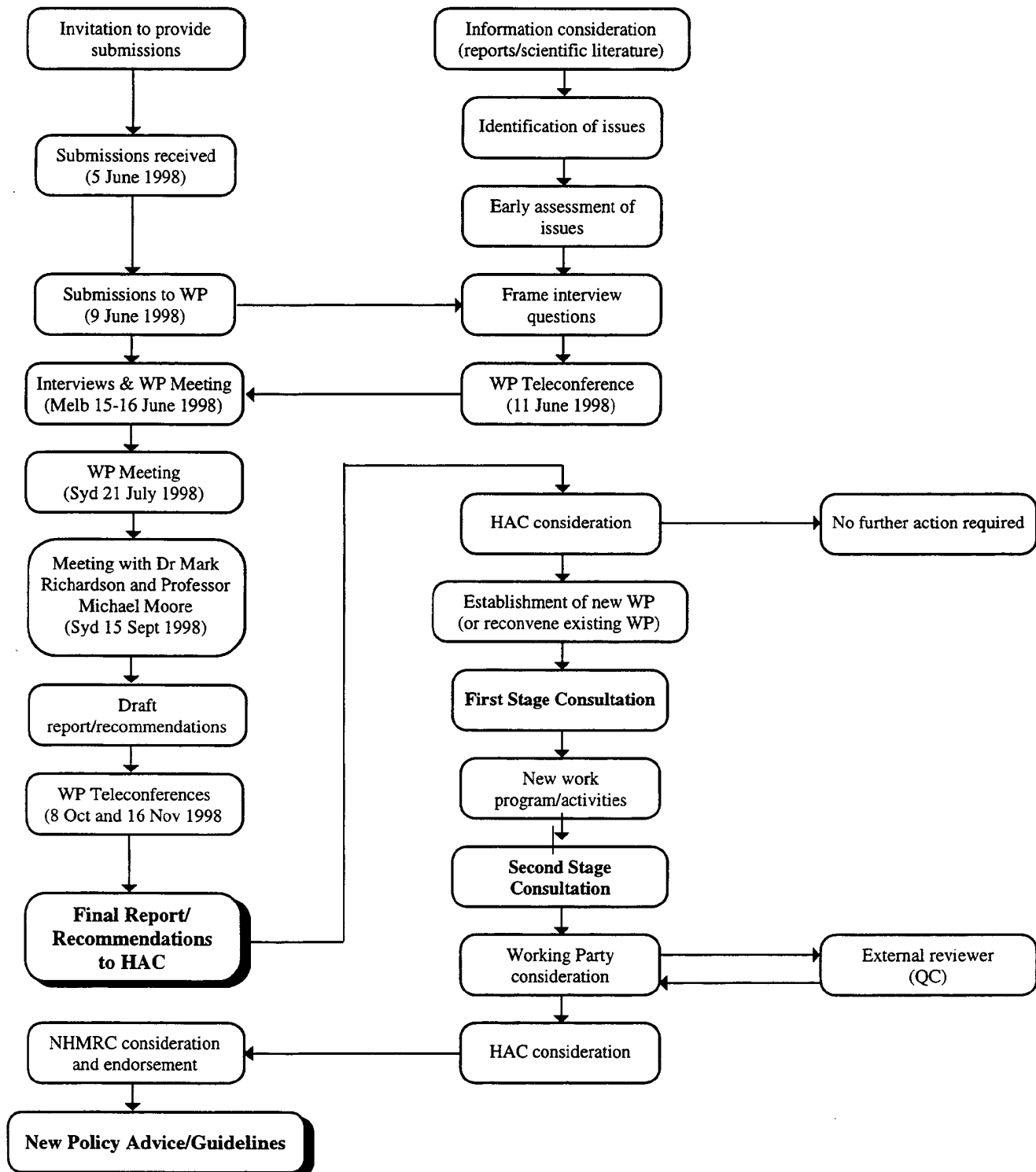
1. To gather information on the issue of the health effects of dental amalgam and mercury in dentistry. This will include:
 - recent overseas literature (post-1991).
 - evidence presented by organisations/individuals who are stakeholders.
2. In the light of that information, to:
 - consider whether there is a need for a full and systematic review of the scientific evidence available on the health effects of dental amalgam and mercury.
 - make recommendations to the HAC, by mid August-1998, on the extent of any revisions required to the NHMRC pamphlet, *Dental Amalgam and Mercury in Dentistry (1992)*.

Approach to the task

The Working Party determined a process for development of advice to the HAC, including examination of current literature, focussing on recent reports and certain published articles, identification of issues, and receipt of written submissions from invited and interested stakeholders as well as personal representations from key individuals who wished to deliberate with the Working Party. The process adopted by the Working Party is outlined in the following flow chart.

Figure 1. NHMRC Working Party on Dental Amalgam and Mercury in Dentistry

Process Flow chart



The Working Party has aimed, despite its limited time frame, to provide advice which would lead to dentists and their clients being better informed regarding dental amalgam and mercury in dentistry.

Progress

The Working Party has met on four occasions and conducted three telephone conferences:

28	May	Initial meeting and organisation of call for submissions by 5 June 1998
11	June	Teleconference
15-16	June	Interviews with stakeholders
21	July	Meeting to consider submissions and interviews
15	September	Meeting with Dr Mark Richardson and Professor Michael Moore
8	October	Teleconference re drafting of report
16	November	Teleconference

Issues identified

A range of key issues were identified as the focus of the Working Party's attention:

Context

- Trends of dental caries
- Management of dental caries
- Trends in the provision of dental amalgam restorations
- Value of dental amalgam restorations in the 1990s

Public perceptions of mercury and dental amalgam restorations

Clinical observations

- Issues
- Diagnostic criteria
- Removal protocols and adjunctive therapy
- Evaluation
- Risk perception

Risk assessment

- Issue and contrasting approaches
- Release and absorption of mercury from amalgam restorations
- Adverse health effects from absorbed mercury
- Alternative direct restorative materials

International reports

- Directions and rationale

1. DENTAL AMALGAM AS A RESTORATIVE MATERIAL

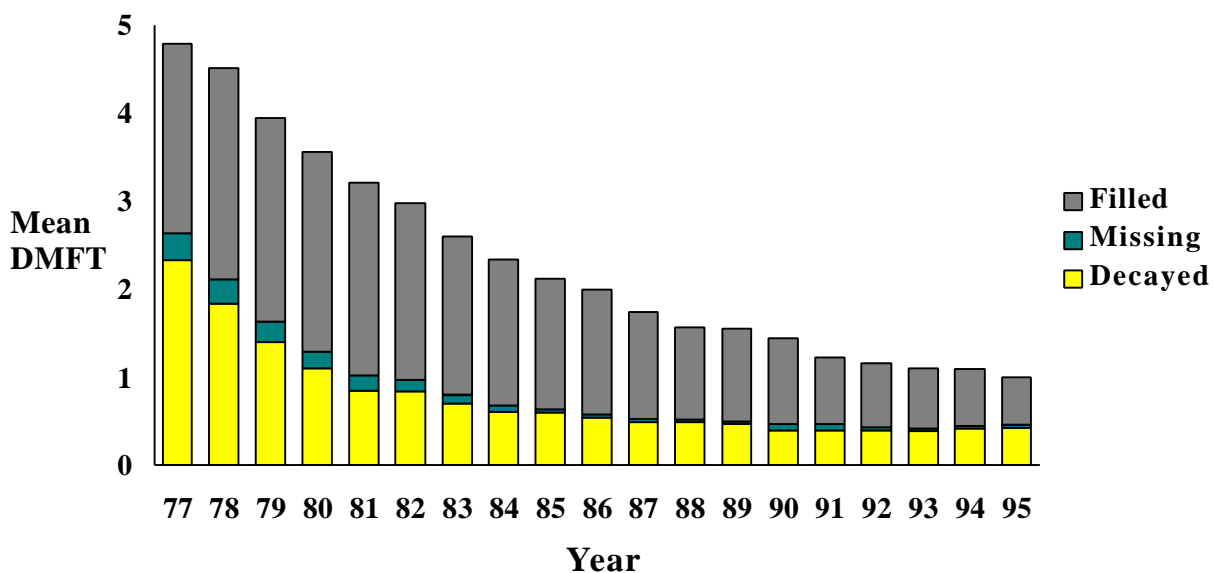
1.1 Trends in dental caries

Dental amalgam is one of several dental materials used to restore the form and function of teeth, deciduous and permanent, affected by dental caries. While dental amalgam restorations were once placed in teeth with caries in what was described as a preventive restoration (prophylactic odontology) and to restore tooth damage in the absence of dental caries (cervical areas of tooth with abrasion or fractured cusps of premolar or molar teeth), most dental amalgam restorations are placed as a result of dental caries.

Dental caries is a dynamic reversible process of demineralisation and remineralisation of the susceptible tooth. Diet and dental plaque are considered to be the major demineralisation factors and fluoride and saliva the main factors facilitating protection and remineralisation. The balance of these risk and protective factors has changed markedly over the last three decades, leading to a markedly altered burden of disease.

Australian children had among the highest levels of caries experience among comparable countries in the 1940s and 1950s. For instance, 12 year olds had a decayed, missing and filled teeth score (DMFT) of approximately nine teeth, with only one per cent without clinical caries (Barnard, 1956). The level of caries experience began to decline in the mid-1960s (Spencer, 1986). When a national monitoring survey was introduced in 1977 the DMFT was just less than five teeth. The trends since 1977 are presented in Figure 1. The DMFT has decreased from 4.8 in 1977 to 1.0 in 1995 (Davies et al, 1997; Davies and Spencer, 1997). This is equal to the Australian oral health target set for the year 2000 of 1.0 DMFT (Health Targets and Implementation Committee, 1988).

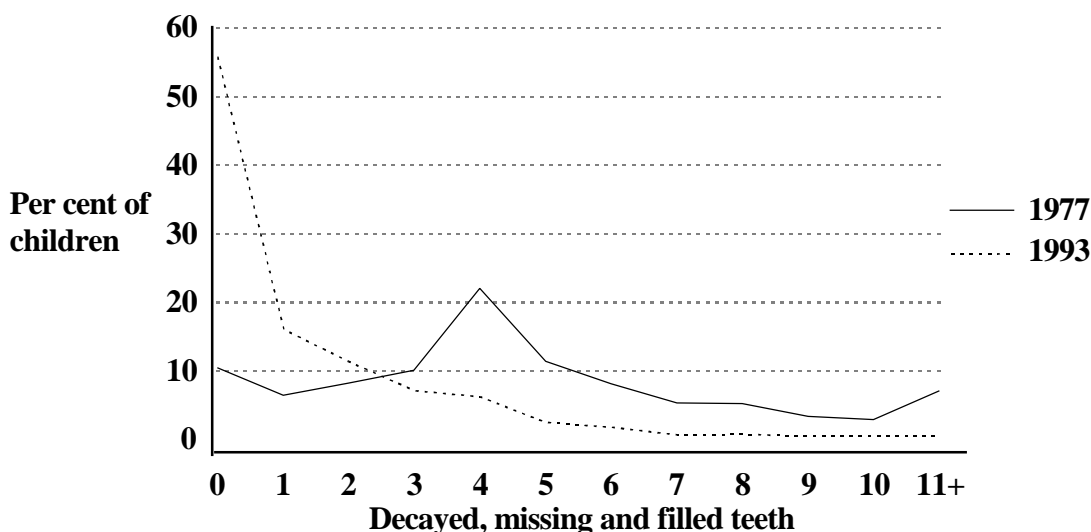
Figure 2. Caries experience in 12 year old children, 1977-1995



The distribution of caries experience in the population of 12 year olds has also dramatically altered. Figure 2 presents the distribution of caries experience in 12 year old Australian children at two points in time: 1977 and 1993. In 1977, the vast majority of children had some experience of caries, with a mode of four affected teeth. Only 10 per cent had no experience of clinical caries. By 1993, over half the children, 56 per cent, had no experience of clinical caries. A minority of children had any experience of clinical caries and most children with experience of clinical caries had only one to two

teeth affected. Higher levels of caries experience, for instance four or more teeth affected, were experienced by only 12 per cent of children (Davies et al, 1997).

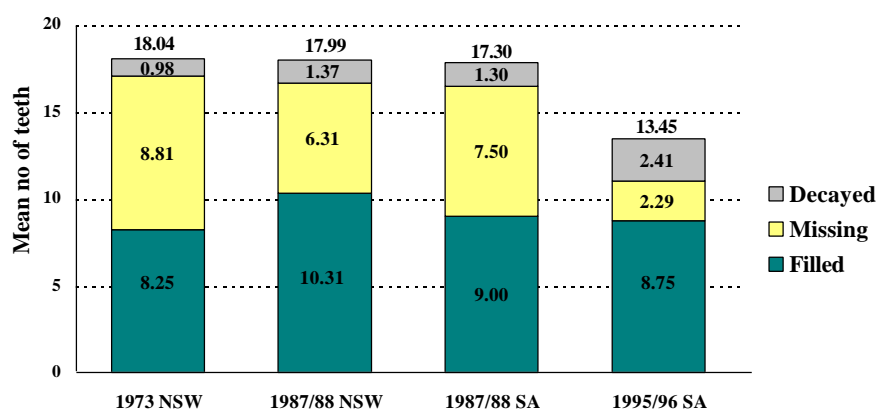
Figure 3. Distribution of caries experience in 12 year olds, 1977 & 1993



These improvements in children are obviously the starting point for future improvements in oral health among adults. However, not all the gain is carried forward into adulthood. Cessation of eligibility for school dental care, changes in lifestyle and possibly some delayed progression of sub-clinical caries sees young adults with up to 7 times the number of teeth with caries experience as 12 year olds. This caries experience among young adults is an improvement on the past, but it illustrates that caries is not a disappearing public health problem. The need for restorations in children has markedly decreased, but a need re-emerges among young adults.

The improvements in oral health among adults will lag behind in time, awaiting cohorts of children to reach their adult years. Middle-aged and older adults have widespread and extensive past and present caries experience. Among 35-44 year olds in Australia the DMFT score showed little change for nearly two decades, but has improved more recently. Figure 3 presents the DMFT of 35-44 year old Australians in 1973 and 1987 (Arnljot et al, 1985; Barnard, 1993) and then more recently in 1995/96 (AIHW DSRU, 1997).

Figure 4. Caries experience in 35-44 year old Australian adults



There was no decrease in the DMFT score between 1973 and 1987, with DMFT scores of approximately 18 teeth, but there has been a substantial decline to the 1995/96 score of 13.5 teeth at least in South Australia.

While the DMFT score was slow to change, the mean number of missing teeth has declined across the whole period from over 9 to 3.6 teeth. The number of teeth extracted has decreased as both the community and profession have sought to alter the management of caries experienced.

The number of filled teeth has remained more constant, reflecting little change in the total need for restorations.

There is an opposite trend emerging in both caries incidence and need for restorations among late middle-aged and older adults. Caries incidence and the need for restorations in the past was reduced by the loss of all teeth (edentulism) or loss of some teeth. Edentulism in Australians aged 15+ years has decreased from 20.0% in 1979 (ABS, 1980) to 14.0% in 1987/88 (Barnard, 1993) and 9.7% in 1996 (Carter, 1997). Among 55-64 year olds edentulism has decreased from 40.2% in 1979 to 19.9% in 1996. For those aged 75+ years edentulism has decreased from 78.6% in 1979 to 48.7% in 1996. This decline in edentulism is leaving greater absolute numbers of middle-aged and older adults with natural teeth with extensive past caries experience. These teeth are at the risk of new disease and the need for retreatment.

The decrease in caries experience in children and adolescents, and the increase in tooth retention in adults and older adults, has led to a marked shift in the burden of caries activity by age and therefore the ages at which greatest need for restorations occur.

Table 1. Annualised incidence/increment in caries activity by age

Caries type	Age						
	1-6	7-11	12-17	18-24	25-44	45-64	65+
Nursing caries -							
Frank	3%						
Demineralisation	17%						
Initial coronal caries	dmfs	DMFS	DMFS	DMFS	DMFS	DMFS	DMFS
Pits & fissures	} 0.4	0.4	} 0.6	} 1.1	} 1.1	} 1.1	} 1.1
Interproximal/smooth surface	}	0.3	}	}	}	}	}
Secondary coronal caries†					Tooth surfaces	Tooth surfaces	Tooth surfaces
					0.5	0.5	0.5
Root surface caries					DFS	DFS	DFS
					0.1	0.4	0.6

† Secondary caries activity is not easily distinguished from traditional epidemiological data. As more than 50% of restorations placed are replacements (Elderton and Nutall, 1983) and approximately 50% of all replacements are for secondary caries (Kidd et al, 1992) the annualised incidence of secondary caries has been estimated at 50% of the increment in DMFS.

