

Dental materials

Reporting of adverse reactions

Nils R. Gjerdet

professor, dr. odont

Faculty of Dentistry - Biomaterials
University of Bergen

Årstadveien 17, N-5009 Bergen, Norway
gjerdet@odont.uib.no

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EXPOSURE to dental materials is **massive**.

- About half of the population in industrialized societies is subjected to dental restorative procedures *each year*.
- The dental products (biomaterials) increase in number and complexity.

DENTISTRY

makes use of a plethora of "medical devices"

•The biomaterials:

- Restorative materials, e.g. tooth filling materials
- Surgical materials
- Orthodontic/maxillo-facial orthopedic materials
- Prophylactic materials



•Custom-made devices

•Reuse of single use devices (?)

Restorative dental materials



Fillings



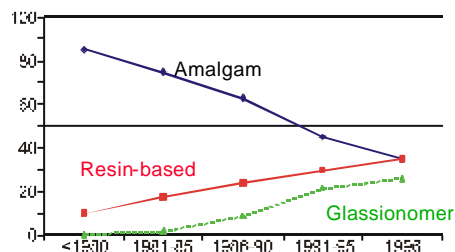
Crowns, bridges



Removable dentures



Proportions of filling materials

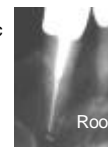


(Mjör IA, Dahl J, Moorhead JE)

Orthodontic and surgical materials



Orthodontic "braces"



Root fillings



Oral surgery - fracture implants



Implants to replace teeth

ADVERSE REACTION

- In a patient.

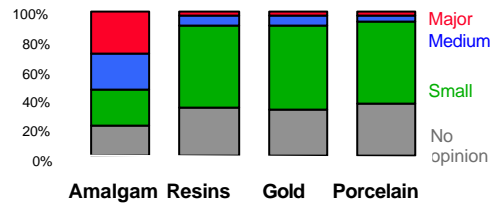


OCCUPATIONAL REACTION

- Work-related in dental personnel.



The public's opinion about adverse effects from dental filling materials



ScanFact 1993

Dental Biomaterials: "The Adverse Reaction Unit"



The purpose:

- to record adverse reactions to dental materials on a national basis (reporting system)
- to examine referred patients
- to supply information to health professionals and to the public

Reporting adverse reactions Dental biomaterials (excluding drugs)

- Reporting of adverse reactions to dental materials is voluntary.
- Forms are to be filled in and returned by a dentist or a physician.
- Forms are published in the Norwegian Dental Journal at intervals.

~900 reports
March 1993 - 1999
(about 10 reports/month)

The reporting form

- Name and affiliation of doctor
- General patient data
- About the reaction (local, oro-facial, general):
 - Objective findings
 - Subjective symptoms
- Type of dental treatment and materials involved
- Causality assessment
- Referrals (earlier and at present related to the reaction(s))

Types of reactions

	Local	Lips, face	General
Subjective	Pain, smarting, burning sensation	Pain, itching	Fatigue, muscle and joint pain
Objective	"Lichenoid" reactions (Topographically related)	Dermatitis, erythema	Dermatitis, erythema
		"Remote reactions"	



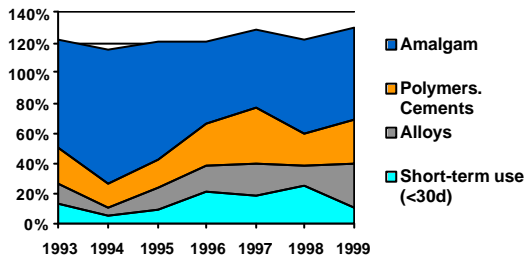
(Gjerdet NR, Bergman M, Høsten-Pettersen A. Bivirkninger og dentale materialer - et problem for pasienten eller personelle? Tandlækartidningen 1999;91:29-35)

General (remote) reaction? patch test positive - Au

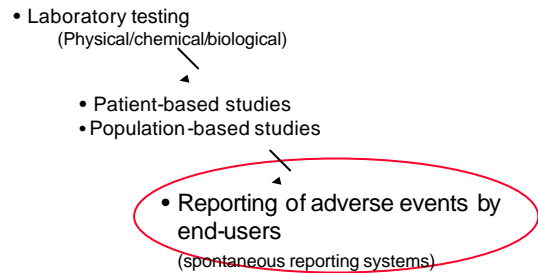


(Vamnes JS, Morken T, Helland S, Gjerdet NR. Dental gold alloys and contact hypersensitivity. Contact Dermatitis 2000;42:128-33)

Adverse reaction reports 1993-99 (Norway) Materials



Reporting of adverse events as a tool in material/device surveillance



Spontaneous reporting systems

Pros +

- A large number of potential respondents (reporting base)
- Can be used for signal-detection and hypothesis-generation
- Cost-effective

Cons -

- Passive system
- Underreporting
- Bias

Overreporting? - Biased reporting?

