Notes from meeting on THE FUTURE USE OF MATERIALS FOR DENTAL RESTORATION 16-17 November 2009, WHO HQ, Geneva, Switzerland

NOTE: These are draft notes intended to mainly track discussion related to environmental aspects of amalgam; other comments have also been added relating to both direct health and environment, to keep general track of what was mentioned at the meeting. It is assumed that the presentations are collected from the presenters, and there is no attempt to reflect the presentation in these notes.

16 November, Monday morning

WHO-Dr. Petersen: Welcomes participants, states purpose of meeting, notes that this is the first meeting happening with UNEP and WHO related to dental amalgam and mercury issues.

UNEP-Per Bakken: Explained what UNEP is and its work on mercury since 2001. Global Mercury Assessment was issued in 2002, UNEP Governing Council (GC) in 2005 asked activities to be undertaken in the form of partnerships addressing consumption and use, 2007 asked for more formalised structure- addressing coal, smelters, products- waste, storage. In 2009, the GC was pleased with partnerships under UNEP- but indicated that more action is needed. Governments agreed to elaborate a legally binding instrument on mercury to reduce emissions and demand, supply, and with parallel track activities to be enhanced.

Flexibility needs to be considered given the diversity of countries and will also depend on the availability of alternative materials.

Mercury represents 20% of use in dental amalgam of all products, with a lot of mercury emissions to air from crematoria. In global trade it is labeled as a medical device so difficult to trace. He raised concerns on the link of amalgam and Artisanal Small Scale Gold Mining (ASGM) which is a major source of emissions.

In negotiations there will be areas of exemptions but these will be time limited-from experience, there is now the intention that the exemptions are reduced and to eventually not have exemptions at all, in the treaties. This is why this meeting is important. Negotiations start in June 2010 to be finalised by 2013 before GC. So the discussion on alternatives is very important. He expressed hope that the discussion will be broader than dental amalgam.

WHO-Dr. Alwan-Underlined that this is an important meeting and that WHO is giving the issue serious consideration, and he is looking forward to conclusions and recommendations. These will be circulated to all member states.

WHO-Dr. Petersen – This meeting is about putting dental restorative materials in focus. It is a cost-burden to countries and in many countries it represents 5-10% of the oral health expenditure. It is a misunderstanding that the dental carries is eradicated. In high income countries the situation is improving with less carries reported in the past years.

But for developing countries it is the opposite. The trend for carries in child population in developed countries is going down, but going slightly up in developing countries (see slide 4).

Reasons for this are the changing living conditions and lifestyles, diet and consumption of sugars, self care practices- proper oral hygiene, appropriate exposure and other factors Dental restoration depends on availability of material, education and training.

Alternatives to amalgam in the future – this is what this meeting is about. Overall objective is to assess the scientific evidence available on the use of dental restorative material

- to assess the potential side effects and hazards to health of existing materials for restorative dental care,
- to assess the feasibility of using those alternatives around the world,
- to address the cost implications of alternative materials to population and society and for situation on low and middle income countries.
- to discuss environmental concerns of mercury pollution and occupational exposure, and
- to suggest principal strategies for further reduction of the contamination (slides 10-13)

NIOM-Dr. Jon Dahl- 20 y experience – did studies on biocompatibility and toxicology and properties of dental restortive materials.

There are 4-5 different type of materials, composites (slide 2)- resin based composites, polyacid modified composites, glass ionomer cement, amalgamated alloy, resin based cements.

Operating procedures, handling (slide 3-4)

Longevity of dental restorations (slide 5)

Material	Ages of replacement	Annual failure rate
Resin based composites	8y	2,3 %
Poly acid modified	7y	3.5%
Resin modified glass	2y	3.1%
Glass ionomer	4y	7,6%
Amalgam	10y	2.2%

Reasons for replacement (slide 6)

- Caries, fracture, marginal failure and other,
- Most are caries and fracture-

Strength and weaknesses of materials (slide 7)

Resin modified glass ionomer – good handling one can mix it and place it, can be used for all types of carries.

Glass ionomer only for some cases.

Resin based composites - less adaptive

Biocompatibility – nearly the same for all materials,

Longevity

There is no material that scores best in all situations

Major challenge of a new material

- Prevent recurrent caries
- Prevent fracture

So we need to

- Create a dental amalgam replacement
- We need to develop new material depending on countries resin could be complicated
 - Characteristics should be simple handling, maybe with some moisture, need good adaptation to tooth structure, sufficient mechanical strength and longevity- to be discussed how long should that be.
- We don't have something like that, we need glassionomer, low shrinking resins, and a high strength fillers it is in progress there is a good interface, no gap there is chemical interaction, material bonds well to the dentin, the strongest they have tested, mechanical properties of this cement could be the start for this material

University of Oslo, Dr. Espledid presentation done by Dr. Dalh

3 studies were conducted in Norway –

In first study:

How did dentists react when they heard they should not be working with dental amalgam? The ban on 1.1.2008- did not create any problem since dental amalgam was not used anyway.

- The sample was 115 dentists all dentist in the county of Troms Looking at the experience of those dentists, 23% said they had no experience with amalgam. In general they had 13 years of experience on average. This reflects the dental community, many new graduates, and some older ones who would prefer amalgam.
- different clinical cases were presented where the dentists were asked; if amalgam was legal, would you prefer to use it in this case?' and 'what material would you prefer today?' (slides 5-8) in both cases examined preference for amalgam was quite low

There was preference for resin modified glassionomer because it sets very quickly in , in less than a minute, whereas glassionomer cement has to set for 5 minutes.

 2^{nd} study – the KVIT project quality development in dental practice. Multi-center study-in connection with a study in DK. Aim- to follow posterior dental filling for at least 4 y and map out factors relevant for the longevity.

It was a practice based study- dental professionals from different clinics. Carried out in real world, so it reflects what materials they use.

There were 4000 fillings done in 4 years in 900 patients.

