

The use of dental filling materials in Norway

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THE USE OF DENTAL FILLING MATERIALS IN NORWAY

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FOREWORD

The use of dental filling materials has been discussed intensively in the Nordic countries in the seventies, eighties and nineties. In 1997 the Norwegian Board of Health was given the task of conducting a study of the use of dental filling materials in Norway, and was asked to give recommendations for use of such materials in the future.

As the Director General of the Norwegian Board of Health, I presented a report in Norwegian containing 25 chapters to the Minister of Health in October 1998 . In consideration of our co-operating partners and other interested parties abroad, the Board of Health has translated the first chapter to English. This chapter contains the assessment of the Norwegian Board of Health and recommendations for future use of dental filling materials. It also contains several references to other chapters and appendices in the report which are available on request (in Norwegian).

The use of dental filling materials is not exclusively a medical or technical odontological issue. Selection of dental materials is influenced by a variety of concerns. Many aspects are covered in the various chapters of the report, from the philosophical aspects of the amalgam dispute to the immunological impact of dental filling materials. The Norwegian Dental Patients Association (Forbundet Tenner og Helse) was represented in the project group and also wrote one of the chapters. The Norwegian Board of Health based its recommendations on the chapters in the report, but studies done in other countries are also taken into consideration.

Important conclusions are:

- The scientific, verifiable methods on which diagnosis and treatment are based at the present time, do not reveal that a connection exists between amalgam and ill health
- Amalgam has some advantages and many disadvantages
- Dental health data and data on use of dental filling materials indicate that amalgam is in the process of being phased out

The remaining question is: How long a time should it take to phase out amalgam as a dental filling material? Recommendations from the Norwegian Board of Health are presented in chapter 1, which we have translated to English here.

The Norwegian Board of Health was responsible for the study. The project was carried out by Centre for Partnership in Development with Liljan Smith Aandahl as project leader.

One objective of this process has been to settle the amalgam dispute. Another objective has been to get both supporters and critics of amalgam to work together constructively to improve public health. The years to come will show if these objectives have been or will be met!

The Norwegian Board of Health extends thanks to members of the project group, the reference group and the participating authors for dedication, constructive co-operation and valuable contributions.

The latest development is that the Ministry of Health is planning a conference to follow up the report. Important issues suggested for the conference are:

- agreement on important research issues, and
- international recording of adverse effects of dental filling materials.

Oslo, August 1999



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ASSESSMENT AND RECOMMENDATIONS OF THE NORWEGIAN BOARD OF HEALTH (STATENS HELSETILSYN)

This chapter is authored by the Norwegian Board of Health and has not been submitted to either the Project Group or the Reference Group in advance. This chapter covers:

- Background
- Organisation of the project and procedure followed
- A brief review of the use of dental restorative materials in Norway
- The current situation
- A summary of the problems involved
- The Norwegian Board of Health's recommendations

BACKGROUND

In both Sweden and Norway the debate surrounding the use of amalgam as a restorative material in dentistry has been especially intense during the last two or three decades. The Norwegian Dental Patients Association (Forbundet Tenner og Helse) has been a driving force in Norway. The association represents people who believe that their health has been impaired as a result of dental treatment, and membership currently stands at about 1200 persons.

The debate started in Sweden, when a number of well-known personalities came forward and recounted how ill the amalgam fillings in their teeth had made them, and how their health had improved after the fillings had been replaced by other materials. The dispute in Sweden was far more heated than in Norway, and in summing up the results of an assessment (1) by the Swedish Council for Planning and Co-ordination of Research (Forskningsrådsnämnden) (FRN), the senior secretary responsible for the report declared:

“During the work on the report, the FRN has been forced to notice a widespread tendency among researchers in the field of amalgam to set aside the scientific, critical approach. The Committee therefore urges both researchers in the field and financing and executive organisations to monitor the scientific quality of the work in a better way.”

It is very rare indeed for such unveiled criticism to appear in an official document. There has been a similar tendency to approach the matter in an unscientific manner on this side of the border as well.

In Norway the public authorities formally entered the arena in 1985 when Dr. Bjørn Oppedal, DDS, sent a letter to the Minister of Social Affairs at that time, Leif Arne Heløe. The letter contained no fewer than 1100 references to damage that may have resulted from use of amalgam. The Minister invited Norwegian specialists in the relevant fields to assess the material, thereby triggering the chain of events described in Chapter 6. One result was the establishment in 1993 of the Dental Biomaterials Adverse Reaction Unit in Bergen (Bivirkningsgruppen for odontologiske biomaterialer). The Group has been made permanent in 1998 and is funded by the Norwegian government.

