Survey on adverse drug reaction (ADR) reporting

Outcome report for survey of healthcare professionals

Pharmacovigilance Team, Medsafe

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Abbreviations

ADR	adverse drug reaction or suspected adverse drug reaction
ARRS	adverse reaction reporting standard
BPAC	Best Practice Advocacy Centre
CARM	Centre for Adverse Reactions Monitoring
CME	continuing medical education
CPD	continuing professional development
DHB	district health board
GP	general practitioner
HCP	healthcare professional
HISO	Health Information Standards Organisation
HPA	Hospital Pharmacists Association
HQSC	Health Quality & Safety Commission
IAER	increasing adverse event reporting
ICMRA	International Coalition of Medicines Regulatory Authorities
IMAC	Immunisation Advocacy Centre
MARC	Medicines Adverse Reactions Committee
MHRA	Medicines and Healthcare Products Regulatory Agency (UK)
NZF	New Zealand Formulary
PHO	primary health organisation
PSNZ	Pharmaceutical Society of New Zealand
RNZCGP	Royal New Zealand College of General Practitioners
TGA	Therapeutic Goods Administration (Australia)
WHO	World Health Organization

Contents

1) Purpose

Medsafe presented the strategy for promoting reporting of adverse reactions to medicines and medical device incidents to the Medicines Adverse Reactions Committee (MARC) on 13 September 2018. The Committee agreed to the strategy.

One of the projects identified in the strategy was to conduct a survey of healthcare professionals and consumers on adverse drug reaction (ADR) reporting. The strategy recommended that this project be started within the next few months.

The project is being managed in two key stages:

1. Survey of healthcare professionals.
2. Survey of consumers.

The survey of healthcare professionals was opened on 5 December 2018 and closed 31 January 2019 – a period of almost two months. This document presents an overview and analysis of responses received.

2) Background

The survey of healthcare professionals on adverse drug reaction (ADR) reporting aimed to explore:

- How much healthcare professionals know about the current ADR reporting scheme and medicines regulation
- How they would like to receive new information on the benefits and risks of medicines.

During the survey, healthcare professionals were asked to reflect on their current practice. Medsafe was interested to know how to make it easier for healthcare professionals to report ADRs to medicines and how best to communicate medicines safety information.

Information gathered from this survey will help guide future campaigns and promotional activities to promote ADR reporting. Repeating the survey after these campaigns and activities can be a way of measuring their success and effectiveness.

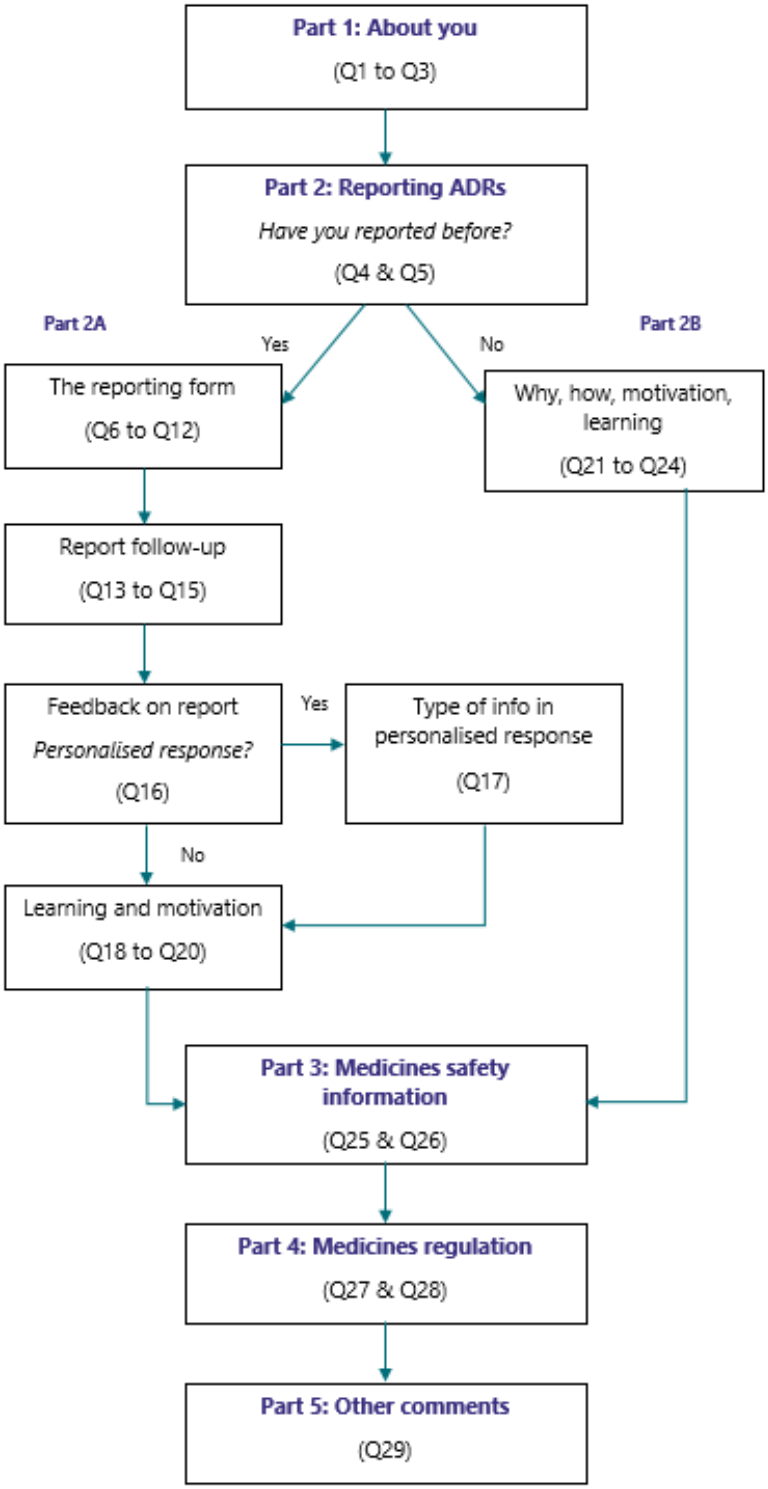
Once the outcome of this healthcare professional survey is complete, the aim is to modify the questions and perform a survey of consumers.

Both surveys of healthcare professionals and consumers will be based on learnings of other regulators that are part of the International Coalition of Medicines Regulatory Authorities (ICMRA) pharmacovigilance subproject on increasing adverse event reporting (IAER).

3) Survey structure

The overall survey structure is shown in Figure 1. Please refer to Appendix 1 for the full list of questions. The survey was hosted on SurveyMonkey from 5 December 2018 to 31 January 2019.

Figure 1: Structure of the survey for healthcare professionals on reporting adverse drug reactions #



ADRs = adverse drug reactions; Q = question(s)

There were 29 questions included in the survey. The majority were optional questions where participants could skip the question if they didn't want to provide an answer. However, there were some questions that were compulsory and these were marked with an asterisk (*). Compulsory questions were required because this ensures the survey structure works in places where it "splits". An example of this is Q5 where the survey splits into Part 2A and Part 2B as shown in Figure 1. Other questions were made compulsory to gather demographic data and also where Medsafe was particularly interested to learn more from participants (eg, Q21 'Is there any particular reason why you have never reported an adverse drug reaction?').

The survey was initially pushed out through various methods including:

- A short blurb in *Prescriber Update* with a sentence in the email to subscribers.
- A tweet using the Ministry of Health's Twitter account.
- The Immunisation Advisory Centre (IMAC) weekly newsletter.

A reminder to complete the survey was sent two weeks before the survey closed and this included:

- An email to subscribers of Medsafe alerts and *Prescriber Update*
- A tweet using the Ministry of Health's twitter account
- Emails to the Pharmaceutical Society of New Zealand (PSNZ), Royal New Zealand College of General Practitioners (RNZCGP) and Hospital Pharmacists Association (HPA) asking them to remind their members about the survey.

4) Survey results

In-built SurveyMonkey tools were used to analyse results and present data.

A total of 455 responses were received. Of these, 357 were received in the last two weeks of the survey closing after reminders were sent. The average time participants spent on the survey was 6 minutes.

Compulsory questions are marked with an asterisk (*) throughout.

