How do UK dentists deal with adverse drug reaction reporting?

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IN BRIEF

- Highlights general dental practitioners were aware of the importance of detecting and reporting adverse drug reactions (ADRs).
- Reports that GDPs rarely see ADRs in practice.
- Recognises a need for additional education on ADR identification and reporting.
- Advises GDPs expressed a preference that ADR education should be delivered as continuing professional development.

Objective Pilot investigation to establish the knowledge, use and education needs of general dental practitioners (GDPs) of the UK yellow card (YC) reporting scheme. **Design** Postal survey. **Main outcome measures** GDP views and experiences. **Results** Of 130 respondents, 74.6% were aware of the scheme. There was greater awareness of the scheme among those with more years in practice ($p = 0.003$) and those who had trained in the UK ($p = 0.002$). Six GDPs reported using the YC scheme in the past four years (estimated overall use: 0.01 of a YC per GDP per year); 88.5% had never used the YC scheme. The main reason given was that they never saw ADRs (58.5%). GDPs who had received their undergraduate training in the UK were more likely to be aware of their responsibility to report ADRs as a dentist than those who had trained outside the UK ($p = 0.009$). While GDPs were able to identify a wide range of sources to help them learn about ADRs, over three quarters of respondents (76.9%) expressed a need for additional postgraduate training. **Conclusions** Under-reporting of ADRs by healthcare professionals is a recognised phenomenon and GDPs appear to be no exception. The effect of providing additional postgraduate training on ADR reporting should be investigated.

INTRODUCTION

In 2010, the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) received over 24,000 reports of suspected adverse drug reactions (ADRs) through its yellow card (YC) reporting scheme.¹ This scheme collects spontaneous reports of suspected ADRs to authorised medicines from patients and healthcare professionals, who complete a yellow card; it is the most important system of pharmacovigilance in the UK. All healthcare professionals are eligible to report, including dentists; but the latter contribute less than 1% of health professional reports.² While the list of those eligible to report has been expanded over the years, with the most recent group added being patients, dentists were among the first professional

groups entitled to report when the yellow card scheme was introduced in 1964.³

Determining the relative reporting rates for different professional groups is problematic as it is influenced by such factors as numbers in practice, opportunities to prescribe, patient demographic and disease profiles and the spectrum of drugs used. However, in general, the YC scheme is considered to be underused and a lost opportunity for early detection of ADR signals of importance, particularly those associated with recently marketed products where the safety profile is far from complete. Reasons for under-reporting are multifactorial and have been discussed by various authors, largely with reference to studies focusing on the medical profession.^{4–10}

Inman and Weber¹¹ were the first to propose the 'seven deadly sins' of personal ADR non-reporting, citing complacency, fear of litigation, guilt, ambition to publish before reporting, embarrassment, failure to recognise and diffidence. A host of additional, external factors, such as reaction severity, time of the product on the market, reporter's age and experience, location of practice and media publicity may also play a part.¹² Which one, or more likely, which combination of these factors, is

most commonly associated with such poor reporting levels for dentists is unknown.

In addition to responding to dental emergencies and referrals from other health professionals, dentists carry out regular check-ups with their patients that include a general health and medication questionnaire and examination of the oral soft tissues. These procedures should provide opportunities to notice ADRs to medicines taken by their patients, even if coincidental to the reasons for the dental visit. ADRs to medicines prescribed by dentists themselves may also be observed. Dentists are advised that medical histories should be checked thoroughly and updated at the start of every new course of treatment that the patient undergoes and that the medication history should be reviewed at every patient visit.^{13,14}

It is likely that, along with other health professions, practising dentists are under-reporting eligible ADRs through the YC scheme; but why might this be and what could be done about it?

We report a questionnaire survey of general dental practitioners (GDPs) aimed at assessing their level of understanding and use of the YC scheme, their reasons for not using it and their potential training needs in this area.

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METHODS

This study, which received a favourable opinion from the University of Portsmouth Biosciences Research Ethics Committee (BSREC 11/070), took the form of a postal questionnaire of a sample of GDPs. The questionnaire was designed by the authors (a copy is available from the authors on request). It contained four sections. The first requested demographic detail including gender, age, years of practice, place of study, size of practice and average number of patients seen per week. The second section assessed the respondent's awareness of the YC scheme, the types of reactions that should be reported on a YC, and the frequency of prescribing of key classes of medication (analgesics, anti-inflammatories, antibiotics). This section also asked respondents to indicate when they had last used a YC, covering options ranging from 'never' to 'last week'; if respondents cited 'never' then they were asked to provide the reasons for this. The third section asked where respondents looked for information on ADRs and if/where they had received training on ADR recognition and reporting. Respondents were also asked to express their level of confidence in recognising ADRs on a semantic Likert scale of 1 (not confident) to 5 (very confident). Section four asked for views on whether there should be more training on ADRs at undergraduate or postgraduate level on five-point semantic Likert scales of strongly disagree to strongly agree with a null point of neither agree or disagree, and offered a list of formats for training delivery from which they could choose any number or suggest alternatives.