Responding to a request from the Storting (National Parliament), the Ministry of Social Affairs and Health (Sosial- og helsedepartementet) made funds available to the Norwegian Board of Health for a review of existing information and current practice relating to the use of dental restorative materials. The study shall provide a basis for determining the future use of such restorative materials in Norway.

The study was inaugurated in January 1998. It embraced all materials designed to replace lost dental tissue, but for various reasons the focus was largely on amalgam.

The principal reasons were:

- Amalgam helped to eliminate edentulousness in Norway
- It has been by far the most common restorative material during the last fifty years
- It is the most controversial
- It is unsuitable for use as a restorative material from a toxicological point of view
- It is classified as hazardous waste by the environmental authorities

ORGANISATION OF THE PROJECT AND PROCEDURE FOLLOWED

To conduct the study a steering committee was formed, supplemented by a quality assurer, a project leader with a project group, a reference group and contributors representative of relevant professions and sectors in Norway. A list of members of the various groups may be found in Appendix 1. The tasks and areas of responsibility for the various groups are set out in the revised project description, available in Norwegian.

It was considered important from the outset to bear in mind the criticism levelled against earlier studies. Several such projects had come under fire because they had been dominated by odontologists, and because these had expressed opinions on matters which lay outside their own fields. It was therefore resolved that contributors would be chosen who were in a position to write on their own primary area of expertise and apply this specialised knowledge to the use of restorative materials in dentistry. To give the study added legitimacy, it was decided that such contributors should, as far as possible, be drawn from circles which had not been strongly involved in the earlier debate surrounding the use of amalgam. This was in order to ensure access to persons with the relevant expertise who would be able to take a fresh and unbiased look at the matters at issue from their own specialised points of view.

When their services were enlisted, it was made clear to these outside contributors that they would be personally responsible for their specialist contributions to the study. The Norwegian Board of Health did not intend to undertake an independent evaluation of such experts' contributions, and the Board has not interfered with the work of the contributors.

Each of these specialist contributors drew up a draft report, which was presented to the Reference Group and the author's fellow contributors for review and discussion. At a two-day meeting of the Reference Group most of these contributors presented the results of their investigations, and opportunity was provided to put questions and to comment. The findings of some of the experts were commented upon by members of the Reference Group in writing. After the hearings the reports were revised and finalised, whereafter

they were sent to members of the Reference Group, who were then allowed to append their own comments to each report. These comments are set out in Chapter 25.

International links

In Sweden, the third national report on the use of amalgam and other restorative materials in dentistry was published in 1998 (1). The head of the Norwegian project participated in one of three open conferences held in conjunction with this report, and the head of the Swedish project and two representatives of the Swedish National Board of Health and Welfare (Socialstyrelsen) were subsequently invited to Oslo to brief the Norwegian contributors on the background for and results of the Swedish study.

The Norwegian Board of Health helped fund a two-day symposium held under the auspices of the Norwegian Dental Association (Den norske tannlegeforening). Entitled “Restorative Materials in Dentistry – Crime of the Century?”, the symposium was conducted in English and included guest lecturers from Britain, Canada and the USA.

A BRIEF REVIEW OF THE USE OF DENTAL RESTORATIVE MATERIALS IN NORWAY

Caries – tooth decay – is treated by filling therapy when the decay has continued for so long that a cavity has formed. In treating any ailment account must be taken of the following fundamental ethical factors:

1. Beneficence: ought treatment to be given or not? The determining factor is whether the benefits outweigh the risks.
2. The obligation to avoid harm, if possible.
3. The obligation to respect the right of individuals to make autonomous decisions.
4. Justice: obligations of fairness, where identical cases will be handled in the same way, and cases that are not alike will be handled differently.

Filling therapy is today a recognised form of treatment; it is of considerable beneficence and is accompanied by few adverse effects. The alternative to treatment is pain and extraction, with edentulousness as a result. There is nothing controversial about filling therapy, and nowadays there is a wide choice of filling materials and methods. It has not always been so.

In Norway, amalgam has been used as a restorative material in dentistry for more than a century, and has helped to eliminate class distinctions with regard to the dental health of the population. Before the introduction of amalgam, gold was used for restorative purposes, which meant that only the more affluent could afford to have their teeth treated. Most Norwegians who are between the ages of 40 and 70 today, have many and extensive amalgam fillings in their teeth, for which reason they are often referred to as the “fillings generation”. However, despite many cavities they were enabled to retain their teeth. This was largely thanks to the availability of such a cheap and durable restorative material as amalgam. In the preceding generation, most persons over age 40 were edentulous.