Part 1: About you

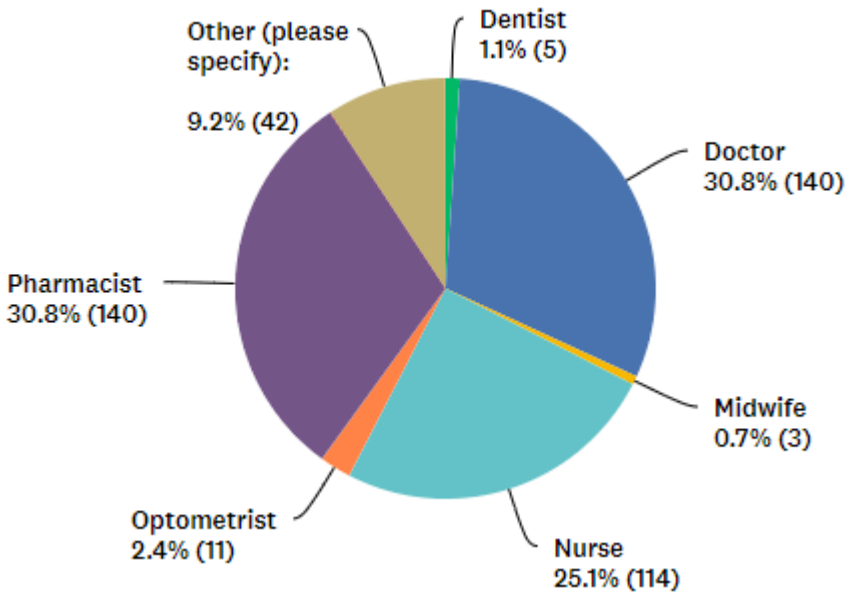
Q1: What healthcare professional group do you belong to? *

The response rate to this question was 100%. All 455 participants provided a response (Figure 2).

There was an even split between participants who were pharmacists and those who were doctors (140 each).

Those who selected 'Other (please specify)' described the following professions: medical student/student (18), nurse practitioner (11), quality and/or patient safety professional (3), academic/researcher (2), sponsor/distributor (2), clinical advisory, did not specify, live-in nanny, natural medicine doctor, pharmacist prescriber, and risk advisor (1 each).

Figure 2: Healthcare professional groups of survey participants



Q2: Do you work predominantly in primary care or secondary care? *

The response rate to this question was 100%. All 455 participants provided a response (Table 1). Just over half of the participants work predominantly in primary care.

Table 1: Part of the health system (primary or secondary) where survey participants work

Primary or secondary care	Count	Percent
Primary	229	50.3%
Secondary	174	38.2%
Not applicable	52	11.4%
Answered question	455	

Q3: Where is your practice located?

A total of 443 participants provided a response.

The options provided for this question were according to the 20 district health boards (DHBs). Most participants' practices are located in Auckland (26.6%) followed by Canterbury (15.8%), Capital and Coast (7.9%), Southern (7.2%), Bay of Plenty (7%) and Waikato (7%).

Table 2 shows location of practices according to the North or South Island. The majority of participants work in the North Island (68.9%) which is somewhat comparable to 77% of New Zealand's total population living in the North Island (according to Stats NZ as at 30 June 2017).

There were 22 participants (5%) who selected 'Other (please specify)'. A few participants provided a city, town or region such as Whangarei, Lower North Island, Wellington, Dunedin, Otago.

Some participants' practices were located outside New Zealand: Australia (5), Colombia (2), Cook Islands (1), Italy (1), Romania (1), Peru (1), and South America (1). These responses have been included in the analysis since the numbers were small and unlikely to significantly affect the results.

Table 2: Location of practices of participants

Location of practices	Count	Percent
North island	305	68.9%
South island	116	26.2%
Other (please specify):	22	4.9%
Answered question	443	

Part 2: Reporting adverse drug reactions

Q4: Who or which organisation would you contact if you wanted to report an adverse drug reaction? *

Participants could select more than one option for this question. A total of 437 participants answered this question (Table 3). The Centre for Adverse Reactions Monitoring (CARM) attracted the most responses (n=393).

Table 3: Organisation participants would contact to report an adverse drug reaction

Organisation	Count	Percent
Centre for Adverse Reactions Monitoring (CARM)	393	89.93%
A colleague	71	16.25%
Medsafe	57	13.04%
The pharmaceutical company that makes the medicine	54	12.36%
Other (please specify):	49	11.21%
Health Quality & Safety Commission (HQSC)	12	2.75%
Professional body	12	2.75%
PHARMAC	10	2.29%
Ministry of Health	5	1.14%
New Zealand Formulary (NZF)	3	0.69%
Best Practice Advocacy Centre (BPAC)	2	0.46%

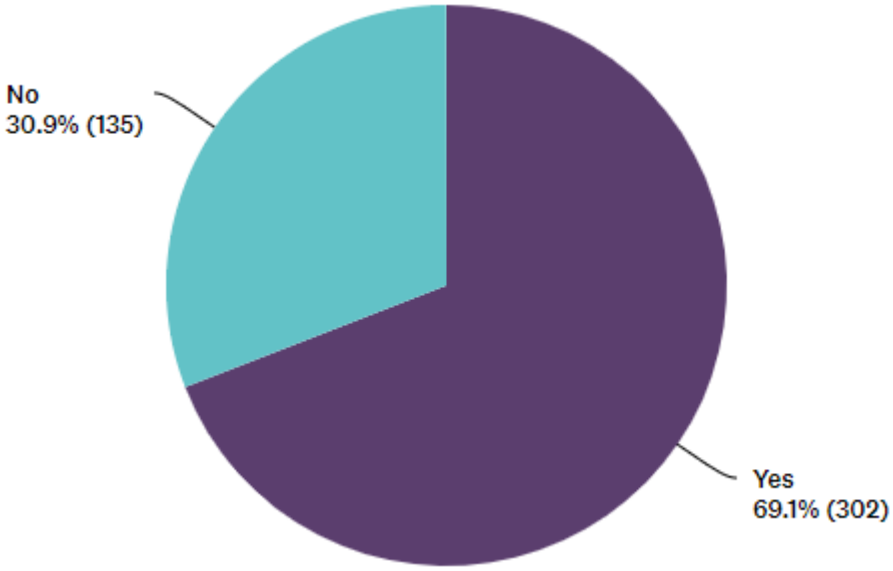
Responses from participants who selected 'Other (please specify)' are shown below:

- A hospital department, another staff member or another healthcare professional (eg, consultant, registrar, prescriber, clinical quality and risk manager, medicines safety committee, pharmacy department, clinical/hospital pharmacist, pharmacist, GP). These responses are variations of 'A colleague'.
- A system for reporting (eg, organisational/internal reporting system, keeping an electronic record for future admissions, DHB ADR reporting, national medical warning)
- Other organisations (eg, PHO, DHB, WHO, IMAC, TGA).

Q5: Have you reported an adverse drug reaction before? *

A total of 437 participants responded to this question (Figure 3). This was a compulsory question indicating that 437 participants completed the survey to this point and there were 18 drop-outs.

Figure 3: Responses to whether participants have reported an adverse drug reaction before

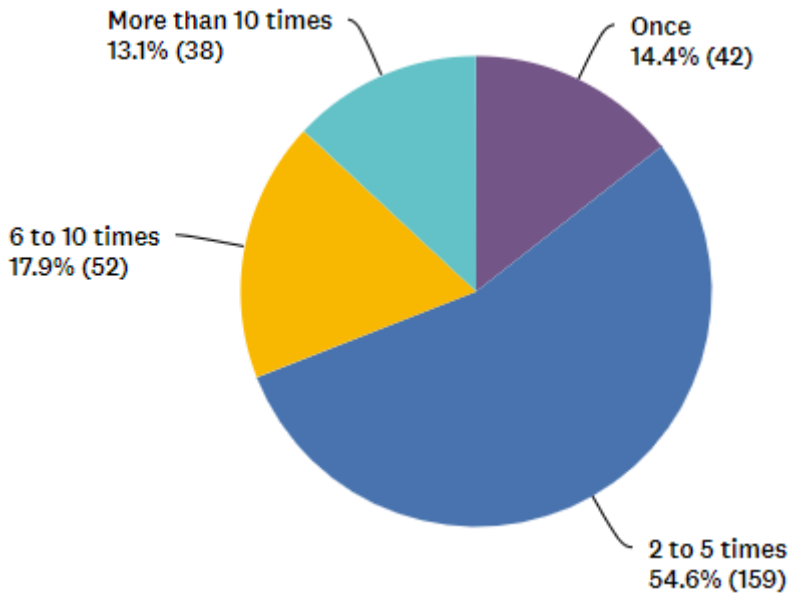


Part 2A: Participants who have reported an adverse drug reaction before

Q6: How many times have you reported?

