

Guidelines for the Use of Dental Restorative Materials (in Norway)

*Information to dental health personnel
about the use of dental materials
for restoring single teeth*

Issued by the Norwegian Directorate for Health and Social Welfare
March 17, 2003
www.shdir.no/index.db2?id=3948

This is an unofficial translation of main portions of the document
by Maryanne Rygg, March 26, 2003

Note: The original document contains 39 pages in Norwegian. It is not possible for me to invest the time required to translate 39 pages for this unofficial version, so I have chosen to translate main portions of the guidelines, and I hope that the Norwegian Directorate for Health and Social Welfare will prepare an official translation of the entire document. The parts I have not translated are mainly explanations and evaluations of the knowledge base.

Preface

The Norwegian Directorate for Health and Social Welfare, by issuing these guidelines, intends to influence decisions regarding the use of dental restorative materials. It is acknowledged that mercury is a problem in relation to the environment, and the public has been increasingly concerned about possible negative health effects from amalgam fillings.

Dental restorative materials are classified as medical devices, and there is no requirement for clinical trials for such materials before they are marketed. Developments in this area also evolve rapidly. By the time experience has been registered for one material, new materials and reportedly improved versions are already available. This is an area where the public health authorities want improved monitoring. These guidelines are a start. Work with these guidelines has shown that a systematic approach is necessary in order to survey the research that has been done, and that good primary studies with robust design are necessary in order to give us additional knowledge.

These guidelines are a follow-up of the study *The Use of Dental Fillings in Norway*¹ that was delivered to the Minister of Health in 1998. Work on these guidelines was started by the Norwegian Board of Health in 1999. The process has been protracted, and has probably already contributed to changes in practice.

The professional guidelines now issued by the Directorate for Health and Social Welfare express what is considered to be good practice at this time. Professional guidelines should in principle be considered as recommendations and advice, and shall build upon updated professional knowledge. The guidelines are meant to aid dental health personnel when considering options which must satisfy requirements for justifiable services that are of good quality.

Professional guidelines are not legally binding for the recipients, but may to a great extent provide steering for the choices to be made. By following updated guidelines, personnel contribute to satisfying legal requirements for professionals. When solutions are chosen that substantially deviate from the professional guidelines, these should be documented and one should be prepared to explain why this choice was made.

Work on the guidelines was taken over and completed by a working group in the Directorate for Health and Social Welfare. Representatives from professions and from the patient organization *Forbundet Tenner og Helse* have commented on the process with both written remarks and in consultative meetings. I would like to thank all those who have been involved for their contributions and engagement, and I hope that these guidelines will be useful for dental health services.

The guidelines will be effective from July 1, 2003.

Oslo, March 17 2003

Bjoern-Inge Larsen, Director

¹ Translator's note: An official English translation of the conclusions of this study may be found at <http://www.helsetilsynet.no/trykksak/ik-2675/ik-2675.pdf>

Short Version

Recommendations

- Preventive care shall be given priority.
- When fillings are necessary, techniques that preserve tooth substance are to be chosen.
- Amalgam shall not ordinarily be the first choice when filling therapy is indicated.
- The use of amalgam shall be limited as much as possible in order to protect the environment and due to possible injury to health.
- Dental filling therapy for pregnant women should be avoided.
- For new restorations, contact between amalgam and other metals should be avoided.
- Allergy to any ingredient in a dental material is a contraindication for use of that material.
- Efforts should be made to reduce exposure of patients and dental personnel to chemical substances from dental therapy when applying and removing fillings.
- A vacuum suction and water-cooling shall be used when removing old fillings.
- Avoid contact with materials before they are hardened.

Assumptions and Principles

- The choice of material should be made based on a complete diagnosis including the patient's medical history and clinical, X-ray and other findings together with an evaluation of the degree to which the patient may be able to follow advice and recommendations about how they can take care of their dental health.
- The dentist is responsible for the choice of dental material, according to the law regarding health personnel §4. This choice should be made in consultation with the patient or parent/guardian. In the event of deviation from these guidelines in the choice of dental material, the reasons must be specified and the patient's informed consent entered in the dental journal.
- Indications, counter-indications and directions for use from the manufacturer shall be followed. Pre-dosed packages ensure correct proportions of a mixture and optimal quality of the material. In addition, such packaging reduces the likelihood that dental health personnel come in contact with unhardened materials.

