IN BRIEF

- The Adverse Reactions Reporting Project for dental materials has shown that adverse reactions to dental materials occur across the UK and that these involve both dental professionals and patients.
- Nobody is immune from the possibility of experiencing an adverse reaction to a dental material. Although the number of cases reported so far may be small, there is a need to continue to raise the awareness among dental professionals of the existence of the Adverse Reactions Reporting Project so as to overcome problems of under-reporting.
- It is only with the full support of dental practitioners that we can build up a true picture of the extent and severity of adverse reactions to dental materials.
- The project would allow us over time to show trends and thus develop an early warning system as regards any materials that present with the high incidence of adverse reactions. For example, an early warning system may have detected problems with the wearing of powdered latex gloves at a much earlier stage.

The national survey of adverse reactions to dental materials in the UK: a preliminary study by the UK Adverse Reactions Reporting Project

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Objective: Dental treatment involves the use of a wide range of materials. Many of the dental materials or their components pose a potential risk to the patient and member of the dental team. Pre-market biocompatibility testing cannot guarantee absolute safety, making monitoring of materials likely to cause an adverse reaction essential. The prevalence of adverse reactions to dental materials amongst dental patients and staff has not been systematically monitored in the UK. This project aims to develop a systematic approach to the evaluation and monitoring of the extent and severity of adverse reactions to dental materials in the UK.

Method: Through the distribution of reporting forms to dental surgeries and laboratories in the UK, the ARRP has received 1,075 complete reports relating to adverse reactions seen or experienced by dental staff and patients.

Results: The main findings were that different materials cause adverse reactions to different groups of people. The largest proportion of patient related adverse reactions were reported to be due to metals (n = 175). These were mainly amalgam associated oral lichenoid reactions (n = 124). Dental technicians reported acrylic resin as the causal factor of hand dermatitis in 61% (44 out of a total 72) of cases reported. Finally, dental surgery staff reported gloves as causing hand dermatitis in 75% of cases (398 out of a total 531).

Conclusions: Different dental materials affect different person groups depending on their exposure to the material. Dental staff are most at risk from an adverse reaction to latex gloves, whereas most reported reactions for patients were due to metals. For dental technicians the biggest danger of an adverse reaction was from acrylic resins. There is a need to continue to raise the awareness among dental professionals of the existence of the Adverse Reactions Reporting Project so as to overcome problems of under-reporting.

Providing dental treatment involves the use of a wide range of materials within the dental practice and many of these materials pose a potential occupational risk as well as a risk to the patient. The range and complexity of materials employed in dentistry is increasing, and the pressures on manufacturers and clinicians are likely to maintain this trend.[1] While the introduction of new materials brings great benefits, there is always a risk of an adverse reaction to one or more components by members of the dental team or members of the public. Pre-market biocompatibility testing cannot guarantee absolutely safety, so it is important to identify materials that can cause an adverse reaction when placed on the open market. There are no dental restorative materials that can be considered as absolute safe under all conditions, for all patients and dental personnel,[2] but it is essential that the adverse events that do occur are monitored and treated appropriately. Whilst the Medicine and Healthcare Products Regulatory Agency has a system for the reporting of severe adverse incidents for all medical devices, which includes dental materials, there is no post-market surveillance system in place in the UK to record the prevalence of all adverse reactions to dental materials by the general population and dental professionals, whether mild or severe. Such a system would be effective in acting as an early warning system and eliminate materials that, although promising in pre-market tests, do not function adequately in the mouth and have a greater tendency to cause adverse reactions.[3]

Adverse reactions associated with dental materials range from contact dermatitis to life-threatening anaphylaxis. Details of these reaction types and relevant cases studies can be found at the

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website of the Adverse Reactions Reporting Project (ARRP) at **http://www.sheffield.ac.uk/~arrp.**

Adverse reactions do occur in patients and staff in the UK as seen by various case studies and research reports.[4–8] The media often report cases of adverse reactions to dental materials, especially to materials such as amalgam;[9,10] which are more often than not opportunities for negative media coverage.[11] In addition to mercury other restorative materials such as nickel and more recently Bisphenol-A have featured in the media.[12,13] Consequently the safety of dental materials is still an area of debate amongst many dental health professionals and the general public. A systematic monitoring system of adverse reactions would provide a vital evidence base, which ensures that the prevalence of cases of adverse reactions to dental biomaterials is measured. The ARRP was set up to develop the evidence base and was funded by the NHS National R&D Programme of Primary Dental Care. In addition to providing information to dental health professionals it has created the opportunity to provide guidelines for the prevention, management and treatment of adverse reactions when they occur.