291 out of the 302 participants that had reported an adverse reaction before answered this question. Responses to this question are shown in Figure 4. More than half of the responders to this question had reported an adverse reaction 2 to 5 times (54.6%). This could suggest that once a healthcare professional learns about the reporting process, this becomes part of their practice and they continue to report adverse drug reactions.

Figure 4: The number of times participants had reported an adverse drug reaction



Q7: Do you usually discuss reporting the ADR with your patient before submitting a report?

Of the 302 participants that had reported an adverse reaction before, 289 answered this question. Approximately 3 out of 4 responders indicated they would have a discussion with their patient before submitting an ADR report (Table 5).

Table 4: Responses to whether there is a discussion with the patient before submitting an ADR report

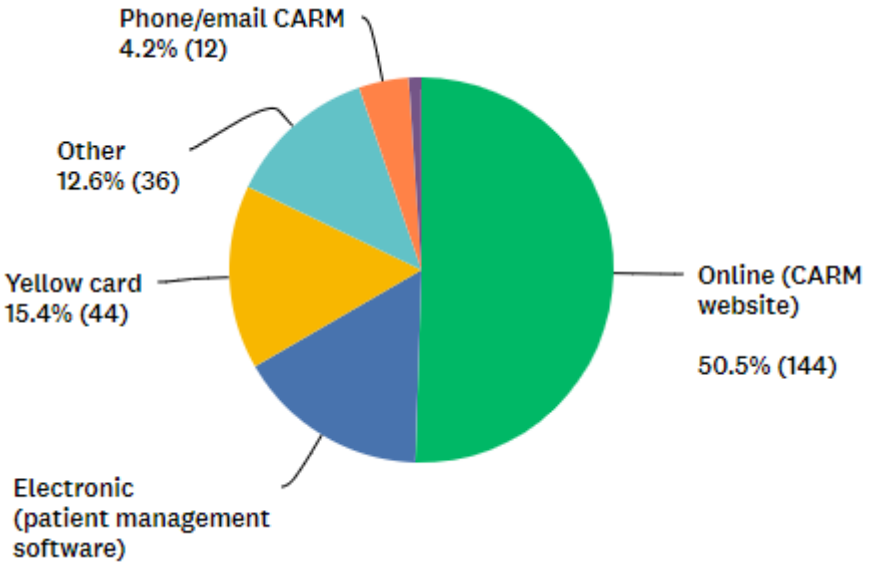
Yes/No	Count	Percent
Yes	219	75.78%
No	70	24.22%
Answered question	289	
Skipped question	13	

Q8: What reporting form do you normally use?

285 of the 302 participants that had reported an adverse reaction before answered this question. Just over half of the participants indicated they normally report ADRs online through CARM's website (Figure 5).

Participants that selected 'Other' specified forms such as electronic reporting, writing a letter, reporting it to another staff member, a DHB or hospital form, and reporting directly to the pharmaceutical company. Some participants indicated they use more than one form.

Figure 5: The reporting form participants normally use to report an adverse drug reaction #

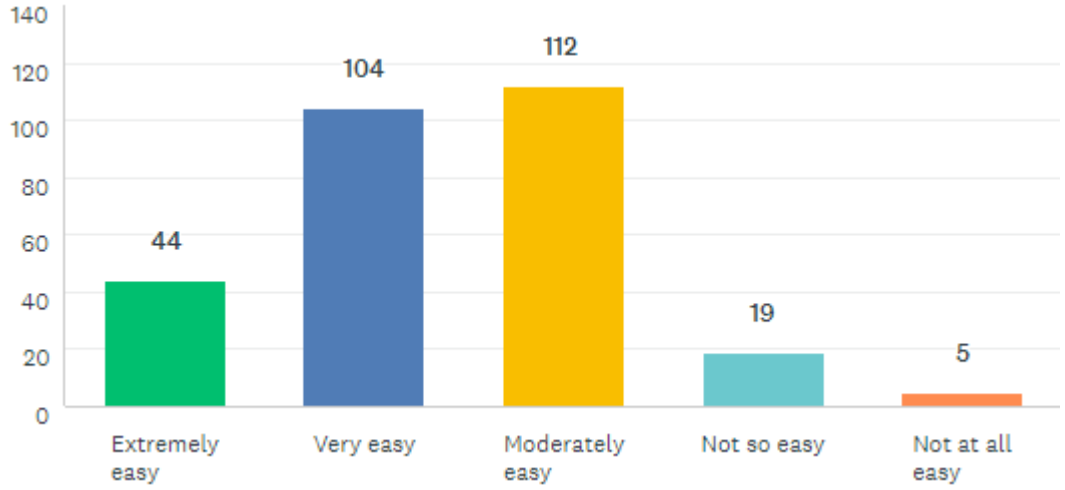


The purple segment in the pie chart represents those who report via the Apple iOS app on their iPhone or iPad (n=3; 1.1%). Electronic (patient management software) attracted 46 responses (16.1%).

Q9: How easy was it to fill in the form?

284 of the 302 participants that had reported an adverse reaction before answered this question. The majority of participants indicated the form was either extremely easy, very easy or moderately easy to complete (Figure 6).

Figure 6: Ease of filling in the adverse drug reaction reporting form



Q10: Was there information you wanted to add but there was no space/opportunity to do so?

280 of the 302 participants that had reported an adverse reaction before answered this question. There were 26 participants (9.29%) who indicated there was information they wanted to add but there was no space/opportunity to do so. Examples of this include:

- Complex medical history or on multiple medicines
- More free space/text required
- Allergies
- Details of vaccine (eg, batch number, route)
- Removing details from the patient record (eg, reactions)
- Unable to remember.

Q11: Was there information needed to be filled in that you found unnecessary?

276 of the 302 participants that had reported an adverse reaction before answered this question. Most participants (n=254; 92.03%) answered 'no' to this question.

Those that answered 'yes' included reasons such as:

- Auto-population of fields would help (eg, NHI, medical history, medicine details)
- Information required that was difficult to locate
- Space for other substances (eg, industrial chemicals)
- Requirement for patient details when they wish to remain anonymous
- Duplication of information
- Unable to remember.

Q12: Is there another way of reporting you would prefer but is not currently available?

284 of the 302 participants that had reported an adverse reaction before answered this question.

There were 44 participants that suggested other ways of reporting. The majority of suggestions related to better electronic or online systems (eg, patient's electronic record, hospital computer system, patient management systems that don't provide direct reporting currently, national reporting system linked with local level data, Android app) and the ability for the form to auto-populate fields such as patient details.

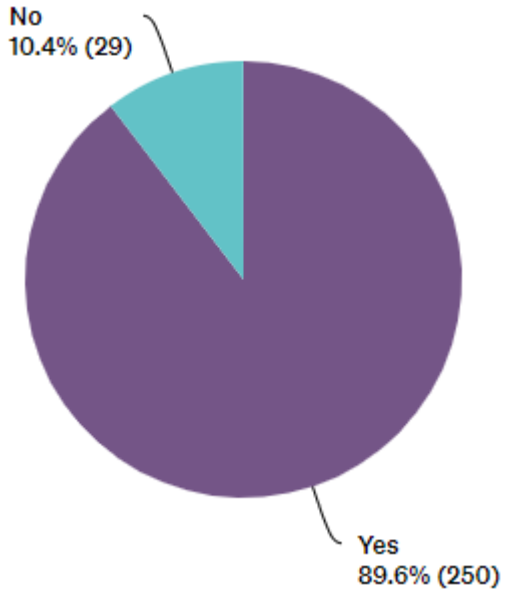
Q13: Are you open to being contacted if further information or clarification about your report is needed?

283 of the 302 participants that had reported an adverse reaction before answered this question. The majority don't mind being contacted if information in the report requires clarification or further information is needed (n=244; 86.22%).

Q14: Should there be a field on the reporting form to select whether we can contact you for further information or clarification?

279 of the 302 participants that had reported an adverse reaction before answered this question. An overwhelming majority of participants selected 'yes' to a field on the form about whether they can be contacted for further information or clarification (Figure 7).

Figure 7: Whether there should be a field on the reporting form to select whether reporters can be contacted for further information or clarification



Q15: Additional comments

This was a free text field and was the third question on the 'Report follow-up' page. This page of questions (ie, Q13 to Q15) was on whether reporters are happy to be contacted if further information or clarification is needed.

Participants were generally agreeable to being contacted if further information or clarification is needed.