The questions used in the questionnaire were constructed by the authors by iteration and reference to standard texts on good questionnaire design. The final iteration was reviewed by a consultant in dental public health, not directly involved in the project, for concept and content.

The questionnaire was piloted with eight GDPs known to the authors and practising separately in a range of settings. After minor modification, the questionnaire was sent to all GDPs in the Southampton City, Hampshire, Isle of Wight and Portsmouth City Teaching Primary Care Trust areas with an accompanying cover letter outlining the purpose of the study, ethical considerations including confidentiality

Table 1 GDP-reported frequency of prescribing various classes of medicines

Drug class	Daily	Weekly	Monthly	Never	No reply
Antibiotics	21 (16.2%)	74 (56.9%)	25 (19.2%)	2 (1.5%)	8 (6.2%)
Anti-inflammatories	4 (3.1%)	20 (15.4%)	31 (23.8%)	52 (40.0%)	23 (17.7%)
Analgesics	4 (3.1%)	18 (13.8%)	29 (22.3%)	50 (38.5%)	29 (22.3%)
Other*	6 (4.6%) Fluoride toothpaste, antifungals, chlorhexidine mouthwash	11 (8.5%) Fluoride toothpaste, antifungals, chlorhexidine mouthwash, fluoride mouth-wash, fluoride supplements, anxiolytics	16 (12.3%) Fluoride toothpaste, antifungals, chlorhexidine mouthwash, benzydamine mouth-wash, saliva replacements, anxiolytics	9 (6.9%)	88 (67.7%)

NB: Some GDPs cited the same medicines

Table 2 GDP-reported YC scheme awareness with years of practice

Years of practice	Yellow card scheme awareness		Total (percentage, n = 130)
	Aware	Unaware	
<5	9	5	14 (10.8%)
5-10	7	10	17 (13.1%)
11-20	16	7	23 (17.7%)
21-30	38	5	43 (33.1%)
>30	27	3	30 (23.1%)
Total (n = 130)	97 (74.6%)	30 (23.6%)	127 (97.7%)*

NB: Three respondents did not answer this question

and specifying a one-month deadline for reply. A reply-paid envelope was provided. The study was conducted during February 2011. Where it was known that the practice contained more than one dentist, adequate questionnaires were mailed to the practice manager to distribute, each with its own cover letter and reply-paid envelope.

Data from completed questionnaires were coded and analysed using SPSS (version 20). Open responses to some questions were analysed separately using theme analysis. Nominal data were compared using the chi-squared statistic.

RESULTS

Demographics

The sample frame contained 430 GDPs and a total of 130 responses were received (response rate = 30.2%). Significant bias towards particular geographic regions of the sampling frame was not detected. The sample of respondents comprised of

67 (51.5%) females and 62 (47.7%) males with one non-response to this question. One hundred and twenty-two respondents (93.8%) were aged between 25 and 65 years; the modal age was 45-54 years (52; 40%) with three respondents (2.3%) being below 25 years of age and three (2.3%) being over 64 years old. Eighty-five (65.4%) reported having between 5 and 30 years of dental practice experience; the mode was 21-30 years (33.1%). Fourteen (10.8%) had less than five years experience, while 31 (23.8%) reported having greater than 30 years' experience.

Ninety-one (70%) reported having been trained in the UK; 31 (23.8%) reported being trained in Europe and 8 (6.2%) outside of Europe. During an average working week, 17 (13.1%) reported seeing fewer than 50 patients personally, 61 (46.9%) reported seeing between 50 and 100, 36 (27.7%) reported seeing between 100 and 150, and 16 (12.3%) reported seeing greater than 150 patients.