The filling materials used where composite 81.5%, componer 12.7%, GIC 1.2% and amalgam 4.6% - Successful fillings after study period – dentists would evaluate their findings differently – were 91.5 % amalgam, 85 % composite, 95% componer 70% GIC But the componer was placed only by one dentist – skewing the results The reasons for failure were looked at, 78% of fillings failed-secondary caries were

The reasons for failure were looked at, 78% of fillings failed-secondary caries were created, 9.8% lost filling,58% there was a fracture of filling.

In relation to survival functions – composite was less than amalgam but there are other studies which show that composite is better.

After 24 months the resin modified GIC was the best option for patient.

Choice whether one drills or not, attitude has changed from 1983 to 2009- from 67% down to 6% (slide 25)

Lessons learnt from the studies:

- Norwegian dentists in 2009- not convinced that the alternatives can fully replace amalgam.
- Composite is now the most commonly used material
- Class II survival after 5 yrs exceeds 80% for the amalgam alternatives, and
- Restorations are placed on other indications in 2009 compared to decades earlier.
- The use of dental materials in a global perspective is also a matter of indication for restorative therapy.
- There is wide disparity in practice between clinicians in selected countries.
- When discussing consequences fo an amalgam ban this should be taken into consideration

If you need to prevent moisture – amalgam is preferable. But otherwise it is up to the patient.

Response on Espelid (Norway) Presentation:

Question - Presentation suggests that in some cases amalgam is still preferred, can you please provide an idea of the percentage of cases that amalgam would be preferred?

Response - Norwegian dentists accepted the amalgam ban and follow it. In some cases, the moisture in the mouth leads to a preference of amalgam, but this is in a very limited number of cases. The need is demonstrated by the reduced replacement time for these fillings. No percentage was given.

Dr. McConnel – Ireland – 38 y dentist- PhD in mechanical engineering, materials science. Teaching clinical dentistry.

Dental practice in Ireland

State funded - Basic oral care , payment for posterior teeth in primary and secondary dentitions, extractions, state does ~NOT pay for composite restorations

- Semi state finded One part from state some from member
- Private 70% composites, 30% amalgam

They have been looking at how many universities are teaching composites.

Why to change- important to teach students other materials- since amalgam is going down.

He doubts that it will be used in future, change needs to start in education –

We need to see survival on the tooth rather than the material

What is best for our patients- for composite restoration, you only remove the disease, you don't have to cut the tooth- caries should be removed and nothing else. Material should be placed in correct way.

Advantages of composite resin materials: preservation of the tooth structure, longevity, environmental factors, patients demands advances in materials

Disandvantages – amalgam is cheap, quick, less technique sensitive, (but it is not a reason not to choose), workforce are comfortable with amalgam, there is lack of continuing education, and the payment systems are covering that.

Question is who decides on treatment and which is mainly the pay master! In Cork the undergraduate programme does 75% composite resins for posterior teeth They don't do amalgam until only at the end, and actually struggle with it since they are used to the resin one.

Moisture is a problem

Outcomes(last slide):

- there is a reduction in the use of amalgam,
- adhesive resin materials allow for less tooth destruction and as a result a longer survival of the tooth itself,
- funding agencies should take the initiative and encourage the replacement of amalgam as the material of choice for posterior teeth with adhesive systems.

Dr. Meyer- DDS, ADA, USA

We need to look at what is the best interest of our patients.

There is no perfect material – we are worried to phase out one material when we don't have replacement for some indications. We need to see the impact on the developing countries

We need to look at prevention restoration risk management and not in restoring only teeth.

What do we do in Developing Countries when there is no privilege to use light curing system? The other materials may not be good enough- we may have shrinkage.

We are talking about organics and a lifetime for ingesting these materials and need to discuss this on what is the best interest of the patient.

Resin composite shrink. In large restorations – we need same coefficient expansion therefore we should not promote one material over the other but look at patients' health. He discussed different materials:

Amalgam.

Gold is also causing mercury pollution - should we the ban gold as well?

In US they call Atraumatic Restorative treatment (ART) as interim filling.

ACP composite- amorphous calcium, Phosphate- maybe this is the way for the future and then maybe we can phase out amalgam,

Fluoride varnishes

Sealants

Composites- may leach bisphenol A- which is an endocrine disruptor (EDC) Cytoxicity could be a problem.

We need to consider that there is mercury with different degree of toxicity , one type may be stored in different tissue, others just pass though the body.

Occupational safety – they have done studies in the US back in 1996- then they came with the pre-encapsulated amalgam, separators etc,

Environment concerns- worked with EPA- saw the impact of amalgam in environment 35 tonnes sold in US- out of those 31 tonnes utilized in dental offices for new amalgams or to remove, out of that 25 tonnes goes into scrap from amalgams, 80% held from dental offices/chairs, 6.5 tonnes to sewers, 1ton to sewage sludge incinerator, deposited SSI emissions 0.1 tonnes, so total discharges to surface waters is 0.4 tonnes. In perspective with gold mining and coal emissions these emissions are minimal.

We need to protect environment, need to phase out amalgam when time is right and need to put separators, traps, clean them, maintain them etc., apply best management practices, recycling, minimising mercury in the environment – look at local environmental issues and populations and find what is best for those populations. With separators you can get down to 0.1 to 0.3 tonnes of emissions –you can remove more than 99% of mercury with separators, and chair traps.

We are phasing out use of amalgam already, declining by 3% per year. If we ban it now additional cost of 8, 2 billion USD, and morewill arise.

New total revamp needed. Need to get rid of amalgam, need to measure releases in environment not in product usage, but no perfect replacement out there. Better job needed on risk assessment and management.

Response to Daniel Meyer (ADA) Presentation:

<u>Lars Hylander</u> (Uppsala University, Sweden) pointed out in response to Daniel Meyer's presentation that the difference in bioavailability of mercury from dental amalgam and natural sources, such as cinnabar, is an important point not raised in Daniel Meyer's presentation. He indicated that yes mercury is naturally occurring in cinnabar, but that there is no bioavailability of mercury from cinnabar as long as it stays in geological deposits below the biosphere.