A large proportion of those who are now below the age of 40 benefited early from the

prophylactic properties of fluoride, and among them tooth decay is less prevalent. This is especially true for persons under 20. The dental health of children and youth has undergone marked improvement in recent years. For example, in 1985 50 per cent of all five-year-olds had caries-free teeth; in 1997 this figure had risen to 70 per cent. The corresponding figures for 18-year-olds were 1 per cent and 13 per cent. Among persons who do need fillings, too, there have been changes in the restorative materials employed. In 1978, 99 per cent of all fillings in the teeth of five-year-olds were of amalgam; eighteen years later the share of amalgam fillings in this age group had fallen to 7 per cent.

As far as the bulk of the population is concerned, amalgam is now used less and less as a restorative material. Children and young people suffer few cavities in their teeth. When filling *is* required, as a rule amalgam is not the first choice, even in molar teeth. To insert an amalgam filling, more healthy dental tissue must be removed to ensure that the filling sits properly than is the case with an adhesive resin-based filling material (composites). Although amalgam has a number of disadvantages of an aesthetic, physical and chemical nature, it remains an inexpensive and sound alternative when the need arises to replace old amalgam fillings. However, there is a growing demand for alternatives to amalgam also in that segment of the population comprising persons who already have many amalgam fillings. A more detailed account of the development of dental health in Norway and the use of restorative materials in dentistry is provided in Chapter 9.

THE CURRENT SITUATION

In conjunction with this study an enquiry was undertaken into the views of dentists, doctors and the general public on the restorative materials used in dentistry. A good deal more uncertainty exists among the population at large regarding possible harmful effects of amalgam fillings than among doctors and dentists. It was found that dentists favoured amalgam or gold if they needed to replace a large filling in a molar, whereas physicians and people in general preferred composite fillings. A more detailed account of this enquiry is given in Chapter 10.

It is assumed that use of amalgam will continue to decline for aesthetic reasons and because of the drawbacks associated with it. It thus follows that this reduction will occur regardless of whether or not the authorities impose restrictions on amalgam use, because other restorative materials are available, people ask for them, and they may be used advantageously to a greater and greater extent.

However, there is in Norway a number of sick individuals who associate their ills with the amalgam fillings in their teeth. Symptoms are unspecific, and vary widely. The most common are joint and muscular pain, lethargy, debility, dizziness, headache, stomach and intestinal ailments, visual disorders, soreness and a stinging sensation in the oral cavity, a persistent metallic taste, loss of short-term memory, circulatory disorders, nervousness, anxiety, sleep disorders and difficulty in breathing. Most of those who associate their problems with amalgam fillings display more than one such symptom. The media often feature interviews with people who claim to have regained their health after replacing their amalgam fillings with a different material. Some scientific studies likewise report that patients have been restored to health after having had the amalgam fillings in their teeth replaced.

It is very difficult to ascertain the extent of the problem because:

- there is no accepted way of making a diagnosis;
- many of those who ascribe their ill-health to amalgam fillings may be suffering from other ailments with similar symptoms of a general nature;
- some of those who are ill today may be allergic to one or more of the components used in dental restorative materials without being aware of it.

An idea of the problem may be obtained from a study of the Norwegian Dental Biomaterials Adverse Reaction Unit's investigations and the results thereof to date.

The Norwegian Dental Biomaterials Adverse Reaction Unit

This unit, which is located in Bergen, commenced its activities in 1993; it was the first such body in the world. The unit is active in three main areas:

- adverse-effects registration
- research and enlightenment
- clinical examination

The work of the unit has been and is closely followed abroad, which shows that in embarking on this project Norway was breaking new ground. In 1996 Sweden opened an adverse-effects register along the same lines as the Norwegian one. For a more detailed description of these registers, see Chapter 11.

From 1993 through December 1997 the Norwegian Dental Biomaterials Adverse Reaction Unit received 674 reports from dentists and doctors on adverse effects resulting from use of restorative materials. The number of reports on adverse effects associated with amalgam fillings appears to be declining, whereas the number relating to adverse effects resulting from the use of restorative materials of other kinds, such as crowns, bridges, composite fillings and cements, is increasing. A total of 420 patients have been referred for closer examination, and 287 of them have been examined.

In regard to allergic reactions, the following was demonstrated by means of patch testing performed as a consequence of well-founded suspicions.