Table 3 GDP-reported YC scheme awareness with source of training

Training location	Yellow card scheme awareness		Total (percentage, n = 130)
	Aware	Unaware	
UK	77	13	90 (69.2%)
Europe	15	14	29 (22.3%)
Outside Europe	5	3	8 (6.2%)
Total (n = 130)	97 (74.6%)	30 (23.6%)	127 (97.7%)*

NB: Three respondents did not reply to this question

Table 4 GDP views on importance of reporting ADRs to various types of medicines using the YC scheme

Reactions to medicine type	Most important (4) n (%)	3	2	Least important (1)	No reply
Dentist (self)-prescribed medicines	100 (76.9)	10 (7.7)	3 (2.3)	10 (7.7)	7 (5.4)
Doctor-prescribed medicines	81 (62.3)	20 (15.4)	6 (4.6)	15 (11.5)	8 (6.2)
Over-the-counter medicines (OTCs)	69 (53.1)	22 (16.9)	22 (16.9)	9 (6.9)	8 (6.2)
Herbal, traditional and complementary medicines	44 (33.8)	33 (25.4)	27 (20.8)	19 (14.6)	7 (5.4)
Foods	34 (26.2)	30 (23.1)	31 (23.8)	28 (21.5)	7 (5.4)

Table 5 GDPs' reasons for not using the YC scheme

Reason for not using the yellow card scheme*	Number of dentists (%)
I never see ADRs in my patients	76 (58.5)
I was not aware that it is a direct responsibility of a dentist	19 (14.6%)
I always refer suspected ADRs to the patient's GP	18 (13.8%)
I have difficulty in distinguishing the significance of reporting a particular ADR	12 (9.2%)
I have difficulty in diagnosing ADRs	12 (9.2%)
I have insufficient knowledge to recognise an ADR	10 (7.7%)

*GDPs were allowed to cite more than one reason

To assess existing prescribing patterns, respondents were asked how frequently they prescribed common classes of drugs; results appear in Table 1. The most frequently prescribed class of drugs was antibiotics with 73.1% prescribing on a daily or weekly basis. Analgesics, anti-inflammatories and other medicines were prescribed much less frequently.

The YC scheme

A majority of respondents (97; 74.6%) stated that they were aware of the yellow card scheme, while 30 (23.1%) indicated that they were not; three respondents (2.3%) did not answer this question. There

was a statistically significant increase in awareness of the YC scheme with increasing years in practice ($p = 0.003$; chi-squared = 15.82 using Yates' correction – see Table 2). There was also a significantly higher proportion of dentists who were aware of the YC scheme among those who had trained in the UK and those that had trained elsewhere ($p = 0.002$; chi-squared = 12.42 using Yates' correction – see Table 3).

When asked what they felt they should report from a specific list of sources, respondents most frequently rated making reports on medicines that they had prescribed themselves as the highest priority;

however, over half felt that it was also most important to report ADRs to medicines prescribed by their patient's doctor or bought in a pharmacy (Table 4).

In response to a direct question a clear majority of respondents (115; 88.5%) indicated that they had never used the YC scheme; one respondent commented that they rarely prescribed and even then any reported ADRs were mild and well known. Three (2.3%) said they had done so in the last year (an unspecified reaction, a rash associated with a non-steroidal anti-inflammatory agent and a reaction to a local anaesthetic requiring hospitalisation). Three (2.3%) said they had made YC reports in the last two to four years (two unspecified reactions and mouth ulceration associated with nicorandil). A further seven (5.4%) said they had made a report in the last five or more years, but understandably, details were scant. Two respondents (1.5%) gave no reply.

Reasons given for not using the YC scheme are shown in Table 5. The main reason, cited by over half the respondents, was that they did not see ADRs in their patients. One GDP remarked that they had not reported a suspected ADR because the patient's doctor was already aware of it; two stated that they had only encountered well-documented ADRs. GDPs who had received their undergraduate training in the UK were more likely to be aware of their responsibility to report ADRs as a dentist than those who had trained outside the UK ($p = 0.009$, chi-squared = 9.455); there was no correlation between awareness and the years a dentist had practised ($p = 0.244$, chi-squared = 5.452).

Previous training on ADRs and confidence in detection

As shown in Table 6, just 34 respondents (26.2%) stated that they had had training on reporting ADRs, while 93 (71.5%) reported that they had not. Three respondents gave no reply. Of the 34 who said they had, 32 (94.1%) said this had been during their undergraduate training; 14 (41.2%) as part of their continuing professional development; 10 (29.4%) in the form of journal articles; and 2 (5.9%) as instruction from colleagues. There was a statistically significant difference between the declaration of previous training and the number of years that the respondents had practised

($p = 0.032$, chi-squared = 10.48), with fewer of those with longer service saying that they had received training on ADRs (Table 7). There was no significant difference in having received training between those having been educated in the UK and those educated outside the UK.

