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Drug safety awareness in New Zealand:

public knowledge and preferred sources for information

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ABSTRACT

INTRODUCTION: To make informed choices about medical treatment options, patients and consumers need knowledge about the benefits and the risks of drugs. Little is known about levels of drug safety knowledge or preferred sources of drug safety information in general population samples.

AIM: To explore drug safety knowledge, experience of adverse drug reactions (ADRs), and preferred sources for drug safety information in the New Zealand public.

METHODS: We undertook a telephone survey of a random sample of adults (N=87) in the Dunedin area of New Zealand.

RESULTS: Although 47% of those currently or recently using prescription or over-the-counter drugs (N=83) were unable to recall any safety information at all about the medicine they were taking, 84% felt confident they could use these medicines in a safe way. The experience of at least one ADR during the last five years was reported by 40%. The five most preferred sources for drug safety information among all participants were: doctor (92%), pharmacist (76%), information on/inside the medicine package (66%), nurse (57%), and the internet (41%).

DISCUSSION: Our results add to findings from specific patient groups to show that there is a low level of drug safety knowledge in the general population. Primary health care practitioners have a recognised and vital part to play in promoting drug safety awareness.

KEYWORDS: Consumer health information; drug safety; medicine information; patient education

Introduction

J PRIM HEALTH CARE 2012;4(4):288–293. S

CORRESPONDENCE TO: Charlotte Paul Professor, Department of Preventive and Social Medicine, University of Otago, PO Box 913, Dunedin, New Zealand charlotte.paul@otago.ac.nz To make informed choices about medical treatment options, patients and consumers need knowledge about the benefits and risks of drugs. Safety aspects of medicine use that are important for patients to know about include dose-related adverse drug reactions (ADRs, e.g. toxic effects or predictable side effects), non-dose-related ADRs (e.g. immunological or idiosyncratic reactions), drug interactions, and effects of incorrect dosage or administration.^{1,2} If patients lack awareness of the conditions for safe use, the potential results are poorer health outcomes, patient dissatisfaction, and unnecessary resource use. The propor-

tion of all hospital admissions that are for ADRs is in the order of 3%,³ and there are likely to be many more that do not result in hospital admission. Best estimates are that a third to a half of all ADRs are preventable.⁴ As well as obvious ethical and democratic rights of patients/consumers to receive information, previous research has identified well-informed patients as central for improving adherence and potentially also treatment outcomes.⁵⁻⁷ Moreover, while the extent to which patients' drug safety knowledge can prevent or decrease the severity of ADRs has not been explored scientifically, intuitively we would expect that better-informed patients would be more likely to avoid interactions, cope better with pre-

dictable side effects, and recognise possible toxic or non-dose-related reactions sooner. Information about possible ADRs has also been reported as one of the top-rated priorities for patients/consumers when learning about their medicines.^{8–10}

For effective communication of drug safety issues, it is necessary for health care providers and medicines regulators to understand the level of drug safety knowledge of patients/consumers and their preferred sources for information.^{11,12} Studies have shown that patients/consumers often use a number of sources to obtain information about their medicines and health-related topics, including friends and family, health professionals, mass media, and the internet.^{13,14} Package insert leaflets with consumer medicine information, though recognised as being an important source of medical information, have often received low scores due to difficult language and a layout that does not meet patient/consumer needs and preferences.¹³⁻¹⁶

New Zealand is one of the two developed countries (the other being the United States) that currently allows direct-to-consumer advertising of prescription medicines. Package inserts with consumer medical information are not mandatory in New Zealand. Little information is available about levels of drug safety knowledge or preferred sources of information in general population samples. We undertook a population survey in Dunedin to explore drug safety knowledge, experience of adverse reactions, and preferred sources for drug safety information.

Methods

Participants

Individuals (N=284) were randomly selected from the 2008 New Zealand general and Maori electoral rolls for the Dunedin city region. All New Zealand citizens aged 18 years or older are required by law to be registered on the electoral roll. To be eligible, selected individuals had to have a telephone number identified in the national online telephone directory. Invitational letters, which included information about the study, were sent to eligible individuals (N=140) and were followed by a phone call to seek consent and arrange an interview. Contact was established

WHAT GAP THIS FILLS

What we already know: Drug safety information is considered to be very important by patients when learning about their medicines, yet previous studies on specific patient groups have shown that their knowledge about the safety of their medicines is limited.