Discussion

<u>Desiree Narvaez</u> (UNEP) provided some feedback on mercury emissions data in response to Mr. Meyer's presentation. She clarified that governments have agreed to transition away from mercury over time through the negotiation of the legally binding instrument. She also noted emissions from coal are high, but we cannot say that dental mercury release is minor – it is not negligible, governments have concluded that it has to be reduced- to transition. So should not be compared.

Meyer – for amalgam phasing out but we need to establish the timeline.

<u>Peter Maxson</u> (UNEP) clarified that the discussion in the forum should lead to an appreciation of how amalgam is used in developing countries and the differences in

different parts of the world. A multi-pronged approach should consider other materials and strategy could look at: How can we move away from amalgam in developed countries? And then look at how amalgam is used in developing countries at the moment and what are the long term needs? He also sees the difference of use in Developing Countries (DC) and develop a strategy on how to phase out amalgam in developed countries and how to deal with it in DC. Another idea would be in banning products with bisphenol A

Benoit Soucy (Canada) mentioned the environmental effect of amalgam in Canada and indicated that there is information that has been evaluated. He noted however that there is no information on environmental effects of composites. He wants to look at the issue in a very broad fashion. He wants to recognize that overall health effect of a ban on mercury may pose problems. He later noted that avoiding carries is the best way to move forward.

<u>Lars Hylander</u> indicated that gold may be a continued option in teeth.

Roberto Vianna (FDI) noted the number of dentists in Norway being 4000. In Brazil, there are 232,000 dentists. Universal treatment in Brazil with a similar (?) ratio of dentist to patients as in Norway. Notes the different needs of developed and developing countries and the interest of the patient.

<u>Robert McConnell (Ireland)</u> noted that we should be looking at removing disease and the longevity of the tooth over the restorative material choice.

<u>Poul Erik Petersen</u> noted that the alternatives were reviewed this morning and wants to structure the discussion on the new materials now. WHO's role is to provide information on alternatives. WHO is also responsible for better overall health, and mostly deals with health ministries.

<u>Sudeshni (South Africa)</u> would make a plea to not separate developed and developing countries. We need to think about one product for all, including cost implications.

<u>David Williams (IADR)</u> wants to focus broader than Norway. Prefer to look at the impact of disease rather than dental issue. Grateful to UNEP to force the pace of the issue. Need alternatives to amalgam and what the requirements are. Big questions are the important bits.

Peter Maxson notes elements of strategy emerging already.

<u>Naidoo</u> notes that some materials include fluoride and wants to know the science behind it.

<u>McConnell</u> noted the survival of composites and amalgams in the US insurance industry was consistent except for when the patient switched dentists. Encourages dentists to find

the "Teflon" tooth, which means a restoration with such a smooth surface that plaque will not attach so that there will no substrate available for bacteria.

<u>Hylander</u> asked a question about cracked teeth due to amalgam and composite fillings. <u>Dahl</u> responded that 4 % of fillings are replaced due to tooth fracture, the same percentage for amalgam as for composite fillings.

<u>Lars Bjorkman (WHO- EMRO)</u> asked if the life time of filling materials is similar for developed versus developing countries. Dahl responded that dental experience will help to increase the life time.

<u>Bian Jin You (China)</u> indicated that larger cities have more choices for filling but in the rural areas there is less opportunity to move away from the amalgam because of the higher price for composite fillings due to additional equipments needed but not a higher material cost if produced nationally.

Lars Bjorkman, Norwegian Dental Biomaterials Adverse Reaction Unit

Adverse reactions to amalgam can be stomatitis, gingivitis, eczema. Other suspected reactions also exist.

There are subjective symptoms or objective findings – both reported. They are reporting problems to the system ,through a form.

Reports are mainly on amalgam, from 1993-2008 – then on composites and cements and other alloys, and then materials for short term use.

The sum exceeds 100 % one report could contain more than one material. Since ban came, there was an increase on composite reports and decrease of amalgam reports. 8% for amalgam after 1 week, 56% on composites.

Many health complaints from amalgam – number of reports in 2008- same pattern analysis like last year.

In orofacial health complaints – similar complaints for both materials.

How to use the study:

- signal generation, is a product over represented in the statistics?
- New types of reactions
- Rare adverse reactions could be detected
- Long term effects
- changes over time.

Reaction to acrylate cement- new type of material and new type of reaction

Conclusion – reporting of adverse reactions or adverse events in the form of a dedicated reporting procedure can reveal changes in adverse reaction patterns and serve as a signal-generating pool. It can be used as a complement to post-marketing surveillance by the maufactureres.

The conclusion to establish a register .. of 1997, is it still relevant?

Summary- slight increase on reports/complaints for composites.

No complaints from dentists

How subjective is the report- it is possible to verify the findings. Some times it is a few months later.

In South Africa- they have 4000 dentists for 15 million people – so surveillance is difficult, where people will report. So we couldnot get the whole picture.

Vianna- very low number of dentists per people in DC.

McCOnnel – need to be concerned with longevity of tooth and not go about material.

With respect to better alternatives – we need to talk about all countries and not separately. Cost implications need to be discussed.

Dahl- maybe we need two materials one for later one for now. Need to solve the problem of big caries.

- Look at whether the material can prevent carries, and what has it shown?
- Dahl- diagnosis of secondary carries, in glass ionomers they thought that they are carriostatic materials, but they found recurrent carries and it was not clear if these were scientific ones

Shrinkage- can cause cracking, statistics on cracks caused by shrinkage, or cracks on amalgam expansion?

Dahl has read that there are 4% of fillings due to tooth fracture and it is the same in both groups.

Q: would life expectancy of material be the same in a low income country vis a vis the results presented by Dahl in Norway?

Dahl- it is up to the dentist to decide when filling needs replacement, so experience may matter.