This conceptualisation of expected caries risk for a typical individual in the community serves as an example of the kind of caries problems to be anticipated, and when it might occur. The presence of caries activity of each type and the estimated incidence indicate the number of teeth requiring restorations each year because of dental caries (Garcia, 1989). The absence of an estimate does not mean that caries of that type will not occur and the need for a restoration will not arise, merely that it is less likely and of less concern (Lewis, 1979).

Several points are apparent from this table:

- all age groups are assessed as having at least one type of caries that is likely and of concern;
- a high likelihood of caries occurs in adult age groups, both because of the risk of a particular type of caries being high, for instance interproximal smooth surface caries or secondary coronal caries, and the cumulative likelihood of more than one type of caries;
- if the risks indicated for each specific age group are compared, the caries likelihood among children is now lower than the caries likelihood among adults;
- there are qualitatively different types of caries — nursing caries, coronal caries and root caries — as well as distinctions for location on a tooth which are relevant to the potential for, and effectiveness of, prevention of caries for specific age groups, and to the alternative treatment approaches, including restorations for the management of caries.

1.2 Management of dental caries

The management of dental caries is altering. Four factors bear upon the issue of mercury and dental amalgams in dentistry:

- replacement of existing restorations (Mjör, 1993);
- repair of the early carious lesion (Elderton, 1988);
- minimum tooth removal (Mount, 1998); and
- greater availability of alternative direct restorative materials (Hickel et al, 1998; Wilson et al, 1997).

As indicated in the notes for Table 1 and the discussion above, about 50% of all restorations are for new disease and 50% for replacement of existing restorations that are considered to have failed or be unsatisfactory. This clearly establishes the importance of clinical guidelines for replacement of restorations in determining the extent to which dental amalgams may be used, and the number of cycles of replacement of existing dental amalgam restorations in an individual's lifetime.

It has become widely recognised that replacement dentistry is a hazard for any tooth's survival and the less replacement the better. Replacement inevitably leads to loss of further tooth structure and a weakening of the remaining tooth. It is for this reason that replacement should only be considered when a restoration has demonstrably failed: when it has been lost, cracked, or there is a positive diagnosis of secondary caries. Small defects should be repaired, rather than the restoration be replaced. The cavity design for replacement restorations should put emphasis on protection and minimising the width of the cavity.

While numbers of replacement restorations might be minimised through more stringent criteria, and their hazard to the remaining tooth minimised through a conservative cavity preparation approach, replacement restorations will always be needed because of the discrepancy between the longevity of restorations and the desired longevity of the tooth. It, therefore, becomes even more desirable to minimise the need for first restorations to be placed. The reduction in caries activity due to the widespread availability of fluoride is assisting in reducing the need for first restorations.

1.3 Alternative direct restorative materials

Direct restorative materials are those that can be inserted into a prepared cavity in a tooth in a workable phase for condensation and shaping and then change to a set phase where they can resist masticatory forces and abrasion. There are three commonly used direct dental restorative materials: dental amalgam, composite resins, glass ionomers.

These direct restorative materials are in contrast to indirect restorative materials which require some intermediate steps of impression taking, preparing a dye and fabrication of inlay or crown, between the

preparation of the cavity and insertion of the restoration. This includes gold and precious metal castings, with or without porcelain laminate facings and porcelain crowns. New computerised imaging and milling of porcelain inlays is opening up a 'virtual' direct restorative approach to large cavities of molar or premolar teeth.

The three direct restorative materials have different qualities and uses. The most obvious is colour, but the most important are qualities of resistance to masticatory forces and resistance to abrasion. These influence longevity which, combined with initial cost, determines cost-effectiveness.

The desire for improved appearance has led to many cavities which would have been restored with dental amalgam now being restored with composite resins and glass ionomers. Changing approaches to cavity preparation are also leading to reduced restoration widths (which is important for the reduction of tensile forces on restorative materials) and surface areas (important for reduction of abrasion). This is leading to circumstances where composite resins and glass ionomers may more readily substitute for dental amalgam in the restoration of posterior teeth.

However, many restorations are replacements of earlier restorations and the physical nature of the cavity is largely determined by the original extent of dental caries and principles of cavity preparation practised decades ago. Such situations place demands on the restorative material that dental amalgam is thought to be best at satisfying (Dunne et al, 1997).

Longevity of the three direct restorative materials still vary, although all are increasing (Bayne, 1992). Given varying longevity and slightly higher initial costs of composite and glass ionomer restorations (ADA SA Branch, 1997), financial constraints will work toward the continued use of dental amalgam restorations.

1.4 Trends in the provision of dental amalgam as a restorative material

Dental amalgam has been the most widely used direct restorative material. However, the predominance of dental amalgam as a direct restorative material has been declining as shown by the data given in Table 2, as the number of dental amalgam restorations provided per year has almost halved across the 1983-84 to 1997-98 period.

The percentage of all restorations that are dental amalgam restorations has decreased from 57.9% in 1983-84 to 43.5% in 1988-89, 35.7% in 1993-94 and 28.0% in 1997-98. Thus, across the period 1983-84 to 1997-98, dental amalgam restorations as a percentage of all restorations provided have halved. Greater percentages of composite resin and glass ionomer cement restorations are being provided as direct restorations and crowns as indirect restorations.

Table 2. Annual restorative services (x1000) by year in Australian private general practice¹

Service type	1983-84	1988-89	1993-94	1997-98
Amalgam (1 surface)	1938.4	1310.4	1264.6	720.5
Amalgam (2 surfaces)	2907.8	2267.9	2452.5	1624.1
Amalgam (3+ surfaces)	1324.1	1277.0	1594.8	1120.7
Total amalgam	6170.3	4855.3	5311.9	3465.3
Fissure sealants	38.6	216.1	407.2	591.3
Composites	2742.8	2859.4	3697.4	4963.5
Ionomer	257.4	938.5	1493.0	1412.1
Acrylic restoration	61.2	8.0	-	-
Adhesive restoration	-	-	133.1	113.2
Inlays	39.3	12.8	39.3	81.8
Crowns	404.6	685.5	1550.2	1736.4
Bridges	92.1	230.6	215.3	194.4
Other restorative	843.6	1350.3	2038.3	1781.5
Total restorative services	10649.9	11156.5	14885.7	12394.2

¹ Data for 1983-84, 1988-89 from Spencer et al, 1994; data for 1993-94 and 1997-98 from D. Brennan (personal communication, May 1998).

The general trends in provision of restoration have not applied evenly across the age groups. This is presented in Table 2. Very substantial decreases in the provision of dental amalgam restorations have occurred in 5-11 year olds, 12-17 year olds, and 18-24 year olds. A small decrease has occurred in 25-44 year olds. Among 45-64 year olds and 65+ year olds the total number of dental amalgam restorations placed each year has increased. This reflects the shifts in the burden of dental caries discussed in Section 1.1.

Table 3. Annual dental amalgam restorative services (x1000) by age group and year in Australian private general practice¹

	Age						
	Year	5-11	12-17	18-24	25-44	45-64	65+
Total amalgam	1983	384.5	745.2	1327.6	2632.2	954.5	75.0
	1988	149.1	365.7	770.5	2468.0	943.6	180.0
	1993	147.0	225.1	485.2	2582.9	1464.8	317.3
	1997	74.8	64.9	187.3	1750.8	1117.5	195.0

¹ Data for 1983-84, 1988-89 from Spencer et al, 1994; data for 1993-94 and 1997-98 from D. Brennan (personal communication, May 1998).

These age-specific trends are more marked if expressed as total dental amalgam surfaces. This is presented in Table 4. Total dental amalgam surfaces provided each year decreased by 76.6% for 5-11 year olds, 92.1% for 12-17 year olds, 84.8% for 18-24 year olds and 28.5% for 25-44 year olds. The total number of dental amalgam surfaces provided increased by 26.3% for 45-64 year olds and 158.8%

for 65+ year olds. The decrease in the use of dental amalgam restorations has been dramatic in children and young adults and substantial in adults of child-bearing age. Only in later middle-aged and older adults has the provision of dental amalgam restorations increased.

Table 4. Annual total surfaces involved in dental amalgam restorative services (x1000) by age and year in Australian private general practice¹

Service type	Year	5-11	12-17	18-24	25-44	45-64	65+
Total amalgam surfaces	1983	555.2	1219.9	2542.8	5299.9	1887.3	157.7
	1988	205.9	500.1	1455.0	5138.4	2002.7	340.5
	1993	263.9	344.6	845.6	5423.8	3224.6	645.9
	1997	130.3	96.9	385.9	3790.7	2365.5	408.2
% change, 1997/1983		-76.6	-92.1	-84.8	-28.5	+25.3	+158.8

¹ Data for 1983-84, 1988-89 from Spencer et al, 1994; data for 1993-94 and 1997-98 from D. Brennan (personal communication, May 1998).

The age-specific trends in the provision of dental amalgam restorations have a further, cumulative effect in reducing the total number of years dental amalgams are present in individuals' oral cavities.

Dental amalgam restorations are now a minority of all restorations provided. Total numbers of dental amalgam restorations or surfaces provided have decreased dramatically in children and young adults and somewhat less in middle-aged adults. This decreases the likelihood of placement or replacement in childhood and child-rearing years, and reduces the total number of years that such restorations could be present in a person's lifetime.

1.5 Conclusions

- 1.5.1 Dental amalgam has been the main direct restorative material used in dentistry. Other direct restorative materials are available: composite resins and glass ionomers. Several indirect restorative materials are available for use, although at much higher cost.
- 1.5.2 Trends in the prevalence and severity of dental caries in combination with approaches to the management of dental caries and the restoration of teeth are reducing the total number of amalgam restorations placed each year in Australia.
- 1.5.3 Altered approaches to cavity preparation, including a philosophy of minimum tooth removal, and the availability of alternative materials are leading to a further movement away from dental amalgam as a direct restorative material.
- 1.5.4 Dental amalgam restorations are now a minority of all restorations provided (28.0% in 1997/98). Total numbers of dental amalgam restorations or surfaces restored with dental amalgam have decreased dramatically in children and young adults and somewhat less in middle-aged adults. This reduces the total number of years that such restorations could be present in a person's lifetime. However, improvements in oral health in middle-aged adults have been less marked and the number of restorations placed has remained reasonably constant. Increased tooth retention has actually increased the number of restorations present and required in older adults.

1.6 Considerations

- 1.6.1 Dental amalgam is still of benefit in the restoration of teeth in certain locations in the mouth because of its physical properties and technical requirements in terms of techniques. Cost and longevity of dental amalgam restorations in these locations were consequent advantages.

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2. PERCEPTIONS OF RISK OF MERCURY FROM DENTAL AMALGAM RESTORATIONS

2.1 The Australian public's perception of mercury/dental amalgam

Any consideration of mercury and dental amalgam in dentistry must be put into context by an understanding of the public's perception of benefit and risk. Not infrequently media coverage is viewed as an expression of the public's perception. However, while media coverage may shape perceptions it is less clear how widely views expressed by the media are held by the public.

There is little published information on the public's perception of mercury and dental amalgam in dentistry. One published study provides recent Australian data. Thomson et al (1997) undertook a postal questionnaire survey of a sample of participants in a national dental telephone interview. The 1995 National Dental Telephone Interview Survey (Carter, 1995) collected information from a random sample of Australian residents aged 5 years and over in all States and Territories. Responses were received from 1010 of the 1185 interviewees selected, a 85.2% response.

The self-complete questionnaire included responses to four statements:

- I am concerned about mercury in fillings;
- I have asked to have fillings that don't contain mercury;
- I avoid dental treatment because of mercury in fillings; and
- I have had fillings replaced because they contained mercury.

While 37.5% of respondents were concerned about mercury in fillings, less than half of these, 16.2%, had asked to have fillings that don't contain mercury. Few respondents (5.8%) had avoided treatment because of mercury in fillings and 4.7% had had fillings replaced because they contained mercury.

These data indicate that while there maybe a substantial level of concern about mercury and dental amalgam restorations among the Australian public, altered visiting behaviour and treatment decisions are less frequent consequences.

The perception of risk may not be translated into avoidance of care because of the perceived benefits of care. Alternatively, the perception of risk may not be translated into replacement of dental amalgam restorations because of advice given by most dental practitioners, the practitioners' unwillingness to acquiesce to such patient requests, or the expense of the dental amalgam replacement restorations.

In common with other public perceptions of health risks, there is a paradox of higher levels of concern about mercury risk as the public has become orally healthier, as provision of dental amalgam restorations has decreased, and as safety measures in the use of dental amalgam have improved. On the other hand, increased information and greater individual autonomy in health care have led more of those persons with amalgam restorations to voice concern.

Information on mercury and dental amalgam in dentistry can come from many sources: parts of the dental and medical profession locally and overseas, allied health personnel, the media and individuals with anecdotal experience. All such information exchange is being accelerated by information technology. Many world wide web sites are associated with the topic of mercury and dental amalgam.

The Working Party was interested in the referral and decision-making processes which lead some individuals to have dental amalgam restorations removed. Some individuals see the removal of dental

amalgams as an action of last resort after unsuccessful searches for the cause of conditions of unknown aetiology.

The Working Party found no evidence of any systematic advice being given by paramedical personnel as part of such individuals' search for solutions to their health problems. A range of "non-mainstream" paramedical health teaching institutions and professional associations were contacted by the Working Party. There was no consistency in what was taught about mercury and dental amalgam in alternative therapy training institutions. Neither was there a consistency in paramedical health practitioners referring to or acknowledging a possible role of mercury from dental amalgam restorations as a cause of conditions of unknown aetiology. Adequate and consistent information on mercury and dental amalgam needs to be available not only within dentistry and medicine, but also across a range of alternative therapy practitioners.

2.2 Conclusion

- 2.2.1 In one large population survey just over a third of adults in the Australian population have expressed a concern about mercury in dental amalgam restorations. However, less than half of these, 16.2%, have asked to have restorations that don't contain mercury. Few, 5.8%, have avoided or delayed treatment because of mercury in dental amalgams and 4.7% have had restorations replaced because they contained mercury.

2.3 Considerations

- 2.3.1 Dental providers, their staff and the public all need to be better informed about mercury and dental amalgam in dentistry. Patients have a right to benefit from available scientific knowledge and to participate in clinical decision making.
- 2.3.2 Dentists should provide their patients with appropriate information on risks and benefits of all dental materials to assist them in making an informed choice regarding alternative dental treatments.
- 2.3.3 Dentists should acknowledge patient's autonomy and the exercising of informed consent for all dental treatment.

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3. OVERVIEW OF SUBMISSIONS AND INTERVIEWS

3.1 Submissions received

The Working Party received a total of 43 submissions (see Appendix B). Of these, 27 were from dentists, 6 from medical practitioners¹ [6,11,12,16,26,39], 4 from alternative/paramedical practitioners [3,18,23,24], 1 from a toxicologist and 5 from patients [10,17,41] or advocacy groups [25,40]. Three submissions were made on behalf of professional organisations (Australian Dental Association [35], Australian Society of Oral Medicine and Toxicology (ASOMAT) [38], International Academy of Oral Medicine and Toxicology (IAOMT) [4]). One Ministerial referral from a patient was also received.

Three submissions [35,36,38] were accompanied by extensive reference material.

3.2 Interviews

Six individuals accepted the Working Party's invitation to make personal and/or organisational representations: Dr Robin Woods (ADA), Drs Roman Lohyn and Robert Gammal (ASOMAT), Dr Noel Campbell (dental practitioner) and Dr Michael Godfrey (general practitioner), and Dr Graeme Stringer (dental practitioner). Presentations and discussions were held over a two-day period.

The Working Party also held a four-hour meeting with Dr Mark Richardson and invited Professor Michael Moore (Director, National Research Centre for Environmental Toxicology, Queensland) [43] to participate as well. Dr Loblay attended presentations by Dr Richardson and Professor Boyd Haley at the ASOMAT annual conference (Sydney, September 1998). Dr Richardson, formerly with Health Canada, and currently with O'Connor Associates, is recognised as an expert in the health risk assessment of mercury from dental amalgam.

3.3 Summary of submissions and interviews

Most submissions expressed concern about the toxicity of mercury and continued use of dental amalgam. One focussed principally on occupational exposure and waste disposal [1], and several others expressed similar concerns [2,22,32,37,38].

Of the 26 dentists who made submissions, 22 indicated that they do not use amalgam at all in their own practice and 21 perform removal of existing amalgam fillings and replacement with other materials. Five indicated that they had personally had their own amalgam fillings removed [15,19,27,29,37].

