Perceptions of the Drug Safety Update newsletter

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The Drug Safety Update newsletter, published monthly by the MHRA, plays an important role in alerting health professionals to new safety information on medicines. Mike Wilcock and Georgina Praed present the findings of their small survey of GPs, nurse prescribers and community pharmacists to gauge their awareness and views of the Drug Safety Update newsletter.

Drug Safety Update

MHRA

Latest advice for medicines users

The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

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Contents

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe.

The Commission on Human Medicines gives independent advice to ministers about the safety, quality, and efficacy of medicines. The Commission is supported in its work by Expert Advisory Groups that cover various therapeutic areas of medicine.

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This month, we inform you of a risk of osteonecrosis of the external auditory canal associated with denosumab used in the treatment of osteoporosis. Alongside the previously reported risk to the jaw with denosumab, there are now reports of osteonecrosis of the external ear canal (page 2). Be aware of the risk of osteonecrosis of the external auditory canal as well as the jaw with denosumab and advise patients to report any symptoms that indicate that the jaw or ear may be affected. Please continue to report any cases to us via the Yellow Card Scheme.

We also feature an article about systemic cardiovascular effects associated with brimonidine gel (Mirvaso) for rosacea. Bradycardia, hypotension, and dizziness have been associated with application of the gel (page 3). Warn patients not to apply brimonidine gel to irritated or damaged skin, including after laser therapy to the skin.

You can also read the outcome of our regular review of the impact of the strategy to minimise the risk of misuse of pseudoephedrine and ephedrine (page 4) and learn more about how you can help us to support the safety of e-cigarettes and e-liquids by reporting suspected side effects and safety concerns (page 5).

Finally, in addition to the usual list of letters sent to healthcare professionals (page 6), this month we feature a short list of some of the Medical Device Alerts issued by MHRA in May (page 7). Be aware of any safety issues that affect devices used by your patients or in your practice and find out whether any recommended actions apply to you.

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As new or updated safety information emerges throughout a medicine's lifecycle, there are occasions when it is important to communicate this information promptly to healthcare providers involved in prescribing or dispensing or in caring for patients who receive medicines. Such correspondence from the manufacturer or national regulatory agency – typically known as 'Dear Doctor' letters or direct healthcare professional communications – is vital to pharmacovigilance by ensuring that prescribers are informed about new evidence of drug benefit and harm that has emerged postlicensing.[1] The correspondence communicates practical advice for the safe use of drugs with the aim of improving patient health outcomes.

How far these warnings actually influence prescribing behaviour is mixed. Studies of the impact of regulatory advisory letters on medicines use have not been resoundingly positive. For instance, one review concluded that although some notices have a significant impact, others have a delayed or no impact.[2] This may be due to the nature and specificity of the warning: recommendations to monitor treatment more closely have little impact whereas recommendations to avoid use of a drug in particular patient subgroups often lead to reductions in use, especially if the risk communication states specific actions that prescribers should take. Another review could not reach firm conclusions because of the limited evidence of any effect, though the authors found that healthcare professionals prefer to be informed by governmental or their own professional bodies, rather than by the pharmaceutical industry.[3]

The monthly Drug Safety Update (DSU) newsletter was launched by the Medicines and Healthcare products Regulatory Agency (MHRA) in August

2007. It is based on robust analysis of pharmacovigilance data and evidence, describes the nature of drug safety problems and in the majority of cases outlines what actions should be taken to mitigate any identified risk. The GMC guidance on good practice in prescribing explicitly highlights that DSU provides information and advice to support the safer use of medicines and alerts practitioners to safety information about medicines.[4] Furthermore, a competency framework for all prescribers has as one of the competencies: "Keeps up to date with emerging safety concerns related to prescribing."[5] An editorial in the *Drug and Therapeutics Bulletin* commented that DSU has established itself as one of the most influential sources of new information about the safety of medicines for UK-based healthcare professionals, but also noted that on occasion, safety notices have not included any practical implementation advice.[6]

Our small survey set out to understand how different healthcare professionals in one CCG viewed the advice offered by the DSU newsletter.

Method

Across Cornwall, locality-based prescribing meetings are held four times a year. These meetings, organised by NHS Kernow CCG Medicines Optimisation Team, are intended to have a focus on clinical prescribing and medicines optimisation. A GP prescribing lead from each surgery is invited to attend these meetings and disseminate the learning within their own practice. At each of the three locality meetings in March 2016, the GPs were asked to complete a questionnaire during the tea break having been advised that it was anonymous and would take only a few minutes to complete.

The survey was also delivered to a convenience sample of nurse nonmedical prescribers (NMPs) working in general practice who attended a prescribing and medicines optimisation educational event in May 2016, and to a convenience sample of community pharmacists who attended a local pharmaceutical committee-organised educational event in July 2016.

The introduction to the survey simply noted that the DSU newsletter is produced each month and is intended to be essential reading for healthcare professionals, bringing the very latest information and advice to support the safer use of medicines. The survey consisted of mainly closed questions with predetermined answers plus one question that allowed respondents to make free-text comments, and hence could be completed quickly (with the aim of achieving a high response rate). Questions were developed following a review of the literature and in discussion with the CCG prescribing lead.