In China – carries rate is rather lowThey have two big manufacturers of capsules.

51 CND (Chinese dollar) for amalgam, twice as high for composite.

They did studies on alternatives, but for carries they have failed

The ideal material is not easy to come out. So again they select amalgam as a first choice.

Dentists may not use the instructions and this is why we have failure of the material. –

WHO- supports providing care that it is evidence based and not manufacture based, countries will get back and ask them whether they like a company or whether they are being paid by it.

<u>David Alexander – Roberto Vianna, FDI</u>- federation of 144 national dental associations over 60 leading specialists

Ceramic – onlay survival is 88% over 15+y, Porcelain crowns 48% at 10 y, biocompatibility – few data, good aesthetics, High degree operator skill (you need good technique to place them)and technical infrastructure required, Considerable expense, not appropriate for most communities.

Precious metals – survival full coverage crowns 68?% at 10 y – biocompatibility: contact allergies, high cost, you need good skills

Resin composite – major advantage, aesthetics, but takes 3 times longer, operative challenge and interproximal placement – material wear and modulus elasticity, supply infrastructure /storage, they are temperature sensitive, need to be in the dark etc problem with transportation and storage in exotic countries. BPA problem

Glass ionomer cements – was developed in a lab in UK, Good aesthetic, good preventing effect through fluoride release, ART, minimally interventive dentistry Amalgam.

FDI principal strategies

- 1. Investigate safe affordable alternative restorative materials to dental amalgam,
 - Amorphous calcium phosphate composites smart composite they believe that if we challenge the IADR and countries, through industry and education and practice,
- 2. Responsible approach to protecting the environment
 - Best Managament Practices bulk collection programmes, chairside traps, vacuum filters, amalgam separators, waste disposal services,
- 3. Adopt minimal intervention approach
 - Minimal intervention approach through modification for the oral flora, patient education, remineralisation of non cavitated lesions, minimal operative intervention of cavitated lesions, repair of defective restorations.
- 4. New paradigm to shift from restorative to preventive model
 - FDI launched wth IADR and FDE Global Caries initiative in Brazil, they have an event in NY 55000 people gathered... to look at caries in completely different light. They see this as a profession led paradigm shift, FDI, IADR, and IFDEA do not come very fast and will gain momentum

General assembly of FDI – determine policy and as they mention the amalgam and joined the UNEP Global Mercury Partnership – they rated it as biggest issue of this decade. Set up a programme to see how to tackle it.

16 November Monday afternoon

Dr. Williams – President of IADR- International association for dental research

Amalgam – used for 150 years, will be going down anyway.

Amalgam safety- US FDA July 2009- levels of elemental mercury released by dental amalgam fillings are not high enough to cause harm in patients. >Amalgam is safe

Mercury Road map – Mercury is safe to use in a setting – FDA monitoring the efficacy. Filter used solmetex.com - to recover 99.5% of waste is tipical. 695 USD for installation and 150 USD for catridges. Company takes back and disposes safely the catridges. Vast majority of mercury from dental amalgam waste can be captured usng BMPs, Best Management Practices difficult to implement in lower or low income countries

Composite - has been used for over 45 years, toxicity can be high but not clinically relevant, Waste – there is no evidence of environmental harm

Amalgam vs. composite

Composite needs more -7 times as many repairs as did amalgam restorations. Do the material shrink or not, what are the decisions made around replacement, why dentists make decisions, and how, this is an area where great objectivity is required?

Research- need to improve basic chemistry to reduce shrinkage- research requires teams of materials scientists, computer scientist, toxicologists, synthesis chemists, and industry collaborators. We need to make a new framework for research where you don't really compare one material with the other but look at the material as such.

We need to have links to industry since they make the materials, in IADR they take conflict of interest very seriously.

He wonders whether we are creative as much as we could be.

Priorities of IADR

1/ reduce the use of dental amalgam

- ➤ Prevention (no1 priority)
 - Primary proper use of fluorides, sealants, community interventions
 - Secondary remineralisation strategies
- ➤ Improved dental materials (near term)_
 - Improved composites +next generation
- > Tissue engineering approaches (longer term)

IADR have a task force on dental materials

- Chair Stephen Bayne
- Members material scientists, clinicians and industry scientists.
- Accelerate developmentst of improved materials
- Provide clinicians with viable alternatives to greatly reduce the use of dental amalgam
- Partnering with FDI to promote the use of BMPs until such time that amalgam use and amalgam replacement has discontinued

<u>Michael Bender</u> welcomed the IADR presentation and indicated that he would like to work together with them to reduce dental mercury pollution. He noted the track record of amalgam separators use in developed countries outside of Canada and some EU countries

are poor and are in great need of improvement. For example, information from amalgam separator manufacturers indicate that only around 25 percent of dental clinics in the U.S. have separators and a review of an ADA survey finds that the states with the higher use of separators (around 10 states) are the ones that require them. Best management practices is an area which needs continued work, given that surveys indicate that a small percentage of U.S. dentists understand what they are so it is likely that they are not being used overall. Mercury emissions from crematoria is also an issue and a reason to move away from amalgam, since the rate of cremations is growing annually and the cost of installing pollution control equipment is likely to be cost prohibitive for many facilities. David Williams responded, noting that they are open to working with UNEP.

Benoit Soucy question. Who is responsible to develop alternatives in the dental industry? Responsible replacement of amalgam. The industry will be responsible to support this change process. The industry needs to know that there will be demand out there if they produce innovative materials.

Lars Hylander, Uppsala university

Separators have not the efficiency claimed to have (see presentation)

Peter Maxson, UNEP consultant_ (see presentation)

- 50-70 tons to air emissions, US thinks that this is significant quantity

Monday 16/11/2009 end of day Discussion

<u>McConnell</u> suggesting moving away from mercury. Developing criteria for future materials, alternatives.

Naidoo. Review immediate, short and long term strategies.

Williams. Common ground for criteria and economics behind this.

Meyer. Organize a systematic review including the status quo.