Conclusions of the Directorate for Health and Social Welfare

1. From an environmental and a public health point of view, it is desirable to reduce mercury exposure in the population. The Directorate for Health and Social Welfare recommends that the use of amalgam as a dental restorative material be reduced.
2. These guidelines do not involve a ban against the use of amalgam, but dentists are encouraged to reduce the use of amalgam.
3. The guidelines do not imply a recommendation for removal of existing amalgam fillings in persons that do not have symptoms in connection with the fillings.
4. Special and weighty reasons must exist for use of amalgam for children and youth.
5. When odontological indications exist for replacing a filling in an adult, a material other than amalgam should be used. In a case where a patient chooses amalgam as a dental restorative material, this should be accepted.
6. The Directorate for Health and Social Welfare is of the opinion that reducing the use of all dental filling materials is important. This will require increased emphasis on preventive measures, and these will be given priority.
7. The Directorate for Health and Social Welfare has not given detailed advice on specific choices for dental restorative materials. The reason for this is that the available knowledge base is too limited. An explanation for the deficient knowledge base is the frequent introduction of new materials and new types of materials. The Directorate establishes, however, some important premises and says something about which considerations should be given weight when choosing materials.
8. The Directorate for Health and Social Welfare is of the opinion that a quality-controlled knowledge base for the use of dental restorative materials/odontological biomaterials should be established and routinely updated, so that advice given on choice of materials that dentists should use, will continually be improved.
9. These guidelines issued by the The Directorate for Health and Social Welfare contribute to the 'Action plan for chemicals that are a hazard to health and the environment' written by the Ministry of the Environment in 1999.

Selections from the rest of the document

Introduction

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Other important considerations in the judgment of the Directorate for Health and Social Welfare have been: the precautionary principle and the substitution principle. These principles are general and apply for choosing all types of dental restorative materials. The views of patients and dental health personnel have also been taken into consideration.

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Goals

- Dental health personnel have knowledge that allows them to make good decisions regarding the use of dental restorative materials.
- The public will receive safe dental care of good quality.
- The mercury burden in the population is reduced.
- The release of mercury to the environment is reduced.

Target groups

Dental health care professionals.

Assessments and recommendations

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Release of mercury from amalgam fillings

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It is known that mercury in high doses leads to health damage such as disturbances in brain function, kidney function, the immune system and fetus development (12). No limit has been established for safe/harmless influence (14). Sub-clinical effects have, however, been shown at doses equaling those which some persons can receive from amalgam fillings (15; 16). In epidemiological studies no relationship has been found between amalgam fillings and illness (17-19), but effects on health cannot be ruled out (20).

The amount of mercury vapor released from amalgam fillings increases when chewing, brushing teeth and with bruxism (grinding the teeth). There have been reports of persons who have had a high level of mercury in blood/urine due to intense chewing of gum while attempting to quit smoking. Considerably lower amounts of mercury have been found after removal of fillings from some of the same people (21-25).

During the last 10-15 years, documentation has become available showing that mercury from amalgam fillings is traced in locations in the human body where it is unwanted. It has been shown that the amount of mercury in the brains of deceased persons correlates with their number of amalgam fillings (26). Mercury passes through the placenta, and the mercury concentration of fetuses correlates with the number of amalgam fillings in their mothers (27).

The amount of mercury in breast milk increases with increasing numbers of amalgam fillings in the mother (28). Those who bear amalgam fillings have more mercury in body fluids than persons without amalgam fillings (12; 29).

It has been reported that a majority of those who assume that their health problems are due to amalgam fillings, experience an improvement in their health after removal of amalgam fillings, but this is a complex area where cause and effect mechanisms have not been clarified (30). A relationship between the mercury level in body fluids and symptoms has not been shown (29).

Several uncertain factors exist; among others the possibility that mercury can be methylated in the human body, making it difficult to determine the mercury exposure from amalgam fillings (12; 31; 32).