The questions for the three professions were very similar apart from the question asking respondents for their views on how they perceive their colleagues' awareness of the DSU newsletter. GPs and NMPs were asked about doctors (locums or partners) in the surgery where they were based, and community pharmacists were asked about their pharmacy colleagues (locums or regular staff) in their place of work.

	GPs (n=38)	NMPs (n=26)	Pharmacists (n=20)
I am registered with the MHRA service enabling me to receive an email alert	13 (34%)	6 (23%)	13 (65%)
I am registered with the NICE Medicines Awareness bulletin, which highlights the DSU newsletter	4 (11%)	0 (0%)	0 (0%)
I receive notification via the CCG prescribing team emails	31 (82%)	17 (65%)	10 (50%)
My awareness of these newsletters is *ad hoc* and haphazard	1 (3%)	5 (19%)	1 (5%)
Actually, I never get to see these newsletters	2 (5%)	2 (8%)	1 (5%)
NMPs = nurse nonmedical prescribers			

Table 1. How are you made aware of the Drug Safety Update (DSU) newsletter?

	GPs (n=38)	NMPs (n=26)	Pharmacists (n=20)
I cannot answer this question as I do not see the DSU newsletter	2 (5%)	1 (4%)	1 (5%)
My perception is that none of them seems to be of relevance to me	0 (0%)	0 (0%)	0 (0%)
A few are relevant to me and it is always clear what action should be taken	24 (63%)	21 (81%)	15 (75%)
A few are relevant to me but it is often vague or unclear what action should be taken	12 (32%)	4 (15%)	4 (20%)
NMPs = nurse nonmedical prescribers			

Table 2. Health professionals' general views of the Drug Safety Update (DSU) newsletter

Results

The three GP meetings were attended by a total of 44 GPs, with completed questionnaires returned from 38 (86%). All attendees (26) at the NMP meeting completed the survey, and likewise all

attendees (20) at the community pharmacy meeting. No other characteristics of the respondents were recorded.

There were some differences between the professional groups in how they perceived being made aware of the DSU newsletter (see Table 1). A greater proportion of pharmacists claimed to be registered with the MHRA service, while a greater proportion of NMPs answered that they did not have a formal process to be made aware of the DSU newsletter. More than half (50–82%) of each profession recognised that they receive an additional communication from the CCG prescribing team highlighting DSU topics.

Regarding the usefulness of the DSU newsletter (see Table 2), similar proportions of each profession (63–81%) responded that a few of the topics are of relevance and it is always clear what action should be taken.

When asked to name one or two examples where they perceived that prescribing or monitoring of drug use had altered as a result of a DSU newsletter, 32 responses were received across all three health professional groups (see Table 3). Valproate, domperidone and metoclopramide were the most frequently named medicines. More pharmacists in particular named some medicines that had not appeared in a DSU newsletter.

A larger proportion (20%) of pharmacists than GPs or NMPs expressed concern over perceptions that their colleagues lacked awareness of the DSU newsletter, though approximately half of the GPs and NMPs indicated that they do not know how aware their respective colleagues are of the DSU newsletter (see Table 4).

Fourteen (37%) GPs, 15 (58%) NMPS and 16 (80%) pharmacists wished there were other resources to which they could refer because they think that drug safety advice is an important aspect of use of medicines and they worry about knowledge gaps. The remainder of respondents indicated that they receive enough information about this topic.

Free-text comments were invited on the subject of drug safety and responses were received from nine GPs and two pharmacists. The two main themes from these 11 comments were about information overload for the practitioner, and ensuring that the relevance and importance of the drug safety topic is better communicated to the recipient.

	GPs (14/38)	NMPs (7/26)	Pharmacists (11/20)
Domperidone	6		1
Metoclopramide	3		2
Nicorandil	3		1
Valproate	3		7
Dapagliflozin		3	1
Diclofenac	2		
Other medicines named that have appeared in DSU	5	1	2
Medicines named that have not appeared in DSU	1	2	5

NMPs = nurse nonmedical prescribers

Table 3. Medicines named by respondents whose prescribing/monitoring has changed due to Drug Safety Update (DSU) newsletter

	GPs (n=38)	NMPs (n=26)	Pharmacists (n=20)
Colleagues seem to peruse each and every issue routinely looking for relevant messages for them	5 (13%)	6 (23%)	3 (15%)
If prompted, colleagues will go back and refer to a specific newsletter about a specific topic	13 (34%)	5 (19%)	8 (40%)
Actually, I'm concerned that colleagues seem not to be aware of this publication	2 (5%)	0 (0%)	4 (20%)
I do not know how aware they are	18 (47%)	15 (58%)	5 (25%)

NMPs = nurse nonmedical prescribers

Table 4. Respondents' perceptions of their colleagues' awareness of the Drug Safety Update (DSU) newsletter

Discussion

Changing the behavioural patterns of prescribers in particular has been the focus of extensive research, and barriers to change such as lack of awareness, knowledge, motivation, belief and skill, as well as practical, financial and political obstacles have been identified.[7] It is important for practitioners to be as aware as possible of any gaps in their knowledge about medicines they are prescribing or supplying and the DSU newsletter potentially provides a useful resource.