Peterson. Discuss how to go post-amalgam, feed into WHO oral health programme.

Lars Bjorkman. Suggested designing a decision based flow chart.

<u>Robert Mcconnell</u>. What are the criteria for an ideal dental material. Kills bacteria, reverses deterioration, can be used in a wet environment, stabilizes the mouth. And then WHO could approach manufacturers to indicate there is a market for this. Williams indicated to get a response in a reasonable period of time is important... these are the properties and needs we have.

<u>Valencia</u> (Colombia) noted that service needs to be discussed. This implies that we need to reduce the goals. Aware of reductions and ambitions.

Insurance companies? Is it possible to convince them to at least reimburse alternatives and later on take amalgam off the list.

<u>Petersen</u> suggested WHO could recommend some guidelines on this. Must be aware of the developed – developing country dynamic in doing this. It's sensitive.

Hylander notes that addressing no-mercury fillings for children and young people is a helpful early step.

<u>Soucy</u> – we agree the use of amalgam should be cut back as soon as possible. Limited reason to treat a kid with amalgam and we should promote that aggressively. Work on the insurance tables and the data there is important – longevity of the tooth.

<u>Maxson</u> notes that the issue of cost is important, particularly in actuarial tables. Also externalities such as water pollution and cost for waste handling need to be considered.

Tuesday 17/11/2009, morning

<u>Jos Van den Heuvel (FDI-Public Health committee)</u> – Representing Chief Dental Officers – EU – but presenting his own views- the way he would present them to the minister of Health – not environment. Amalgam vs. alternatives.

He questions the cost of the amalgam if you consider the cost of separators and other environmental costs.

In EU problem for big fillings – dental education, patients' preferences, reduced availability of mercury products.

Sweden 1978 /1979 – amalgam 74% composites 26% Finland 2000- amalgam 5% composites 79% glasionomer 11% Australia 2005- amalgam 28%, composites 55%, glasionomer 11% NL 2007 – amalgam < 10% composites > 81% glasionomer ca. 5%

Choice of material: Education and training, regulation and recommendations by authorities, professionals views and patients opinions, aesthetics, costs.

Not ban amalgam filling but not be routine treatment – to be on thorough indication based on risks and benefits.

Recommendations

- Necessity to improve prevention and patient information ,regarding the health information in relation with the prevention message, but to get informed consent so patient knows what happens to his mouth and what is the risk he gets into.
- Need to put effort in research on devices adverse effects of dental materials, devices

- Improve glass inonomers quality
- Industry should put some work on glasionomers and modern amalgams also for the poor countries.
- Third party payers to consider cost ./benefits of restoration materials.

Who decides on the treatment? Dentist or third party, he would consider it unethical for the dentist to leave to others to decide ... apart from the patient. Dentists say that they don't like to be told what to do

He noted that a near term ban on amalgam would be disastrous. Glass ionomers have a real potential. Amalgams imported into the developing world should be of better quality to protect human health. Convince insurance companies to refund more than amalgams.

Question - What is the difference between modern amalgam and older? Gamma are the older, more unsafe amalgams. The differences are the composition of the alloy. Better, consistent packaging could also be considered / supported, such as encapsulated amalgam.

Question – what is relevant for the minister of health. Not relevant in the Netherlands anymore. 20 years ago the decision was to continue to use amalgam safely, noting risks and advantages with alternatives as well.

Roberto Vianna (FDI) –Brazilian: Mercury sold in plastic bottles is a problem. These are sold although there is an encapsulating law.

McConnell. Criteria for using amalgam. Population based or situation based?

<u>Elena Lymberidi-Settimo:</u> Notes that European Parliament has some political will. Phase out of amalgam was proposed for 2007, although there is no follow through yet. Dentists may not have all the information needed to inform patients of the risk. Dentists need better mechanisms to be aware of the risks and benefits.

COUNTRY PRESENTATIONS USA

Meyer- ADA said that there is no advisory for children and women-Limitations – diagnostic codes, medical profession has , dentists professiondoes not have, to properly diagnosedisease before treating it. ADA came out with a risk assessment tool. Was manipulated by those who had interest They are worried wether patients are over treated.

CDC and ADA support that amalgam is the best.

Bisphenol A – Ray Bowen-works for ADA- lot of work on composites and adhesives, and yes there are composites – the best majority do not have bisphenol a- but if there is

not complete bonding or incomplete polymerisation or in saliva for a long time – then you might find it.

Standards – ISO TC106 on separators to be potentially revised - invited Lars Hylander to make a comment.

Composites really going up in the US – especially the single-side ones, in multi-side fillings the amalgams may be more.

Conclusions:

Insurance coverage will need to be modified to cover alternate materials Service in public clinics need to be offered to all

The vast majority of all composites do not contain BisphenolA. If there is incomplete polymerization, there can be trace quantities of it. It is a by-product.

There is discrepancy in the reporting on mercury capture in the US.

Latin America

<u>Dr. Sandra Valencia- from</u> Colombia presented statistics on encapsulated versus other mercury. Cost of encapsulated mercury is more expensive and could discourage dental treatment in some cases.

- Cost is almost double resin and ionomer to amalgam
- The insurance system is reimbursing resin for front teeth.
- They have not quantification of the proportion of consumption of mercury in dentistry

Main focus is in ASM

In health services, countries already have standards for biosafety

Some ideas to consider:

- Economical cost but functional cost too
- Covering
- Biocompatibility
- Quality of attention dn services
- Health public policies

In transition they need:

- Skills of professionals and governments,
- Introduction of best dental materials (all mercury is precapsulated)
- Decrease the cost of new dental materials,
- Model of Primary Health care.

Question concerning environmental release standards in Latin America? Peru has a standard and in some cases there is work going on in this area.