Table 1: Results of "allergy testing" ("patch testing") of patients referred to the Norwegian Dental Biomaterials Adverse Reaction Unit

	Tested positive	Tested negative	Total tested
Amalgam components	17	168	185
Gold/palladium compounds	55	132	187
Resin components	19	164	183
Chromium/cobalt	33	153	186
Nickel	54	134	188

In addition, the unit's investigations have in some cases disclosed underlying medical conditions.

A SUMMARY OF THE PROBLEMS INVOLVED

The Norwegian contributors to this study have largely confirmed the findings of similar investigations. However, in drawing conclusions relating to conditions in Norway it is important that updating be undertaken of knowledge based on available national data. The contributions from specialists that make up this report provide the basis of this summary review, but results and conclusions derived from studies conducted in other countries have also been considered.

Should use of amalgam be prohibited?

Media coverage of this subject has mainly centred on the question of whether or not to ban the use of amalgam. This is not surprising, considering the publicity given to the problem in the daily and weekly press for many years past, and now this past year on television. Persons rendered permanently unfit for paid employment have come forward and recounted the course of their illness and described the improvement they had undergone when their amalgam fillings were replaced by fillings of a different material. The Norwegian Dental Patients Association would like to see the use of amalgam prohibited, and several members of the Storting have similarly proposed that its use be banned. Studies reveal a large measure of subjective improvement after replacement of amalgam by other substances.

In the light of the foregoing, the following questions need to be asked: Who would benefit from a ban? What would it cost?

The environment would be one beneficiary. If amalgam fillings represent a health risk for the individual, future generations would benefit if such a risk could be eliminated. Much the same result could also be achieved by phasing out the use of amalgam over time. However, the imposition of a ban would not help those whose health has already been impaired and who ascribe their symptoms to amalgam fillings; in their case, something entirely different is called for.

A ban on amalgam would mean that persons who have had amalgam fillings in their teeth for many years with no ill effects would have to pay more when the time came to replace them. Is it reasonable to put such persons to extra expense if they themselves have no wish to adopt a more costly alternative?

The scientific community's credibility

The controversy surrounding continued use of amalgam has been between those who believe that the mercury in amalgam fillings is detrimental to some of the population and those who maintain that there is no scientific proof for this belief. In Norway the public health authorities base diagnosis and treatment on methods which are to the greatest possible extent scientifically established. This is generally accepted as correct.

Nonetheless, throughout history there have been many cases in which those who possess knowledge have been an obstacle to development and the advancement of

mankind; new knowledge and innovative thinking have encountered stubborn resistance. This subject is dealt with in Chapter 20, where the credibility of the scientific community is illuminated in relation to non-scientific factors which may explain the emotions and strong involvement from that side.

Chapter 20 also explores factors which may help to explain the commitment of those who set out to gain acceptance for the view that a connection must exist between amalgam fillings and ill health.

The chapter goes on to discuss the limitations of scientific methods when discussing causes for illness where there is a complex interplay of many influencing factors.

The public authorities' dilemma

In the modern welfare state the public authorities have assumed responsibility for preventing and treating illness and disease. These activities are based in large measure on results arrived at by scientifically verifiable methods. In addition, nowadays users are themselves encouraged to participate in their treatment. Problems arise when users insist on treatment for which no scientific foundation exists. This problem is examined in Chapter 21, where, among other things, the consequences of accepting or denying that there is linkage between exposure to mercury from amalgam fillings and symptoms believed to be related to such fillings are discussed.

Should it be true that there is indeed a connection between exposure to amalgam and such symptoms, and the public authorities accept that this is so, various rational measures will be introduced with a view to alleviating the health problems of the persons affected. If there is no real link, but the authorities accept that there is, the result may be a series of irrational actions designed to improve the condition of such patients.

If the public authorities deny that a connection exists and the truth is that it does, it will result in our neglecting to undertake rational action which may improve the lot of persons with such symptoms, and the problem will fall upon their friends and relations, the primary health service and, not least, the alternative health sector, which is treatment-oriented and expensive. As we are unable to prove that a link exists, what ought we to do? In the report on the latest Swedish study (1) the senior secretary of the Study Group, who is personally involved in research into mercury, has this to say:

“When mercury binds to sulphur groups in amino acids, there often occurs a very severe deformation of the proteins in which the amino acids are the building block. I find it unreasonable to exclude a priori that these severely deformed proteins would trigger some form of biological reaction in some group of individuals in the population.”

It is possible that no adequate measuring methods are available or that the wrong methods are employed to demonstrate connections, assuming that they exist. The problems involved in determining the causal relation are discussed in Chapter 21.