This survey aims to measure the extent and severity of adverse reactions to dental materials in the UK, and to identify risk groups and potential problematic dental materials. This article reports the main findings of the ARRP after its initial 3-year period.

METHOD

Reporting forms were designed based on examples from the Adverse Reaction Units in Bergen (Norway) and Umea (Sweden). The forms were distributed and following comments from dental professionals and the success of the information collected they were redesigned to be smaller and easier to complete. Figure 1 shows an example of the final reporting form used by the ARRP. This form has also been used to develop a reporting form approved by the FDI as a proposed European data collection system (**http://www.fdiworldental.org/**). Along with the reporting form a set of guidelines on how to complete the form were prepared.

Data is gathered on the affected person, adverse reaction symptoms and severity, and the dental material suspected of causing the adverse reaction. In addition contact details of the reporting dental health professional and referral details are also required.

From December 1999, reporting forms were sent to 27,000 dental practitioners and 2,700 dental technicians on a regular basis, with a covering letter and the guidelines, requesting their continued participation in the project. The ARRP encouraged dental professionals to report to us any adverse reaction, whether mild, moderate or severe, as defined in the guidelines, that they had experienced, or a member of staff or patient had experienced whilst in the dental surgery, laboratory or using dental hygiene products at home.

The project's definition of a dental material is any material found in the dental practice or sold for dental purposes, such as restorative materials, rubber gloves, toothpastes and oral rinses. This does not include drugs and anaesthetics, which are systematically recorded by the Yellow Card Adverse Drug Reactions Scheme.[14]

A national database was designed using *Microsoft Access* software to record the data collected. This enabled quantitative and qualitative analysis of the reports to be carried out. Trends and relationships were identified to enable further investigations to be initiated when required.

In addition a website was developed at the following URL: **http://www.shef.ac.uk/~arrp**. This provides dental professionals with sources of information, and advice through case studies and publications. The website also allows the analysis of the reports received to be published, to enable dental professionals to be aware of the development of the project.

As the project developed the question of under-reporting arose, especially as the reporting forms do not have an option to report a nil response. The ARRP sent questionnaires to a random sample of 1,000 dental practitioners throughout the

Fig. 1 An example of the green reporting forms used by the ARRP

Dental Adverse Reactions Reporting Form

ARRP

- This form can be used for patient and occupational adverse reactions
- Please report all suspected adverse reactions, including minor ones
- Please order further green forms or photocopy, as required

Data regarding person affected:

Reporters identification of affected person: _____

Person affected is: ☐ Patient ☐ Dentist ☐ Dental nurse ☐ Dental hygienist ☐ Dental technician ☐ Other: _____

Age: ☐ under 20 ☐ 20-29 ☐ 30-39 ☐ 40-49 ☐ 50-59 ☐ 60+

Gender: ☐ Male ☐ Female

Was the adverse reaction first noticed by? ☐ Affected person ☐ Yourself

What month/year was the reaction first noticed: Month ____ Year ____

If the reaction occurred after dental treatment/handling dental materials, did it occur:

☐ within 1 hour ☐ within 1 day ☐ within 1 week ☐ within 1 month ☐ months to years ☐ unknown

General diseases:

Medications:

Known allergies:

Reactions (objective findings and subjective symptoms):

Local reaction – intra-oral:

Reaction – lip/face:

General reaction (other than mouth, lip and face):

PTO

Type of material(s) suspected:

_____

Suspected products: (state brand name and manufacturer if known)

_____

Type of dental treatment(s) suspected:

☐ Fillings
☐ Inlays, veneers
☐ Dentures
☐ Crowns and bridges
☐ Endodontic treatment
☐ Temporary restorations
☐ Periodontal treatment
☐ Oral surgery
☐ Orthodontics
☐ Preventive dentistry
☐ Other (please specify):

Assessment of relationship:

Reporters assessment of relationship between material(s) and reaction(s):

☐ Probable ☐ Possible ☐ Uncertain ☐ Unlikely

Degree of the reaction:

☐ Mild ☐ Moderate ☐ Severe

Referrals:

Has or will the affected person be referred for further investigation? ☐ No ☐ Yes

If yes, to whom?