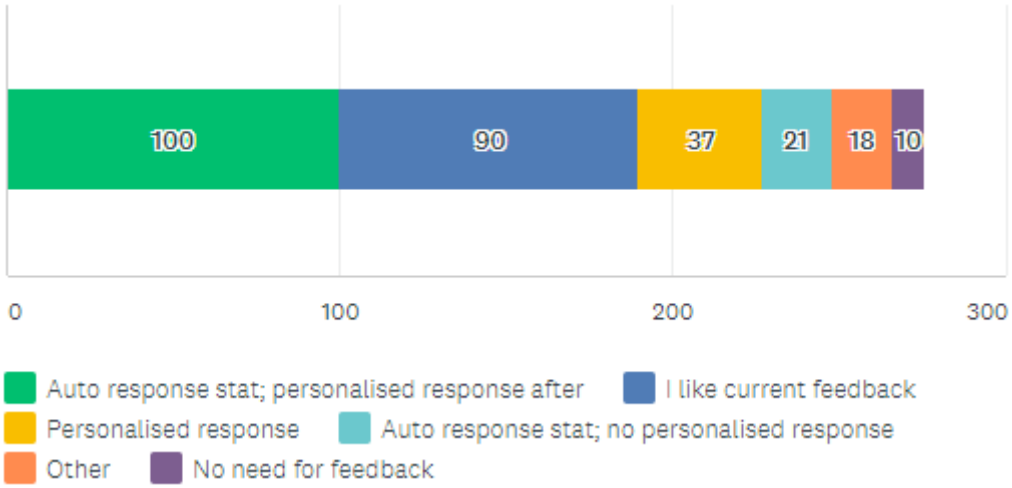
There were some comments that the person completing the report isn't always the best person to be contacted for further information. Therefore perhaps the question should be reframed from 'Can we contact you if we require further information or clarification' to 'Who is the best person to contact if we require further information or clarification'.

Some participants indicated that all the relevant information they have is submitted at the time of making the report so additional follow-up would be fruitless as there would be no further information to provide.

Q16: What type of feedback would you like on your report? *

276 of the 302 participants that had reported an adverse reaction before answered this question. As shown in Figure 8, 121 participants indicated they would like an automated response immediately after submitting a report, the majority of whom (n=100) would also like a personalised response some time after. There were 90 participants that liked the current feedback and considered no changes were necessary.

Figure 8: The type of feedback participants would like to receive after submitting an adverse drug reaction report



Some suggestions from those who selected 'Other (please tell us more)' described feedback that were variations of the options provided (eg, automated response and a personalised response if it is part of a pattern or raises concerns; automated response then some information on the adverse reaction such as the frequency, whether it is brand specific or related to a class effect). Some participants suggested more detailed information would be helpful while others preferred more general information. Being able to choose the type of feedback and receiving feedback via email were also suggested.

Q17: Please tell us the type of information you would like to see in the personalised response to your report

Those that indicated they would like a personalised response as part of Q16 were directed to this question (these are shown as the bright green and yellow bars in Figure 8; n=137), and the remaining participants moved directly to Q18 (ie, were not shown Q17).

Q17 was a free text field. However, participants were given examples of the type of information that could be included in their personalised response as shown below:

"Feedback on your report can include elements such as:

- How many similar cases have been reported
- Whether the reaction is known and listed in the medicine data sheet
- How to search for adverse reactions to medicines reported in New Zealand
- Where to find more information."

A total of 107 responses were received out of the eligible 137. Of the 107 responses:

- 32 indicated one or more of the suggested elements would be helpful. How many similar cases have been reported was one of the preferred pieces of information. Some of these responses also mentioned the mechanism for the reaction would be helpful.
- 25 were interested in further advice or recommendation (eg, how to manage the adverse reaction, what to do for the patient in future including any medicines that should be avoided, predisposing factors to the adverse reaction etc.).
- 24 indicated all of the suggested elements would be helpful.

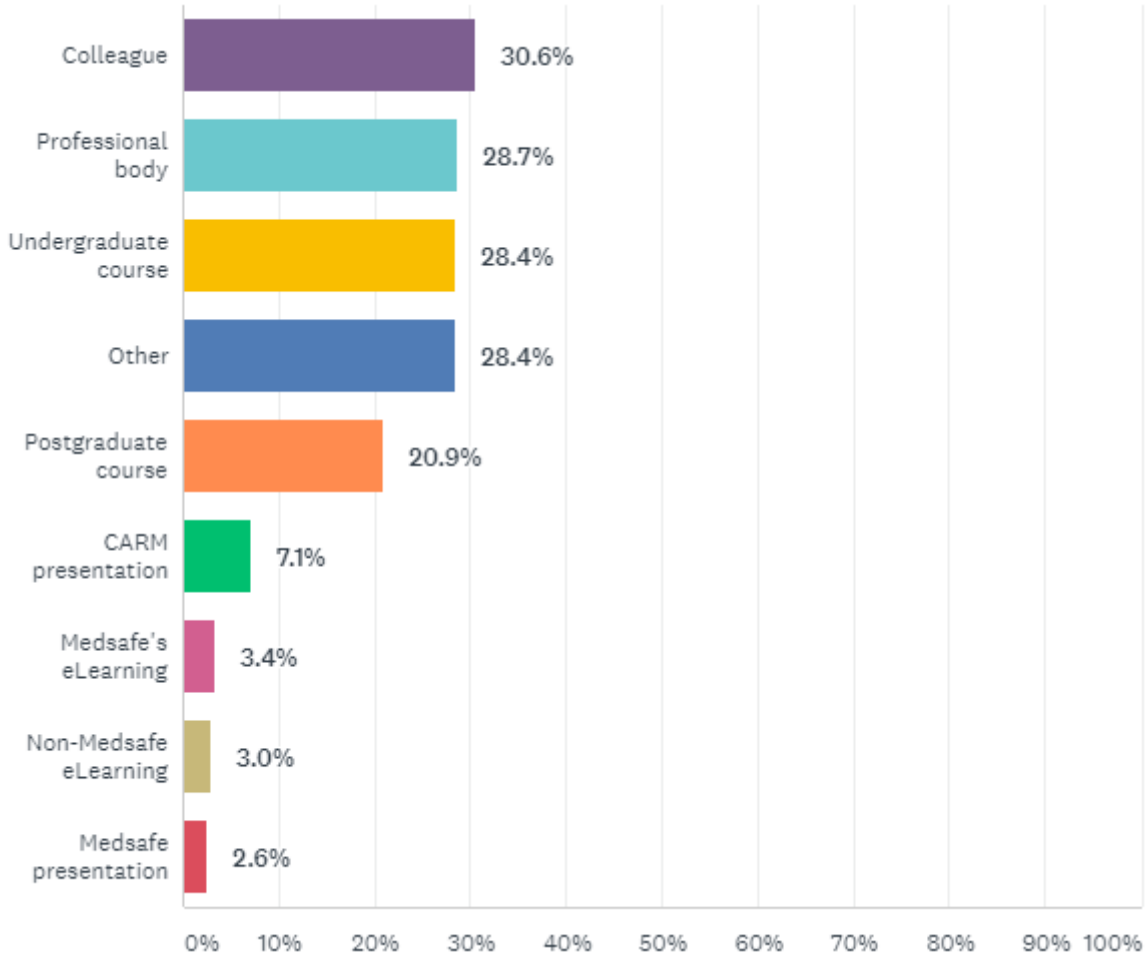
- 10 responses related to whether there would be actions taken as a result of the report (eg, regulatory action, updating the data sheet etc.).
- 5 indicated the current feedback is adequate.

Please note the above is not an exhaustive list of all responses received to this question. Some level of interpretation was also required to group the comments.

Q18: How did you learn about reporting adverse drug reactions? Please select all that apply

268 of the 302 participants that had reported an adverse reaction before answered this question and they could select more than one option. As shown in Figure 9 learning from a colleague attracted the most responses (n=82; 30.6%) followed by a professional body (n=77; 28.7%), part of their undergraduate course (n=76; 28.4%) and other (n=76; 28.4%).

Figure 9: How participants learned about reporting adverse drug reactions



Of the 76 participants who selected 'Other (please specify)', responses included:

- 38 who learnt through their workplace or as part of a course (eg, vaccinator course)
- 15 who could not remember how they learnt.

Q19: In your own words, what is the biggest motivator for reporting adverse drug reactions?

This was a free text field. 254 of the 302 participants that had reported an adverse reaction before answered this question.

The majority of participants (n=104) said improving patient safety and/or public safety was their main motivator for reporting adverse drug reactions.

Q20: Is there anything that would motivate you to report more adverse drug reactions? *

268 of the 302 participants that had reported an adverse reaction before answered this question (Table 6).