Canadian Dental Association- CDA

Benoit Soucy talked about demographics of the Canadian population and dentistry and the Canadian health system. Canada has no dental material industry and it is a challenge to engage alternative materials. Payment service is not the way to go in Canada, because dentistry is primarily private. CWS (Canada Waste Scheme?) for amalgam waste called for reduction of releases of mercury by 97% over 5 years, based around the use of amalgam separators. An obtained 70% reduction over 5 years did not meet the target but still it was viewed as progress. EC has since published a Noi ??? to regulate for offices that do not have separators, they would need to write a pollution prevention plan.

Health and social services are provincial /territorial., except for public health and medical devices which are federal. They need devices and get this from abroad...

They have high infrastructure of cost, spread over land mass and not used much.

Medicine is covered by public insurance schemes.

Dentistry is private but 60% of Canadians have private dental benefits.

Social and children programmes vary from province to province.

Federal provinces coverage for first nation s and Inuit.

Free children healthcare in Quebec, in Ontario... maybe as well.

The prevention of dental decay is decreasing. It pays of when children are treated....

They have no dental material industry so cannot ask for special materials, it si a small market so no interest to come over.

Dentists in Canada did not know of width of material available because manufacturers they don't see the interest of selling in Canada.

They mainly use amalgam????- in 2006- sales of amalgam dropped from 3000kg in 1999 to 2500 in 2006. In 2003 around 5000kg of amalgam removed

Based on the precautionary principle – but not on evidence, pregnant and children not to receive, recommendation not regulation. Called reduction of amalgam by preservation.

In Canada- You have to reduce mercury releases by 97%, through BMP-separators. by 2007 70% of dental offices in Canada had voluntarily implemented the BMPs of Canada wide standard for mercury. 18000 professionals, you know who they are you can regulate them. They were nervous if they were to regulation –

So they did not meet the 97% - as of jan 1, 2010 any dental office which is using amalgam, they need to submit a waste management plan –

Advice from them is to use the best restorative material – for the patient. For small caries it is best to use the composite.

No information is available on composites, but should be available in 6 months. The Environment NGO indicated in follow-up that it is worth noting the process for the compliance rate on amalgam separators in Canada; this is an example to follow. Luke

Trips article with the CDA (Canadian Dental Association) was noted as valuable. How to get to the trade unions to work on the reimbursement issue is a problem for the CDA.

China - Bin Jin You

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Presentation includes Chinese data, internet, and from Thailand.

Production in China- there are two major dental amalgam manufacturers in Shanghai and Beijing and others are located some provinces. Difficult to shift to alternatives due to cost and technique issues. Shifting to alternatives might create a social problem for the Chinese population.

Antai science and technology company, Beijing, manufactures amalgam capsule for 8.5 million pieces per year and 1 million Chinese dollars income per year.

Shanghai dental material manufactures- producers amalgam capsules

In hospital you cannot apply raw mercury – only pre-encapsulated. <u>www.ehsy.com</u> There are national standards defining the ingredients of amalgam,

- In Shanxi province composite resin is used more than amalgam in large hospitals about 70% and 60% in middle level hospitals and 50% of them in small ones.
- Guangxi province still use amalgam 8-10 %, more than 80% of private dental clinics used on need of patients.
- Beijing, composite resins are used in the large hospitals instead of amalgam,
- In Shanghai, 45% dental amalgam used. For teeth restorations. Most of them do not have guidelines.
- Anjyi province, amalgam as one of teeth restorative materials, for post molars is popular and common in large cities.
- Dalian city amalgam Not used for children and very few used in other hospitals and clinics.
- Zhengzhou city of Henan province, amalgam common for teeth, cost is about 50 chinese dollars, composite double,

South East Asia. Prathip Phantumvanit.

Atraumatic Restorative Treatment

Thailand- amalgam is used in every dental clinics but amount decreased because of aesthetics.

Vietnam- in Hanoi, teeth filled root canal, 40-50% amalgam

For caries 5-10% amalgam

In other 30-35 and 5-10 for same categories

Philippines already decreasing amalgam, but some still use it.

Side effects of dental amalgam – topical allergic reactions , systemic allergic reactions related to amalgam fillings.

There is little evidence of any health risk from amalgam- from a study in children teeth-they made own analysis and recommendation (2001) do not replace unless there is a new material There are studies – databases .

Several dentists have been found documented to suffer from mercury poisoning.

Exposure from working in dental office was as if you had 19 fillings.

Mercury will be excreted after 8 days,

Indonesia they have a local producer of glass ionomer and this is cheaper so this is what they use!

Many dental schools are using amalgam

In China as well because there is a composite locally produced it is cheaper than amalgam!

They concluded that amalgam is mostly used, but if you look at tables – and put together resin with ionomer they appear to be rather 50-50.

Trend is more resin and ionomer than amalgam in the future. !

Middle East –Dr. Honkala

Use of ART

Interesting tables – composite quite used.

Africa

Hardly any information

In south Africa- there are more problems on infection control

She spoke to traders, a lot of amalgam, but the composite has increased.

We need some empirical research

Amalgam is material of choice for posterior teeth restorations

The majority of 4000 dentists in S. Africa mainly practices in private.

Patient pursue forcing amalgam out.

If countries can afford alternatives – they should phase out mercury based on the precautionary principle.

There is no manufacturer in S. Africa, all imported, composite 4-5 times more than amalgam, not double as we saw in most of other countries.

Discussion Time

<u>Michael Bender</u>. Proposed the idea for a global dental mercury "phase down," which could be a positive step for the group to consider moving forward with. Supported by Poul Erik Petersen with some nodding of heads and no objections expressed from others.

<u>McConnell</u> noted that education is important. We can't move away without engaging the education sector. This needs to be an integral component.

<u>Phantumvanit</u> noted that the developing countries are open to moving to a phase down. Why are the rich countries reluctant to take action? Is it the industry reluctance?

<u>Lars Hylander</u> noted that where there is will, mercury phase down can be accomplished rapidly.

<u>Maxson</u> noted the local availability of composites make them more affordable in some cases. There was some defense of the time to place a composite.