☐ General practitioner
☐ Dentist
☐ Dermatologist
☐ Allergist
☐ Oral physician
☐ Other (please specify):

Reporters details: (Please print clearly)

Title: _____

Name: _____

Address: _____

_____

_____

Post code: _____

☐ Dentist ☐ Physician
☐ Hygienist ☐ Dental technician
☐ Other (please specify):

_____

Telephone: _____

Email: _____

Date: _____

Number of additional form(s) required

_____

Postal address:
Adverse Reaction Reporting Project (ARRP),
The University of Sheffield,
Department of Restorative Dentistry,
FREEPOST NEA5451, Sheffield, S10 1BQ.

Contact information:
E-mail: arrp@sheffield.ac.uk
Tel: 0114 271 7979
Fax: 0114 266 5326
Website: http://www.shef.ac.uk/~arrp

Table I – Table of the signs and symptoms of adverse reactions to dental materials by location (n = 1075)

Intra-oral reactions (n = 375)		Hands, wrists and/or finger reactions (n = 425)	
Lichen planus type reaction	162	Dermatitis, eczema or urticaria	147
Swelling, tenderness and/or reddening	112	Itching, dry, cracked and/or burning skin	120
Burning sensation and/or taste changes	38	Swelling, tenderness and/or reddening	47
Ulceration or blisters	29	Ulcers, blisters or vesicles	33
Other	34	Other	78
Face and/or Lip reactions (n = 156)		**General reactions (n = 119)**	
Swelling, tenderness and/or reddening	84	Breathing problems, wheezing and/or asthma	31
Dermatitis, eczema or urticaria	31	Runny, irritated eyes and/or nose	25
Burning sensation and/or tingling	9	Coughing, sneezing and/or sore throat	23
Ulceration or blisters	6	Headache, nausea and/or dizziness	10
Other	26	Other	30

UK to gather information regarding the number of individuals that are practising dentistry but have never reported an adverse reaction to the ARRP. One reminder was sent out 3 months after the initial distribution.

RESULTS

Total number of reports

The total number of reports received since December 1999 was 1,266, of these 1,075 were valid, 191 were not included as they were either reporting drug or device adverse reactions or they contained insufficient information. Of the 1,075 valid reports, 468 were relating to patients and 607 to staff. Staff included 329 dentists, 181 dental nurses, 74 dental technicians, 22 hygienists and 1 receptionist. The ratio of male to female patients was 1:4, and male to female staff was 1:1.5. Table 1 provides a breakdown of the signs and symptoms associated with adverse reactions to dental materials by site.

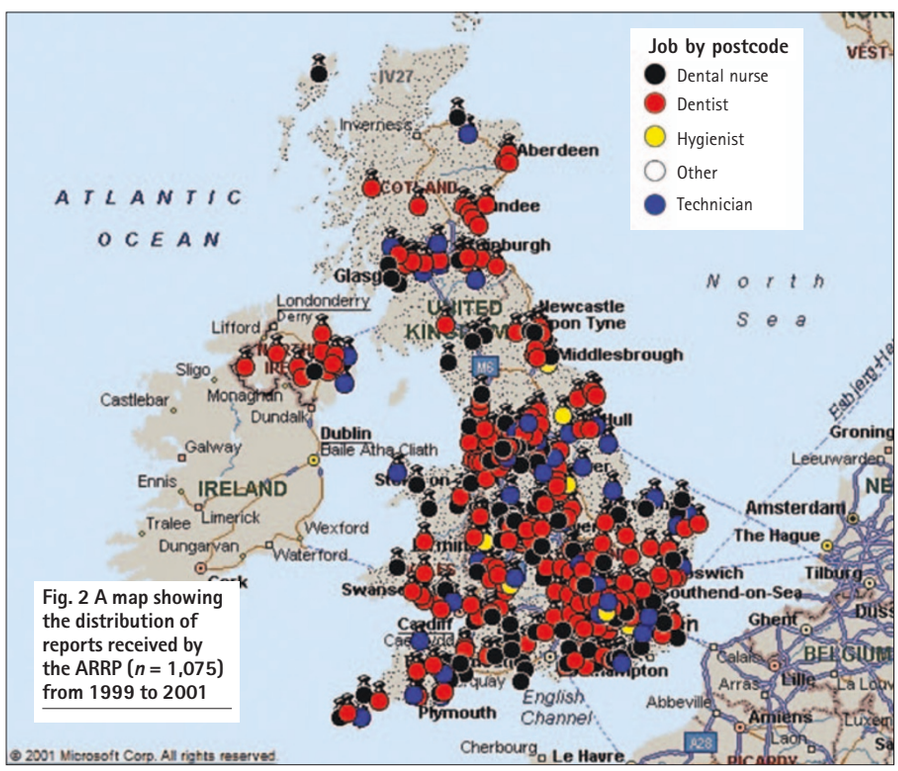

Fig. 2 A map showing the distribution of reports received by the ARRP (n = 1,075) from 1999 to 2001

Response rate

The total number of reporting forms sent out since December 1999 was approximately 86,000 to 27,000 dental professionals. The total number of reports received was1,266, sent in by 846 dental professionals. This gives a 3.1% response rate for the dental professionals.