All 6 medical practitioners considered that amalgam fillings could cause chronic ill-health and recommended their removal. Three indicated that they had personally had their own amalgam fillings removed [11,12,16].

Many submissions were critical that ASOMAT had been excluded from representation on the Working Party [5,6,8,10,11,13,16,20,25,27,29,30,31,38]. Nine made allegations, alluding to conspiracies, vested interest groups and cover-ups [8,12,18,20,26,27,29,30,38].

Three submissions supported the continued use of amalgam [34,35,42]. They stressed that reviews of the evidence by credible national and international bodies indicated that the toxicity of mercury released from amalgam had been exaggerated and that amalgam continues to have an important place in dentistry.

¹ Four of these practice "Nutritional and Environmental" medicine and/or other alternative modalities.

Most submissions welcomed an expert assessment of current evidence by NHMRC. One submission was concerned about the expertise and credibility of the Working Party [42].

3.4 Amalgam “toxicity”: clinical and laboratory diagnosis

All 21 practitioners who undertake removal of amalgam fillings, as well as the 6 medical practitioners and 4 alternative/paramedical practitioners who made submissions, consider that removal results in significant improvements in health in the majority of cases. Several submissions listed symptoms or diseases which improved, and some reported individual cases (see Table 5).

Some practitioners use symptom check-lists [28,30,37] which include questions about 100 symptoms / conditions (past or present occurrence, or percent improvement — see Table 6). These questionnaires clearly have a common origin, but the source was not indicated. One submission [28] included photocopies of 24 questionnaires filled out by patients. The submission of the Australian Society of Dental Mercury Patients [10] included a shorter questionnaire (30 items) derived from Dr Hal Huggins, a well-known US anti-amalgam campaigner.

Some submissions referred to diagnostic testing for mercury “toxicity” [6] or to “DMPS [Dimercaptopropane Sulfonate] provocation testing” [26]. Hair analysis and electrodermal testing was also mentioned in some of the oral presentations [39]. One of the dentists [36] assumed that patients must have been suffering from “micromercurialism” if their symptoms or clinical condition improved after removal of amalgam fillings. He gave as an example a patient with thyroid disease who was on thyroxine and had an elevated TSH level. After removal of amalgam fillings the TSH level fell and there was no further need for thyroxine treatment. One interviewee [39] claimed to see mercury toxicity “every day” — he considered the diagnosis was extremely obvious. One of the medical practitioners [39] presented a case history of a patient who was eventually diagnosed with spinocerebellar atrophy. He concluded that the patient had mercury toxicity on the basis of a “DMPS challenge” — a test he performs routinely for diagnosis. This practitioner claimed that in 12 years of general practice he had only seen two patients who were *not* affected by amalgam.

Table 5. Symptoms reported to improve after removal of amalgam fillings

<i>SYMPTOMS / DISEASE</i>	<i>Reported in submission no.</i>
Chronic ill health	5,8,9,14,15,16,23,26,27,29,31,37
Fatigue	5,11,12,16,24,32,33
Headaches, migraine	5,22,27,32,33
Memory impairment	5,27,32,33
Mood changes (irritability, anxiety, depression)	5,24,32
Shyness	5,18
Psycho-behavioural changes	6,31,32
Mental foginess	5
Sleep disturbance	19,24,27,33
Poor eyesight / colour vision	5,12
Limb mobility	5
Paraesthesias	32
Tachycardia / palpitations	12
Tinnitus	12
Metallic taste	22,5
Gingival disease	5
Salivation	22
Lichen Planus	22
Asthma	11
Allergies	11,24
Rhinosinusitis	22
Dyspnoea	12
Chemical sensitivities	11
Skin problems	33
Neurological disease	6,7
Endocrine / thyroid disease	6,24
Cardiovascular disease	24
Kidney / urinary tract disorders	24
Gastrointestinal disease	6,24,27
Immunological disease	6,7
Multiple sclerosis	12,22
Rheumatoid arthritis	12
Cancer	12,24

Table 6. Symptom / disease checklist

Rheumatic fever	Choked feeling	Prostate problems
Leukaemia	Flashing lights	Endometriosis
Multiple sclerosis	Air hunger	Pituitary problems
Hepatitis	Diabetes insipidus	Chronic fatigue
Herpes	Muscle weakness	Chronic sore throats
	Muscle atrophy	Back pain
Crohn's disease	Shooting pains	Foot problems
Meniere's disease	Osteoarthritis	Scoliosis
Infectious diseases	Sour taste	Headache
Shingles	Metallic taste	Migraine
Parkinson's disease	Dry mouth	Neck & shoulder pain
	Excessive saliva	Pain in arms & hands
Heart problems	Frequent urination	RSI
Heart murmur	Kidney problems	Scalp tenderness
High blood pressure	Shortness of breath	Jaw pain
Low blood pressure	Chest pains	Face pain
Angina	Forgetful	Teeth pain
Tachycardia	Depression	Limited mouth opening
Palpitations	Poor concentration	Pain when chewing
Anaemia	Hallucinations	Jaw locking
Fainting tendency	Suicidal feelings	Blurred vision
Dermatitis	Sudden anger	Dry itchy eyes
Eczema	Rapid mood swings	Sinusitis
Itching	Irritability light sensitivity	Ear pain
Acne	Gut problems	Dizziness
	Colitis	ringing in the ears
Epilepsy	Diarrhoea	Reduced hearing
Nervous disorders	Constipation	Tooth grinding
Muscle twitches	Ulcers	Candidiasis
Bell's palsy	Irritable bowel	Hypoglycaemia
Movement problems	Heartburn	Peripheral neuritis
Speech problems	Diabetes	
Leg jerks	Thyroid problems	
Restless leg	Cold hands & feet	
Numb / tingling sensations	Frequent colds	

3.5 Amalgam removal protocols

Some submissions [eg. 37] referred to amalgam removal according to “IAOMT protocols” and “ASOMAT protocols”. None of the written submissions gave any details of such “protocols”. However, the Working Party was able to explore this issue during the interview sessions. Removal protocols involve protection of the patient from mercury vapour during the procedure by the use of rubber dams; suction behind the dam; special “systems” (Clean-Up) to fit over the tooth; an external air supply (\pm O₂ / N₂O); flooding the mouth with water; and cutting away rather than drilling out the amalgam [30,39]. Without attention to such mercury minimisation procedures, high levels of blood mercury can result from the removal of amalgam restorations. In addition [30], the dentist and nurse each have a separate air supply, with large air filters and negative ion generators. It is recommended [39] that removal should be done one quadrant at a time, beginning with the one that has the “highest current” in relation to oral galvanism (The phenomenon of microcurrent flow within the oral cavity due to the presence of metallic filling components). Because of “the 7-day immune cycle” successive treatments on the same day of the week are avoided, and an 8-day interval between amalgam clearance of each quadrant is recommended. Alternatively, all fillings can be removed during one session (in hospital, under general anaesthesia if necessary).

3.6 Associated therapy: chelation, “detoxification” and nutritional therapy

Several submissions referred to the use of chelating agents (EDTA), Dimercaptopropane Sulfonate (DMPS), 2,3-Dimercapto Succinic Acid (DMSA) for reducing mercury levels in conjunction with the removal of amalgam fillings [6,16,19,39] and to nutritional “support” [29]. These issues were explored further by the Working Party with those making verbal representations [30,38,39]. One [39] advocated “antioxidant and nutritional therapy” with high-dose intravenous vitamin C (infused continuously during the amalgam removal procedure) and other supplements based on hair analysis. He also advocated classical homoeopathic treatment (6C, 12C or 30C preparations, as tolerated) for symptoms of mercury toxicity, and dietary modification for “hypoglycaemia” and “candida”, based on the results of electrodermal testing. He also diagnoses “leaky gut syndrome” based on urine and faecal testing performed by the Great Smokies Diagnostic Laboratory in North Carolina or by ARL in Melbourne.

3.7 Working Party assessment of submissions and interviews

The majority of submissions and interviewees expressed strongly held beliefs concerning the dangers of amalgam. Common themes are that:

1. Mercury is highly toxic.
2. Mercury is released from amalgam fillings and is detectable in blood, urine, CNS, kidney.
3. DMPS challenge demonstrates the presence of an accumulated “body burden” of mercury in people with amalgam fillings.
4. No “safe” level of mercury exposure has ever been found.
5. Patients with amalgam fillings have symptoms characteristic of mercury intoxication.
6. Patients report improvements in health following removal of amalgam fillings.
7. The “weight of evidence” in the literature shows “beyond doubt” that amalgam fillings are hazardous.

On the basis of these considerations, most considered the dangers of amalgam fillings to be established and incontrovertible.

Several submissions also reflected outrage factors described in the risk perception literature [e.g. 12,19,22,27,30].

The fact that the ADA and other official bodies continue to maintain that amalgam is safe is taken in many submissions to be evidence of cover-up and conspiracy.

3.8 Working Party concerns

A number of serious misconceptions were evident from the submissions and from the interviews. Many did not appear to have a clear grasp of:

3.8.1 The relative nature of “safety” and “risk”

Citing a WHO report, the ASOMAT submission states: “... for mercury vapour ‘a specific no-observed-effects-level (NOEL) cannot be established’, meaning that NO level of mercury vapour that can be considered harmless has been found.” [Submission # 38, Part A, page 8]

It is widely recognized that to establish a clear NOEL for any chemical has certain limitations in regard to the end-point measured and the sensitivity of the measurement. However, it is generally accepted that not being able to establish a NOEL does not mean that any level of exposure to a chemical can cause harm (see also 3.8.2).

The IAOMT submission [4] states: “Shockingly, we have not uncovered any formal studies establishing the safety of amalgam mercury exposure. ... Risk assessment studies ... have concluded that patient exposure to amalgam mercury is not without risk. A number of review committees that have promoted conclusions that amalgam mercury is harmless have failed to include these studies in their determinations”.

The understanding of the concept of “risk” has received much attention in toxicological and regulatory circles. To say that something is “not without risk” has little meaning if one considers that there is a finite health risk associated with virtually every human activity and chemical exposure. The real issue is what level of risk do we accept in the context of simultaneous benefits?(For further discussion see Baume, 1991).

3.8.2 The dose-dependence of “toxicity”

Some interviewees considered that mercury was “toxic at all levels”, and when questioned on this asserted that even a *single molecule* could be “toxic” (ie. could “kill” a cell).

This belief is reinforced by statements from Boyd Haley, Professor of Chemistry at the University of Kentucky:

“Any biomedical research scientist with credibility would acknowledge that mercury is toxic at all levels and that a daily, low level dose would lead to an unacceptable health risk. ... [research supports] the contention that mercury and other metals escape from amalgam fillings at significant levels and that soaking amalgams in aqueous solutions renders them ‘severely cytotoxic’.”

There are two important issues here. Firstly, we are all exposed to “background” levels of a multitude of hazardous chemicals. For example, mercury is present at low levels in our environment as a naturally-occurring element in air, water and food. Secondly, the view that a

single atom of mercury (or of anything) can kill a cell is without toxicological foundation. A 70-kg adult is permitted to consume mercury in food at a rate of 50 µg per day. On average, Australian adults consume only about 15 µg per day; this amount is equivalent to 75 nmoles since mercury has an atomic weight of 200 daltons. Knowing Avogadro's Number (6.02×10^{23} atoms per mole), then 75 nmoles (75×10^{-9} moles) is equivalent to 4.5×10^{16} atoms. It is clear that exposure to this number of mercury atoms every day does not have toxic consequences.

3.8.3 The subjective evaluation of clinical experience

- Non-specificity of the symptoms attributed to amalgam “toxicity” (Table 5). There appears to be a strong tendency to attribute almost any disease or symptom of unknown aetiology to the effects of amalgam. This is specially so with neuropsychiatric disorders (Maltet al, 1997).
- Fluctuating natural history of complaints attributed to amalgam “toxicity”— considering the *number* of candidate conditions (Table 5), there is a very high probability that some will appear to improve after amalgam removal through *chance alone*.
- Undefined effects of treatments used in conjunction with amalgam removal, and associated changes in diet, lifestyle, etc; non-specific treatment (“placebo”) effects;
- Lack of independent, objective assessment;
- Misleading conclusions resulting from short-term and incomplete follow-up.

3.8.4 The interpretation of diagnostic information

A clear distinction was not made between biomarkers of *exposure*, biomarkers of *effect*, and markers of *disease or adverse effect*. Some assumed that demonstration of high levels of urinary mercury following ‘DMPS challenge’ was an indication that whatever symptoms a patients may have were likely to be due to mercury intoxication.

Diagnostic test ‘abnormalities’ were frequently misinterpreted in the submissions, and also in some of the published literature:

3.8.4.1 Immunological tests

Skin patch tests— these are markers of *exposure*, and *immunological response*, but not of disease. In relation to clinical contact hypersensitivity (oral lichenoid lesions) they are neither sensitive nor specific. It is inappropriate to estimate the prevalence of clinical hypersensitivity to mercury using patch tests alone.

In vitro lymphocyte proliferation tests— these also have poor diagnostic predictive value (Laine et al, 1997).

Peripheral blood lymphocyte subsets— these tests are quite non-specific. Alterations can be found in relation to age, sex, time of day, hormonal status, cigarette use, alcohol consumption, physical activity, anxiety, use of medications, sun exposure, etc. These are of no clinical significance. Levels do not appear to differ in people with amalgam fillings (Mackert et al, 1991).

3.8.4.2 Neuropsychological tests

Few of those making submissions seemed to appreciate the importance of biases and confounding factors in tests of neuropsychological functioning.

Hartman (1988) makes this clear:

“Neuropsychological testing results from toxicity research are not diagnostic in the same way as medical laboratory results. With few exceptions, toxic exposures do not tend to produce consistent and focal patterns of neuropsychological impairment. Since impairments tend to be non-specific, the study must be constructed as carefully as possible to rule out potential confounding influences” (p 263).

In his hazard analysis, Richardson cited 15 such studies — the “weight of evidence” — said to demonstrate “dose-dependent subclinical impairment” of CNS function in people exposed to mercury in various settings (Richardson M, personal communication, 15 September 1998). However, it appears not to have been recognised that many of the factors which confound these measurements (e.g. age, educational level, dietary habits such as consumption of coffee and alcohol, psychological parameters, etc.) are also likely to correlate with occupational exposure levels or with number of amalgam fillings.

The key study used in Richardson’s risk assessment (Fawer et al, 1983) is a good example. Mackert and Berglund (1997) have identified at least seven major flaws in the Fawer et al study. (see also Section 4.4).

3.8.4.3 Tests of renal function

The presence of elevated levels of N-acetyl-β-glucose aminidase (NAG) in the urine may be regarded as a biomarker of mercury *exposure* from amalgam. However, it has no predictive value in terms of impairment of renal function by amalgam (Sandborgh-Englund et al, 1996).

3.8.5 Removal protocols and concomitant therapeutic regimens

The Working Party was particularly concerned about the apparently widespread use of chelation therapy with DMSA and DMPS. Available evidence does not support their efficacy, and they may give rise to hypersensitivity reactions. One randomised controlled study of 50 patients who attributed illness to amalgam fillings showed no difference in outcome between active and placebo treatment arms (Grandjean et al, 1997). Another randomised controlled trial (RCT) (23 patients having amalgam removal because of suspected toxicity) showed no benefit of DMSA treatment compared with placebo, and had to be terminated prematurely due to the occurrence of hypersensitivity (Sandborgh-Englund et al, 1994).

3.9 Conclusions

3.9.1 A limited number of dental, medical, paramedical practitioners and patients attribute a wide range of diseases and symptoms of unknown aetiology to the effects of dental amalgam. A range of factors may contribute to this clinical situation, not the least of which is a desire to assist people who see them as a provider of last resort.

3.9.2 The attribution of a range of diseases or symptoms of unknown aetiology to the effects of mercury from dental amalgam showed a number of misconceptions about the relative nature of safety and risk, dose-dependence of toxicity, evaluation of clinical experience and interpretation of diagnostic information.

3.9.3 Claims of improvement in health or relief of symptoms upon removal of amalgam restorations may be confounded by diet, lifestyle and placebo effects.

3.9.4 Some dental practitioners engage in the removal of dental amalgam restorations, following protocols for collection of diagnostic information and clinical procedures for which there is a lack of supportive scientific evidence.

3.10 Considerations

3.10.1 The use of chelation therapy with DMSA and DMPS, for patients with symptoms attributed to mercury from dental amalgam restorations is a matter of concern.