In our small survey, awareness of this monthly newsletter was mixed, with 8% of GPs, 10% of pharmacists and approximately a quarter of NMPs indicating they infrequently or never get to see the actual newsletter. The CCG prescribing team was seen to have an important

role in promulgating DSU messages with between 50% and 82% of professionals responding that they receive notification about DSU from the CCG. For organisations such as CCGs, having a medication/prescribing communication strategy directed at practices is important for the promotion of high-quality prescribing.[8]

Though a majority of respondents from each profession (63–81%) acknowledged that a few of the topics are relevant and they have an understanding of any necessary action, a third of GPs thought that for some topics relevant to them, it was not clear what action should be taken. This is a potential concern as prescribers need a concise assessment of any safety risk that makes it easy for them to bring about change in clinical practice at the point of prescribing. Others have argued that pharmaceutical companies and licensing authorities should word the information in Dear Doctor letters more precisely and, above all, in a way that allows the information to be put into practice by clinicians.[9] The *Drug and Therapeutics Bulletin* recognises that leaving healthcare professionals without a clear indication of the severity, urgency and appropriate course of action increases the risk of a fragmented and incomplete response.[6]

In a survey of over 1000 Dutch doctors and pharmacists, almost one-third reported taking action following a direct healthcare professional communication.[3] This might be considered a disappointing figure, but the authors argued that in some other areas, achieving a behavioural impact by a single act of communication in one-third of the targeted audience would be seen as a success. A much larger survey (with over 3000 respondents) across nine European countries found that healthcare professionals are generally familiar with the safety communication tools (*ie* direct healthcare professional communications and national competent authority communications) and these tools are considered useful.[10]

Of the 32 respondents who gave specific examples of where they thought DSU had altered the prescribing or monitoring of drug use, valproate was mentioned the most frequently (10 instances) and domperidone the second most frequently (seven instances). Changes in the prescribing of domperidone in general practice subsequent to the DSU warning[11] have been noted in two reports, though in both these reports it would appear that additional focused action was required within the surgeries to ensure that medication safety alerts were integrated into practice.[12,13] A further report noted no significant change on domperidone prescribing patterns in Ireland.[14]

Safety topics identified through DSU may impact on both hospital and primary care prescribers, and the opinion of the specialist may be sought for some individual patients. When primary care seeks advice, this hopefully emphasises to the specialist (and their junior hospital doctors) that there is a safety issue with the named drug and that both primary and secondary care need to respond to DSU topics together to mitigate risk.

As stated earlier, safety warnings have been shown to have variable effects on medicine usage.[15-17] In an observational study examining the impact of risk communications on antipsychotic prescribing, the authors concluded that risk communications from regulators do change clinical practice, although the study raised important questions about how such risk communications should best be designed and disseminated.[18] A similar study looking at antipsychotic prescribing in the UK and Italy noted that safety warnings combined with proactive national initiatives in the UK may have contributed to a more sustained reduction in prescribing than occurred in Italy.[19]

A 2005 study evaluated the quality of a group of direct healthcare professional communication letters sent during 2000 and 2001 that were intended to communicate important new drug safety information.[20] This study found a correlation between the perceived quality of the letter and the extent to which physicians regarded the new information as important. Letters that were evaluated as clearer, more concise, and better organised and formatted, and that focused on the most important aspects of the new safety information were considered more effective in communicating the new information.

Furthermore, a survey of healthcare professionals in nine European countries found that the perceived usefulness of the safety communication, and the trustworthiness of the national competent authority, influenced how often healthcare professionals took action.[21]

The small number of free text comments in our Cornish survey supports the need for a clear, concise message that is unambiguous in describing the action to be taken. Computerised decision support software such as OptimiseRx and ScriptSwitch can be utilised to prompt prescribers about safety updates and any necessary action to be taken at the time of prescribing the target drug.

Limitations of our study include the relatively small sample size, and the reliance of the survey on self-reporting with the associated potential for social desirability bias where respondents may have given expected, anticipated answers. Attempts to minimise this bias were made by emphasising that the responses would be processed anonymously. In addition, there were limitations associated with delivering a questionnaire that was brief and consisted of mainly closed-ended questions, which limited the respondents to the answers provided on the questionnaire, as well as gauging the views of GPs who, in their role of practice prescribing lead, could be described as a self-selected group.

Conclusion

This small study has identified deficiencies in how patient safety information is received and effectively translated into practice by a range of healthcare professionals. Additional efforts are needed to ensure that such information reaches healthcare professionals in such a way that enables appropriate action to be undertaken. Medicines optimisation teams have a role in signposting to and promoting DSU messages, while decision support software can potentially intervene at the point of prescribing.

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Declaration of interests

None to declare.

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