The position of the patient

People who believe amalgam fillings to be responsible for their health problems are of the firm opinion that having them replaced by another material will result in an improvement. Such beliefs have no scientific foundation at present, but the results of trials involving replacement of amalgam fillings are reasonably encouraging. The report entitled “Replacement of amalgam – results and appraisal” in Chapter 19 reveals that some people do indeed undergo an improvement in their health after such fillings are removed.

Scientific conclusions

It is recognised that amalgam fillings release mercury and that this is absorbed by the organism. Mercury has been found in urine and blood, it passes the placenta and it has been detected in foetuses and in the milk of nursing mothers. There is a correlation between the amount of mercury found in a foetus and the number of amalgam fillings in the teeth of the mother. It is also recognised that mercury causes a dose-dependent biological response. It has not been proved that this biological response from mercury emitted by amalgam fillings results in health problems. Risk studies (2) have, however, demonstrated the probability that in a minority of the population this biological response can become injurious to health.

Such resultant ill health has not been substantiated by clinical-scientific methods. To prove causality it is necessary to measure such ill effects and distinguish them from effects of a similar nature. The fact that the requisite links are tenuous or absent altogether does not necessarily mean that they are non-existent; their seeming absence may also stem from a lack of methods and instruments by which to demonstrate their presence.

In her conclusion the author of the report on toxicology in Chapter 12 says:

“As far as the population at large is concerned, exposure to mercury from dental amalgam does not appear to be a problem. The effects demonstrated at the lowest urinemercury values are equivalent to an exposure five to ten times higher than that to which persons who do not come into contact with amalgam in the course of their normal work are exposed. In saying this it is important to emphasise, however, that there appear to be wide variations both in regard to absorption of mercury and in sensitivity to mercury. The possibility can thus not be ruled out that persons who are exposed to substantially more mercury than the average person, and who in addition are more sensitive to mercury than the average person, may feel some effects from mercury derived from amalgam.”

The Swedish report entitled “Low-dose Exposure to Mercury” (“Lågdos Exponering för Kvicksilver”), generally referred to as the LEK report, which is discussed in Chapter 6, declared as early as 1987 that, from a toxicological point of view, amalgam was unsuitable for use as a dental filling material.

Odontological factors

From the odontological aspect the most important question is: Are acceptable replacements for amalgam available? The answer is yes. Dentists want a material capable of replacing amalgam in all its areas of indication. No such material is available at present, but a number of materials possess technical and aesthetic qualities which satisfy the needs of most people, though not of all.

It is important to have access to amalgam when dental treatment is performed under general anaesthesia, the time taken being a critical factor. General anaesthesia in itself carries a risk. Out of consideration for the patient's health it is important that the number of treatments given under general anaesthesia be kept to a minimum and that the time spent under general anaesthesia be as short as possible. Amalgam fillings take less time to insert than do fillings composed of other materials.

A ban on the use of amalgam might make it necessary to undertake more and more timeconsuming treatments under general anaesthesia. It is also possible that in practice the patients concerned would not receive treatment under general anaesthesia when they need it, with the result that their teeth would have to be extracted. Care must be taken to ensure that edentulousness does not again become a health problem in vulnerable segments of the population.

From a professional odontological point of view, use of amalgam is indicated in special cases.

Medical factors

A variety of medical disorders of undetermined etiology are associated with release of mercury from amalgam fillings. No causal relation has, however, been established.

Economic factors

All alternatives to amalgam are at present more expensive. Gold and ceramics are several times more expensive than amalgam, but resin composite fillings too cost more, both from the outset and in a lifetime perspective, as they do not last as long.

Children and young people up to the age of 18 years now receive dental treatment free of charge under the auspices of the Public Dental Health Service (Den offentlige tannhelsetjenesten). Phasing out amalgam or prohibiting its use entirely would have little influence on the costs of dental treatment where this particular age group is concerned, as little amalgam is used in their treatment.

The additional expense involved in changing from amalgam to other materials will be most noticeable in the adult population. Accordingly, if the use of amalgam were to be prohibited, consideration should be given to providing financial assistance to impoverished patients.

Environmental factors

The environmental authorities classify and treat amalgam as a hazardous waste, and in Chapter 17, which deals with the environmental aspect, the author says: "... should take steps to limit all local discharges", and in its appended comment the National Pollution Control Authority (Statens forurensningstilsyn) expressed a wish for a more environment-friendly dental restorative material.

In Denmark and Finland environmental considerations have prompted the authorities to seek alternatives to amalgam.