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4. RISK ASSESSMENT

4.1 What level of mercury is absorbed?

In order to understand the health risks posed by elemental mercury in dental amalgam, it is important to consider the amount of mercury absorbed from amalgams. There are many data on this, and it is evident that the level of mercury released from amalgams is affected by numerous factors including number of filled teeth and number of surfaces per filling, eating habits including gum chewing, tooth brushing and oral breathing habits, and bruxism. Published studies on mercury absorption often do not take these factors into consideration.

In one recent comprehensive and widely reviewed exposure assessment, in which 60% of the dental mercury exposure was attributed to inhalation of mercury vapour and 40% to ingestion of mercury in saliva, the following data were generated for various fixed numbers of fillings (Richardson and Allan, 1996):-

Table 7. Exposure (mgHg/day) for fixed numbers of fillings

Age group	1	2	4	8	12	20
Toddler	0.3	0.6	1.2	2.4	-	-
Child	0.7	1.3	2.6	5.3	8.0	-
Teen	0.4	0.8	1.6	3.2	4.8	8.0
Adult	0.4	0.9	1.7	3.6	5.3	8.9

toddler, 12kg; child, 40kg; teen, 55kg; adult, 70kg

Some other estimates of dental mercury exposure for the general population are: 3.9-21 µg/person/day (IPCS, 1991); 1.3-27 µg/person/day (Vimy and Lorscheider, 1990); 1-5 µg/person/day (ATSDR, 1994); 12 µg/person/day for a group of 9 volunteers with an average of about 47 amalgam-filled tooth surfaces (Skare & Engqvist, 1994). From a review of 14 independent studies examining the dynamics of amalgam-released mercury levels in blood, urine, brain or kidney, it was concluded that the probable mercury dose from amalgam is below 10 µg/person/day (Halbach, 1994). This is similar to other work suggesting estimates of below 5 µg/person/day (Barregård *et al.*, 1995; ATSDR, 1994) and in the range of 1-2 µg/person/day (Eley, 1997a).

4.2 Australian data on tooth fillings and estimate of amalgam mercury exposure

A major health survey conducted in Australia in 1987-1988 showed that adults between 20 and 64 years of age had, on average, 5 to 10 filled teeth (Barnard, 1993). A study conducted in South Australia in 1995/96 showed a mean number of 8 teeth with fillings for 35-44 years olds (See Section 1.1, Figure 4). Assuming that these fillings are all dental amalgams, then the information in the above table would suggest that 5-10 fillings might be associated with a daily mercury exposure of 2-5 µg. This appears to be in general agreement with estimates of daily amalgam mercury exposure mentioned above. However, it must be stated that such information is simplistic in that it does not take into consideration important issues such as the number or location of filling surfaces. For 12 year old children, intake of about 0.3µg mercury per day might be expected from their mean number of 0.5 fillings per person.

Mercury exposure in the population is not confined to release from dental amalgams, and many data exist on dietary mercury intake. The mean mercury absorption from amalgams, as a proportion of total absorbed mercury (i.e. amalgam mercury / amalgam mercury + dietary mercury and methylmercury), is variously reported as being 50-85% (IPCS, 1991) and 30-50% (Richardson and Allan, 1996). According to the most recent information on Australian dietary mercury intake, the average daily adult intake of mercury (all forms) in food is 15 µg (ANZFA, 1996). It has been estimated that about 40% of dietary mercury will be bioavailable (IPCS, 1991). Thus, taking the above 2-5 µg/person/day intake from amalgams in Australian adults, and 5.8 µg/person/day retained from the diet (i.e. 40% of 15 µg/day), it can be seen that in the Australian context mercury from amalgams represents on average about 25-50% of total body mercury retained. This therefore appears comparable to other reports in the literature. For 12 year old children, average dietary intake of mercury is about 8 µg/day, and exposure to mercury from dental amalgam restorations represents about 4% of total intake.

Reference to mercury bioavailability necessitates mention that there is considerable literature on the pharmacokinetics of elemental mercury. It appears that the overall removal rate of elemental mercury is about the same as the rate of elimination from the kidney, where most of the body burden is localized (half-life ~60 days). One key issue in the current debate concerns the movement of mercury into and out of brain tissue. Elimination from the brain is reported to occur in several phases; an initial rapid phase, a second phase with half-life of 20 days, and possibly a longer terminal elimination phase (Cavanagh, 1988; ATSDR, 1994). Various estimates have been made on the concentration of mercury expected in the brain for mercury arising from dental amalgams, based on different models of brain uptake and elimination (Vimy & Lorscheider, 1990). The difficulty in this area of work will be to determine what concentration is likely to result in central nervous system dysfunction, and to understand the extent and effect of brain mercury arising from sources in addition to amalgam. The Working Party considers that this complex aspect will require close surveillance of research developments.

4.3 Derivation and mercury exposure levels associated with dental amalgam restorations

The data in Table 7 above have been derived using a Monte Carlo analysis (Richardson and Allan, 1996). This computer-generated iterative probabilistic approach was based on the known or assumed population distribution of the following variables in the Canadian population:

- mercury release rate per amalgam-filled surface
- stimulation magnification factor
- lasting effect of stimulation
- inhalation absorption factor
- ingestion absorption factor
- numbers of filled teeth
- number of surfaces per filling
- eating, tooth brushing, sleeping and oral breathing habits
- body weight

Similar estimates of average mercury exposure were computed with an approach that only considered inhalation of mercury vapour (Richardson and Allan, 1996). This approach took into account empirical associations reported between the numbers of amalgam-filled teeth and a biomarker for mercury inhalation exposure (urine [Hg], µg/g creatinine), and between this biomarker and quantified inhalation exposure to mercury vapour.

The work of these authors probably represents the most comprehensive amalgam mercury exposure analysis published to-date. However, this recent work has been the subject of major reviews and major criticisms. It is beyond the brief of this Working Party to comment on the issues raised by others. Any future official review of this area will need to address these issues in depth.

4.4 At what level does absorbed mercury elicit adverse health effects?

When urinary levels of mercury exceed 100 µg/g creatinine signs of mercury toxicity are usually obvious clinically. The target organs principally involved are the brain and the kidney. The most prominent symptoms are usually changes in mood, memory and intellectual function, development of tremors, reduced reaction times and proteinuria.

A series of studies undertaken over the past 30 years have suggested that abnormalities are detectable using a variety of sensitive tests at substantially lower levels of exposure. However, there are no studies which have compared groups of dental patients with and without amalgams to determine whether there may be differences in symptoms associated with mercury neurotoxicity. The studies which have examined adverse health effects of mercury have compared psychomotor performance and various mood and behaviour scales in groups of individuals either exposed or not exposed to metallic mercury in their occupation.

Most of these studies have performed a battery of tests on the participants and found the average reading of some of these to be different in the exposed and unexposed groups. None have reported clear-cut illness amongst those exposed and in most cases the difference between the test results in those two groups has been small.

This is probably the most important and contentious issue of the present debate. In order to ascertain the mercury levels which are causal for neurotoxicological endpoints, it is necessary to examine reports of occupational exposures to mercury where such endpoints have been recorded. Recently, this exercise has been attempted by various groups, including the US-EPA (US-EPA, 1996), the US Agency for Toxic Substances and Disease Registry (ATSDR, 1994), and Richardson and Allan (Richardson and Allan, 1996) in an effort to establish a No-Observed-Adverse-Effect Level (NOAEL) or a Lowest-Observed-Adverse-Effect Level (LOAEL).

A range of occupational mercury exposure studies has been examined by these groups, who concluded that no study published has revealed a NOAEL; in other words, a threshold for mercury effects has not been noted. This may be due not so much to a real lack of a threshold but to a deficiency in the study design in exposure-response analysis. Nonetheless, one of these studies has been selected in common by the above-mentioned groups as providing the best data on a LOAEL for neurotoxicity of mercury in humans.

The study in question examined intention tremor of the forearm in a group of 26 male workers exposed to metallic mercury in several fluorescent tube factories, in an alkali plant, and in an industrial plant which produced acetaldehyde (Fawer et al., 1983). The time-weighted average air mercury exposure was $26 \pm 4 \mu\text{g}/\text{m}^3$; a group of 25 non-exposed workers served as control.

It is not the purpose of the current exercise to examine the Fawer et al. study in detail, but a fuller review would need to accomplish this task. The reason for this is that the data from the study have been used in setting health-based guideline values for air mercury levels. In one approach, Richardson and Allan derived a Tolerable Daily Intake (TDI) based on several assumptions and use of safety or uncertainty factors (Richardson and Allan, 1996). [A TDI is defined as an estimate of the intake of a substance which can occur over a lifetime without appreciable health risk.] This is a standard toxicological method for establishing guideline values for xenobiotics in various exposure media. The

TDI thus generated (i.e. 0.014µg/kg/day), together with computed information on mercury release from dental amalgams, has been used to suggest a maximum number of amalgam fillings for which the TDI would not be exceeded. The exercise conducted by Richardson and Allan using two exposure models generated values of 2-4 amalgams for adults, while a separate TDI derivation reported by Eley generated a value of 14 amalgams per adult (Eley, 1997c). Clearly, adopting one or other of these guidelines would greatly influence public health policy in relation to continued use of dental amalgam.

It can be said that the use of the Fawer et al. data for risk assessment, and the TDI approach and safety factor selection by Richardson and Allan, have attracted considerable criticism, which has been amply published. Again, it is beyond the brief of this exercise to document these criticisms; this would require a larger expert panel of toxicologists.

Nevertheless, listed here are some of the criticisms of the Fawer et al. paper which are apparent to this present Working Party:

1. There is a lack of information on other chemical exposures.
2. It is not clear how to assess the clinical significance of hand tremor.
3. Blood mercury in the exposed group is given as 41.3µM, which is 8.3 mg/L (the IMVS toxicology laboratory reports that the blood upper limit for occupational exposure to mercury is 0.45 µM or 0.09 mg/L), while in the control group blood mercury is given as 16.6µM, which is 3.3 mg/L (IMVS report <0.25 µM or 0.05mg/L for non-occupationally exposed people). The extraordinarily high blood mercury levels are without explanation. [The work of others has indicated that the air mercury levels experienced by the workers in the above study (26µg/m³) would be expected to yield only about 0.37µM of mercury in the blood (see Eley, 1997b), far less than the 41.3 µM reported by Fawer et al.]
4. There is lack of information on mercury-air exposure in controls. However, blood and urine levels of mercury in controls would suggest that they were exposed to about one-third the mercury-air levels as the exposed group. In such a case, it would seem illogical to use a Safety Factor of 10 for deriving a NOAEL from the LOAEL; this generates a NOAEL which is lower than the likely mercury-air level of the control group.

Indeed, one of the authors of the Richardson and Allan (1996) publication agrees that the Fawer et al. paper is poor for risk assessment purposes, but has indicated it was used because it was often what other agencies had used, eg USEPA, ATSDR. It appears, however, that in spite of this acknowledgement of deficiency in this key paper, its use is being justified on the grounds that it is representative of many more studies showing some indication of subclinical neurological manifestation of mercury toxicity. There is now a substantial number of other studies conducted in various occupational settings and an assessment of the overall results of these studies should supersede undue reliance on the Fawer study.

The Working Party devoted considerable effort to the consideration of the 15 studies placed before it by Richardson (15 September, 1998). These 15 studies include those used by Richardson and Allan (1996), but extend up to 1998. These studies are summarised in Table 8. A number of general concerns were raised.

First, use of industrial and dental occupational studies to estimate a LOAEL has focussed on published studies with “suggestive” or positive associations between mercury exposure and one or more end points. Little recognition has been given to studies with equivocal findings. There is a possibility of a selection bias in the studies reviewed. The Working Party has not conducted a systematic review of

industrial and dental occupational exposure to mercury and neurotoxicological outcomes. However, conclusions about the lowest effect levels for mercury could be modified if omitted studies, unpublished 'negative' or equivocal studies, or 'negative' studies published in less widely available journals were to be found.

There exists a small number of 'negative' studies involving large groups of workers exposed occupationally to mercury. The dose-response relationships in these studies suggested thresholds for mercury toxicity considerably greater than those surmised or extrapolated from the larger number of positive studies. It is apparent also that the few 'negative' studies are sometimes not acknowledged by those espousing the concept of no threshold for mercury toxicity and by those seeking the lowest LOAEL. A careful review of these 'negative' studies should be undertaken.

An example of a potentially important study not receiving attention is that of Smith et al (1970) which examined large numbers of chloralkali plant workers in the US and Canada. (The number of study subjects was 10 times that included in the Fawer et al (1983) study).

Second, all the studies have case and control designs that leave open questions of bias. This is more likely with the small sample sizes involved and the less than desirable attention given in some studies to pre-existing conditions, other potential exposures (multiplicity) and control of known influences (confounding). It is possible that the effects noted were pre-existing and were more common amongst individuals selected for work in the relatively "dirty" exposure conditions in industry. Few studies have taken account of confounders such as alcohol consumption, which may have been more common amongst those assigned to the "dirtiest" jobs.

Third, variation exists in the exposure measurement (personal air, blood, urine /creatinine ratios, challenge or unchallenged) which adds complexity to the comparison of studies or conversion to common units of exposure.

Fourth, variation exists in the end points used (kidney function or neurobehavioural function) and specific tests employed. Studies include sizeable batteries of tests, leading to an increased chance of significant findings for single tests.

Fifth, nearly all the studies are cross-sectional and therefore they report associations at a point in time. Time precedence is not established and therefore an important element in causality is not known.

Sixth, most of the studies test group differences between exposed and control subjects. Some lack controls. For some controls exposure data are not provided. Few explore dose-response within exposed subjects. Hence, frequently all levels of mercury exposure of the 'exposed' subjects are included in the estimation of LOAEL. Richardson and Allen (1996) present the full range of mercury exposure in 'exposed' subjects in their representation of the LOAEL, and more recently Richardson (1998) has averaged all exposures. This fails to adequately consider dose-effect and the existence of a threshold required for exposure to produce an adverse health effect. It could be argued this is a conservative approach, but it requires careful assessment before acceptance of estimated LOAELs.

Neither should the number of studies available with "similar" results on adverse health effects of mercury be taken as support for a lowest observed adverse-effect level. If each study has limitations, some unavoidable given their design, then each study does not add to a weight of evidence confidently ascribing the effects to mercury exposure.

The Working Party considered the systematic review and analysis of studies on occupational exposure to mercury as important to provide a balanced and complete perspective of levels at which mercury exposure shows adverse effects. Considerable work will be required to review these studies, convert exposure measures to common units, examine the methodology employed and establish whether one or

more of these should be regarded as a pivotal study. An extensive search should be made for unpublished negative studies. The results of the individual batteries of neuropsychological tests should be examined to determine whether any consistencies exist in nature of the tests shown to be positive and negative.

We have not conducted a systematic search of cohort studies of workers involved in industries with exposure to mercury. If such studies can be identified and if they involve exposure that is much greater than would be produced by dental amalgam then these may be of value in providing reassurance or in pointing to potential long-term health effects.

Table 8. Studies of adverse health effects of mercury

Authors	Design & Study Description	Exposure levels		End Points	Outcomes ¹	
Fawer et al, 1983	Cross-sectional study of industrial mercury vapour exposure among 26 cases from glass blowers, chloralkali plant and chemical industry male workers, and 25 controls from the same factories.	Air sampling, urine and whole blood. Duration exposure (yrs) Air (personal) exposure (mg/m ³) Hg urine (µmol/mol creatinine) Hg blood (µmol/L)	Exposed 15.3 0.026 11.3 41.3	Controls - - 3.4 16.6	Hand tremor, at rest and with weight using accelerometer	Increase hand tremor. No dose response relationship defined. [Mean 0.026mg/m ³ taken as LOAEL].
Echeverria et al, 1995	Cross-sectional study of occupational exposure among 19 exposed dentists and 20 unexposed dentists.	Urine sampling Hg urine (µg/L)	Exposed 36	Unexposed not detectable	Vocabulary, mood scale, symptom questionnaire and six behavioural tests: digit span, symbol digit substitution, simple reaction time, ability to switch between tasks, and One Hole Test Control for age, race, gender and alcohol consumption.	Vocabulary, two symptoms, and mood score associated with urine Hg. Pooled sum of behavioural test associated with urine Hg, but not individual tests. [LOAEL mean urinary level for exposed group of dentists].
Gonzalez-Ramirez et al, 1995	Cross-sectional study of occupational exposure among 5 dentists, 10 dental technicians and 13 non-dentists. Little use of encapsulated dental amalgam, leading to high occupational exposure.	Urine sampling 6hrs before and after DMPS challenge Dental technicians Dentists Nondental personnel	Excretion (µg/L) Before 29.7 19.8 3.00	After 481.0 275.0 37.2	Vocabulary, mood scale, symptom questionnaire and behavioural tests. Control for age, alcohol consumption, eye glass wear and vocabulary.	Symptoms, mood and some behavioural tests associated with post chelation urinary Hg.
Ngim et al, 1992	Cross-sectional study of occupational exposure among 98 dentists and 54 controls, Singapore.	Mercury monitored by personal air sampling badges and blood samples Air Hg vapour (mg/m ³) Average duration (yrs) Hg blood (µg/L)	Exposed 0.014 5.5 9.8		Neuro-behavioural tests (10) and intelligence tests (4) Controlled for age, sex, education, dental fillings, smoking, alcohol, fish, Chinese traditional medicine consumption.	Dentists score significantly worse in the neuro-behavioural tests. Dose-response tested within exposed dentists.