<u>Michael Bender</u> noted the similarity of the health care sector of phase down in products and welcomed the help of the dental sector in doing this.

<u>Japan</u> has moved away from amalgam, mainly for aesthetic and mercury reasons. It is not taught in the education system very significantly. Materials for dental restoration are manufactured in Japan. Industry should be included in the discussion.

Desiree Narvaez – UNEP Global Mercury Partnership on Mercury in Products (see presentation)

Question on whether there was consideration of crematoria and releases from composites. UNEP does not have data for this, but being an organic material it is transformed into carbon dioxide and water during cremation.

Michael Bender – UNEP Global Mercury Partnership on Supply and Storage (see presentation) – WHO-no safe level of mercury.

Request for reduction quantities from around the world. Notes that discrepancy in the reporting on mercury capture in the US may be due in large part to the US Environmental Protection Agency failing yet to update is 2002 estimates for dental mercury releases.

Carolyn Vickers – WHO chemical safety

WHO is preparing to announce mercury as one of 10 chemicals of concern globally in 2010. WHO has capacity to support advocacy. WHO's role in negotiations will be that countries will turn to WHO for independent advice regarding health care issues. If there need to be exemptions, They will play important role in implementation She noted some parallels with DDT under the Stockholm Convention. DDT was given an excemption under POPs — WHO is now taking care of that how to decrease use.

Benoit Soucy comment - community based care could use more support for waste disposal.

Poul Petersen - Provided an overview of the discussion. Noted little discussion on occupational exposure.

Petersen's summary (which was presented as an overhead):

Issues in use of dental restorative

Issues in use of dental restorative (copied from the slides as they were presented)

Country based information based on existing reporting systems?

Health information systems established and in which countries High income countries Low and middle income countries

Decline in use of amalgam and increasing use of alternatives?? i.e. Phasing down of amalgams is already in progress but due to other reasons than political

- --outcome of preventive dentistry and improved lifestyles
- --changes in diagnostic practices
- --increasing demand for tooth coloured

Trend under way in ,middle income countries Decline in use of amalgam and increasing use of alternatives

Need info from lower and middle income country reports

1. Evidence correlated to use of existing /future biomaterials

Glass ionomer/composite have great potential, need for minimising failures, need for alternatives

<<relevant alternative for children – yes
What about adults in general?
Old age?</pre>

Indicators of success- outcome oriented is retention of restoration, or retention of teeth is better indicator of success re. WHO goals for oral health – dental statuprevention of dental carries. We need to make this orientation outcome indicators to be more prominent

Longevity

- Extension of disease, : ex. Occlusal caries fillings (higher) vs class II fillings
- Small or large lesions

Criteria for use of restoration materials?? Alternatives to amalgam??

- Posterior teeth??
- Anterior teeth?
- User/provider friendly or patient friendly?

2. Oral health care provider patient interaction

Who decides for use of dental restoration materials? Patient? third party payer? provider of dental care??

On information to patients about advantages/benefits and disadvantages is important to choose material

Safety of dental restoration material is of concern to patient, and to occupational exposure.

3. Cost of dental care

Amalgam vs glass ionomer/composite

Cost of materials is relatively higher to people in LI and MI countries than in HI countries.

Implications to health of the poor disadvantaged people, children and adults.

Health insurance systems is a way to tackle that.

4. Responsibility of industry

Improving the standard of existing tooth coloured materials and development of new materials of high quality

- Reducing price of materials alternative to amalgam
- Better distribution
- Increase availability of new dental materials
- Market for alternatives to amalgam

5. Oral health care providers

In high income countries we can count on dentists, in middle income dentists and auxiliaries, and primary health workers are important In lowe income countries we have to relay on primary health care workers

Skills in dental restorative care

Paradigms in dental restoration

Safety of dental materials to provider for care

- 6. Health service system advanced,less advanced, or poor We depend on facilities, needed to have water, electricity and suction ensured. Particularly important to lower income countries
 - 7. Future Challenges to healthcare community
 - There is a need for risk assessment and indications for restoration
 - Evidence in dental restorative care
 - Criteria for quality of restorations
 - Stronger clinical guidelines are needed for making dental restorations

Research community should help us with above

8. Public health context

In 2007 WHA 60.17 action plan, promotion of health and integrated disease prevention

The gaps in implementation of prevention of dental caries – translation of evidence (Nairobi)

- Prevention is the most efficient way to phase down the use of amalgam

Primary health Care WHR 2008-9

- -Universal coverage in health care
- ensuring fairness in financing health care
- providing essential care to population

Who decides for use of dental restorative materials? Patient? Third party payer? Provider of dental care?

9. Partnership UNEP global mercury partnership Continuous phasing down of amalgam.

Initiative to lower mercurt emissions of concern also concern to WHO

- --prevention is the goal
- --need to remind dentists about the INC,
- --partnership with manufacturers (glass iomers combined with resins) suitable for populations. Both small and large manufactures
- --education for dental undergraduates, continuing education for dentalpractitioners

Closing Discussion

Hylander suggested a more holistic approach to dental restoration be considered, including cost and cost externalities.

- overall environment perspective seems missing
- Cost include environmental cost of mercury releases and amalgam management

<u>Lymberidi</u> suggested including in cost considerations that mercury supply will go down with the upcoming treaty and therefore cost of mercury will go up. The data showing figures from around the world indicates that the developing world is using a lot of the alternatives already. This should be reflected in the meeting summary.

<u>Bender</u> noted that the continuing use of amalgam is not globally sustainable, because of the difficulty and high costs of controlling dental mercury releases (ie from cremations, sludge, landfills, waste disposal,) but also in light of the upcoming treaty. Canada has a demonstrable waste management practice that seems to be effective but for the rest this doesn't even exist in the rest of the developed world. Make the connection that dental mercury releases to the environment contribute to global methyl mercury loading and its build up in fish.

<u>Bender</u> asked about how can we look at a phase down approach that contributes to the global negotiation process. We should be looking at a 50% reduction target goal for dental mercury use over a certain period.