Table 5: Whether there is anything that would motivate participants to report more adverse drug reactions

Yes/No	Count	Percent
No	166	61.9%
Yes	102	38.1%
Answered question	268	
Skipped question	34	

Those that answered 'yes' to this question suggested a simplified way of reporting would be helpful (eg, integration into existing electronic systems or linking between systems, easier form to fill). Incentives for reporting were also suggested. Time constraints were identified to be a de-motivator.

Part 2B: Participants who have never reported an adverse drug reaction

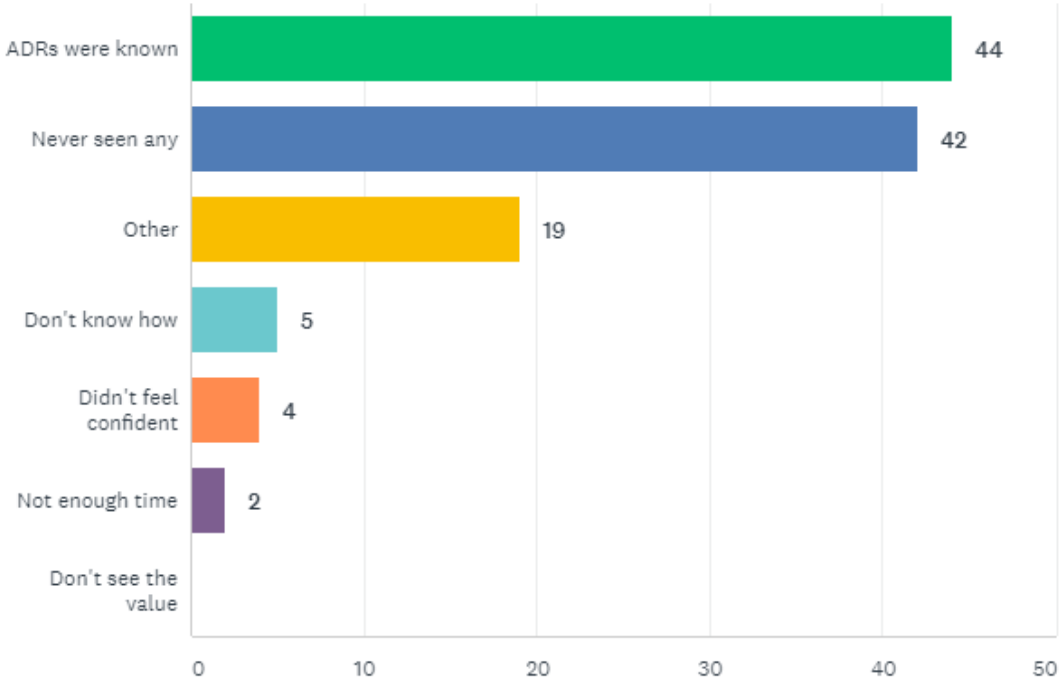
Q21: Is there any particular reason why you have never reported an adverse drug reaction?*

135 participants indicated in Q5 that they had never reported an adverse drug reaction before. Of these 135 participants, 116 answered this question the majority of whom either didn't report because the ADRs were known (n=44; 37.9%) or they had never seen a patient with an ADR (n=42; 36.2%). Responses are shown in Figure 10.

No participants selected 'I don't see the value in reporting adverse drug reactions', which is encouraging.

Those that selected 'Other (please tell us more)' predominantly indicated the reporting of ADRs was delegated or passed on to a colleague or someone else in their team.

Figure 10: Reasons why participants had never reported an adverse drug reaction



Q22: What would motivate you to report an adverse drug reaction?

This was a free text field. There were 89 responses received to this question out of 135 eligible participants. Of the 89 responses potential motivators mentioned included:

- Adverse reactions that are serious, severe, unexpected, unknown, unusual (n=38)
- Ease of reporting (n=19), including better online or integrated electronic systems, being able to upload a photo, use of tickboxes.

Some participants indicated again that they would report an adverse reaction if they saw one.

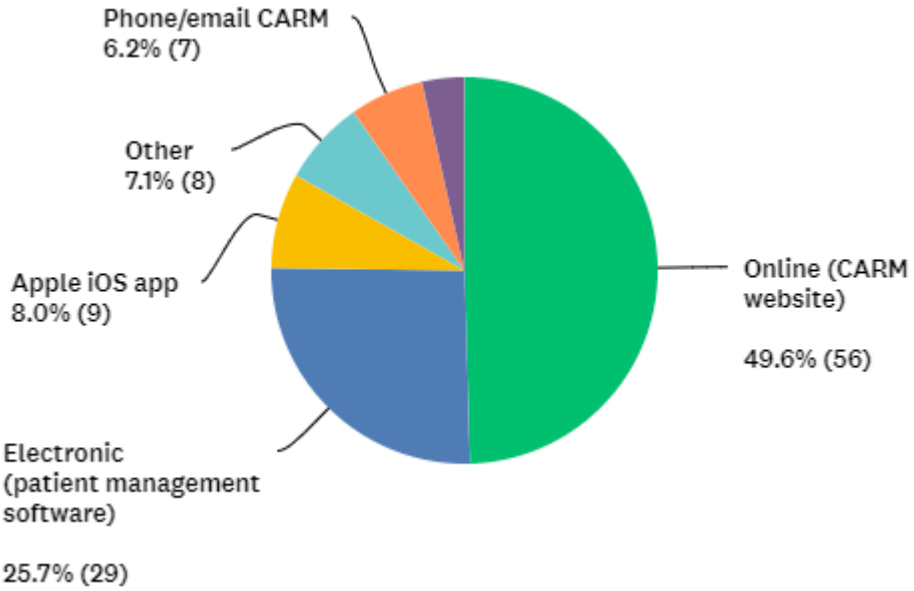
Q23: How would you like to report adverse drug reactions?

113 of the 116 participants who had never reported an adverse drug reaction answered this question (Figure 11).

This is a similar question to Q8 for those that had reported an adverse reaction before. As with responses to Q8, reporting online through the CARM website attracted the most responses.

Those that selected 'Other (please specify)' were supportive for all the above options to remain available. As with responses to Q12 participants also suggested making better use of electronic or online systems to reduce the manual burden of reporting.

Figure 11: How participants would like to report adverse drug reactions [#]



The purple segment in the pie chart represents those who would like to report using a yellow card (n=4; 3.5%)

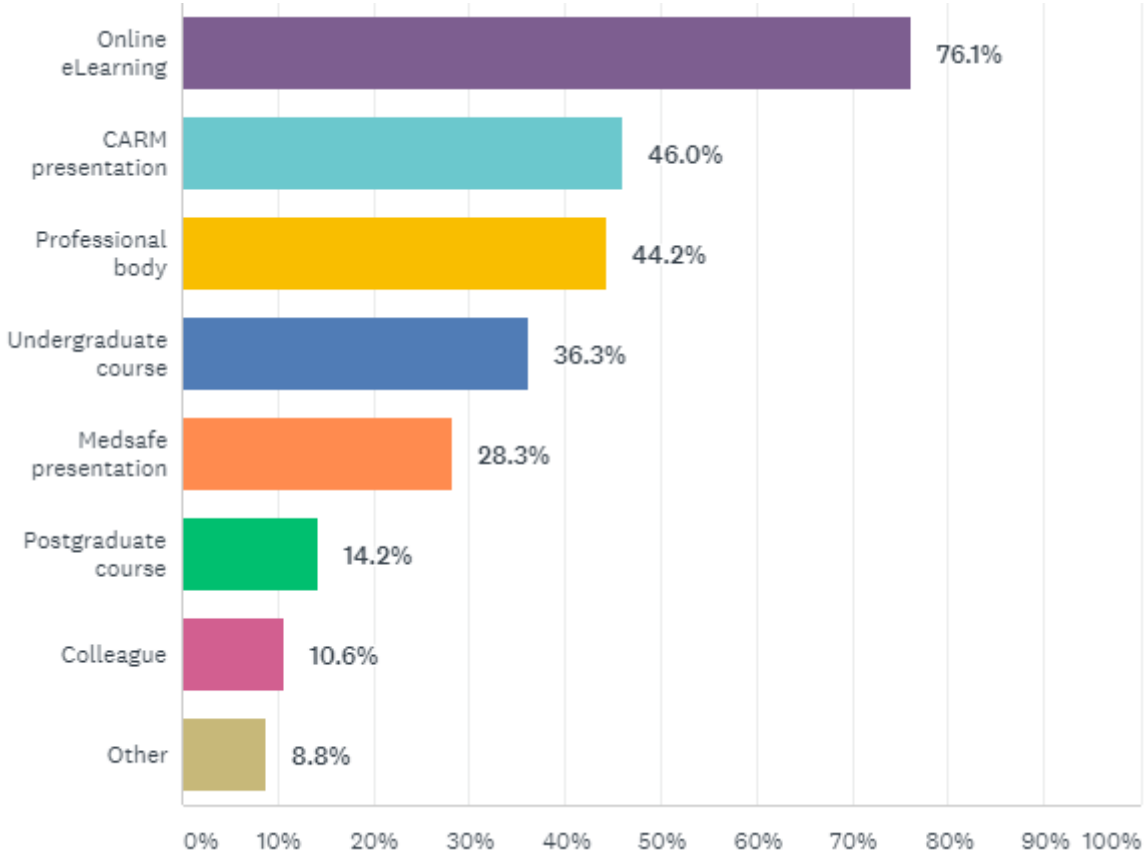
Q24: How would you like to learn about reporting adverse drug reactions? Please select all that apply

113 of the 116 participants who had never reported an adverse drug reaction answered this question (Figure 12). Participants could select more than one option for how they would like to learn about reporting adverse drug reactions.