Respondents were asked to indicate how confident they were in recognising ADRs on a Likert scale of 1 (no confidence) to 5 (very confident). The modal response was 3 (neither confident or not confident = 52; 40%); however, 27 (20.7%) gave responses lower than this and 49 (37.7%) indicated greater confidence (two respondents did not reply). There was no correlation between confidence levels and place of study, training on ADRs received or not, or years of practice.

ADR information sources and training needs

Dentists were asked where they might look for information on ADRs with responses shown in Table 8. A clear majority (93%) cited the British National Formulary (BNF) as a source of information on ADRs.

As shown in Table 9, 41 respondents (31.6%) either agreed or strongly agreed with the statement 'I think there is room for more training on ADRs at undergraduate level' and 100 (76.9%) agreed or strongly agreed with the statement 'I think that there is room for more training on ADRs as continuing professional development'; the responses to these two features were not mutually exclusive. When specifically asked, 96 (73.8%) respondents indicated that they would like additional training on the significance of ADRs; 86 (66.2%) on the recognition of ADRs and 68 (52.3%) on the reporting of ADRs.

When asked about their preferred CPD format the following were cited by respondents: lectures (80; 61.5%); journal articles (52; 40.0%); webinars (27; 20.8%); deanery generated materials (24; 18.5%) and podcasts (13; 10%).

DISCUSSION

The response rate to the questionnaire (30%) is considered to be typical for this type of postal survey of busy GDPs. It is noteworthy that the ratio of respondents who trained in Europe and the UK was very similar to that reported by Patel *et al.*¹⁵ who found that in 2010, 28% of GDPs registered

Table 6 Respondents' statements on ADR training received

Training received on ADRs (n = 130)			
Yes		No	No reply
34 (26.2%)		93 (71.5%)	3 (2.3%)
Source of ADR training (n = 34)*			
As part of the undergraduate course	32 (94.1%)		
As postgraduate CPD	14 (41.2%)		
Journal articles	10 (29.4%)		
From a colleague	2 (5.9%)		

*Respondents were allowed to indicate more than one source

Table 7 Distribution of respondents stating that they had or had not received training by years of practice

Years practised	Training received		
	Yes	No	Totals (n = 130)
<5	7	7	14 (10.8%)
5-10	6	11	17 (13.1%)
11-20	9	14	23 (17.7%)
21-30	6	37	43 (33.1%)
>30	6	24	31 (24.8%)
Totals	34 (26.2%)	93 (71.5%)	127 (97.7%)*

NB: Three respondents did not reply to this question

Table 8 ADR information sources cited by GDPs

Source of ADR information*	Citations number (%)
British National Formulary (including the online version)	121 (93.1)
Internet (unspecified)	75 (57.7)
Product patient information leaflet	55 (42.3)
Product labelling	45 (34.6)
The patient's GP	39 (30.0)
A colleague	28 (21.5)
The patient's specialist doctor	23 (17.7)
A local pharmacist	23 (17.7)
A textbook	19 (14.6)
The summary of medicinal product characteristics (SmPC)	9 (6.9)
The local medicines information service	6 (4.6)
Other	<i>British Dental Journal</i> (1; 0.8%) Calling the MHRA (1; 0.8%)

*GDPs were allowed to cite more than one source

with the GDC had not qualified in the UK. The sample can therefore be interpreted as representative in this respect. In other aspects, the data cannot be taken as representative of the sampling frame because

the response rate is low; the findings are nonetheless interesting.

While the majority of GDPs were aware of the YC scheme they seldom used it. This is supported by the relatively low

Table 9 GDP responses to statements on ADR training

	Statement 1*	Statement 2**
Strongly agree	20 (15.4%)	32 (24.6%)
Agree	21 (16.2%)	68 (52.3%)
Neither agree nor disagree	9 (6.9%)	14 (10.8%)
Disagree	3 (2.3%)	3 (2.3%)
Strongly disagree	0 (0%)	0 (0%)
No reply	77 (59.2%)	13 (10.0%)

*Statement 1: 'I think that there is room for more training on ADRs at undergraduate level'
 **Statement 2: 'I think that there is room for more training on ADRs as CPD'

incidence of YCs emanating from dentists as reported by the MHRA.² The finding resonates with several studies with doctors, where a majority reported their awareness of the scheme but still did not use it.^{8–10} In the present study, the 130 GDPs reported using the YC scheme a total of six times in the past four years. This amounts to an average of 0.01 of a YC per GDP per year (or one card per GDP every 100 years).