What this study adds: Findings from this study suggest a low level of drug safety awareness in the general population, paired with a surprisingly high confidence in the ability to use medicines in a safe and effective way. To promote the safe use of medicines in New Zealand, it is important for primary health care practitioners to be aware of this low level of drug safety knowledge in their consultations with patients.

with 104 potential participants, of whom 87 (84%) agreed to take part.

Interview measures

Structured telephone interviews (approximately 15 minutes) were carried out from 30 April to 12 May 2010. Information was sought on demographic characteristics and current or recent (last 12 months) use of prescription and over-the-counter (OTC) medicines. Participants were asked to select one of these medicines—the one that they knew the most about and would be comfortable discussing—and were asked their recollections of warnings and precautions, and possible side effects of that medicine. Details of personal experience with a side effect of any medicine in the last five years were sought. Finally, a list of possible sources of drug safety information was read to participants and they were asked to indicate their preferred sources.

Prescription and OTC medicines were classified according to their therapeutic use, and ADRs were classified according to MedDRA—the Medical Dictionary for Regulatory Activities (www. meddramsso.com). Participants' recollections of drug safety information (possible ADRs, warnings and precautions) were compared with official information in data sheets publicly available on the website of the New Zealand medicines' regulator, Medsafe (www.medsafe.govt.nz). Narrative comments on source/channel preferences were grouped by topic.

We calculated simple proportions and 95% confidence intervals (CIs) for the main findings using

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Table 1. Demographic characteristics, proportion using prescribed and OTC medicines, and experience of adverse drug reactions (ADR)

Characteristic	Men (n=39)	Women (n=48)	Total (n=87)
Age group			
20-39 years	23%	10%	16%
40-59 years	62%	42%	51%
≥60 years	15%	48%	33%
Currently using prescribed medicines	54%	75%	66%
Currently using OTC medicines	26%	33%	30%
Currently using both prescribed and OTC medicines	8%	17%	13%
Currently not using any prescribed or OTC medicines	28%	9%	17%
Experienced ADR during the last five years	31%	48%	40%

Stata version 12. The study was designed and conducted by final year medical students under supervision as part of a larger pharmacovigilance project. The study was approved by the Lower South Regional Ethics Committee.

Results

Characteristics of the study population, medicine use and experience of adverse drug reactions

Of the 87 participants in the study, 39 were men and 48 women; the age distribution was weighted towards older women and younger men (Table 1). At the time of interview, 66% (95% CI 55–75) of participants reported they were currently using prescribed medicines; this was more common among women than among men (75% of women compared to 54% of men). As expected, the prevalence of prescription medicine usage increased with increasing age for both women and men, with the prevalence being higher for women than men within each age group.

Overall, the most commonly used classes of medicines were antihypertensives (used by 28% of the study population) followed by hypolipidaemic agents (24%) and antithrombotic medicines (15%)—these three therapeutic classes all had similar figures for both sexes. The largest difference in usage between men and women was seen for medicines against hyperacidity (21% of women and

5% of men), sedatives/hypnotics (17% of women and 5% of men) and antidepressants (16% of women and 3% of men). Prescribed simple analgesics and antipyretics were used by 9% of the study population, with similar proportions for both sexes.

The usage of OTC medicines (excluding supplements and natural remedies) was lower than prescription medicines, with a total of 30% (95% CI 21–41) using OTC medicines at the time of the interview (Table 1). Similar to the usage of prescription medicines, a larger proportion of women than men used OTC medicines within each age group.

For OTC medicines, the overall usage was dominated by analgesics/antipyretics (25%) with similar figures for both sexes. Use of supplements and natural remedies such as vitamins, glucosamine and fish oil were more frequently reported by women than by men (35% women, 18% men). In total, 13% reported using both prescribed and OTC medicines at the time of the interview (Table 1). Women were more likely than men to combine OTC and prescription medicines (17% women, 8% men). A total of 14% reported using supplements or natural remedies and prescription medicines, with similar figures for both sexes.