¹ LOAEL when noted is taken from Richardson GM. Mercury exposure from dental amalgam: re-evaluation of the Richardson model, standardization by body surface area, and consideration of recent occupational studies. Ottawa: O'Connor Associates Environmental Inc., 1998

Table 8. Studies of adverse health effects of mercury (Cont^d)

Authors	Design & Study Description	Exposure levels			End Points	Outcomes ¹
Soleo et al, 1990	Cross-sectional study of industrial mercury exposure among 8 chronically exposed, 20 occasionally exposed and 22 control workers from the same factory.	Urine sampling over 1979-1987 Chronic Occasional Control	Hg urine (µg/L) 18.2 11.7 8.5		Neuro-behavioural tests- personality traits, reaction time, recognition, dexterity, digit span, digit symbol, clinical depression. No controlling variables.	Short-term memory impaired, more depression and some personality changes
Liang et al, 1993	Cross-sectional study of 88 workers in a fluorescent lamp factory exposed to mercury vapour matched with 70 non-exposed controls from an embroidery factory.	Air and urine samples Air Hg (mg/m ³) Duration at least 2 yrs Mean (yrs)	0.033 10.4	Exposed Controls not detected	Neuro-behavioural tests - Profile of Mood States and 10 tasks in a computer - administered neuro-behavioural evaluation system. Include intelligence, memory, vision perception and psychomotor areas. Control for age as a confounder.	Negative mood state found for fatigue and confusion. Poorer performance with mental arithmetic, switching attention and two-digit search tests. Evidence of cumulative effects with long-term exposure.
Piikivi and Tolonen, 1989	Cross-sectional study of 41 exposed workers in a chloralkali plant and a matched group by age and sex of workers in mechanical wood processing plants	Blood and urine samples Exposure (estimated) Air (mg/m ³) Duration (yrs) Hg blood (total) (µmol/L) Hg urine (µmol/mol creatinine)	Exposed 25 15.6 58.0 11.6	Controls 15 18.8 1.1	Electro-encephalograph.	Tendency for increased number of EEG abnormalities on visual inspection. Exposed workers had significantly slower and more attenuated EEGs than the controls. No clinical pathology [LOAEL is the mean urinary Hg in the exposed workers].

Table 8. Studies of adverse health effects of mercury (Cont^d)

Authors	Design & Study Description	Exposure levels			End Points	Outcomes ¹
Roels et al, 1982	Cross-sectional study of 43 exposed workers from electric storage battery and chloralkali plants and 47 controls from the same plants.	Blood and urine samples Hg blood (µg/100ml) Hg urine (µg/g creatinine) Yrs of exposure	Exposed	Controls	Renal function and psychomotor tests- orthokinesimeter test and hole tremometer test.	Increased proteinuria and albuminuria among exposed workers. Psychomotor tests less satisfactory in exposed workers, especially arm-hand steadiness. No clear-cut relationship found between psychomotor scores and Hg blood or Hg urine. Exposed group divided into three by urinary Hg concentration. Higher urinary Hg groups showed some differences [LOAEL is lower limit of urinary Hg concentration interval (50-99.9 µg/g creatinine) that demonstrated significant impairment].
Roels et al, 1985	Cross-sectional study of 131 male workers and 54 female workers exposed to mercury vapour from a range of Belgian plants and 114 male and 48 female control workers from mercury-free plants.	Blood and urine samples Exposure (yrs) Hg blood (µg/dl) Hg urine (µg/g creatinine)	4.8 Exposed Male Female	Controls Male Female	Symptoms, central nervous system tests- simple reaction time, critical flicker fusion, colour discrimination, short-term memory and hand tremor and renal function.	Symptoms (memory disturbances, depressive feelings, fatigue and irritability more prevalent in exposed workers, but not related to exposure parameters. No significant differences in short-term memory, simple reaction time, critical flicker fusion, or colour discrimination ability. Increased renal tubular activity. No difference in females in hand tremor. Males with longer term exposure, > 10 years, showed preclinical signs of tremor. Authors indicated the relative safety of urinary Hg less than 50 µg/g creatinine. [LOAEL is mean urinary Hg concentration for exposed group (females)].
Roels et al, 1989	Cross-sectional study of 54 male exposed workers from chloralkali and dry alkaline battery plants and 48 control workers from the same plants.	Blood and urine samples Exposure (yrs) Hg blood (µg/dl) Hg urine (µg/g creatinine)	Exposed 7.7 3.32 75.0	Controls 0.25 1.8	Hand tremor measured by an accelerometer and two psychomotor tests: eye hand co-ordination and hand steadiness.	Preclinical alterations in hand steadiness and eye-hand co-ordination. No dose-response relationship. No significant differences in accelerometer tests. [LOAEL is mean urinary Hg concentration in exposed group].

Table 8. Studies of adverse health effects of mercury (Cont^d)

Authors	Design & Study Description	Exposure levels	End Points	Outcomes ¹	
Ritchie et al, 1995	Cross-sectional study of two groups of dentists (20 older dentists and 19 trainees), Scotland, and two-age matched control groups (mainly doctors).	Urine samples Hg urine (nmol/mmol creatinine) Older Younger	Dentists Control 3.65 0.95 1.8 1.25	Computerised cognitive and motor skills assessment (8 tests) (Cognitive Drug Research). Also a general health questionnaire.	All urinary Hg within occupational limits. Five (of 8) psychomotor tests showed no differences between the four groups. Older dentists showed significantly better performance on simple reaction time and poorer performance on immediate word recall and delayed word recall tests. [LOAEL is mean urinary Hg concentration in older exposed dentists].
Gunther et al, 1996	Repeated measurements (4 rounds) of 14-21 high exposed and 34-50 low exposed chloralkali workers and 37-43 control workers from non-exposed departments of a factory (first three rounds only). 14 high exposure, 33 low exposure workers participated each of 4 rounds and 30 controls participated in 3 rounds.	Urine samples Exposure (yrs) Hg urine (µg/L) Round	12 Low exposure High exposure 1 26 2 28 3 22 4 23	Psychological examination including symptom questionnaire, personality, amnesic function and attention, sensorimotor functions and coordination functions. Age, verbal intelligence and gender controlled.	Symptoms and personality traits did not vary significantly with exposure. Finger dexterity, tapping and aiming were 3 out of 13 performance measures which showed lower performance with increasing current exposure. No dose-response could be demonstrated. Cognitive deficits above 50 µg/L urinary Hg not confirmed. Fine motor function deficits at 50-150 µg/L.
Cavalleri et al, 1995	Cross-sectional study of 33 exposed workers in four factories making precision instruments matched with 33 referents for sex, age, alcohol consumption and cigarette smoking.	Urine sample Exposure (yrs) Hg urine (µg/g creatinine)	8.3 Exposed 28-287	Colour confusion tests	Subclinical colour vision loss, mainly in the blue-yellow range. Urinary Hg > 50µg/g creatinine can induce colour vision loss [Lowest urine Hg value selected as LOAEL because no threshold].

Table 8. Studies of adverse health effects of mercury (Cont^d)

Authors	Design & Study Description	Exposure levels			End Points	Outcomes ¹
Langworth et al, 1997	Cross-sectional study of 22 dentists and 22 dental nurses at 6 Swedish dental clinics and 44 age and sex matched controls.	Air, blood and urine samples			Neuro-behavioural symptoms and questionnaires- Q16, Eysenck Personality Inventory and Profile of Mood Scales- physical examination and renal function (excretion albumin and NAG).	Air levels were influenced by method of amalgam preparation and inserting, and by the method of air evacuation during drilling and polishing. Duration of exposure did not influence Hg in biological samples. Physical examinations showed normal outcomes. Positive answers Q16 higher exposed group. No differences EPI questionnaire. With POMS, only anger was higher in the exposed group. Correlations symptom, questionnaire scores and exposure measures not significant. No significant differences in renal function. [LOAEL is mean urinary Hg concentration for exposed group].
		Hg Air (µg/m ³)				
		Dental nurse	3.1			
		Dentist	2.9			
		Stationary point	3.0			
				Exposed		
Hg blood (nmol/L)	18	18				
Hg plasma (nmol/L)	5.1	4.2				
Hg urine (nmol/mmol creatinine)	3.0	2.3				
Echeverria et al, 1998	Cross-sectional study of 34 dentists and 15 dental assistants.	Urine Hg samples before and after DMPS challenge.			Neuro-behavioural tests, including symptoms, Profiled Mood States, hand steadiness, simple reaction time, finger tapping, one-hole pins, vocabulary, recognition memory test, trail marking, visual retention test, switching task and symbol digit. Control for age, race, sex, vocabulary and wearing eyeglasses.	Unchallenged urinary Hg represented as recent exposure while post-chelation urinary Hg represented as Hg body burden. Associations between Hg and symptoms, mood, motor functions and non-specific cognitive alterations, in task performance.
		Hg urine (µg/L)	Pre chelation	Post chelation		
		Number of amalgams placed/week, wearing a mask and number of amalgams in own mouth associated with pre-chelation Hg urine.	0.9	9.1		

4.5 Other comments on TDI and TDI exceedance

As mentioned previously, one component of generating a TDI involves dividing the NOAEL or LOAEL by a set of safety factors (SF). These are employed when developing a 'safe exposure' guideline value by extrapolating from a particular set of exposure-response data to a general human exposure scenario. In the absence of specific information on, for example, a NOAEL and the inter- and intra-species variability of response, SF serve to ensure a conservative final guideline value. As stated earlier, the US-EPA and Richardson and Allan have both used the data from the Fawer et al (1983) study as the starting point for setting a guideline value for mercury. In comparing SF employed, the US-EPA has used a total SF of 30, comprising 10 for sensitive human subpopulations (i.e. intra-species variability) and for use of a LOAEL, and 3 for lack of data base, particularly developmental and reproductive studies (US-EPA, 1998). However, Richardson and Allan used a total SF of 100, being 10 for use of a LOAEL rather than a NOAEL and 10 for sensitive human subpopulations (Richardson and Allan, 1996).

Clearly, use of different total SF by different groups of risk assessors will result in disparate final guideline values. One frustration with understanding any reported SF is that the precise justification of choosing or not choosing a particular SF is rarely discussed in great detail. Further, it is well-known that SF selection is based largely on subjective judgement which is best arrived at by consensus agreement amongst a group of toxicologists.

Finally, it is important to make the point that TDI approaches are generally conservative so that minor exceedance of the TDI is usually not considered to engender a health risk. However, it is difficult to determine at what dose above the TDI significant health risk becomes a concern. In the case of mercury it would clearly be desirable to have a very large safety margin if this were practical. However, at present there is a substantial margin between the intakes of mercury associated with the effects observed in humans and the intake of mercury from a limited number of amalgam restorations.

4.6 Toxicological information on alternative resin-based restorative materials

On various occasions during the numerous discussions and interviews conducted by the Working Party, the issue of alternative dental restorative materials (composite resins) was raised. This has principally been in the context of their toxicologic potential *vis-à-vis* mercury in amalgam. The Working Party therefore considered that it was worthwhile to briefly and generally summarize current knowledge on the toxicity of the many components that constitute composite resins. Inorganic components such as silica and other glass materials are essentially inert, so the focus here will be the approximately 20 organic components which are being used.

From a qualitative viewpoint, there is a dearth of information on these 20 components. One recent review indicated that for 9 of these compounds there were *non vivo* toxicity data, 6 were lacking mutagenicity or genotoxicity data, while for 17 there were no carcinogenicity data (Mjör and Pakhomov, 1997). On the other hand, several compounds were positive in genotoxicity tests. Also, for methacrylic acid, Bis-GMA, formaldehyde, MMA, benzoyl peroxide, 2-hydroxy-4-methoxy-benzophenone and *p*-methoxyphenol there is evidence of epithelium irritation and/or allergic sensitisation.

Regarding the quantitative aspects of release of composite materials from dental restorations, again scant information is available. For most components, nothing is known of their release rates. An attempt to estimate the amount of release of silica, BisGMA, formaldehyde and methacrylic acid from composite resins has suggested mean daily release rates of 1.14µg/kg, 0.41µg/kg, 0.02µg/kg and 3.3x10⁻⁵ µg/kg body weight, respectively (Richardson, 1997). This author concluded that these rates would not present an appreciable health risk. However, for all other composite materials, it is

acknowledged that the insufficient quantitative and qualitative data makes it impossible to fully assess their toxicity to humans.

This Working Party wishes to point out that there is a clear need for a comprehensive review of this area and for more toxicological research on composite materials to be undertaken. Furthermore, information on the health risk uncertainty associated with alternative composite resins should be provided to dentists and patients.

4.7 Conclusions

- 4.7.1 Mercury is released at a slow rate from dental amalgams, generally of a few micrograms per person per day among adults, the amount being dependent on many variables including number and shape of fillings, eating habits, and bruxism.
- 4.7.2 For the current mean numbers of amalgam fillings in Australian children and adults (0.5 and 8, respectively), a reasonable estimate of daily mercury absorption per person is about 0.3 μ g and 3.5 μ g, respectively. In comparison, dietary mercury retained in the body is, respectively, about 10-fold and 2-fold higher than these amounts.
- 4.7.3 Attempts have been made to determine the safe level of mercury exposure in humans. The main approach has involved studying people occupationally exposed to mercury in air, and examining a range of subclinical symptoms of neurotoxicity, e.g. hand tremor. While this has been taken further by some risk assessors and combined with safety factors to generate a Tolerable Daily Intake, the Working Party has serious reservations about the quality of data used in such calculations.
- 4.7.4 Of recent studies of exposure to mercury in industry and dental occupational settings, no study was identified which reported clear-cut illness amongst those exposed to mercury.
- 4.7.5 No studies have been completed which have compared the health outcomes among dental patients with and without dental amalgams to determine whether there may be differences in symptoms associated with mercury neurotoxicity.
- 4.7.6 For the numerous compounds used in alternative restoration materials, it is evident that for most there has been little or no toxicological testing and analysis of release rates from fillings.

4.8 Considerations

- 4.8.1 Special initiative status should be awarded to research projects that address issues of the effectiveness of alternative restorative materials for direct restorations of occlusal and approximal surfaces of permanent teeth, the release of mercury from amalgam restorations, the health-related effects of mercury from dental restorations, and the efficacy of the removal of dental amalgam restorations (singularly or in combination with other interventions).
- 4.8.2 It is desirable to move toward alternative direct restorative materials to dental amalgam. However, the alternative direct restorative materials, which are being increasingly used have been infrequently studied in terms of their toxicology. Therefore, such toxicological research is a high priority.

- 4.8.3 The quality of data readily available in published reports on the adverse health effects of low levels of mercury is a matter of concern. The concerns include selectivity in the use of studies, multiplicity of exposures, pre-existing conditions and confounding. Further, a number of studies identified with 'suggestive' or positive findings of sub-clinical effects, are methodologically flawed or have interpretational problems that fail to add to a 'weight-of-evidence'.
- 4.8.4 The potential encroachment of intake of mercury from dental amalgams on the safety margin for the lowest-observed-adverse-effect level is sensitive to the safety factor used. Some published work uses more conservative safety factors than necessary given that the observed adverse effects are minor and subtle.
- 4.8.5 The safety factor between exposure and adverse health effects from mercury could be contrasted with that of other heavy metals, particularly lead.
- 4.8.6 This is a need for closer surveillance of the growing literature on the pharmacokinetics of elemental mercury, from the diet and dental amalgams, especially with regard to the central nervous system and renal function.