The precautionary principle

The precautionary principle has been accepted as an important administrative principle. Implicit in this principle is the need to foresee and prevent rather than to be wise after the event and make repairs. The Norwegian Board of Health applied this principle to the subject of dental restorative materials early on, in a press release commenting on a toxicological report in March 1988, and again in 1991, in its guidelines on dental biomaterials, which were designed for doctors and dentists. The Board made the following recommendation:

"The results of research based on segments of the population have so far not disclosed any risk to health resulting from the use of amalgam in treating pregnant women. Because it cannot be ruled out that such a connection will be demonstrated in the future, the Board of Health recommends that in the public interest, extensive therapeutic treatment of pregnant women with amalgam should be avoided" (Page 15, "Guidelines for doctors and dentists" IK 51/91 ("Veileder til leger og tannleger", IK 51/91")). For a more detailed discussion of this subject, see Chapter 6.

- The author of Chapter 13 on immunology concludes by saying that had amalgam been submitted for approval as a restorative material in dentistry today, he would have withheld approval, as the gap between the mercury exposure which some persons believe may be injurious to health and the exposure to which ordinary carriers of amalgam are subjected, is too narrow from a risk-assessment point of view.
- This principle ought also to apply to the introduction of new materials and to increased use of existing materials. The report on working environments deals with the reactive substances in composite (resin-based) filling materials, and points out that dental personnel who handle such materials run a greater risk of developing allergies. To take the matter a step further, we know little about what the effect may be on the health of patients. Care must be taken not to adopt the wiser-after-the-event principle in regard to the increasing use of resin-based filling materials (composites) and the development of new materials.

The substitution principle

This principle rests on the premise that if treatment can be avoided, i.e., if precautionary measures can be taken or a less hazardous material used, this should be done. The substitution principle decrees that the emphasis should be on prevention and that the material that is considered the safest should be employed.

Rules and regulations

In Chapter 22, which is concerned with legislation, it is stated that it is possible to have a dental restorative material withdrawn from the market, but that doing so is by no means easy. It is also stated that if the Norwegian authorities should wish to impose restrictions, prior study of the matter would be necessary.

In Chapter 23, which deals with EU legislation, the author recommends that the Norwegian authorities should make active use of the legislation Norway has agreed to adopt. Under this legislation influence can be exerted on the process to the point at which manufacturers are entitled to apply CE-marking to their products. Norway is entitled to take active steps to draw up scientifically substantiated standards as a basis for certification and by which to assess conformity.

The present trend is phasing out amalgam

In all probability amalgam as a dental material will be phased out. The current tendency to do so is described in Chapter 9. The public's views on amalgam as a restorative material in dentistry are set out in Chapter 10, the indication being that the demand for alternatives will increase. As far as the Norwegian Board of Health is concerned, it will be a question of whether the authorities ought to intervene to speed up the phasing-out process.

THE NORWEGIAN BOARD OF HEALTH'S RECOMMENDATIONS

The reports assembled here reveal that the problems related to use of dental restorative materials are highly complex. The scientific, verifiable methods on which diagnosis and treatment are based do not reveal that a connection exists between amalgam and ill health, but it does seem probable that in the case of a small segment of the population the natural biological response to exposure to mercury may lead to adverse health effects. Nor can responses to other dental restorative materials be discounted.

The question of adverse effects on health resulting from the use of amalgam and other restorative materials in dentistry is not solely a professional medical issue. Aspects other than those of a purely medical nature have therefore also been considered in the course of this study. After an overall consideration, the Norwegian Board of Health recommends the following measures:

1. Measures for persons with symptoms and reactions assumed to be related to dental restorative materials.

2. Measures at population level.
3. Measures to improve the quality of products and services.

1. Measures for persons with symptoms and reactions assumed to be related to dental restorative materials

- The public health service must have something to offer people who are ill also when the cause of their symptoms is unclear. It is important to provide a health service which, through its personnel, shows empathy with people who are ill without the nature of their illness having been reliably diagnosed. It is a challenge for health personnel to relate to patients with an unclear condition, and respect that the patient is, in fact, an expert on his/her own situation.
- Health services for those who have symptoms assumed related to dental materials should be continued and improved. This should include adequate examination and, where appropriate, treatment. It is necessary to develop examination standards in order to eliminate possible underlying disorders before any amalgam fillings are replaced or other relevant therapy proceeded with.
- Procedures for removal therapy must be established, and removal should be done according to established criteria, regulations and reporting routines. The Dental Biomaterials Adverse Reaction Unit should play a central role in developing criteria and procedures.
- Symptoms assumed to be related to dental restorative materials are often of a general nature, and for this reason examination and treatment should follow the same financing principles as generally apply in the health service as a whole, where examination and treatment costs are met from National Insurance funds.
- Examination and treatment facilities should be made regionally available. The Dental Biomaterials Adverse Reaction Unit would be expected to play a central role in the establishment of regional facilities, which to as great an extent as possible should be a part of and be integrated with the existing health services.
- Treatment in the form of replacing dental restorative materials is a suitable area for structured collaboration between the private and public dental health services and those who carry out patient examinations.