Half of the women and one-third of the men reported having experienced side effects/ADRs to their medicines during the last five years (Table 1). Of the whole study population, 40% (95% CI 30–51) had experienced at least one ADR during the last five years. The most commonly reported types of ADRs were gastrointestinal (e.g. nausea, diarrhoea, dyspepsia, constipation), psychiatric (e.g. insomnia, mood swings), and related to the immune system (e.g. hypersensitivity reactions such as rash, urticaria).

Drug safety knowledge

When asked about the safety information of the chosen medicine (warnings and precautions, and possible side effects), 47% (95% CI 36–58) were unable to recall any such information at all at the time of the interview (Table 2). In each age group, a larger proportion of men than women were unable to recall any safety information about their medicines. In all, 54% of the men and 42% of the

women could not recall any safety information about their medicines. With regards to the type of safety information recalled, 25% (26% of the men and 25% of the women) mentioned possible ADRs to the medicine and 31% (20% of the men and 40% of the women) mentioned warnings or precautions about their medicine (statements regarding correct dosing and possible interactions were also accepted as such safety information).

In response to the question 'Do you feel you know enough about the medications you take to use them in a safe and confident way', 84% (95% CI 74–91) answered in the affirmative, with a larger proportion of women (90%) than men (77%) (Table 2). There was a tendency for older medicine users to feel more confident than younger users.

Information preferences

The preferred sources/channels for drug safety information are shown in Table 3, together with comments on the preferred source. The five most preferred sources were: doctor (92%), pharmacist (76%), information on/inside the medicine package (66%), nurse (57%), and the internet (41%). Magazines, newspapers, TV, and radio were used by 10-20% of the study population. Word of mouth was more frequently reported by women than men as a preferred channel for drug safety information (29% and 14%, respectively). The internet was more popular in the younger age groups, particularly among men (data not shown). Of those who had selected the internet as a preferred source for drug safety information, 65% used Google to find what they were looking for, and 6% would go to the Medsafe website.

Participants were also asked why they preferred accessing drug safety information from the sources/channels they had selected. A summary of the common responses is presented in Table 3.

Discussion

In this sample of the general population, current use of both prescribed and OTC medicines was high and 40% had experienced an ADR in the previous five years. Hence it was a sample with considerable experience of medicine use. Even so, nearly half of the responders could not recall any

Table 2. Proportion recalling drug safety information and confidence as medicine users

	Men (n=35)*	Women (n=48)	Total (n=83)
Could not recall any safety information	54%	42%	47%
Mentioned possible ADRs	26%	25%	25%
Mentioned warnings or precautions	20%	40%	31%
Felt that they knew enough about their medicines to use them in safe and confident way	77%	90%	84%

* Four men had not used any prescription or OTC medicines during the last year, and were thus excluded from questions on drug safety information recollection.

Table 3. Proportion reporting specific preferred channels and comments on preferred information sources/channels

Source/channel	Percent of total*	Main themes in participants' comments
Doctor	92%	Knowledgeable about medications, trustworthy
Pharmacist	76%	Knowledgeable, trustworthy, convenient, available when doctors may not be available
Information on/ inside packaging	66%	Convenient, immediately accessible, accurate source of information
Nurse	57%	Trustworthy and knowledgeable, second (more convenient) line to doctors
Internet	41%	Easy and convenient, not generally first line source of information. Used to access broad perspective of opinions about medications
Word of mouth	23%	Useful if obtained from people in health care field. Useful to hear about other people's experiences of medications
Television	17%	Useful only if from trusted source. Potentially easy way to pick up information
Radio	14%	Useful only if from trusted source. Potentially easy way to pick up information
Magazines	14%	Convenient
Newspapers	14%	Accessible

* Participants could report multiple sources

safety information about one chosen medicine they had taken in the last year. Of those that could, half mentioned possible adverse reactions and half mentioned warnings or precautions. The five most preferred sources of information about drug safety, in order, were the doctor, the pharmacist, information on or inside packaging, the nurse, and the internet.