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5. POLICY ON MERCURY AND DENTAL AMALGAM: INTERNATIONAL RESPONSE

5.1 Synopsis of international reports

Mercury and dental amalgam in dentistry have been under increased scrutiny in numerous countries over the last few years. Much of the most recent consideration of mercury and dental amalgam seems to have been initiated in response to the risk assessment conducted by Richardson for Health Canada in 1996. The Working Party identified a number of international reports from 1996 to 1998. These included:

- Health Canada. The safety of dental amalgam. Ottawa: Minister of Supply and Services, Canada, 1996.
- Conseil d'évaluation des technologies de la santé du Québec (CÉTS). The safety of dental amalgam - a state of the art review (CÉTS 97-3 RE). Montreal: CÉTS, 1997.
- World Health Organization. Consensus statement on dental amalgam, 7 March 1997. Geneva: WHO, 1997.
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- US Environmental Protection Agency. Mercury Study Report to Congress. Vol. V: Health effects of mercury and mercury compounds. Washington, DC: US Environmental Protection Agency 1997.
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- Cuttress TW (in collaboration with Godfrey ME, Miller JH, Whyman RE). Dental amalgam and human health - current situation. Prepared for the New Zealand Ministry of Health. Wellington: Ministry of Health, 1998.

An overview and synopsis of each of these reports is presented in Appendix C.

Information from these reports has been summarised in Table 9. The reports are noteworthy for their similarity, variation occurs only occasionally and is limited to only two issues.

5.2 Similarities

Where mentioned all the reports concur that mercury is released from dental amalgams. Mercury is released in small amounts, between 1-5 µg per day in adults, contributing detectable amounts to the body. Levels of mercury released from dental amalgam restorations were considered not to approach those recognised to cause harmful effects, although one report noted that the mercury released might be affecting people adversely, but the evidence was inadequate.

Mercury released from dental amalgams was considered not or very unlikely to have links with specific diseases, with the exception of a very few cases of hypersensitivity.

Concerns were expressed about specific or susceptible populations.

Developing organisms are considered the most sensitive sub-populations. Mercury can cross the placental barrier and be taken up by the foetus. Susceptible population groups, those which may experience more severe adverse effects or effects at lower exposure levels might include children.

Therefore, concerns exist for the use of dental amalgam in pregnant women (placement or replacement). Further, dental amalgam should be avoided, where possible, in children's primary teeth. These concerns do not derive from evidence, but from a combination of uncertainty and application of general public and environmental health principles. Such principles dictate to reduce exposure to mercury where safe and practical alternatives exist. This is considered a prudent response.

Other materials do exist that are as well suited as dental amalgam in certain circumstances. However, there are still clinical situations where dental amalgam, because of its ease of handling and good physical properties, is the material of choice.

No evidence exists to justify the removal of dental amalgam restorations to relieve certain symptoms or treat particular conditions (other than hypersensitivity).

Preventive and 'conservative' or 'minimum intervention' approaches could continue to reduce exposure to mercury from dental amalgams.

5.3 Differences

Only in two areas are differences in interpretation noted.

First, a number of reports have regarded impaired kidney function as possible at sub-clinical levels of exposure to mercury. On this basis dental amalgam is to be avoided in people with impaired kidney function. On the other hand, some reports have stated no conclusion with regard to persons with pre-existing renal disease. Sandborgh-Englund (1998) has found no detectable signs of kidney dysfunction associated with amalgam removal. Further, Sandborgh-Englund et al (1996) have stated that elevated levels of N-acetyl- β -glucose aminidase (NAG) has no predictive value in terms of impairment of renal function by amalgam restorations. The UK Committee on Toxicity of Chemicals in Foods, Consumer Products and the Environment (COT) concluded that mercury from amalgam was not associated with nephrotoxicity, but no conclusion could be drawn on the effects of mercury from amalgam restorations on persons with pre-existing renal disease. Whether persons with pre-existing renal disease are a susceptible population remains unclear. There appears to be little evidence that renal insufficiency increases the likelihood of mercury toxicity or that the mercury released from dental restorations is more likely to worsen disease in those with pre-existing renal insufficiency. Both propositions appear unlikely given the low concentrations of mercury involved but need to be researched in more depth before we can make recommendations.

Second, some reports have concluded that the available clinical data are not reliable enough for establishing a Tolerable Daily Intake (TDI). Further, Health Canada (1996) expressed concern about the interpretation of any TDI established. On the other hand, the US Environmental Protection Agency (1997) proceeded with the establishment of an Inhalation Reference Concentration, but expressed only 'medium' confidence in the estimate.

The Working Party was supportive of the estimation of a TDI, with appropriate explanation about its meaning in any information made available to practitioners and the public. There is a steadily accumulating literature on studies of the possible adverse health effects of low levels of mercury. There is also a greater emphasis on the systematic review of the evidence of all health matters. This includes a literature providing a methodology for systematic reviews and meta-analysis. The Working Party considered that a targeted review of the adverse health effects of low levels of mercury would be

advantageous and a contribution to the international discussion of mercury and dental amalgam in dentistry.

Table 9. Summary of recent international reports on dental amalgam and mercury in dentistry

	Health Canada 1996	Conseil d'évaluation des technologies de la santé du Québec (CÉTS) 1997	World Health Organization 1997	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) 1998	US Environmental Protection Agency 1997	Research Council Committee (FRN) Sweden 1998	Cutress New Zealand 1998
Mercury released from dental amalgams	Yes Contribute detectable amounts to the body	Yes	Yes Small amount	Yes 1-5 µg per day	-	-	Yes Small amounts
Whether levels released approach those recognised to cause harmful effects	No	Might be affecting people adversely, but evidence inadequate	No	No Free of systemic toxicity	-	-	-
Links with specific diseases	Not in general. However, small percentage of population hypersensitive	Very unlikely	No	Very few cases of hypersensitivity occur	-	No scientific proof of wider medical system-wide effects	Allergy or sensitivity reaction
Concerns in specific or susceptible populations	Recognition of transport across placental barrier. Impairment of kidney function at sub clinical levels of exposure	Dental amalgam be avoided, where possible in children's primary teeth, in pregnant women and in people with impaired kidney function	-	No conclusion with regard to persons with pre-existing renal disease. Mercury can be taken up by the foetus. No evidence that placement/removal dental amalgam fillings during pregnancy is harmful.	Developing organisms most sensitive sub-populations.	-	-

Table 9. Summary of recent international reports on dental amalgam and mercury in dentistry (Cont^d)

	Health Canada 1996	Conseil d'évaluation des technologies de la santé du Québec (CÉTS) 1997	World Health Organization 1997	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) 1998	US Environmental Protection Agency 1997	Research Council Committee (FRN) Sweden 1998	Cutress New Zealand 1998
Specific concerns on use of dental amalgam	Advisable to avoid procedures using dental amalgam in pregnant women or individuals with kidney disease.	-	-	Mercury from amalgam not associated with nephrotoxicity. Prudent to avoid, where clinically reasonable, the placement or removal of amalgam fillings during pregnancy	-	-	Possible adverse effects on health of some susceptible people
General concerns	Risk management principles - reduce exposure to mercury where safe and practical alternatives exist	Concerns do not derive from evidence, but from combination of the uncertainty in the literature and application of general public and environmental health principles	-		-	-	-
Establishing a TDI	Available clinical data not reliable enough. Concern about misunderstanding of TDI	-	-	-	Inhalation reference concentration estimated, with 'medium' confidence in the estimate	-	A matter of contention

Table 9. Summary of recent international reports on dental amalgam and mercury in dentistry (Cont^d)

	Health Canada 1996	Conseil d'évaluation des technologies de la santé du Québec (CÉTS) 1997	World Health Organization 1997	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) 1998	US Environmental Protection Agency 1997	Research Council Committee (FRN) Sweden 1998	Cutress New Zealand 1998
Removal of dental amalgam fillings	Not warranted	Any potential benefit very uncertain	No evidence that general symptoms are relieved	-	-	No evidence that removal will lead to actual improvement in the general level of health	Difficult to justify on available clinical or scientific evidence
Benefits	-	Clinical situations exist where no other material is as well suited as dental amalgam. Short- and long-term costs of other materials substantially higher	Wide indications for use, ease of handling, good physical properties	-	-	-	-
Other	-	Preventive and conservative treatment could reduce unnecessary exposure to mercury from amalgam fillings	Collection and recycling technology to reduce environmental pollution. Occupational exposure in dentistry a potential risk.	Occupational exposure of concern	-	Swedish Parliament's decision to phase out for environmental reasons the use of dental amalgam as soon as satisfactory replacement material is available was noted	Higher levels of mercury in blood and urine of dental personnel, but health problems similar to those with no occupational exposure

5.4 Considerations

- 5.4.1 An emphasis should be given to population and personal dental caries preventive measures to reduce the incidence of caries requiring any type of direct restorative treatment.
- 5.4.2 Application of general public health and environmental health principles dictate that where possible exposure to mercury be reduced where a safe and practical alternative exists.
- 5.4.3 The trend toward the use of alternative direct restorative materials in the deciduous and permanent teeth of children be encouraged as a prudent measure.
- 5.4.4 During pregnancy it is prudent to minimise exposure to all foreign substances including materials used in dental restorations. This indicates that placement or replacement of dental amalgam restorations should be avoided, especially during the first trimester.
- 5.4.5 Since the kidney is a target organ for elemental and inorganic mercury it could be prudent for exposure to mercury to be minimised in persons with existing kidney disease.
- 5.4.6 Dentists should be aware of the remote possibility of allergic hypersensitivity to mercury from amalgam restorations.
- 5.4.7 The NHMRC guidelines on dental amalgam hygiene be followed to reduce occupational and patient exposure to mercury in dental practices and environmental exposure to mercury from dental amalgam waste.

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APPENDIX A.

Draft version of NHMRC statement on dental amalgam and mercury in dentistry. Prepared 1995.

DENTAL AMALGAM AND MERCURY IN DENTISTRY

Amalgam is a metal alloy in which one component is mercury. Dental amalgam is made by mixing liquid mercury with a powder consisting of silver (approx. 60%), tin (approx. 25%) and copper (approx. 15%) to produce a paste. A complex chemical reaction occurs resulting in progressive hardening of the paste over several hours.

Apart from gold, dental amalgam is still the best and most durable material for repairing decayed teeth. The present composite resins (plastics) or synthetic cements are more prone to wear and their shorter life will add both to costs and the extent of dental treatment.

Dental amalgam has been in use for 150 years. During this time, questions about the safety of amalgam have been raised more than once. The controversy surrounds the possible toxicity of mercury vapour released from amalgam fillings and the potential health hazards to dental patients and dental health professionals from mercury exposure.

The vapour of pure mercury does pose a health hazard to humans if it is inhaled either in very high concentrations for a short time, or in moderate concentration for months or years. Mercury vapour crosses the lungs into the blood quite readily and then moves from the blood into other tissues.

In a large population study involving 1,024 Swedish women aged between 38 and 72, researchers examined whether there was any link between the number of dental amalgam fillings and the women's health and well-being⁽¹⁾. The results of the study showed:

- that women with many amalgam fillings did not report more health complaints and symptoms than women with few amalgam fillings. In fact the opposite was found;
- That the relationship between number of amalgam fillings and different symptoms and complaints usually disappeared, when number of teeth was taken into account.
- that the relationship with abdominal pain and poor appetite were independent of both number of teeth and socio-economic status.

The study did not support the claim that removing amalgam fillings leads to an improvement in health.

A later study, conducted during a 20 year follow-up period, did not provide any evidence for a link between amalgam fillings and higher rates of cardiovascular disease, diabetes, cancer or early death⁽²⁾.

The scientific literature regarding the possible effects of mercury in people with amalgam fillings has been reviewed by a number of investigators⁽³⁻⁷⁾. On the basis of these reviews and current scientific information there is no sound evidence that dental amalgam poses a health risk to any individual who is not allergic to the material. Mercury allergy is extremely rare. Its effects are local (in the mouth) and can easily be recognised.

Dental health care workers can be exposed to mercury either through direct skin contact or through the inhalation of mercury vapour if proper mercury hygiene practices are not followed. Dental health professionals have higher exposure rates than the general population, yet they do not demonstrate any adverse health effects related to mercury exposure⁽⁵⁾.

Dentists and dental researchers are interested in finding ways to repair teeth without using dental amalgam because of the occupation risks which amalgam poses to dental health care personnel. Patients sometimes request fillings made with material other than amalgam, because of concerns about safety or appearance. Some alternative materials can be used. However, they are often less satisfactory than amalgam and the materials have not been available for sufficiently long to fully assess their efficiency or their long term health effects⁽⁴⁾.

The NHMRC does not recommend that amalgam fillings be removed without a clear indication of the need for removal. Dental amalgam is still the material of choice for the repair of most areas of tooth decay in premolar and molar teeth.

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APPENDIX B.

Submissions received (following limited invitation to various stakeholders) -as at 16 June 1998

#	Name	Expertise / Affiliation	Key Points
01	Glenda Farmer	Dentist No affiliation	Occ health and safety and environmental concerns: <ul style="list-style-type: none"> · Single use only alloy capsules should be recommended, · Plumbers should be trained re dental surgery hazards, · Dental surgeries should not be converted to residential and · Australian amalgam waste should not be sent off-shore
02	Richard Bell	Dentist ASOMAT	Has treated 12 patients for amalgam removal (10 of whom report subsequent health improvement): <ul style="list-style-type: none"> · Wants critique of Threshold Limit Value, points out a recommendation for reducing TLV to 1µg/m,³ and · Greater awareness of the subtle health risks to dentists (sic) from mercury exposure
03	Mark Ninio	Sports Podiatrist ASOMAT	Anecdotal evidence of significant health improvements post amalgam-removal, for the majority of patients to whom he recommends this procedure
04	Micheal Ziff	Dentist International Academy of Oral Medicine and Toxicology, Orlando, Florida	<ul style="list-style-type: none"> · Mercury exposure has not been found to be harmless at any exposure level, · dental amalgam is 50% mercury, · mercury leeches from fillings and accumulates in body tissues, and · this can and does transfer to the foetus. <ul style="list-style-type: none"> · Wants standardised removal protocols and urges caution with detoxification interventions. <ul style="list-style-type: none"> · Suggests risk assessment should be part of WP deliberations and that population sub groups at risk should be protected.
05	Laurie Kobler	Dentist ASOMAT	Anecdotal account of positive health effects following amalgam removal for a number of his patients

#	Name	Expertise / Affiliation	Key Points
06	Emmanuel Varipatis	Medical Practitioner - Environmental medicine specialist ASOMAT	Claims to have treated hundreds of cases of 'dental amalgam toxicity' Notes that: <ul style="list-style-type: none"> · dental amalgams similar to tobacco in toxicity, illness potential, morbidity and disease, · similar to tobacco in that not all people appear to have significant problems related to usage, · vast support in the scientific literature re toxicity/would be banned if not for “Grand Fathering”, · foetuses and breast-fed children most at risk, and · amalgams/mercury toxicity contributing factor to wide range of illnesses, eg., neurological, endocrine, immunological, psycho-behavioural and gastro-intestinal.
07	Geoff McNeil	Dental surgeon ASOMAT	Has completed 300 full mouth amalgam clearances over past 10 years. Cites decisive and dramatic health improvements, especially with neurological and immunological disorders.
08	Eric Davis	Dental surgeon ASOMAT	Protest re HAC not including ASOMAT on the WP. Thinks that the ADA, either directly or indirectly infiltrated the decision-making process. Alleges that the American Dental Association channelled a significant portion of its \$60m patient education fund into pro amalgam campaign/s. Anecdotal account of many patients recovering from chronic ill health (sic- following amalgam removal), many of whom would be happy to testify to this effect. Cites the DPMS provocation tests and demonstrable correlation between improved symptomatology and decrease in body burden stores of mercury.
09	Ben Olstein	Dentist ASOMAT	28 years of clinical practice on “thousands of patients” and is firmly convinced that placement of amalgams constitutes a significant health risk and is unnecessary. Cites many recoveries from acute and chronic ill health in patients following amalgam removal.
10	Anna Priest	Associate member of ASOMAT Involved in a patient support group	Cites many years of personal poor health exacerbated by incorrect procedures during removal of 10 amalgam filings [there are significant decreases in mercury release/exposure if certain removal techniques are employed - eg, use of rubber dam, extra suction]. Cites some improvement since amalgam debris removed by ASOMAT dentist. Has anecdotal evidence from 'several hundred' contacts, who report full or partial recovery, post removal of fillings. Common concerns are: <ul style="list-style-type: none"> · medical profession's lack of credulity