This is a similar question to Q18 however the responses were quite different between these two questions. Participants in Q18 learnt how to report adverse drug reactions from a colleague (30.6%), from their professional body (28.7%) and as part of their undergraduate course (28.4%). In contrast, participants in Q24 wanted to learn how to report adverse drug reactions through online eLearning eligible for CPD/CME credits (76.1%), presentations from CARM (46%) and from their professional body (44.2%).

Those that selected 'Other (please specify)' suggested a Goodfellow unit webinar, BPAC article, in-hospital teaching, reminder from immunisation coordinator, include in nursing update day, have multiple methods for different learning styles, and part of a larger public education that includes the general public.

Figure 12: How participants would like to learn about reporting adverse drug reactions



Part 3: Medicines safety information

Q25: Please select the sources that you routinely use to obtain information about the benefits and risks of medicines. You can select more than one.

377 of the 455 survey participants answered this question (Table 7). Participants could select more than one option. Medicine data sheets (n=299) and the NZF (n=273) attracted the most responses.

Table 6: Sources participants use to obtain information about the benefits and risks of medicines

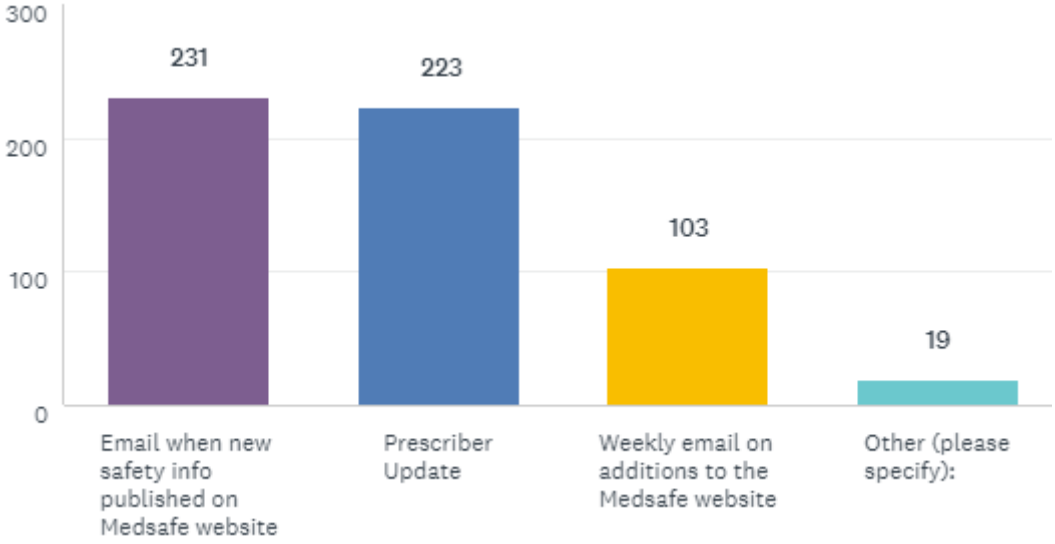
Source	Count	Percent
Medicine data sheets	299	79.3%
New Zealand Formulary (NZF)	273	72.4%
Prescriber Update	241	63.9%
Medsafe website	222	58.9%
Colleagues	209	55.4%
Scientific literature	197	52.3%
Communications from my professional body or college	180	47.7%
PHARMAC	114	30.2%
Pharmaceutical companies' websites or written communications	95	25.2%
Consumer medicine information	79	21%
Health Quality & Safety Commission (HQSC)	71	18.8%
Ministry of Health	69	18.3%
Other (please specify)	52	13.8%
General media (eg, newspapers, radio, TV etc.)	26	6.9%
Patient organisations or consumer groups	8	2.1%

Of the 52 participants who selected 'Other (please specify)', the majority (n=36) used an alternative reference book or electronic resource (eg, MIMS, Micromedex, UpToDate, BPAC, Medscape, data sheets in other countries).

Q26: How would you like to receive *new* information on medicines safety from Medsafe? You can select more than one.

370 of the 455 participants responded to this question (Figure 13). Some participants that selected 'Other (please specify)' suggested being able to subscribe to information that was specific to their field of work, and using existing sources rather than creating new ones.

Figure 13: How participants would like to receive new information on medicines safety from Medsafe

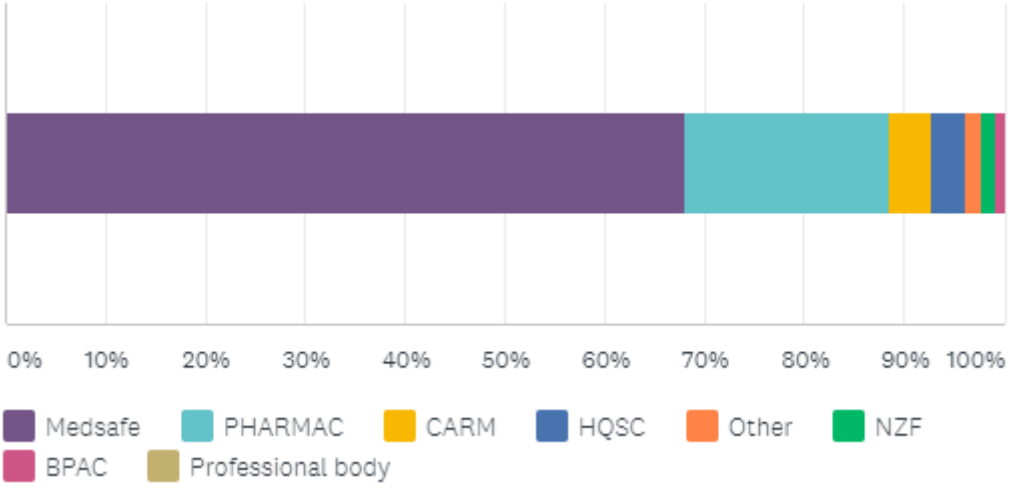


Part 4: Medicines regulation

Q27: Who or which organisation do you think regulates medicines to make sure they work and are acceptably safe and effective?

370 of the 455 participants responded to this question. The majority of participants selected Medsafe (68.1%) and there were 20.5% who selected PHARMAC (Figure 14).