There are limitations to this survey. Although the response rate was high, phone numbers were

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not accessible for about half the original sample. Telephone interviews were chosen to enhance the quality of the information, although this limited the proportion of the original sample that could be contacted. Moreover, only one city was surveyed, hence generalisation to the whole country is uncertain. More women than men were included in the final sample and the women were older, so comparisons between the sexes should be interpreted cautiously, though direct comparison within age groups is valid. Precision is also limited by small numbers. Nevertheless, these data provide information on drug safety knowledge and preferred sources of information within a population-based sample with a high use of medicines. Patterns of use for men and women within age groups are similar to those found elsewhere (e.g. Fernandez-Liz, 2008; Eggen, 1997).^{17,18}

Previous research on ADR recollection has mainly been restricted to samples with particular medical conditions. For example, a small study on Australian patients with Type 2 diabetes found that 37% of the participants could name possible ADRs for their medicines. Phonog ambulatory cardiovascular patients in Michigan USA, only 10% of participants could mention any common side effects of their medications. In a recent New Zealand study of patients with glaucoma, only 20% were aware that their glaucoma medications could have systemic side effects.

In the present study, 84% of the participants felt confident about their ability to use their medicines in a safe way. At the same time, 47% could not recall any safety information about their medicines. While these figures may seem contradictory, they are in line with findings that patients' perceptions of being well informed about medical treatment options corresponded poorly with actual tested knowledge.²² Our results add to information from specific patient groups to show that there is a low level of knowledge about adverse effects of medicines in the general population.

Concerning preferred sources of drug safety information, trustworthiness was a commonly mentioned reason for preference for all health professionals and also for package information, while convenience was commonly mentioned for pharmacist, nurse, package information, and the

internet. A higher level of criticism was expressed in the comments about information from the radio and television than for information from the internet, magazines and newspapers. In previous studies, health care professionals often stand out as highly preferred and trusted channels/sources;^{13,15,23} however, the high rating for package information among participants in the present study differs from previous research, where package insert leaflets have been rated as having poor layout and difficult language.^{13,14}

The reason for a high preference for package information may be explained by the results from a recent study in which New Zealand consumer medicine information ranked very highly in comparison with written medicine information from other English-speaking countries. The study found that the consumer medicine information from New Zealand conformed to international standards for such information to a much higher degree than that from other countries such as the USA and the UK.²⁴

In New Zealand, where package inserts are not mandatory,25 they have been judged to be of high quality²⁴ and were highly rated as sources for drug safety information by the participants in this study. This raises the question of whether New Zealand should retain these good quality inserts but follow other developed countries (for example in the EU and Australia) where package inserts with consumer medicine information are required by law for approved medical products. The use of direct-to-consumer advertising (DTCA) for prescription medicines in New Zealand may have influenced the low ratings for television and radio as preferred sources of drug safety information. Previous studies have shown that the risk-benefit information provided in drug advertisements is often biased towards the benefit side, ^{26,27} and that consumers perceive DTCA to do a better job at conveying benefit information than risk information about the medicines advertised.²⁸ A study by Dens et al. indicated that New Zealand patients were more positive than Belgian patients in their perception of the usefulness and reliability of DTCA; still, only one-third of the New Zealand study participants considered DTCA for prescription medicines to be useful.29

Further research on larger and more representative samples should seek to define the patient groups and types of medicines that are associated with lower levels of knowledge about precautions and adverse effects, and examine more closely the sources of information, especially the use of particular websites. The discussion of suspected adverse effects with the doctor, pharmacist, or others requires further investigation, as does the apparent mismatch between confidence in use of medicines and knowledge about adverse effects. Considering the fast-changing nature of communication technologies, it would be valuable for future studies to investigate public views on possible upcoming channels of interest for drug safety communication, e.g. use of social media on the internet (Facebook, Twitter, YouTube) and mobile phone messaging. These new communication channels have recently been introduced for drug safety communication by regulators in a number of countries worldwide. 30 Finally, more work needs to be undertaken in order to establish whether well-informed patients are indeed more likely to avoid interactions, cope better with predictable side effects, and recognise and act on possible toxic, idiosyncratic, or immunological reactions sooner.

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ACKNOWLEDGEMENTS

Participant selection, questionnaire design and testing, letter correspondence, telephone interviews and data transcription were conducted by trainee interns Gregory Macleod, Ah Rin Choi, Michael Makary, Awang Haji Md Taib, Ili Ruslan, Norirwanie Ismail, Noor Abd Latib, Shuichi Suetani and Rahul Prasad.

FUNDING

This research was supported by funding from the Health Research Council of New Zealand and the New Zealand Ministry of Health, as part of a larger research project aiming to create an integrated pharmacovigilance system in New Zealand.

COMPETING INTERESTS

None declared.