Seymour *et al.*¹⁶ observed that unwanted drug effects appear to be less common in dental practice than in general medical practice but that the GDP may be the first to observe an ADR to a drug prescribed elsewhere. While they are encouraged to take a drug history, GDPs do not take, or have access to, a full clinical history and are disadvantaged when trying to distinguish unusual affects to drugs from signs and symptoms of underlying conditions that the patient might have. Spicer¹⁴ reported the outcome of a UK audit suggesting that dentists lack vigilance when recording medical histories, with just 68.2% concordance with clinical governance standards. If this were to be the general case this too would mitigate towards under-recognition and hence under-reporting of suspected ADRs. In our study, the commonest reason for not using the YC scheme, cited by 58.5% of respondents, was that they never saw ADRs in their patients.

Information on ADRs and how to report them is readily available. The BNF,¹⁷ which 93% of respondents in our survey said they used as a source of ADR information, contains a specific section on the oral side effects of drugs, including effects on the oral mucosa, teeth and jaw, periodontium, salivary glands and taste;¹⁷ and the MHRA website contains advice for dentists

on ADR reporting.¹⁸ Over three quarters of respondents stated that they were aware of the YC scheme so it is likely that a low ADR reporting rate among GDPs is due to lack of ADR recognition rather than knowing how to report.

Those who said that they had been trained in the UK displayed a greater awareness of the yellow card scheme and of their professional responsibility to use it, yet they still did not. There was no difference in the expressed levels of confidence in using the scheme when comparing the responses of those who had trained elsewhere; however, only a third of respondents indicated some degree of confidence in recognising ADRs while about one fifth did not. Confidence was measured on a Likert scale with a null mid-point and 40% of GDPs chose this option. We cannot say why such a large proportion chose this option, but it does indicate that these GDPs remained doubtful. This supports the notion that while GDPs know how to report they lack confidence in doing so.

There was evidence to suggest that the longer the GDP had been in practice, the greater the awareness of the existence of the YC scheme; however there were too few YC reports made in this study to establish whether more experienced GDPs used the scheme more. Over half of the respondents indicated a willingness to report ADRs, not just to medicines that they prescribed, but also to those prescribed by the patient's doctor or purchased over the counter by the patient.

The British Pharmacological Society core curriculum for dental courses, which is taught at most UK dental schools, does contain specific topics related to the mechanisms and recognition of adverse drug

effects for drugs that are commonly prescribed to a patient by their medical practitioner or a GDP. There is also a description of post-marketing surveillance – specifically the YC scheme, and how to use the Dental Practitioner's Formulary (DPF) to access information on any drug prescribed by a GDP or medical practitioner, with particular reference to adverse effects, contraindications and drug interactions.¹⁹

Limited evidence from studies with specialist paediatric physicians,²⁰ hospital doctors²¹ and general practitioners^{22–26} suggests that education and training may improve both reporting rates and the quality of reports. No such evidence could be found for GDPs in the literature or from responses to our questionnaire; this remains a target for a further investigation.

Respondents listed a range of sources they would use to obtain further information on ADRs, the most frequently cited source being the British National Formulary. Appreciable minorities of GDPs cited fellow healthcare professionals as a source of help, including dental colleagues, GPs, specialist doctors and pharmacists. A large majority of GDPs expressed a need for more training on ADRs with over three quarters of respondents thinking this should take place at postgraduate level on topics such as identification, determining significance and reporting; the most popular format was lectures. Collaboration between the dental and pharmacy professions in this area may prove fruitful.

CONCLUSIONS

This study indicates that one of the reasons that comparatively few ADRs are reported by GDPs via the YC scheme is that they rarely see or recognise them in practice. Most were aware of their professional responsibility to do so. So attempts to improve ADR reporting among GDPs should be aimed at education on recognition.

GDPs did recognise the importance of reporting ADRs, not just to medicines they prescribed themselves but to medicines obtained from other sources. While GDPs were able to identify a wide range of sources to help them learn there was a need expressed by over three quarters of respondents for additional postgraduate training. As the dental postgraduate deaneries are increasingly providing

CPD to meet GDC requirements and the type of postgraduate education to enable practitioners to provide evidence against Care Quality Commission outcomes, this is a subject that should be adopted in the portfolio courses that they provide. This is therefore an area of CPD that might benefit from closer collaboration with the pharmacy profession.

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