#	Name	Expertise / Affiliation	Key Points
			<ul style="list-style-type: none"> · doctor shopping · neurological and psychological impairment. Wants improved education, for medicos and dentists, regarding diagnosis, removal techniques and detoxification.
11	Annette Hayes	Medical practitioner	Personal story of alleviation of asthma post removal of amalgam fillings. Cites many patients having similar relief of symptomatology for chronic fatigue, allergy and chemical sensitivities, following amalgam removal. Regrets ASOMAT not on WP
12	Zenon Gruba	Medical practitioner	Personal experience with amalgam removal resulting in increased vitality, loss of shortness of breath and atrial tachycardia and return of colour vision. Cites a small number of patients ashaving, post removal of fillings, gratifying outcomes regarding illnesses such as tinnitus, multiple sclerosis, rheumatoid arthritis and cancer.
13	David Santleben	Dentist ASOMAT	In principle support for mercury free dentistry - conducts amalgam free practice
14	Donald Bartram	Dentist ASOMAT	Cites recent British government directive to dentists and doctors advising against amalgams for pregnant women. Newer composite filling materials superior mechanically and, in terms of boicompatibility, to amalgams.
15	Tony Kelaher	Dental surgeon ASOMAT	Almost exclusive non use of dental amalgam for past ten years. Most patients, including self, report health improvements post removal.
16	Paul Ameisen	Medical practitioner and Naturopath ASOMAT	Practises chelation therapy (EDTA, DPMS,DMSA). Anecdotal reports of patients experiencing increase in vitality and amelioration of symptoms of chronic fatigue and other medical syndromes(sic – post removal). Personal experience (having own amalgams removed) led to increase in vitality and well-being.
17	Beryl Clark	Patient ASOMAT	Removal of amalgams responsible for amelioration of allergy symptoms and weight gain.
18	Peter Robb		Has observed patients benefit from amalgam removal, especially one older

#	Name	Expertise / Affiliation	Key Points
		Chiropractor ASOMAT	woman who was pathologically timid. Finds it disturbing that NHMRC has alienated (from the WP) a group which has been researching the issue for years - thinks this decision is political and not scientific. Many health professionals, other than dentists, keenly interested in amalgam toxicity and whole of body health are awaiting committee's findings
19	Russel McLean	Dentist ASOMAT	Relates personal and clinical experience of health benefits of amalgam removal . Uses air filtration system for himself during procedures and has noted increased vitality, less depression and loss of craving for alcohol
20	John Osborne	Medical practitioner ASOMAT	Why exclude an organisation founded to deal with the very issue you are investigating? Your closed committee now lacks scientific integrity and will hold a biased investigation Amalgam free practise since 1981 and tries to allow patients to make informed choice by providing them with balanced and unbiased information which discards anecdotal evidence
21	Micheal Prineas	Dentist	Supports amalgam free dentistry. Finds glass ionomer cement in most facets of its use, especially biocompatibility, to be material of choice. Does not actively pursue full amalgam clearance - awaiting standardisation of removal protocols and team effort for multidisciplinary approach to detoxification.
22	Laurence Henbest	Dental surgeon	Practises amalgam free dentistry (since 1986) Suspects mercury poses health risk for self and nurse. Confidently predicts vast improvements in the following, post removal of

#	Name	Expertise / Affiliation	Key Points
			amalgam fillings: <ul style="list-style-type: none"> · chronic sinusitis · post nasal drip · migraine headaches · oral lichen planus · metallic taste · excessive salivation
23	W R Smith	Massage therapist Ipswich Therapy and Health Studio ASOMAT	Reports numerous cases of improvement, for patients with long-standing health problems, following removal of amalgam fillings and detoxification program. Electrical potentials generated by dental amalgams potentiate mercury leeching, with far reaching toxic effects, eg increasing incidence of Alzheimers Disease.
24	Gary Martin	Naturopath ASOMAT	Specialises in detoxification and nutrition and has studied mercury toxicity for the past 8 years. Has referred hundreds of people for amalgam removal, detoxification and nutritional support. Claims astounding results with a multitude of disorders. Wants amalgams phased out of dental practice.
25	Jeanette Neave	Total Environment Centre (TEC) ASOMAT	Regret the ASOMAT was not allowed to be on the WP Suggests that the WP solicit information from professionals in environmental medicine Notes that the TEC is frequently asked about the toxicity of dental amalgams
26	Gerrard Collins	Dentist ASOMAT	Debate, to date on the issue, is political rather than scientific. NHMRC's previous position an embarrassment and utterly impossible to justify. New committee must go beyond the dogma of other committees and reassess scientific data. It is paradoxical that: <ul style="list-style-type: none"> · dental amalgam as an alloy of heavy metals should be chosen as a biological marker · should be considered chemically stable despite electrogalvanism and clinical corrosion

#	Name	Expertise / Affiliation	Key Points
			<ul style="list-style-type: none"> · set amalgam scrap material is biohazardous waste and must be stored under radiographic fixer
27	Mark Wilson	Dentist ASOAMT	<p>Amalgam free practice for past 18 months.</p> <p>Anecdotal account of significant cognitive health improvements for himself following removal of amalgams. Similar successes, especially increased vitality, for wife and mother-in-law post amalgam removal.</p> <p>Aust Dental Assoc position appalling.</p> <p>Mind boggles that NHMRC has not included ASOMAT on the Committee.</p>
28	Nigel Cluer	Dentist ASOMAT	<p>Amalgam free practice for the past 8.5 years.</p> <p>Includes 12 patient self-assessment forms where they tick against 102 conditions/symptoms and then assess, post removal of amalgams, any improvement. (Interestingly 10 of the 12 had assigned themselves one or more of the neurological/psychological disorders). Improvement estimations range from 50 to 100%</p>
29	Andrew Taylor	Dentist ASOMAT	<p>Amalgam free practice for 6 years. Reports many patients citing health improvements following removal of amalgam fillings.</p> <p>Amalgam is an outdated and toxic material.</p>
30	Robert Gammal	Dentist ASOMAT executive	<ul style="list-style-type: none"> · Queries ASOMAT exclusion from WP. · Questions Prof Micheal Moore's impartiality when reviewing previous ASOMAT submission. · Wants it noted that trade organisations involved in dentistry exert heavy pressure to maintain the status quo re amalgam's alleged safety. · Refutes allegation of amalgam removal being directed by perceived financial gain for dentists. <p>In practise for 23 years, amalgam free for past 10 years. Has removed amalgams from several hundred patients who subsequently self-report health improvements. Calls for:</p> <ul style="list-style-type: none"> · medicine and dentistry to acknowledge the resultant clinical observations in spite of their being anecdotal. · Calls for discerning policy which reflects the statements of the British, Canadian and Swedish governments. · WP endorsement of the following contraindications for amalgam use

#	Name	Expertise / Affiliation	Key Points
			<ul style="list-style-type: none"> · In proximal or occlusal contact to dissimilar metal restorations · In patients with severe renal disease · In patients with known allergies to amalgam · For retrograde or endodontic filling · As a filling material for a cast crown · In children 6 and under · In expectant mothers <p>Wants the WP to adopt the Health Canada recommendations in full.</p> <p>(Included as an attachment to the submission are 22 pages of critique of the report of the E.U's Ad Hoc Working Group on Dental Amalgam)</p>
31	Graham Hawkins	Dentist ASOMAT	<p>Is about to practice 'amalgam free' dentistry.</p> <p>13 years in clinical practice includes witnessing improvements in health and attitude of patients post removal of amalgam.</p> <p>Disturbed about reported problems and benefits of removal.</p>
32	Ross Mackay	Dentist ASOMAT	<p>Nine years of amalgam free dentistry.</p> <p>Has removed amalgams from numerous patients, many of whom report health improvements/cure from symptoms, especially in the areas of:</p> <ul style="list-style-type: none"> · Chronic fatigue · Psychological symptoms, eg, anxiety and/or depression · Neurological symptoms, eg, poor concentration, poor short term memory, peripheral parasthesia and headache. <p>In addition, queries whether low level chronic release of mercury from amalgam fillings could depress/inhibit immune function.</p>
33	John Golbarani	Dentist ASOMAT	<p>4 years of amalgam free clinical practice.</p> <p>Has performed many amalgam removals, with variable health effects, ranging from slight improvement to dramatic changes</p>
34	Martin Tyas	Dental Academic ADA	<p>Many recent studies by highly credible organisations affirm safety of dental amalgam.</p> <p>Refer to the Eley series of articles (1997) in the British Dental Journal</p> <p>Gives his total support to the Aust Dental Association submission</p>

#	Name	Expertise / Affiliation	Key Points
35	Robert Butler	Executive Director ADA	<p>Accuses special interest groups of relying on “bizarre theories, poor science, misquotation and incorrect references from scientific literature...”</p> <p>Dental amalgam is a valuable and effective material for use in a number of applications.</p> <p>Minimal intervention and preventive measures see the use of dental amalgam very much restricted.</p> <p>There is no guarantee that other materials pose any less risk.</p> <p>Some dentists promote amalgam removal as a means of alleviating the symptoms of ill-health and many of these practitioners would be sincere believers in holistic / alternative medicine, rather than seeking financial gain.</p> <p>ADA members ignore this temptation to profit.</p> <p>Hypersensitivity to mercury released from amalgam fillings would appear to be extremely rare.</p> <p>The submission included the following attachments:</p> <ul style="list-style-type: none"> · <i>Effects and Side Effects of Dental Restorative Materials</i>, The International Association of Dental Research, 1991 (Conference proceedings) · <i>Potential Biological Consequences of Mercury Released from Dental Amalgam</i>, MFR Swedish Medical Research Council, 1992 · <i>Dental Amalgam: A Scientific Review and Recommended Public Health Strategy for Research, Education and Regulation</i>, US Public Health Service, 1993 · <i>Dental Amalgam and Alternative Direct Restorative Materials</i>, World Health Organisation 1997 · <i>The Safety of Dental Amalgam</i>, Health Canada, 1996 · <i>The Eley series</i> of articles from the British Dental Journal, Vol 182, Nos 1,7,8,9,10,11,12. · <i>Mercury Exposure from Dental Amalgam Fillings: Absorbed Dose and the Potential for Adverse Health Effects</i>, Mackert & Berglund, Critical Review of Oral Biological Medicine, Vol 8, no 4, 1997 · <i>Dental Amalgam: Update on Safety Concerns</i>, ADA Council on Scientific Affairs, JADA, Vol 29, 1998
36	Graeme Stringer	Dentist (ASOMAT)	<p>130 page report (excluding references and appendices) Contents page chapter headings as follows:</p> <ol style="list-style-type: none"> 1. Executive summary 2. Introduction: recent reviews and reports 3. Exposure to mercury from dental amalgam fillings

#	Name	Expertise / Affiliation	Key Points
			<p>4. Setting a TDI</p> <p>5. Literature critique - scientific objectivity and bias in studies</p> <p>6. Safety of dental amalgam fillings for patients and workers</p> <p>7. 'At risk' groups</p> <p>8. Multiple heavy metal exposure and interactions</p> <p>9. Diagnosis/Workers health effects</p> <p>10. Biomarkers</p> <p>11. Composite resins and other alternatives</p> <p>12. Research needs/novel ideas for Australia</p> <p>13. Recommendations</p> <p>Appendices A - D, References.</p> <p>Recommendations were as follows:</p> <ul style="list-style-type: none"> · Review extent of problem of micromercurialism/erethism in Australia -requires standard diagnostic criteria, agreed parameters for test results and identification/examination of at risk groups · Develop a Tolerable Daily Intake (TDI) for non-occupational exposure to elemental mercury vapour in Australia · Actions to decrease the body burden in most 'at risk' groups, primarily avoidance of usage in pregnant/possibly pregnant women, those with kidney disorders, nervous system problems, immune system problems and chronic gum chewers · Register of adverse reactions to dental materials · Biocompatibility testing of dental materials researched to enable clinical testing · Research and development of newer and more thoroughly tested dental materials · Preventive dentistry implemented on a more widespread basis · Education of dentists and general practitioners in diagnosing and management of micro-mercurialism · Research on 'at-risk' groups to determine numbers involved and severity of any problems
37	Geoff Bell	Dentist ASOMAT	<p>Masters thesis on durability of amalgams - abandoned amalgam use 10 years later due to recurrent decay underneath, rather than toxicity.</p> <p>Concern re toxicity - since being told to store amalgam scrap under radiographic fixer.</p> <p>Amalgam removal is now a small part of his practise, but toxicity of dental amalgam is personal interest- hundreds of articles collected.</p> <p>Stunning results, in some patients, following removal of amalgam fillings.</p> <p>Significant increase in personal well-being following removal of own amalgams.</p>

#	Name	Expertise / Affiliation	Key Points
			<p>One anecdotal case history attached.</p> <p>Questions the number of individuals with sub-clinical impairment of health who are undiagnosed/untreated.</p>
38	Roman Lohyn and Robert Gammal	Dentists ASOMAT Executive officers	<p>The submission consists of Parts A and B. Part A makes a dissertation in support of the following 19 statements:</p> <ul style="list-style-type: none"> · Dental amalgam is not a true alloy. It is made up of 50% mercury which escapes continually during the entire life of the filling... · The absorption rate of inhaled mercury vapour is extremely high, approx 80% of inhaled dose reaches brain in one circulation cycle. · The extreme toxicity of mercury is well documented...Inorganic mercury is just as toxic as organic mercury under various physiological conditions. · The toxic threshold for mercury vapour has never been found. · Controlled, broad-scale scientific studies investigating the health effects of mercury released from amalgam fillings have never been conducted. · The brain is the critical target organ for mercury vapour and methyl mercury and is significant in cases of chronic low level exposure. · Mercury released from dental amalgam fillings will be transported across breast milk of lactating women. · The halftime for the elimination of a single dose of mercury is 30 days for the body and perhaps as long as 10,000 days for the brain. · Multiple small doses result in accumulation · Sheep and monkey studies have confirmed that mercury from dental amalgam enters and accumulates in the patient throughout the body, including the brain. · Human autopsy studies have shown that the concentration of mercury in the brain is related to the number, size and age of amalgam fillings in the mouth · Mercury interferes with tubulin synthesis in rats.. · Mercury from dental amalgams has been shown to be related to antibiotic resistance in the gut and oral cavity. · Health Canada and WHO consider dental amalgams to be the largest single source of mercury exposure for the general public - WHO figure is 84% of total daily intake. · Amalgam fillings have been associated with a number of health problems..... (lists them) · Claims by US and Australian Dental Associations that the incidence of mercury allergy is less than 1% are totally refuted by the scientific literature. · The earliest symptoms of long term, low level mercury poisoning are sub-clinical and neurological...and are easily missed/misdiagnosed. · Some studies show that 50% of dentists with elevated mercury levels have peripheral nervous disorders. · Research shows that female dental personnel have twice the rate of infertility, miscarriage and spontaneous abortion than the rest of the population. · "It is generally agreed that if amalgam was introduced today as a restorative material, it would never pass FDA approval" (Wolff et al)

#	Name	Expertise / Affiliation	Key Points
			<p>Pages 79 - 146 of Part A consist of Richardson's rebuttal of the CDA's Jones critique of Richardson's risk assessment done for Health Canada</p> <p>Part A contains the following recommendations:</p> <ul style="list-style-type: none"> · Amalgams should not be used in: pregnant women, breast feeding women, children under 6 years, people with kidney disorders, neurological problems, retrograde root-canal fillings, as cores underneath metal based crowns, in conjunction with other metals in the mouth, people with diagnosed lichenplanus, and people with compromised immune systems. · Amalgams should be phased out...dentists should be retrained. · The NHMRC's previous policy statement should accurately reflect current research including Richardson's work · TDI for elemental mercury vapour should be developed · Research should be undertaken to determine levels of mercury in sewage systems. · dental surgeries should have mandatory amalgam traps. · Dental suites should be monitored for mercury vapour levels
39	Noel Campbell and Michael Godfrey	Dentist and medical practitioner	<p>Have treated over 1,000 patients with DMSA and DMPS urine provocation tests with 80% of patients experiencing dramatic reduction in signs and symptoms.</p> <p>DMPS internationally recognised tool for diagnosis of chronic mercurialism and mercury induced neuro-psychiatric impairment in dental technicians.</p> <p>Many New Zealanders have been continuously exposed to 15 or more amalgam filled teeth since childhood.</p> <p>The submission presented the Health Canada recommendations as laudable.</p> <p>Statements made included the following:</p> <ul style="list-style-type: none"> · A person does not have to be allergic to a toxic heavy metal to suffer adverse effects. · Mercury levels in the limbic brain correlate directly with the number of amalgam filled surfaces. · Rats exposed to mercury vapour levels consistent with those in human mouths with amalgams, develop neurofibrillary lesions identical to those of humans with Alzheimers · Amalgam which releases mercury into the body should not be classified as a medical device, it should be classified as a drug. · Mercury levels in saliva can increase from a baseline of 4 micrograms to over 800 mcg following chewing. (Max water level is 1-2 mcg/litre) · Mercury vapour is cardiotoxic · Mercury vapour is immuno-modulatory with known impaired leucocyte phagocytosis. · Mercury vapour is oxidised at the oxygen binding sites of haemoglobin. Oxyhaemoglobin levels shown significantly reduced in patients with large numbers of amalgams and chronic fatigue · Mercury vapour impairs glycolysis and ATP production by inhibiting phosphoglycerate, pyruvate and creatine kinase