Justification

“To treat persons whose ill health is thought to have amalgam-related causes on the basis of such patients’ own diagnoses and desire for treatment, could be justified as an exception if the politico-scientific reason for doing so is that, despite extensive studies, researchers have been unable to rule out a link” (Report in Chapter 20).

The problems at issue may be odontological in origin and their solution may likewise be odontological. To exclude other underlying disorders, further medical studies are required, studies which must be multidisciplinary and include a wide range of medical specialist fields. In collaborative projects of this kind it is important that dentists and general medical practitioners keep an open mind, and that medical specialists in different fields remain aware that in some cases dental restorative materials may engender general symptoms and manifestations far removed from the oral cavity. There are similarities between the symptoms displayed by such patients and those associated with a chronic fatigue syndrome, sensitivity to electricity and other conditions.

The Norwegian Board of Health considers the existing provision for studies under the auspices of the Adverse Reaction Unit to be professionally satisfactory. An assessment made in 1998 (discussed in Chapter 6) of the unit's activity revealed that both patients and health personnel were satisfied with the study. However, the lack was felt of facilities for treatment.

Because the activity of the Norwegian Dental Biomaterials Adverse Reaction Unit is not at present covered by the National Insurance regulations, patients referred thereto find that neither travelling expenses nor board and lodging are reimbursed in the normal manner.

2. Measures at population level – plans to reduce amalgam use

The wish has been expressed in various quarters that use of amalgam should be reduced or be discontinued altogether. The Norwegian Board of Health envisages four alternatives:

- **Alternative I:** Use of amalgam will probably be phased out along with the “fillings generation”. The use of amalgam in the teeth of children and young people has greatly declined over the last few decades. New generations will therefore not have the same need for amalgam as a replacement for old fillings as have today's adults.
- **Alternative II:** Professional recommendations that will result in reduced use of amalgam.
- **Alternative III:** The setting of a firm date by which an end must be put to insertion of new amalgam fillings.
- **Alternative IV:** The banning of amalgam and offering replacement of amalgam fillings to those who wish to do so.

Of these four alternatives, the Norwegian Board of Health would recommend Alternative II. Further details, and the Board's reasons for doing so are set out below:

Professional recommendations that will result in reduced use of amalgam.

- Amalgam shall not be the first choice as a filling material in treating children and young people up to the age of 18 years under the auspices of the Public Dental Health Service.

- It should be impressed on dentists that it is their duty to provide relevant information and to obtain the informed and competent consent of patients before treatment commences.

It is a strategic aim that the use and discharge of chemicals harmful to health and the environment must not result in damage to health or the natural environment (Stortingsmelding (Parliamentary Report) no. 58 1996/97).

The use of potentially hazardous substances should be avoided when acceptable alternatives exist. This is an extension of the substitution principle set out in the same parliamentary report.

The adverse effects on health of mercury released by amalgam fillings have not been documented by clinical scientific methods, but risk assessments have revealed that the likelihood exists that a minority of the population may develop such adverse effects.

- Restraint should be exercised in regard to extensive use of dental restorative materials in pregnant women.

In the past, the Norwegian Board of Health has advised against extensive amalgam therapy in pregnant women. The sound dental health of young women and the uncertainty surrounding possible adverse effects, also those caused by other dental restorative materials, indicate that extensive dental treatment in pregnancy should be avoided.

- Restraint should be exercised in using amalgam on persons with specific health problems, e.g., persons suffering from allergies or renal (kidney) ailments.
- Amalgam can be used where specific indications exist.

It is important to have access to amalgam for use in cases where, for example, a person needs dental treatment under general anaesthesia. In such cases, the time required for treatment is a critical factor. General anaesthesia in itself entails a certain risk. Out of regard for the patient's health, it is important that the number of treatments under general anaesthesia be kept to a minimum and that the time spent under general anaesthesia be as limited as possible. Amalgam takes less time to set in place than do other restorative materials. Care must be taken to ensure that edentulousness does not recur in vulnerable segments of the population.

- Amalgam fillings that function satisfactorily should not be replaced. Evaluating whether an amalgam filling should be replaced by another dental material should be undertaken when replacement is indicated on professional grounds.