<u>McConnell</u> suggested reflecting a positive approach in the document. Dentists don't like to be told what to do. We can not lose the sight of prevention. The message about the treaty needs to get out to the global dental community. Cost implications need to be reflected in terms of cleaning up the mercury. Work with the manufacturers in partnership to promote and develop alternatives such as ionomers, which are suitable for small and large restorations also in environments with weaker infrastructure. Include education.

- Report should be positive
- Prevention is still the goal
- Governments need to be reminded and cost implications have to be modified in cost reducing pollution
- Need to go to partnership with manufacturers
- Develop the perfect product, materials suitable for different categories
- Continuous education

Roberto, FDI. FDI proposed a statement and opened it for discussion.

Statement issued on screen- FDI- on behalf of its membership of national dental associations, takes its responsibilities with regards to mercury and dental amalgam with WHO and UNEP, both in terms of human health and the global environment with utmost seriousness and acknowledges the importance of this meeting

FDI

Takes its responsibility with regards to mercury and dental amalgam, both in terms of human health and the global environment, with utmost seriousness and importance of meeting

Pleased to work with WHO and UNEP and identify several areas;

General health and well being

Promote adoption minimal intervention

Consensus evidence based science

Improve oral health

Need to improved collection amalgam separators

Pre-encapsulated as preferred

Many dental schools have de-emphasized the teaching of amalgam resulting in minimal intervention

FDI reaffirms' amalgam safety

Cost effective unit cost of alternatives

Joined FDA in Feb 09 in development of global caries initiative

No complete ban, nor timelines considered, until alternatives are available to all communities worldwide.

<u>Poul Petersen</u>. Reviewed the objective of the meeting - to discuss the oral health and the contribution to the broader initiative.

Best way to phase out amalgam is prevention. WHO is doing this anyway. Examine the evidence for those materials that are new, to make use by providers of health care instead of amalgam. Waste mgt to the environment, applies not only oral health but health care in general. Explore what we know about alternatives and what barriers we see for health care providers to phase down use of amalgam. FDI statement fits to that, objective of the meeting was to explore what we know about the alternatives and what barriers we see for care.

<u>Benoit Soucy.</u> It is clear that the need for amalgam is going down. There is still need for dental restoration. Existing materials have usage limitations making implementation in poorer countries more difficult. With urgency to replace amalgam, we need to do it

right—ionomer you don't need much for glassionomer, you need more expertise for composite nd Precapsculated glass iomer

<u>Lymberidi</u>: Criteria is needed for when we actually need to use amalgam. Raised the attention of the NGO letter for WHO consideration. NGO letter signed from over 70 NGOs worldwide. We could advance by WHO recommending to phase out amalgam for children and take it from there gradually.

<u>Bian You.</u> Learned a lot. Can't create new problem to fix the mercury problem. Do not do RA for amalgam we ve been using it for 100 years

<u>Peter Maxson.</u> Need for amalgam is under question. Considering urgency of replacing amalgam with something else, Phasing down in children. When is mercury really needed? Phasing down in small steps as long as we are clear the steps we are going Can we achieve a 50% reduction over a certain time frame? This seems reasonable, does it not? Noted the balance of health and environment. Can we find a way forward to meet both aspects? Make progress in both areas.

<u>Prathip.</u> Sees WHO summary as comprehensive. Point is missing about the use of amalgam and preservation of the tooth structure. It should be emphasized that all fresh tooth material may be preserved at restoration with glass ionomers while amalgam requires some caries free tooth material to be removed. On FDI- they want to deal with better material, but he cannot accept that amalgam is the best – what is best? Need to have better –

<u>Meyer.</u> Worried about the terminology. Amalgam is not toxic. Wonderful if mercury went away.

<u>Hylander.</u> Noted the significance of amalgam contribution to wastewater. There is methylation of dental mercury – proven in separators. In room temperature – you have mercury liquid with potential for volatilisation Dental clinics major sources, crematoria, and one third from mouths – flue gas cleaning 50-100%, Non degradable, Removal of fillings before cremation could be considered as a practical step to avoid mercury emissions from crematoria. Mercury is non-degradable. This is important in terms of final disposal.

<u>Mcconnell</u> suggests that we move forward on education and alternatives. Does not agree with ADA comments that amalgam is not toxic.

Meyer. Agreed that mercury is toxic. Health care providers should consider this.

<u>Vickers</u>. Noted the comment about the balance health and environment interests. This is an overall serious health issue. Health sector should look at itself. Amalgam isn't the largest contributor, but it is a contributor. The proportion argument isn't good enough. The contributors need to look at the problem.

<u>Bender.</u> WHO fact sheet from 2005 states clearly the environmental releases from dental amalgam and the consequences.

<u>Poul Petersen</u> gave a summary list of recommendations based on the meeting discussions which will be the outline of the meeting report. He highlighted the need to have more research and development of biomaterials as alternatives to amalgam for dental restoration.

<u>Poul Petersen.</u> In what way can health care providers contribute to phase down of amalgam? Noted the positive attitude of all. Meeting is a platform to move forward. Education is important and so is behaviour modification. It has been the attitude that we need to phase down .. – WHO has a dream to phase down .

There are many ways to phase down, and this is why he put the different elements ion paper, to find good material, education – and ;alternative third party payments systems could 'educate', so there are different ways forward. Process already taken place for other reasons that are political. WHO will definitely continue the work for that.WHO to work closely with UNEP in moving forward. He noted that the report of the meeting will not reflect all comments, but delegates should be reassured because he is aware of them and will remember them. So they will make a new effort to continue the discussion and make it more policy oriented, since we learnt from this meeting what are the potential to replace amalgam. There is now a new discussion to take forward between WHO and UNEP. When we make a report shouldn't expect all comments taken on board Involved with reporting for the meeting, together with UNEP, a new effort to continue the discussion, make it more policy-oriented, what are the potential for placing or replacing alternatives... He thanked all for participation.