No data has been presented that proves it likely that mercury impact from amalgam leads to health effects other than allergic reactions. Risk studies have, however, indicated that a possibility for health damage caused by mercury from amalgam fillings exists in a small minority of the population (33).

The margin of safety between the mercury burdens some persons with amalgam fillings experience and the burden that can set off illness, is small. The Norwegian National Institute for Public Health points out that 'Although the overall judgment is that it is unlikely that the metals lead, mercury and cadmium represent a significant health risk in the Norwegian population, it must be said that the safety margin for all of the metals is relatively small in relation to the potential for triggering subtle health effects' (34).

Mercury from amalgam fillings is the only component of dental restorative materials that is considered as an actual environmental problem. The strong increase in the concentration of mercury in the food chain is especially a problem. Consideration of both public health and the environment requires that the use of heavy metals be held at the lowest possible level. Although all dental clinics are now required to collect amalgam waste in special separators, the Norwegian Pollution Control Authority is still of the opinion that it is desirable to find more environmentally friendly dental materials than amalgam. In the Ministry of the Environment's 'Handlingsplan for helse- og miljøfarlige kjemikalier' (Action plan for chemicals that are a hazard to health and the environment) from 1999, strong action is recommended in working to reduce the release of or phase out environmental toxins. Mercury is among the most problematic environmental toxins (35; 36).

Assessment: The use of amalgam shall be limited as much as possible in order to protect the environment and due to possible injury to health.

For this assessment, particular emphasis is placed upon the following: Although it has not been documented that amalgam fillings result in health damage in groups of the population that have such fillings, doubts about the release of mercury from amalgam fillings have increased as new knowledge becomes available.

Alternatives to amalgam

It is documented that materials that contain composite resins can release unreacted resin components immediately following polymerizing. The breakdown of such materials can later lead to release of resin components (37). Except for allergic reactions, there is at present little conclusive information about possible injurious effects from these substances. Attention has especially been directed towards bisfenol A and/or bisfenol A derivatives. These substances mimic hormones and it has been shown that they have an estrogen-like effect on cell cultures. The amount of these substances that is released is small however. We have little knowledge today of whether or not low dose exposure to substances that mimic hormones can result in negative health effects (38). This should be clarified, especially regarding possible negative synergic effects when combined with substances in the environment having similar effects.

Assessment: Dental filling therapy for pregnant women should be avoided.

In the first paragraph above, reference is made to two articles, both of which have been excluded in chapter 11.² These articles have been excluded because they do not meet the Directorate's criteria for a good, systematic overview. We have nonetheless referred to them and they are included in the list of references because it is assumed that review articles contain more knowledge than primary studies. Both conclude that more knowledge is necessary.

...In the guidelines from 1991 the health authorities recommended avoiding extensive amalgam therapy for pregnant women. Due to little knowledge available for new materials, the Directorate has decided to expand this recommendation to include all filling therapy.

Other recommendations for good practice

In accordance with the previous guidelines from 1991 and with advice from the Adverse Reactions Unit for Odontological Biomaterials, the Directorate for Health and Social Welfare recommends that:

- **For new restorations, contact between amalgam and other metals should be avoided.**
- **Allergy to any ingredient in a dental material is a contraindication for use of that material.**
- **Efforts should be made to reduce exposure of patients and dental personnel to chemical substances from dental therapy when applying and removing fillings.**
- **A vacuum suction and water-cooling shall be used when removing old fillings.**

² Translator's note: Chapter 11 is entitled 'Knowledge Base'. This 10-page chapter has not been translated here.

Working environment

Handling unreacted composite resins seems to involve the greatest risk for development of allergies for dental health personnel (39). Since a separate publication covering health, environment and safety for the working environment in dental clinics is planned, this subject will not be elaborated on in these guidelines.

Assessment: Avoid contact with materials before they are hardened.