#	Name	Expertise / Affiliation	Key Points
			<p>functions; it therefore has a detrimental effect on basic essential cellular function.</p> <ul style="list-style-type: none"> · Mercury's high affinity for selenium reduces the latter's availability for glutathione production and thus adversely affects the antioxidant system. <p>These and other statements are supported by abstracts of the relevant research/studies.</p>
40	Heather Thiele	Pink Disease Support Group	<p>Medical terms- Acrodynia, feer-Swift, Erythredema, Dermatopolyneuritis. Chronic mercury poisoning, often fatal in infants prevalent earlier this century, causative factor was mercury level in calomel teething powder.</p> <p>An estimated 7,000 infants affected in Australia when powders became available in the early 1950's.</p> <p>Writer has gathered over 1,000 case histories. Sufferers present with increased incidence of photophobia, bronchiectasis, kidney and bladder disorders, costalchondritis, hearing loss and neurological problems - all of which can be exacerbated by mercury exposure from amalgam fillings.</p> <p>Wants amalgams banned.</p>
41	Roland Bryant	Dentist ADA	<p>Do not use the term 'mercury amalgam' -its a misnomer.</p> <p>WP should be suspended until it contains at least two persons of each area of expertise.</p> <p>As an 'expert witness' the writer has spent 70 hours reading/studying various aspects of mercury from dental amalgams and came up with a report which states that:</p> <ul style="list-style-type: none"> · 'dental amalgams pose no known health risk to individuals who are not hypersensitive to the material.....' · Dental community has focussed on the need for optimum mercury handling practises and controls for environmental contamination and the need for further research - well controlled epidemiological studies · Everything is poison · The overwhelming volume of expert world opinion supports the US NIDR statement which says that there is no risk (see dot point 1 above) · Symptoms are vague and non-specific, if they do exist · The US PHS 1993 report states that only a small number of allergic individuals would be at risk · Alternative materials have not been shown to pose fewer risks <p>In addition, in defence of the dental amalgam manufacturers who have put warning labels, for certain population sub-groups, on their product - this was a poorly conceived decision which they are now amending.</p>

#	Name	Expertise / Affiliation	Key Points
42	Vicki Armstrong		<p>Pinks Disease sufferer who had dental amalgams removed without protective protocols and subsequently which may have contributed to marked health decline.</p> <p>Wants all qualified practitioners to be educated on amalgam removal techniques</p>
43	Michael Moore	Toxicologist	<p>There is no Tolerable Daily Intake set by the WHO or the US EPA for exposure to elemental mercury vapour.</p> <p>The Fawer et al LOAEL was probably conservative.</p> <p>There is undoubtedly exposure from amalgam fillings.</p> <p>Refer to Eley in the British Dental Journal which is an excellent critical review of the literature. Eley's assessment of 14 fillings to reach the TDI may itself be upgraded to no restrictions if studies were better designed.</p> <p>Dentists themselves are well enough aware to manage risks.</p> <p>There are pathways of contamination of soil and water which need to be noted.</p> <p>New materials should be subject to rigorous evaluation.</p> <p>Occupational and environmental contamination should be addressed in any guidelines.</p>

APPENDIX C.

Synopsis of international reports 1996 - the present.

Canada	Health Canada	The Safety of Dental Amalgam	1996
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Overview: Health Canada concluded that although amalgam fillings contribute detectable amounts of mercury to the body, these levels do not approach those recognised to cause illness. Most clinical information on the toxicity of mercury comes from studies of industrial workers exposed for long periods of time to high vapour concentrations in factories. There are relatively few clinical studies of the effects of mercury vapour at low levels, or disease prevalence in amalgam-bearers compared to people without amalgam. Current evidence does not indicate that mercury contributes to Alzheimer's disease, amyotrophic lateral sclerosis, multiple sclerosis or Parkinson's disease. Mercury can cross the placental barrier and can impair kidney function at sub-clinical levels of exposure. Therefore, it is advisable to avoid procedures involving amalgam in pregnant women or individuals with kidney diseases.

Health Canada stated as a principle in risk management of toxic metals that exposure to toxic metals should be reduced as far as possible, provided this can be done at an acceptable cost. Canada has taken measures to reduce or eliminate mercury in many products and to control its emission into the environment. Dental waste contributes to total mercury effluent, a factor leading to Sweden's proposal to end the use of dental amalgam by 1997. Health Canada considered it prudent to reduce human exposure to mercury where safe and where practical alternatives exist.

Health Canada considered the Health Canada Report Assessment of Mercury Exposure and Risks from Dental Amalgam (Richardson, 1995)¹ and stated that available clinical data were not reliable enough to permit making a confident estimate of a Tolerable Daily Intake (TDI) for mercury from amalgam. Health Canada indicated that estimation of mercury intake from dental amalgams and other sources is difficult because mercury occurs in a number of chemical forms which have different routes of intake by the body, different absorption rates, different excretion rates, different threshold effect levels and different adverse effects. A number of estimates and assumptions have to be made to extrapolate down from adverse effects of mercury vapour at high levels in industrial settings to a level at which there can be confidence that there will be no harmful effects. As there is uncertainty about available data, safety factors are applied in order to err on the side of caution. This extrapolated down estimate for a level of mercury at which there is no observable adverse health effect in adults is then compared with quantities of mercury absorbed daily.

In addition to uncertainties about available data, Health Canada raises a concern about misunderstanding of a TDI. Many people assume that the TDI sets a maximum level above which illness will result. However, because of the conservative safety factor used and the sub clinical effect on which the calculation was based (slight tremor of the forearm) exposures several times greater than the TDI would not probably produce any harmful effects. Health Canada decided it would not use the calculated TDI as the basis for safety recommendations.

Health Canada also concluded that the evidence does not warrant the removal of existing amalgam fillings from individuals who have no indications of adverse effects.

¹ Richardson GM. Assessment of mercury exposure and risks from dental amalgam. Final report. Ottawa: Medical Devices Bureau, Health Canada, 1995.

Considerations:

1. Health Canada considered that the current evidence did not indicate that dental amalgam is causing illness in the general population. However, there is a small percentage of the population which is hypersensitive to mercury and can suffer severe health effects from even a low exposure.
2. A total ban on amalgam was not considered justified. Neither was the removal of sound amalgam fillings in patients who have no indication of adverse health effects attributable to mercury exposure.
3. As a general principle, it is advisable to reduce human exposure to heavy metals in the environment, even if there is no clinical evidence of adverse health effects, provided the reduction can be achieved at reasonable cost and without introducing other adverse effects.

Overview: Dental amalgam has been widely used as a dental filling material. Elemental mercury does escape from intact amalgam fillings and is absorbed, at least some of it entering the central nervous system. Such mercury exposure might be affecting people adversely, but the evidence currently available is inadequate to determine whether this is so. The end points are subtle, subclinical impairments. While found as consequences of occupational exposure at levels relatively low for the workplace, these are still higher than mercury exposure from dental amalgam. To date no large studies of people whose main exposure is from dental amalgam have been carried out. Therefore the existing evidence is weak. It is very unlikely that the large number of diseases claimed to be the result of dental amalgam fillings are due to amalgam fillings, because they have not been associated with higher occupational levels of mercury exposure.

While new restorative materials have been available, clinical situations still exist where no other material is as well suited for use as amalgam. Short and long term costs of other materials are substantially higher and some other materials do not last as long, requiring replacement more often.

Current recommendations from Health Canada that amalgam be avoided, where possible, in children's primary teeth, in pregnant women and in people with impaired kidney function do not derive from evidence of harm, but from a combination of the uncertainty in the scientific literature and the application of general public and environmental health principles.

Conclusions:

1. Any potential benefit of removing intact amalgams and replacing them with other materials is very uncertain.
2. A greater emphasis on preventive and conservative dentistry could play a role in reducing unnecessary exposure to mercury from dental amalgam.
3. Recommendations to reduce the use of amalgam in the primary teeth of children, in pregnant women and in individuals with kidney disease are logical from a public health standpoint.
4. Patient and dental personnel exposure to mercury should be minimised, to the extent possible.

Overview: There is currently no direct filling material that has the wide indications for use, ease of handling and good physical properties of dental amalgam. Alternative restorative materials significantly increase the cost of dental care. Dental amalgam restorations are considered safe. Components of amalgam may, in rare instances, cause local side-effects or allergic reactions. The small amount of mercury released from amalgam restorations has not been shown to cause any other adverse health effects. No controlled studies have been published demonstrating systemic adverse effects from amalgam restorations. There is no scientific evidence showing that general symptoms are relieved by the removal of amalgam restorations.

A potential health risk to oral health personnel from mercury exposure exists if working conditions are not properly organized, necessitating proper mercury hygiene practices and monitoring of mercury vapour in the work environment.

Mercury used in dentistry may contaminate the environment via the disposal of waste products from dental clinics or pollution from crematoria. Collection and recycling technology is available to reduce mercury pollution of the environment.

Overview: COT noted the problems in accurate assessment of mercury release, in the form of elemental mercury, from dental amalgams. It understood that dietary intake of mercury was of a similar order as that from amalgam fillings. Exposures to trace quantities (estimated as 1 to 5 µg per day) were noted. It was concluded that mercury from amalgam was not associated with nephrotoxicity, but no conclusion could be drawn on the effects of mercury from amalgam on persons with pre-existing renal disease. COT recognised that neurotoxicity was of potential concern. However, evidence on the balance between organo-mercury compounds in the diet and elemental mercury which may undergo methylation and demethylation in the large bowel was limited. Exposure to mercury vapour was accepted to be of greater concern for dentists and their staff. COT noted that mercury could be taken up by the foetus and placenta during pregnancy. However, there was a lack of data on whether the mercury was present in an unreactive metallothionein-bound form. There was no evidence that occupational exposure to mercury during pregnancy or the placement or removal of amalgam fillings during pregnancy is harmful. This was despite recognition that the placement or removal of amalgam fillings were occasions of greatest exposure of individuals to mercury from amalgam.

Conclusions

COT considered that:

1. the use of dental amalgam is free of risk of systemic toxicity and that only a very few cases of hypersensitivity occur.
2. nephrotoxicity was not associated with exposure of healthy subjects to mercury from dental amalgam. It considered that neurotoxicity by exposure to mercury vapour is a matter of more concern in the occupational setting than in dental patients.
3. there is no available evidence to indicate that placement or removal of dental amalgam fillings during pregnancy is harmful. However, COT was of the opinion that the toxicological and epidemiological data were inadequate to assess fully the likelihood of harm and therefore it concurred with the view that it may be prudent to avoid, where clinically reasonable, the placement or removal of amalgam fillings during pregnancy.

On the basis of the statement from COT, the Chief Dental Officer and Deputy Chief Medical Officer issued a Precautionary Advice on Dental Amalgam Fillings (29 April 1998).

Overview: The US EPA noted that most of the population may be exposed to mercury through inhalation of ambient air, consumption of contaminated food, water, or soil, dermal exposure to substances containing mercury and mercury release from dental amalgam. The health effects of three forms of mercury: elemental mercury, mercuric chloride (inorganic mercury) and methylmercury (organic mercury) are examined.

The toxicokinetics (absorption, distribution, metabolism and excretion) of mercury is highly dependent on the form of mercury to which an individual has been exposed. Elemental mercury vapour is absorbed rapidly through the lungs, but is poorly absorbed from the gastrointestinal tract. Once absorbed, it is readily distributed throughout the body. Elimination is via urine, faeces, exhaled air, sweat and saliva. Excretion is dependent on the extent to which elemental mercury has been oxidized to mercuric mercury. Effects on the nervous system appear to be the most sensitive toxicological end point observed following exposure to elemental mercury. Symptoms associated with elemental mercury-induced neurotoxicity are numerous, but include tremors, emotional lability, insomnia, neuromuscular changes, headache, polyneuropathy, memory loss and performance deficits in tests of cognitive function.

Inorganic mercury is absorbed through the gastrointestinal tract. Absorption decreases with decreasing solubility of the mercuric salt involved, but as much as 20% may be absorbed. There is a limited capacity to penetrate blood-brain or placental barriers. The majority of ingested inorganic mercury is excreted through the faeces. The most sensitive general systemic adverse effect observed following exposure to inorganic mercury is the formation of mercuric mercury-induced auto-immune glomerulonephritis.

Methylmercury is rapidly and extensively absorbed through the gastrointestinal tract, and is distributed throughout the body. Methylmercury in the body is considered to be relatively stable and is only slowly demethylated to form mercuric mercury. Excretion occurs via the faeces, breast milk and urine. The critical target for methylmercury toxicity is the nervous system, particularly in the developing foetus. For the general population, the critical effects observed following methylmercury exposure are multiple central nervous system effects including ataxia and paraesthesia.

A susceptible population is a group that may experience more severe adverse effects at comparable exposure levels or adverse effects at lower exposure levels than the general population. Developing organisms are the most sensitive sub-populations. Data indicate that other factors associated with the identification of sensitive sub-populations may include age, gender, dietary insufficiencies, predisposition to auto-immune glomerulonephritis, and predisposition for acrodynia.

The US EPA has made no estimate of dose response for developmental effects of elemental mercury. An inhalation reference concentration (RfC) for elemental mercury was based on studies in exposed workers (Fawer et al, 1983)¹ for which there was no reported NOAEL: there is uncertainty in estimating the no effect level in these populations. The RfC calculated, based on neurotoxic effects in exposed workers, was $3 \times 10^{-4} \text{ mg/m}^3$. Confidence in the critical study, the data base, and thus the RfC were rated as medium. RfC was the expected amount that can be incurred on a daily basis for a lifetime without anticipation of adverse effects. This expectation was for populations including susceptible sub-populations.

US Environmental Protection Agency. Mercury Study Report to Congress. Vol. V Health effects of mercury and mercury compounds. Washington, DC US Environment Protection Agency, 1997.

¹ Fawer RF, de Ribaupierre Y, Guillemin MP, Berode M, Lob M. Measurement of hand tremor induced by industrial exposure to metallic mercury. Br J Industrial Med 1983; 40:204-8.

Overview: The FRN noted the considerable international consensus that, as far as the application of amalgam in dental fillings is concerned, there is agreement that unusual side effects are limited to inflammations near fillings in the mouth cavity without any scientific proof of links to any wider medical system-wide effects, and that there is no scientific proof that the removal of dental amalgam fillings will lead to an actual improvement in the general level of health.

The FRN also noted that the Swedish Parliament has decided to phase out the dental application of mercury for environmental reasons as soon as a satisfactory replacement material becomes available.

The FRN did not have the intention of checking the assessments of others concerning the medical and toxicological aspects. The Committee noted that new data indicate that variations in exposure, absorption and susceptibility in individuals with regard to mercury from amalgam fillings are important and that they underline the importance of taking into account individual differences in future risk assessments of dental filling materials.

Overview: Despite no substantial scientific evidence to indicate an existing or emerging public health problem associated with the continued use of amalgam, it is possible that small amounts of mercury released from amalgam and accumulating in body tissues may have adverse effects on the health of some susceptible individuals. Small amounts of mercury vapour are inhaled from amalgam fillings. The acceptable, safe or tolerable level of total mercury exposure (from amalgam, diet or other sources) is a matter of contention. While most medical and scientific opinion considers that exposure of the general population to mercury is within safe limits, the possibility remains that some individuals may show adverse mercury related health effects (although the evidence for this is equivocal).

Higher levels of mercury in blood and urine have been found in dental personnel but their health problems did not conspicuously differ from persons not occupationally exposed to mercury.

Amalgam removal or replacement for health reasons are difficult to justify on presently available clinical and scientific evidence, except where an individual allergy or sensitivity reaction to mercury is confirmed.

Among the recommendations made were:

1. That the issue of mercury absorption on human health be monitored and that relevant clinical and epidemiological research should be encouraged in New Zealand.
2. That the investigation of the mercury levels and health profiles of appropriate groups of children and adults, with and without amalgam fillings, should be undertaken to resolve the issue.
3. That the benefits and risks of continuing the use of amalgam as the primary tooth restorative material in dentistry should be monitored and compared with other restorative materials.
4. That relevant 'Occupational and Safety Health' regulations should be enforced for dental personnel.
5. That the criteria and tests for differential diagnosis of chronic mercury toxicity be reviewed.
6. That the contribution of mercury from amalgam waste to environmental contamination is minimised by increased use of mercury containment systems in dental clinics and offices and controlled waste disposal procedures.
7. Medical records of individuals undergoing amalgam replacement therapy should be evaluated.