(From: Amalgam Digest May 12-13 2000 (AMALGAM@LISTSERV.GMD.DE))

MERCURY FREE PRESS

SEND LETTERS TO FDA.....BE HEARD.....SEE INFO BELOW

MEDIA ATTENTION SEEMS TO BE THE ONLY WAY.....AND SO FAR THEY ARE AFRAID TO TOUCH THE SUBJECT MATTER.

PLEASE SEND YOUR STORIES INCLUDING PROOF OF YOUR ILLNESS FROM MERCURY DENTAL AMALGAMS TO:
Dr. Liz Jacobson, Deputy Director for Science
Center for Devices, FDA
9200 Corporate Blvd., suite 100 Rockville, MD 20850

THE ONLY WAY WE WILL GET RECOGNITION IS BY SPEAKING UP.
PLEASE TAKE THE TIME TO WRITE YOUR PERSONAL STORY.

Causality assessment

WHO (drugs)	Adverse Reaction Unit (dental materials)
<ul style="list-style-type: none"> • Certain • Probable/Likely • Possible • Unlikely • Conditional/Unclassified • Unassessible/ Unclassifiable 	<ul style="list-style-type: none"> • Probable/Likely • Possible • Unclassifiable

Causality assessment (from reports, %)

	Patients	Respondents	A. R. Unit
Probable/likely	47	29	9
Possible	36	38	25

Dental materials/devices classification Nomenclature systems

- European Committee for Standardization (CEN)
 - CR 12401: 1996E - Guidance on the classification of dental devices and accessories.
 - pr EN ISO 15225 - Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange
(Work in progress)

The N2- example...

0301
Bureau Veritas Quality
International Ltd.
Milton Keynes Branch, UK



WHO



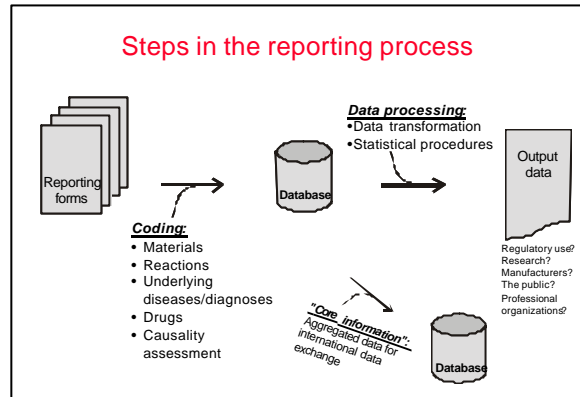
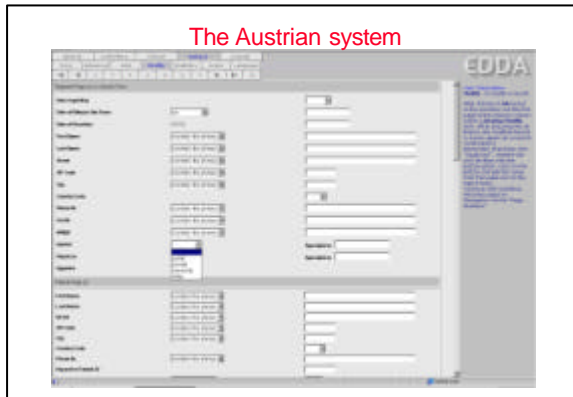
Research agenda to improve health:
The research topic unanimously agreed on was to establish a:

Global registry of biological and adverse health effects for monitoring of dental material related symptoms/diseases in various populations (patients and professionals) including the formation of an international advisory group to establish guidelines and evaluate the collected data.

(WHO Consultation on Dental Amalgam and its Alternatives, Geneva, 3-7 March 1997)

The UK system





Who should handle the reporting?

<p><i>Regulatory bodies</i></p> <ul style="list-style-type: none"> • Adhere to Directives? • Reporting to the manufacturers? • May take direct regulatory action 	<p><i>Dedicated "Units"</i></p> <ul style="list-style-type: none"> • Research oriented - Process signals • Cause-and-effect relationships • Can handle cases where no manufacturer can be identified • Cannot take direct regulatory action
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- ### Some issues of concern
- The identification of an adverse reaction (side-effect, adverse event)?
 - The implications of the data collected? Who should use the data?
 - Availability and acceptance of a reporting system among clinicians
 - Validity of data
 - Causality assessment
 - Feedback to reporters
 - Information about composition of materials
 - International harmonization