Figure 14: The organisation participants think regulates medicines

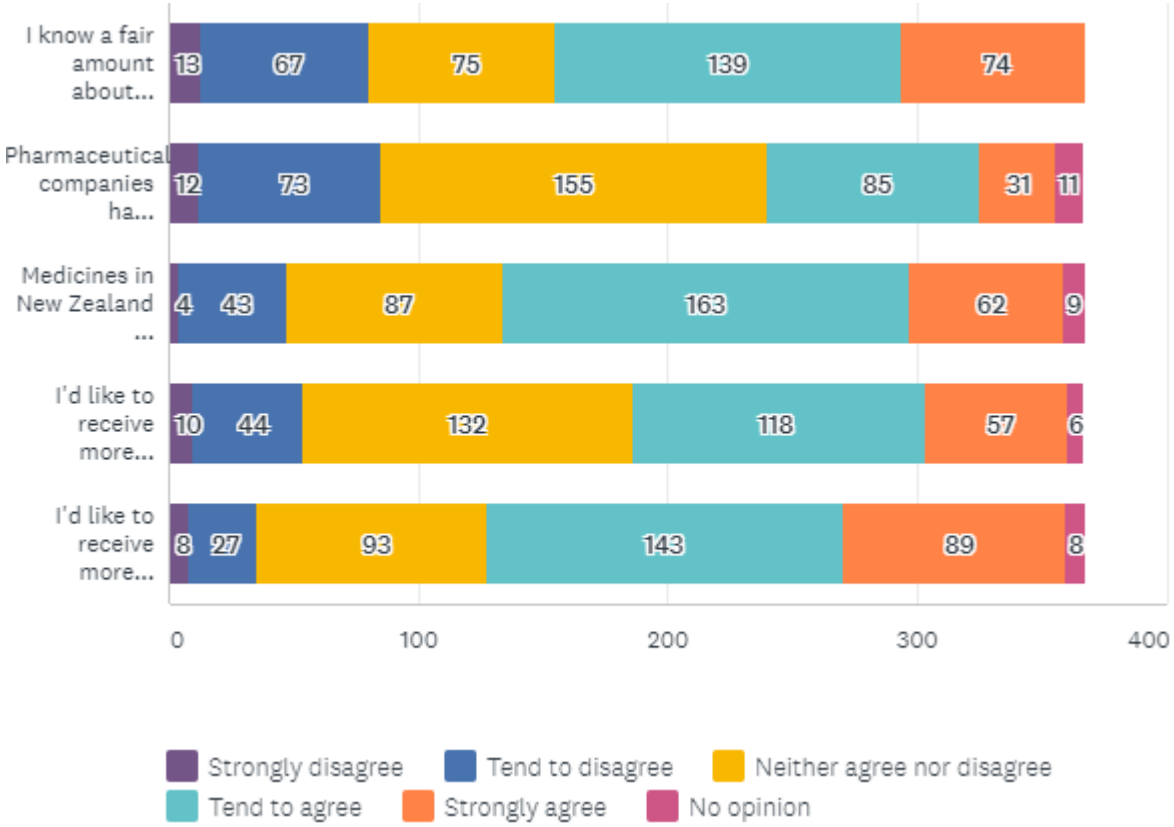


Q28: Please select to what extent you agree or disagree with each of the following statements

368 of the 455 participants responded to this question (Figure 15):

- Participants tended to agree or strongly agreed with the statement 'I know a fair amount about how medicines are regulated in New Zealand' (n=213; 57.9%). However, there is much potential for Medsafe to improve healthcare professionals' awareness of what we do as there were 80 participants that strongly disagreed or tended to disagree with this statement (21.7%), and 75 neither agreed nor disagreed (20.4%).
- The majority of participants (n=155) neither agreed nor disagreed with the statement 'Pharmaceutical companies have too much influence over the way medicines are regulated'.
- Participants tended to agree or strongly agreed with the statement 'Medicines in New Zealand are adequately regulated at the moment' (n=225).
- Participants appeared to want more information on the risks of medicines rather than the benefits (232 tended to agree or strongly agreed for information on risks vs. 175 for information on benefits). However, there was also a high proportion of participants who neither agreed nor disagreed with both these statements.

Figure 15: The extent participants agreed or disagreed with five statements [#]



The full statements were 'I know a fair amount about how medicines are regulated in New Zealand', 'Pharmaceutical companies have too much influence over the way medicines are regulated', 'Medicines in New Zealand are adequately regulated at the moment', 'I'd like to receive more communication on the benefits of medicines', 'I'd like to receive more communication on the risks of medicines'.

Part 5: Other comments

Q29: Do you have any other comments, questions or feedback?

This was a free text field. The intent was to provide an opportunity for participants to comment, ask questions or provide feedback on anything that may have not been addressed in the survey.

96 comments were received. Many of the participants said they had no further comments (n=44).

The remaining comments received were general and covered a wide range of topics, therefore they have not been summarised here but Figure 16 shows a "word cloud" of the comments received. Medsafe will take time to analyse these comments in greater detail at a later date.

Figure 16: Word cloud showing the number of word mentions

Summary of results

The denominator of the percentages shown in this section is the total number of participants that provided a response to that particular question. Participants could also select more than one option for some questions.

- 455 participants started the survey but not all completed the survey.
- The top three healthcare professional groups were doctors (30.8%), pharmacists (30.8%) and nurses (25.1%).
- The vast majority of participants would contact CARM to report an adverse drug reaction (89.93%).
- The majority of participants **had reported** an adverse drug reaction before (n=302, 69.1%). Of these:
    - More than half had reported 2 to 5 times (54.6%).
    - Just over half report online through CARM's website (50.5%).
    - 14.6% suggested other ways of reporting the majority of which related to better electronic or online systems and the ability for some of the fields to auto-populate.
    - 86.2% don't mind being contacted if information in their report requires clarification or further information is needed.
    - 43.8% indicated they would like an automated response immediately after submitting a report; of these the majority would also like a personalised response some time after submitting the report (82.6%).
    - Learning about reporting adverse drug reactions from a colleague attracted the most responses (30.6%); however, learning from their professional body (28.73%), during their undergraduate course (28.4%) and through other methods (28.4%) also attracted a similar proportion of responses.
    - 38.1% answered 'yes' to whether there is anything that would motivate them to report more adverse drug reactions.
- Of the participants that **had never reported** an adverse drug reaction before (n=135; 30.9%):
    - 37.9% have never reported because the adverse drug reaction they've come across were known, and 36.2% had never seen a patient with an adverse drug reaction.
    - Some indicated potential motivators include adverse reactions that are serious, severe, unexpected, unknown or unusual, and some commented ease of reporting would be a motivator.
    - Almost half (49.6%) would like to report online through CARM's website, and 25.7% would like to report electronically through patient management software.
    - Learning about reporting adverse drug reactions through an online eLearning module eligible for CPD/CME credits attracted the most responses (76.1%).
- The top three sources that participants routinely use to obtain information about the benefits and risks of medicines were medicine data sheets (79.3%), the New Zealand Formulary (72.4%), and *Prescriber Update* (63.9%).
- Either an email when new safety information is published on the Medsafe website (62.4%) or through *Prescriber Update* (60.3%) were the top two ways participants would like to receive new information on medicines safety.

- Most participants identified Medsafe as the organisation that regulates medicines (68.1%); however there were 20.5% who selected PHARMAC as the medicines regulator.
- Participants tended to agree or strongly agreed with the statement 'I know a fair amount about how medicines are regulated in New Zealand' (57.9%). However, there is much potential for Medsafe to improve healthcare professionals' awareness of what we do as there were 21.7% who strongly disagreed or tended to disagree with this statement, and 20.4% neither agreed nor disagreed.

5) Discussion

The majority of responses were received in the last two weeks of the survey after a reminder was sent. One possible reason for the slow uptake was the time of year the survey was held. December and January are holiday months for many New Zealanders as we take a break for Christmas, New Year and the summer holidays. Despite this, 455 healthcare professionals participated in the study even if they didn't quite manage to complete the whole survey. The number of responses received likely represents a very low response rate considering the number of healthcare professionals that practice in New Zealand. It is difficult to know how many participants completed the survey due to the way it was structured. However, there were 18 drop-outs in question 5.

The way reminders were sent (eg, to *Prescriber Update* subscribers, RNZCGP, HPA) could have biased responses towards those that subscribe to Medsafe's communications and are aware of what we do, as well as GPs and pharmacists. This is indeed reflected in the results where the professions with the most participants were doctors and pharmacists (140 each). The third largest profession was nurses (n=114) who represent the largest group of reporters over the last five years (see *Prescriber Update* article on adverse drug reporting in New Zealand – 2018).

Many of the questions included an option for 'Other (please specify)'. This made analysis of the responses more challenging as it is a manual process and requires some level of interpretation. However, the "tagging" feature of SurveyMonkey did help with grouping some of these responses together. The same challenge was found when analysing any question with a free text field. The benefits of participants being able to provide comments is the richness of the data that we wouldn't receive otherwise. It is also a good opportunity to hear about other aspects that may not have been covered by the questions, and to obtain new ideas that we may not have known about.

Striking the balance between providing pre-specified options and free text fields is a difficult task and it is not known if this balance was struck in this survey.

A theme that appeared throughout comments to more than one question related to having better electronic and online systems. These systems would allow for features such as auto-population of some fields and reduce the time required to locate this information and remove duplication into a separate reporting form. Medsafe has been part of the Health Information Standards Organisation (HISO) working group on the Adverse Reaction Reporting Standard (ARRS). This standard is designed to ensure that adverse reaction information captured by a healthcare provider or patient is recorded in a standardised way. This is one way in which work is being done to improve the reporting experience through better electronic systems.

Next steps

There are areas for improvement identified from survey responses. Medsafe is keen to explore, or is already taking steps to address the following:

- Removing barriers to reporting:
    - Better electronic and online systems (eg, auto-population of some fields, integration into more patient management software, contribute to work on the adverse reaction reporting standard).