Governing principles and regulations

Governing principles

Public health perspective and the precautionary principle

Amalgam is one of the oldest filling materials we have, and it has periodically been controversial during the whole time it has been in use. It has been known for a long time that mercury is released from amalgam fillings, and during the last decades a relatively large amount of documentation has appeared showing that more mercury is released than earlier estimates assumed and that more mercury is absorbed from amalgam in the human organism.

Mercury is among the most problematic environmental toxins. It has been documented that mercury from amalgam fillings contributes substantially to the total mercury exposure of the population (12). The documentation that exists at present is not accepted as evidence that mercury from amalgam fillings leads to health damage in patients without a clearly defined clinical picture, although many of them have experienced complete or partial improvement after removal of amalgam fillings. For precautionary reasons it is important that the exposure of the population to mercury is limited to the lowest possible level (35; 36: 40). **It is therefore natural to discontinue use of amalgam and instead use other dental restorative materials as much as possible, since good alternatives are available** (emphasis added).

Newer materials can also possibly have negative effects that we have not yet discovered. There is some documentation of undesirable conditions regarding tooth-colored materials (37; 38). There is therefore reason to practice precautionary measures when new materials are introduced. Dental restorative materials, including fissure sealers, should only be used when clear indications are present.

In practice this will mean considering preventive measures, maintaining a reasonably hesitant attitude towards filling therapy, and using conservative forms of preparation that remove as little tooth substance as possible when a filling is required. The precautionary principle also requires restraint in the use of filling therapy for pregnant women.

The substitution principle

The substitution principle entails that chemical substances which can result in damage to health or disruption of the environment, be considered replaced by less harmful substances.

The law regarding control of products ('produktkontrollloven') §3 provides for the duty of substitution. This means that establishments that use products that contain chemical substances that can entail damage to health or disruption of the environment, shall choose an alternative that entails less risk for such effects if this may be done without unreasonable costs

or disadvantages. The Norwegian health administration is required to follow the substitution principle, which became law through passage of Ot. prp. nr. 40 (1998-99) through Innst.O.nr.70 (1998-99). **The Directorate for Health and Social Welfare is of the opinion that the provisions of the law regarding control of products §3 also includes amalgam, due to the high mercury content** (emphasis added). Alternatives to amalgam seem to represent considerably less of an environmental problem, and therefore represent a lower risk to public health than amalgam.

Dentists today have several good alternatives to amalgam available. None of the alternatives can replace amalgam for all indications, but in sum they cover the entire spectrum of indications.

It is well known that resin-based materials can be a hazard for the working environment. This is related to skin contact with unreacted resins. By practicing no-touch techniques, risk can be eliminated. The dentist is responsible for informing assistants about possible risk, and for seeing to it that assistants learn to handle the materials in a safe way, according to the law on health personnel §5. (A reference to two Norwegian laws follows here).

Some important regulations

Responsibility and professional justification

The dentist is responsible for the odontological treatment of a patient, including choice of dental restorative material. As health professionals, the dentist is obliged to perform in accordance with the requirements for professional justification and careful help that can be expected based on his/her qualifications, the character of the work and the situation in other respects, see the law on health personnel §4. In addition, justifiable practice assumes that the patient has the right to participate, among other ways also in the choice between available and justifiable treatment methods, see the law about patient rights §3-1. The dentist has a duty to inform required by the law on health personnel §10 and the law about patient rights §3-2 to §3-4.

Treatment in accordance with the requirement for justifiable practice means that each case must be considered separately. The choice of material must be based on medical history, clinical, X-ray and any other findings, and a detailed diagnosis based on this information. The wishes of the patient and evaluation of the prognosis must also be considered. When choosing treatment, the patient's ability to follow-up advice and guidance from the dental health personnel must also be considered. The competence, skill and experience with various materials of the person performing the treatment, can be important for a successful result.

The producer's directions for indications, contra-indications and handling of the material must be followed. Pre-dosed packages ensure correct proportions of a mixture and optimal quality of the material. In addition, such packaging reduces the likelihood that dental health personnel come in contact with unhardened materials. The patient journal must contain an exact specification of which products have been used.