The reporting forms were distributed across Great Britain and Northern Ireland and Figure 2 shows the distribution of adverse reaction reports returned to the ARRP. It can be seen that the distribution of reported adverse reactions covers the whole of the United Kingdom.

From the 1000 questionnaires concerning nil responses a response rate of 64% (n = 640) was achieved. It was established that 75% (n = 479) had heard of the ARRP through a variety of sources, while 23% (n = 149) had never heard of the ARRP. Those that had not come across an adverse reaction since the project began in the year 2000 was 48% of all respondents (n = 309). Those that had never seen or experienced an adverse reaction in their lifetime was 32% (n = 207). In addition 5% of respondents (n = 34) had already reported an adverse reaction to the ARRP and 8% (n = 51) had not reported to the ARRP for other reasons. These reasons included not having the time, having problems contacting the ARRP, not being able to find the form when needed, not really knowing what to report and problems identifying an adverse reaction.

Dental materials causing adverse reactions in dental patients (n = 468)

Dental materials causing adverse reactions can vary depending on the person group and amount of exposure. Figure 3 shows the dental materials suspected of causing adverse reactions in patients. Metal reactions (n = 175) can be broken down into 124 amalgams, 43 base metal (of which 17 are nickel) and 8 precious metals. Symptoms were primarily related to intra-oral lichenoid type reactions, or sometimes a burning sensation and/or swelling of the buccal mucosa, but most were symptom free.

Dental materials causing adverse reactions in dental technicians (n = 74)

From the data presented in Figure 4 it can be seen that resins (n = 45) are the main cause of adverse reactions in dental technicians; these are primarily acrylics (n = 36). The type of symptoms experienced are hand and most often fingertip reactions such as dry, cracking and flaking skin, itching, irritation and swelling.

Dental materials causing adverse reactions in dental staff (n = 533)

Dental staff that have experienced adverse reactions to dental materials in the dental surgery include dentists, dental nurses, hygienists and a receptionist. Figure 5 shows the dental materials

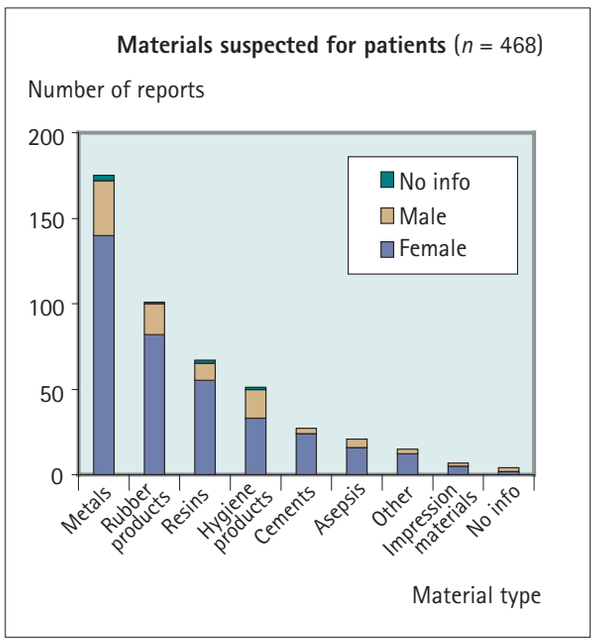

Fig. 3 Dental materials suspected of causing adverse reactions in patients (*n* = 468)