- Reminding healthcare professionals there are only 4 requirements for a valid report: (ie, patient details, medicine, reaction, reporter details). Patient details can be their initials, gender, date of birth, age etc. and only one of these is required so anonymity can be maintained.
- Reminding healthcare professionals a *suspicion* of an adverse reaction is all that's needed to prompt a report.
- Reminding healthcare professionals that anyone can make a report (eg, they can report to CARM directly instead of forwarding details to another hospital department)
- Providing education on how common adverse drug reactions generally are and how to recognise them.

- Reporting form:
    - Have the space to include complex medical history and multiple medicines
    - More free space
    - Vaccine specific details (eg, batch number, route)
    - Ability to attach a photo
    - Space to add information on allergies, other non-medicinal substances
    - Ability for healthcare professionals to request removal of medical alert warnings from their patient's records.
- Response or feedback once a report is submitted:
    - An automatic response is received by the reporter immediately after a report is submitted so reporters know their report has been received. This should include a reference number for the report in case of follow-up.
    - Include the ability for reporters to select the type of detailed feedback they would like (including no feedback) and how they would like to receive this (eg, via email, letter in the post etc.).
- Investigate ways for healthcare professionals to provide follow-up information to a report they have previously submitted.
- Explore whether 'local adverse reaction champions' can be implemented in DHBs and PHOs to improve awareness of adverse drug reactions and how to report.
- Improve healthcare professionals' awareness of Medsafe (eg, who we are, what we do), including education on reporting adverse drug reactions (eg, how to report, importance of reporting, the type of advice Medsafe and CARM can provide etc.).

Appendix 1 – Survey questions

Questions marked with an asterisk (*) were compulsory.

1. What healthcare professional group do you belong to? *
    a. Dentist
    b. Doctor
    c. Midwife
    d. Nurse
    e. Optometrist
    f. Pharmacist
    g. Veterinarian
    h. Other (please specify):
2. Do you work predominantly in primary care or secondary care? *
    a. Primary care
    b. Secondary care
    c. Not applicable
3. Where is your practice located?
    a. Auckland
    b. Bay of Plenty
    c. Canterbury
    d. Capital and Coast
    e. Counties Manakau
    f. Hawkes Bay
    g. Hutt Valley
    h. Lakes
    i. Mid Central
    j. Nelson-Marlborough
    k. Northland
    l. South Canterbury
    m. Southern
    n. Tairawhiti
    o. Taranaki
    p. Waikato
    q. Wairarapa
    r. Waitemata
    s. West Coast
    t. Whanganui
    u. Other (please specify):
4. Who or which organisation would you contact if you wanted to report an adverse drug reaction? You can select more than one. *
    a. Centre for Adverse Reactions Monitoring (CARM)
    b. Health Quality & Safety Commission (HQSC)
    c. Medsafe

d. Ministry of Health
e. PHARMAC
f. Professional body
g. New Zealand Formulary (NZF)
h. Best Practice Advocacy Centre (BPAC)
i. A Colleague
j. The pharmaceutical company that makes the medicine
k. Other (please specify):

5. Have you reported an adverse drug reaction before? *

   a. Yes
   b. No

6. How many times have you reported?

   a. Once
   b. 2 to 5 times
   c. 6 to 10 times
   d. More than 10 times

7. Do you usually discuss reporting the ADR with your patient before submitting a report?

   a. Yes
   b. No

8. What reporting form do you normally use?

   a. Online through the Centre for Adverse Reactions Monitoring (CARM) website
   b. Electronic through patient management software
   c. Completing a freepost yellow card
   d. Using the Apple iOS app on your iPhone or iPad
   e. Contacting the Centre for Adverse Reactions Monitoring (CARM) directly via phone or email
   f. Other (please specify):

9. How easy was it to fill in the form?

   a. Extremely easy
   b. Very easy
   c. Moderately easy
   d. Not so easy
   e. Not at all easy

10. Was there information you wanted to add but there was no space/opportunity to do so?

    a. No
    b. Yes (please tell us more):

11. Was there information needed to be filled in that you found unnecessary?

    a. No
    b. Yes (please tell us more):

12. Is there another way of reporting you would prefer but is not currently available?
    a. No
    b. Yes (please tell us more):
13. Are you open to being contacted if further information or clarification about your report is needed?
    a. No, I don't want to be contacted after my report has been submitted
    b. Yes, I don't mind being contacted if information in my report requires clarification or further information is needed
14. Should there be a field on the reporting form to select whether we can contact you for further information or clarification?
    a. Yes
    b. No
15. Additional comments
16. What type of feedback would you like on your report? *
    a. I like the feedback that we currently receive and no changes are considered necessary
    b. A general, automated response immediately after submitting an electronic report with a personalised response some time after
    c. A general, automated response immediately after submitting an electronic report with no personalised response
    d. A personalised response some time after submitting a report
    e. No need for feedback
    f. Other (please tell us more):
17. Please tell us the type of information you would like to see in the personalised response to your report
18. How did you learn about reporting adverse drug reactions? Please select all that apply.
    a. Medsafe's online eLearning module
    b. A non-Medsafe online eLearning module
    c. It was part of my undergraduate course
    d. Presentation from Medsafe
    e. From a colleague
    f. It was part of my postgraduate course
    g. From my professional body
    h. Presentation from the Centre for Adverse Reactions Monitoring (CARM)
    i. Other (please specify):
19. In your own words, what is the biggest motivator for reporting adverse drug reactions?
20. Is there anything that would motivate you to report more adverse drug reactions?*
    a. No
    b. Yes (please tell us more):
21. Is there any particular reason why you have never reported an adverse drug reaction? *

a. I haven't seen any patients or consumers who have experienced adverse drug reactions
b. The adverse reactions I have come across were known so I didn't report them
c. I don't have enough time to fill in a report
d. I didn't feel confident enough to report them
e. I don't know how to report adverse drug reactions
f. I don't see the value in reporting adverse drug reactions
g. Other (please tell us more):

22. What would motivate you to report an adverse drug reaction?

23. How would you like to report adverse drug reactions?

a. Online through the Centre for Adverse Reactions Monitoring (CARM) website
b. Electronic through patient management software
c. Completing a freepost yellow card
d. Using the Apple iOS app on your iPhone or iPad
e. Contacting the Centre for Adverse Reaction Monitoring (CARM) directly via phone or email
f. Other (please specify):

24. How would you like to learn about reporting adverse drug reactions? Please select all that apply.

a. Online eLearning module eligible for CPD/CME credits
b. Should be part of the undergraduate course
c. Presentations from Medsafe
d. From a colleague
e. Should be part of a postgraduate course
f. From my professional body
g. Presentations from the Centre for Adverse Reactions Monitoring (CARM)
h. Other (please specify):

25. Please select the sources that you routinely use to obtain information about the benefits and risks of medicines. You can select more than one.

a. Colleagues
b. Communications from my professional body or college
c. Consumer medicine information
d. General media (eg, newspapers, radio, TV etc.)
e. Health Quality & Safety Commission (HQSC)
f. Pharmaceutical companies' websites or written communications
g. Medicine data sheets
h. Medsafe website
i. Ministry of Health
j. New Zealand Formulary (NZF)
k. Patient organisations or consumers groups
l. PHARMAC
m. Prescriber Update
n. Scientific literature

o. Other (please specify):

26. How would you like to receive *new* information on medicines safety from Medsafe? You can select more than one.
    a. Prescriber Update
    b. Email when new safety information is published on the Medsafe website
    c. Weekly email on additions to the Medsafe website
    d. Other (please specify):
27. Who or which organisation do you think regulates medicines to make sure they work and are acceptably safe and effective?
    a. Centre for Adverse Reactions Monitoring (CARM)
    b. Health Quality & Safety Commission (HQSC)
    c. Professional body
    d. New Zealand Formulary (NZF)
    e. Best Practice Advocacy Centre (BPAC)
    f. PHARMAC
    g. Medsafe
    h. Other (please specify):
28. Please select to what extent you agree or disagree (strongly disagree, tend to disagree, neither agree nor disagree, tend to agree, strongly agree, no opinion) with each of the following statements.
    a. I know a fair amount about how medicines are regulated in New Zealand
    b. Pharmaceutical companies have too much influence over the way medicines are regulated
    c. Medicines in New Zealand are adequately regulated at the moment
    d. I'd like to receive more communication on the benefits of medicines
    e. I'd like to receive more communication on the risks of medicines
29. Do you have any other comments, questions or feedback?