An estimated 1.5 million Norwegians over the age of 30 have amalgam fillings in their teeth, and for the majority these fillings are no trouble at all. It is thus only reasonable that persons who wish to retain their amalgam fillings should be permitted to do so.

- Current guidelines for dentists and physicians relating to dental biomaterials should be revised.

Greater emphasis should be placed on the obligation to provide patients with relevant information, and the obligation to obtain the informed and competent consent of patients.

3. Measures to improve the quality of products and services

By products and services is meant in this context factors associated with the development and use of dental restorative materials.

Recording of adverse effects

The present system for reporting adverse effects associated with odontological biomaterials should be continued, and Nordic and international collaboration in this area should be strengthened. Collaboration with other adverse-effects registers should be strengthened. The World Health Organization (WHO) has recommended that such registration be made global, which will necessitate, among other things, standardisation.

Occupationally-related adverse effects should be registered. Certain such responses among dental health personnel appear to be on the increase; this is in itself a problem. Furthermore, such responses may provide a pointer to possible responses among persons with the same materials in their teeth.

Product register

A register of products covering the materials at issue should be established. Such a register should contain systematised information on what the materials concerned contain and the quantities involved. It may also provide information on specific substances which are a potential source of problems from a biological point of view.

The Scandinavian Institute of Dental Materials (Nordisk Institutt for Odontologisk Materialprøvning) (NIOM) is an expert body which it would be natural to draw upon for such a purpose. The register should be designed and developed in collaboration with the Adverse Reaction Unit.

A more detailed assessment must be made of the formal aspects of such a register, and of how it should be funded.

Such a register is important for dentists, who will then be given the opportunity to inform their patients about ingredients in the dental restorative materials they use.

Specification of requirements

Purchasers are entitled to define the standards they require of products over and above the basic standards provided for by current laws and regulations.

Organisations and government bodies which represent purchasers of dental restorative

products should be encouraged to draw up specified research-based requirements. They should also require that the products they purchase meet established standards.

Directions for use of dental restorative materials must be readily accessible, and packaging must be designed to ensure minimal risk of undue exposure.

Occupational health aspects

Dental clinics use a wide variety of volatile chemical compounds. Allergic responses appear to be on the increase among dental health personnel.

The regulation governing health, the environment and safety (3) makes it incumbent upon employers to provide for a safe working environment.

In collaboration with experts on such environments, guidelines should be drawn up relating to the physical working environments of dental clinics.

Teaching in Dental Schools/Refresher courses

Dental schools should plan their teaching in such a way that the main goal of reduced mercury exposure will be reached. Teaching must give priority to knowledge about and proficiency in the use of alternatives to amalgam, and better reflect the use of dental materials that occurs in practice.

The training of dental health personnel in the field of dental biomaterials should aim to imbue students with knowledge, attitudes and skills which will prepare them for choosing restorative materials in a clinical situation.

Teaching should focus on good record-keeping, making identification of materials used possible.

Research and development

The transition to use of alternative materials in place of amalgam has long been in progress. Research in this area should be conducted with an eye to the future and concentrate on developing new materials and relevant treatment techniques. Assessments of dental restorative materials, independent of manufacturers, should be made available. This work should proceed on a Nordic basis within the collaborative structure already established by the Nordic Council of Ministers (Nordisk Ministerråd).

The Scandinavian Institute for Dental Materials (NIOM) possesses a spearhead expertise developed over a period of more than twenty-five years. In the context of EU collaboration, NIOM could play an important role with respect to a variety of fields relevant to dental materials. One aspect is the important efforts being standards as a

basis for certification and comparative assessments. NIOM is a Notified Body under the EC Directive 93/42 concerning medical devices.

Information

Information should be prepared for the various media on the advantages and disadvantages of different dental restorative materials, information which should be made available to the general public. Such information must in a balanced manner reflect disparate opinions on the use of restorative materials in dentistry and available risk assessments. Current regulations require that unbiased information is given to the patient on the advantages and disadvantages regarding the use of dental restorative materials.

Follow-up measures

When National Insurance funds are made available for treatments which involve the use of dental restorative materials, steps should be taken to ensure that relevant information be compiled, to enable the effects of such measures to be studied in retrospect.

At present little is known about the effect of government rules for subsidies which have been in effect regarding, for example, replacement of dental restorative materials. To expedite quality assurance of these services, facilities should be introduced to permit assessment of the effects of such measures, both on individuals and at population level. Responsibility for this should be vested in the Dental Biomaterials Adverse Reaction Unit.

References: <http://www.helsetilsynet.no>

APPENDIX 1***Steering committee***

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