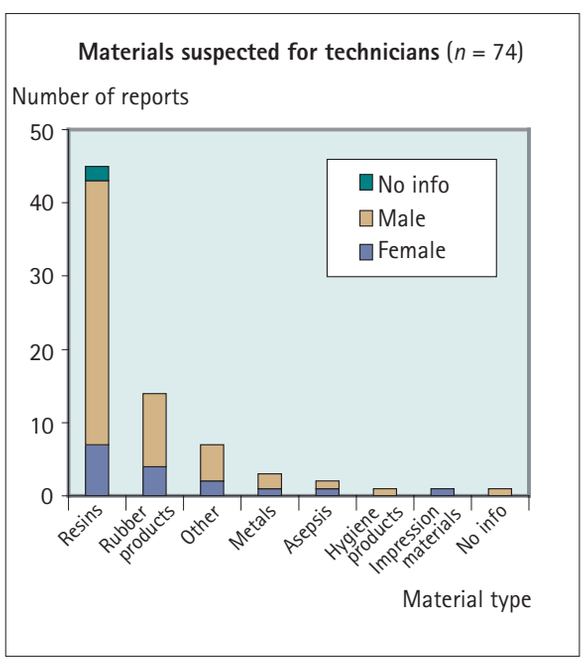

Fig. 4 Dental materials suspected of causing adverse reactions in dental technicians (*n* = 74)

responsible for causing adverse reactions to staff in the dental surgery. It can be seen that the most common dental material are rubber products (*n* = 230), of which 229 are gloves. The type of reactions being seen include facial swelling and watering eyes and/or nose, or sneezing and wheezing. In addition, hand and wrist reactions such as urticaria or dermatitis were reported. This included redness, irritation and tenderness of the skin on the hands, between the fingers and wrists.

Further work was carried out in this area in an attempt to validate the reports received and collect more specific information on these reactions, and forms the basis of a separate publication.[15]

Degree of reaction

Although the degree of the reaction is a subjective interpretation by the reporter; the ARRP guidelines sent out with the reporting forms give definitions.:

- A mild reaction is one requiring only dental treatment.
- A moderate reaction is one where the signs and symptoms are significant and the affected person needs specialist referral.
- Finally a severe reaction is one that leads to death or is life-threatening, causing serious deterioration in health or where emergency treatment is required.

Figure 6 shows the recorded reaction types for patients and dental professionals. When comparing the degree of reactions for all reported cases 22% were mild, 44% moderate and 18% severe (16% gave no information).

Number of referrals

The percentage of persons referred to a specialist following a suspected adverse reaction to dental materials was 46% for patients and 35% for dental health professionals. It can be seen in Figure 7 that patients were most likely to be referred to oral physicians.

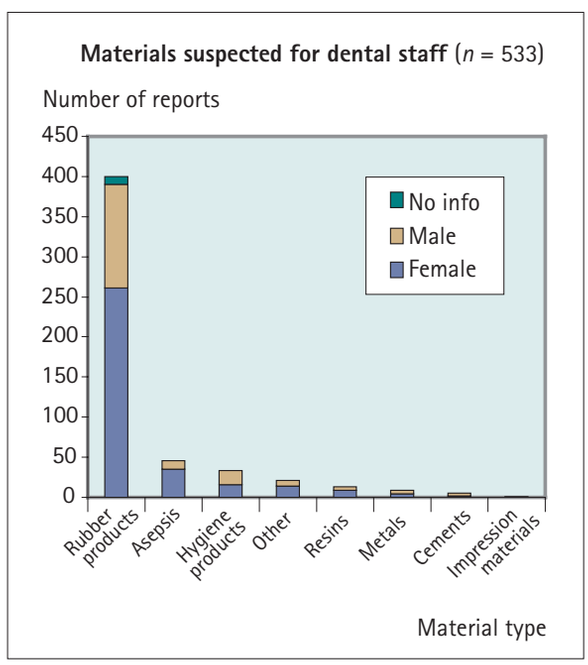

Fig. 5 Dental materials suspected of causing adverse reactions in dental staff (*n* = 533)

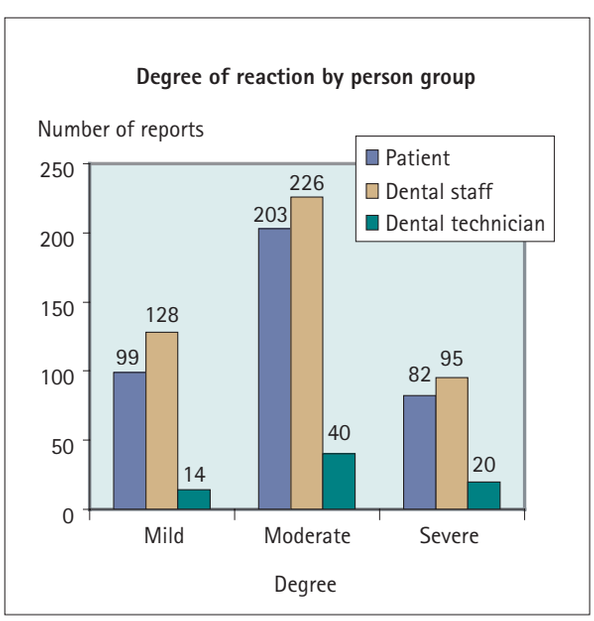

Fig. 6 Degree of reaction by person type (*n* = 1,075)