A vacuum suction and water-cooling shall be used when removing old fillings, in order to avoid an unnecessary burden of harmful substances for both patient and personnel. For advice concerning removal of amalgam fillings, we refer to the website of the Adverse Reaction Unit for Odontological Biomaterials (Bivirkningsgruppen): www.uib.no/bivirkningsgruppen (English version at http://www.uib.no/bivirkningsgruppen/BVGtxt/am_rem_english.htm).

Participation, information and informed consent

In the law on patients' rights, the right of the patient or next of kin to participate and to receive information is specified. The patient's right to participate in decisions where several different treatments are considered professionally justifiable, is particularly emphasized. In practice this means that the patient/next-of-kin must be consulted when choosing restorative materials. The dentist has a right to, and under the circumstances a duty to refuse to carry out treatment that the dentist does not find professionally justifiable, according to the law on health personnel §4.

The patient is to receive, both before and during treatment, information that is necessary to understand their condition and the contents of the help to be given, including information about possible risks or adverse effects. This also means that the patient/next-of-kin must be informed of recommendations from the health authorities. Information must be appropriate for the individual qualifications of the receiver such as age, experience and cultural and language background. The contents of the information shall be recorded in the patient journal to the degree that is relevant and necessary. This is provided for in the law about patients' rights chapter 3 and the patient journal regulation §8j. In the event there is agreement to choose a treatment or a material that is not recommended, the reasons must be specified and the patient's informed consent entered in the dental journal, according to the patient journal regulation §8i. When information is given and conditions for informed consent are present, the appearance for treatment may be understood as tacit consent, according to the law on patients' rights §4-2.

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Conditions in other Scandinavian countries

Sweden

Sweden has had several rounds of studies on the use of amalgam in dental health care. The last study was completed in 1998 (43). The Swedish government has aimed to ban amalgam. In the national budget proposal for 1999 (prop. 1998/99:1) it was announced that the government intended to do whatever was necessary to introduce a ban on the use of amalgam. The ban was to take effect at the latest from 2001. It appears, however, that the EU regulations and agreements entered into probably prevent a ban. In the national budget proposal for 2001 (prop 2000/01:1) the government said that it would explore the possibility of banning amalgam out of consideration for the environment.

Many of the 'landstingene' (state or county parliaments) have decided that amalgam shall not be used in dental care for children and youth.

In Sweden the general national insurance plan also covers dental care. No refund is given for amalgam fillings, while adhesive resin-based filling materials (composites) do qualify for a refund. It is assumed that this has contributed to the phasing out of amalgam.

Finland

As early as 1993 STAKES in Finland sent out recommendations to reduce the use of amalgam in dental health services (44).

- In consideration of the environment, the use of amalgam as a dental filling material should be reduced.
- Amalgam shall be used as a dental filling material only when other filling materials cannot be used.
- Since it has not been shown that amalgam fillings are harmful to health, there is no reason to routinely remove satisfactory amalgam fillings.

Denmark

Denmark has had a ban against the sale of mercury since 1994, but an exception has been made for the time being regarding mercury for dental amalgam.

Implementing, evaluating and updating

The guidelines will be effective from July 1, 2003. They will be posted on the website of the Directorate at www.shdir.no

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Development of the guidelines

(This chapter has not been translated)

The knowledge base

(This chapter has not been translated)

Attachment 1:

Participants in the working group of the Norwegian Board of Health

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Paul Christoffersen, Norwegian Board of Health

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Ola Johan Basmo, Norwegian Board of Health, leader of the WG

Attachment 2:

Participants in the reference group

that considered and commented on the draft document at a national conference in May 2000:

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Maryanne Rygg, Forbundet Tenner og Helse (substitute for Dagfinn Reiersoel)
Christer Malmstroem, DDS, Sweden (recommended by patient organization FTH)
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Magnar Torsvik, representative for Chief County Dental Officers
Tore Ramstad, National Social Insurance Office
Vibeke Qvist, Dental School, Denmark
A representative from 3M (a manufacturer) was also invited.

Attachment 3:

Working group from the Directorate for Health and Social Welfare

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Attachment 4:

Participants at meeting on July 10 2002 (presentation and discussion of draft document)

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Attachment 5:

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for Health and Social Welfare working group
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