COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

STATEMENT ON THE TOXICITY OF DENTAL AMALGAM

Introduction

1. The Committee has been asked to advise the Medical Devices Agency on the toxicity of mercury in dental amalgam. This request was made in order to help formulate the United Kingdom's response to the report of an ad hoc group of experts established by the European Commission to consider dental amalgam within the context of the Medical Devices Directive.[1] Particular topics on which the Committee's views were sought included: the risk assessment, the risks of neurotoxicity or nephrotoxicity, the risks of amalgam use during pregnancy or in patients with renal disease, and the adequacy of the toxicological database.

Background

2. The Committee last considered the safety of dental amalgam in 1986. At that time we recognised that some mercury may be released from completed restorations but were of the opinion that the use of dental amalgam is free from risk of systemic toxicity and that only a very few cases of hypersensitivity occur.[2]

3. Recently there has been a resurgence of interest in the toxicity of mercury in dental amalgam. We have been informed that dental restorative materials, including dental amalgam, are considered to be medical devices under the terms of the Medical Devices Directive 93/42/EEC and have seen the report of the ad hoc group established to review dental amalgam in relation to this directive.[1]

Exposure to dental amalgam and intake of mercury

4. We have been informed that the use of dental amalgam in the UK has declined. Whereas the annual placement rate in 1986 was 30 million amalgam restorations per year, the estimate for 1996 in National Health Service patients in England and Wales of 12 to 13 million restorations is considerably lower. The decline is possibly due to a decrease in the incidence of dental decay as well as a reduced usage of amalgam by dentists.

5. The Committee noted that there were problems in accurately measuring the intake of elemental mercury from amalgam fillings and that other sources of exposure, such as the diet, might result in the absorption of mercury in other chemical forms (e.g. as cations or as organo-mercury compounds). It was

understood that the contribution of dietary intake to mercury exposure was of a similar order as that from amalgam fillings. It was agreed that the placement or removal of such fillings were occasions during which the greatest exposure of individuals to mercury from the amalgam could occur.

6. We also noted that when studies of metabolism and excretion of mercury have been carried out these were undertaken most frequently in individuals who were exposed occupationally to mercury. Such exposures might not be relevant to the individual exposed to the trace quantities (estimated as 1 to 5 micrograms (µg) per day, or in a more recent paper as 1 to 2 µg per day [3]) released from dental restorations *in situ*.

Toxicity of mercury to humans

7. The Committee considered the toxicity of mercury to the kidney and noted that epidemiological studies of the effects of dental amalgam on renal function have been conducted only in healthy subjects. In these individuals mercury exposure from dental amalgam was not associated with the urinary excretion of *N*-acetyl-β-D-glucosaminidase, which is an enzyme that is a sensitive indicator of kidney damage. The Committee concluded that, in healthy subjects, exposure to mercury from dental amalgam was not associated with nephrotoxicity. On the basis of the available data it was not possible to draw any conclusions about the effects of mercury from amalgam on persons with pre-existing renal disease.

8. The Committee agreed that immunologically-mediated mercury-induced glomerulonephritis (a form of kidney damage) was poorly understood and that studies in occupationally-exposed individuals indicated the existence of a possible dose-response relationship for this effect. This could be an appropriate subject for further research. In our last consideration of dental amalgam we noted the occurrence of a few cases of hypersensitivity but considered that this area did not warrant further study.

9. The Committee recognised that neurotoxicity was of potential concern. Both elemental mercury and organo-mercury compounds can contribute to this. The major source of organo-mercury compounds is the diet but the Committee noted that methylation and demethylation of mercury compounds by micro-organisms in the large bowel might occur. Evidence on the balance of these reactions is limited. The Committee accepted that exposure to mercury vapour is of greater concern for dentists and their staff than for patients.

10. The Committee noted that there was some evidence that mercury could be taken up by the fetus and placenta during pregnancy, however there was a lack of data that would determine whether the mercury was present in an unreactive, metallothionein-bound form. Apart from one study [4] which had been severely criticised,[5] and which was discounted, there was no evidence that occupational exposure to mercury during pregnancy in modern dental practice was harmful. There is no evidence that the placement or removal of amalgam fillings during pregnancy is harmful.

Conclusions and Recommendations

11. The Committee welcomes the report [1] and appreciates the opportunity to comment on it. Although the report includes information published since the Committee last reviewed dental amalgam we *consider* that our former conclusions regarding hypersensitivity and the lack of risk of systemic toxicity remain unchanged.

12. The Committee *concluded* that nephrotoxicity was not associated with exposure of healthy subjects to mercury amalgam from dental restorations. Also, we *consider* that neurotoxicity caused by exposure to mercury vapour is a matter of more concern in the occupational setting than in dental patients.

13. We *conclude* that there is no available evidence to indicate that the placement or removal of dental amalgam fillings during pregnancy is harmful. We *are of the opinion*, however, that the toxicological and epidemiological data are inadequate to assess fully the likelihood of harm occurring in such circumstances. Until appropriate data are available we *concur* with the view that it may be prudent to avoid, where clinically reasonable, the placement or removal of amalgam fillings during pregnancy.

14. Accordingly, we *consider* that pregnant women and patients with kidney disease are groups who should be included in future studies. We *recommend* that such studies should incorporate measurements of dietary intake of the various chemical forms of mercury. Additionally, we *consider* that studies to elucidate the mechanism of immunologically-mediated mercury-induced glomerulonephritis should also be included in further research. Studies should be done to ascertain the kinetics of mercury in the body at low doses and verify whether the kinetics determined from occupational studies are applicable to patients with dental amalgam restorations.

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References

1. Dental Amalgam (1997). A Report with reference to The Medical Devices Directive 93/42/EEC from an Ad Hoc Working Group mandated by The European Commission. [Seen as the draft of June 1997]

2. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (1986). Statement on Dental Amalgam prepared for the Committee on Dental and Surgical Materials.

3. Eley BM (1997). The future of dental amalgam: a review of the literature. Part 3. Mercury exposure from amalgam restorations in dental patients. *Br Dent J*, **182**:331-338.

4. Sikorski R, Juszkiewicz T, Paszkowskie T and Szprengier-Juszkiewicz T (1987). Women in dental surgeries : reproductive hazards in occupational exposure to metallic mercury. *Int Arch Occup Environ Health*, **59**:551-557.

5. Larsson KS (1995). The dissemination of false data through inadequate citation. *J Internal Med*, **238**:445-450.