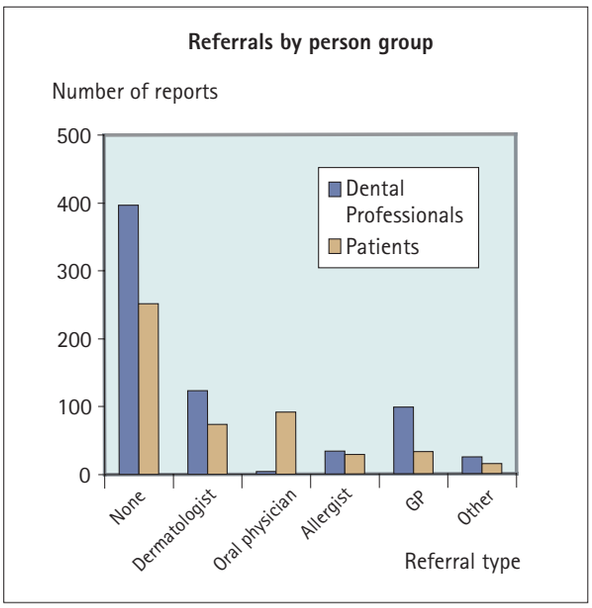

Fig. 7 Type of specialist referred to by each person group studied

Dental health professionals are most likely to be referred to a dermatologist. However, the majority of reports (60%) of adverse reactions are not referred to a specialist for a definitive diagnosis.

DISCUSSION

Adverse reaction units were set up in Norway and Sweden in 1993 and 1996 respectively, these have been recording and validating adverse reactions to dental materials for nearly a decade now. The Dental Biomaterial Adverse Reaction Unit set up in Norway recorded a total of 777 case reports during 1993–1998 (72 months),[16] which represents 129.4 reports per annum. The ARRP received 1,075 reports during 1999–2002 (27months); 477.8 reports per annum. However, Norway has a population of 4.3million and there are 3,800 practising dentists,[1] the UK has a population size of 59.7 million and 27,500 practising dentists.[17] Using the 1993–1998 figures,[16] Norway has recorded approximately three times more adverse reactions per practising dentist; 3.4 per annum/100 compared with 1.7 per annum/100 in the UK. In addition there were nearly four times more adverse reactions recorded per million people; 30 reports per annum/million, compared with 8 per annum/million in the UK. These differences may be due to the reporting unit in Norway being fully established compared with the UK preliminary study. Norway may also have a higher rate since they have asked specifically for suspected adverse reactions relating to amalgam and they have seen an increase in the number of observed adverse reactions to amalgam being reported.[16] In this study nearly all the amalgam-related adverse reactions were associated with clear physical symptoms (lichenoid reactions), no intolerance reactions to amalgam were reported, although these were not excluded. Different parts of Norway have shown differing degrees of reporting when calculating the response rates.[18] The Eastern part has 50% of the total population but in 1996 only 17% of the reports received came from this area, in 1997 this was reduced to only 12.5%. In addition, it may also be that dental professionals from different countries have different perceptions on what constitutes an adverse reaction and whether or not to report it. However, probably the most overriding factor is that differences are mainly due to a higher degree of under-reporting than occurs in Norway and Sweden. The questionnaire indicated that a significant percentage of dental practitioners are still unaware of the project, maybe as many as 23%. In addition some 8% of dental practitioners who responded to the survey did not report adverse reaction(s) they have seen despite knowing about the ARRP. This indicates that there is still a considerable amount of under reporting, and although it is impossible to put a true figure on this it is not unreasonable to suggest that we may only see 50% of adverse reactions being reported. There is therefore a need to continue to raise the awareness among dental professionals of the existence of the Adverse Reactions Reporting Project so as to overcome problems of under reporting.

The difference in the number of male and female patients (1:4) that report adverse reactions may be explained by social circumstances, where females are more likely to visit their GDP or report an adverse reaction than males, rather than females being more likely to experience an adverse reaction to dental materials.[19] The difference amongst dental professionals was less pronounced.

Since the project has only just completed its initial 3 year programme the general awareness and participation is very encouraging, but continuation is required to ensure the awareness is increased and dentists are encouraged to continue reporting. When information is sent out to dental professionals the ARRP receives an influx of reports, as seen in Figure 8, this gradually

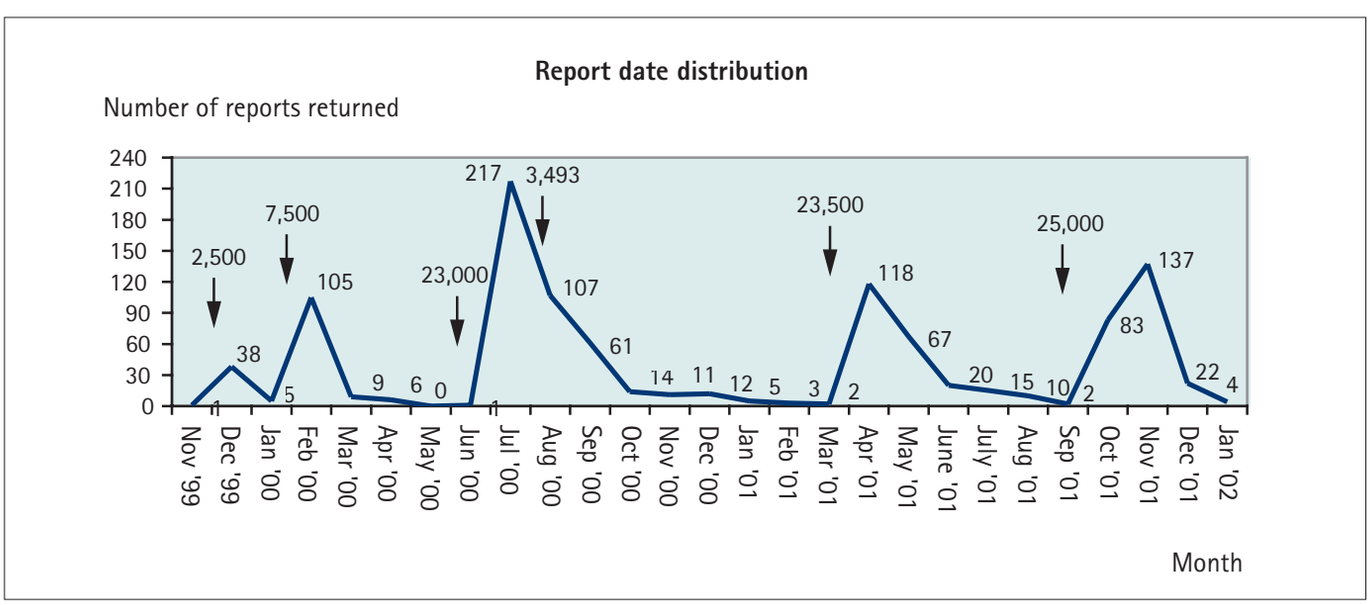

Fig. 8 The ebb and flow of reports received by the ARRP since January 2000, showing the importance of the need for repeated requests for reports. The arrows indicate the time the requests for report were sent out as well as the number of requests

slows down over a period of a couple of months until the next reminder is sent out. Other authors have also seen this pattern of reporting[1] and could be a contributing factor to the low number of reports received compared with a more established reporting unit, such as in Norway.

In the light of the discussion above about under-reporting it would be unwise to consider incidence rates calculated on the basis of the number of reports received at this stage of the Adverse Reactions Reporting Project. Nevertheless, the ARRP has been able to provide the first evidence base of adverse reactions to dental materials across the UK.

The dental material seen to cause most reported adverse reactions in patients is amalgam. Intense, and sometimes irrelevant, discussions regarding the possible harmful effects of mercury in dental amalgam, has led to the decrease in mercury use in many countries, increasing the use of alternative products.[20, 21] However, published research[22] also found that the incidence of oral lichenoid reactions adjacent to amalgam restorations occurred more often than other long-term side effects to dental materials. In addition, despite a reduction in dental caries in younger people[23] and an increase in the number of older people with their own teeth, this has not reduced the need for restorative dentistry. In particular older people will be more likely to have amalgam restorations than other materials, and as these restorations are given a life expectancy of 8-12 years[24] it is likely that further replacement of the restorations will be required. The American Dental Association (ADA) recorded that 50% of the general dental practitioner's time is spent on restorative care.[25] Of these restorative procedures 60–70% involve replacing a restorative material that is no longer functional. As the most widely used dental material it is not unexpected therefore that amalgam is reported as the material causing most adverse reactions in patients.

Dental technicians are regularly exposed to acrylic monomers, as these are predominantly used for the manufacture of dentures and other intra-oral prostheses.[26] Acrylic monomers can cause irritant contact dermatitis as well as allergic contact dermatitis reactions.[27] Our research found that for dental technicians the primary source of adverse reactions was acrylic resin. This is not surprising when we consider that methyl methacrylate is a potent sensitiser.[27] It has been reported that the incidence of contact dermatitis to methacrylate resins in dental personnel is increasing due to the increased use of methacrylate containing materials (compomers, composites, RMGICs) to replace amalgam as a restorative material, especially in Europe.[20] The timescale of the ARRP is still too short to confirm this. The symptoms reported to the ARRP include dry, cracked, flaking skin on the hands and often fingertips with itching, irritation and swelling. This describes the typical clinical pattern of contact dermatitis where the first, second and third fingertips of the non-dormant hand often demonstrate a dry, chronic dermatitis with deep fissures and erythema.[26] Further investigative work is required to determine the type of dermatitis experienced by dental technicians to enable comparisons with other surveys. Wearing gloves whilst handling acrylic monomers such as methyl methacrylate, rather than being protective, can increase the problems associated with contact dermatitis.[28] Acrylic monomers can penetrate all natural rubber latex (NRL), PVC and polyethylene gloves in a few minutes providing a high-localised concentration of resin. It is essential therefore no-touch techniques are developed to ensure dental technicians are protected,[29] especially as the wearing of gloves may itself be the cause of adverse reactions.

The use of rubber gloves to avoid infection has become part of everyday hygiene routines in all fields of clinical dentistry, the majority of occupational skin diseases reported by dentists and dental nurses relate to rubber gloves.[24] Adverse reactions to protective gloves are seen as the primary concern of all dental staff in our survey. Further analyses by the ARRP into glove related adverse reactions have been carried out and forms the basis of a separate article in the *British Dental Journal*.[15]

The degree of reactions reported was mainly moderate (n = 469: 44%) however most of these reports did not always follow closely to the ARRP guidelines, mainly through a lack of referring the affected person to a specialist for diagnosis which is a prerequisite of the ARRP moderate reaction type definition. When the figures were revised to follow the guidelines, 43% were mild (n = 457), 30% moderate (n = 324) and 12% severe (n =126). Of the severe cases reported none had resulted in a fatality. This would concur with other reports in the literature, which have also stated that the intensity of local reactions that do occur in most cases is slight.[21] In addition it is not unlikely that some side effects will be overlooked, especially when we consider that systemic effects due to sensitisation can occur without oral symptoms and in many cases are characterised in general terms as complaints or inconveniences.[21] This shows the importance of a systematic reporting system to ensure all adverse effects are recorded and dealt with appropriately.

The number of reported referrals to a specialist, such as a dermatologist or allergist was few (n = 427:40%). This may be due to increasing self-diagnosis by the affected person or dentist, where the dental material is removed to avoid further reactions, for example amalgam restorations may be replaced with composites when oral lichenoid reactions are seen or latex gloves are replaced with other gloves following a hand reaction.[30] Self-diagnosis is not always the best thing to do since the reaction may be a Type I allergy, which should be properly diagnosed so that appropriate action is taken. Type I hypersensitivity reactions such as contact urticaria can be potentially life threatening if they become systemic and affect the gastrointestinal and respiratory tract to cause anaphylaxis.[31] The reasons for a lack of referral are unclear, it may be caused by a lack of available resources in a given geographical area, and time constraints or simply that avoidance is easier and quicker than referral.

CONCLUSION

Different dental materials affect different person groups depending on their exposure to the material. Dental personnel are most at risk from an adverse reaction to latex gloves, whereas most reported reactions for patients were due to metals. For dental technicians the biggest danger of an adverse reaction was from acrylic resins. The degree of adverse reactions is predominantly mild to moderate indicating adverse reactions are not life threatening or even job-threatening in most cases. It would be encouraging if the low rate of reporting seen is due to a low rate of adverse reactions to dental materials in the UK. However there is most likely a degree of under-reporting, which is difficult to estimate. Only a sustained approach to the reporting of adverse reactions will allow the collection of sufficient data to determine realistic rates of adverse reactions to dental materials. This is vital if we aim to have reliable evidence to support the safe use of dental materials.

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