

BARRIERS TO CANADIAN PHYSICIANS REPORTING OF ADVERSE DRUG
REACTIONS

by

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Barriers to Canadian Physicians Reporting of Adverse Drug Reactions

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F. Abstract

Background: Voluntary reporting of Adverse Drug Reactions (ADRs) by physicians and other healthcare professionals currently is the single most important source of information for early signal detection of ADRs. Despite the importance of ADR reporting, there is evidence that less than 10% of ADRs experienced by Canadians are reported to Health Canada and the factors contributing to this under-reporting are unclear.

Objectives: The purpose of the present study was to ascertain the barriers to reporting ADRs, including knowledge; attitudes and beliefs; and the accessibility of the reporting system as the first step in understanding the problem of underreporting of ADRs. In addition, information was collected about physician engagement in a dialogue about ADRs with their patients, and whether their office practice was structured to allow patient follow-up of an ADR.

Methods: An online survey was administered to BC physicians in the spring of 2008. The survey was designed to obtain information in the following areas: knowledge of and attitudes toward ADRs; patient dialogue about ADRs and structure of the clinical practice; access to the report form, knowledge about if and what needs to be reported and educational support required for ADR reporting and appropriate utilization of new medications.

Results: Eighty-seven physicians completed the survey, a response rate of 2%. There is a 95% level of certainty that the quantitative results provided in this survey are within a sampling margin of error of plus or minus 10.5%. Descriptive statistics were calculated and responses to some questions were analyzed using cross-tabulation by whether the physician had ever reported an ADR. A difference of $p < 0.05$ was considered significant. The majority viewed the reporting of ADRs as a professional responsibility, discussed ADRs with their patients and structured their office practice to permit follow-up with suspected ADRs. However, 70% percent had never reported an ADR. Gaps in knowledge about adverse drug reactions and the subsequent reporting process were revealed. Participants indicated the need for decision-making support at the time an ADR is suspected and feedback on the reports they submit.

Conclusion: The responses of this small and highly motivated subset of physicians, indicate that difficulties in the actual mechanism of reporting ADRs, rather than negative physician attitudes as suggested in the literature, may be an important first barrier to reporting.

Words 375

G. Text

Background

Approximately 185,000 out of 2.5 million hospital visits in Canada each year are associated with ADRs and a significant number of Canadians (40,000) die as a result ^[1]. Importantly, about 38% of the ADRs reviewed in that study were judged to be preventable. Although the future will likely see the emergence of new post-marketing surveillance systems utilizing the power of linked databases and other approaches ^[2-5], voluntary reporting of Adverse Drug Reactions (ADRs) by physicians and other healthcare professionals currently is the single most important early source of information for early signal detection of ADRs. Most studies evaluating alternative surveillance systems recognize the role of ADR reports in signal detection and capturing the individual patient experience ^[6-8]. A systematic review of the literature (English language sources) found a range of 6-100% with a mean of 94% of under-reporting of ADRs ^[9]. Other studies indicate that in Canada less than 10% of adverse outcomes are reported to Health Canada ^[1,10]. Even in those instances when reports are filed, the quality of information provided does not permit a full assessment of causality ^[11].

Problems in under-reporting can be classified broadly into two categories; failure to identify an adverse reaction, and failure to report it. The identification of an adverse reaction is not a simple task and the degree of difficulty increases with the complexity of the patient's illness, the number of other medications and substances administered, the existing baseline incidence of the problem within the population and what is known about the drug. The ability to diagnosis the occurrence of an ADR is greatly influenced by the knowledge and experience of the physician. In contrast, the reporting of an ADR may be more subject to influence by the attitudes and beliefs of the physician. In 1976, Inman ^[12], proposed that seven beliefs i.e. "seven deadly sins", likely contributed to the under-reporting of ADRs in the UK. This framework may not be applicable to the Canadian temporal context but has been useful in analyzing under-reporting behaviour in several countries. The list was subsequently modified into ten areas ^[13,14]. 1. Complacency- that only safe drugs are marketed; 2. Fear of Litigation or criticism for having prescribed the drug; 3. Guilt for harm to a patient; 4. Ambition to collect sufficient information to publish; 5. Ignorance- don't know how or what needs to be reported, 6. Diffidence-belief that one should only report if there is certainty that it is related to the drug, and not wishing to appear ignorant to those who receive these reports; 7. Indifference that one case that a physician might see will not contribute to medical knowledge, 8. Lethargy which incorporates procrastination, lack of time to either report or follow-up with the patient, 9. Financial-lack of an incentive; and 10. Insecurity- the belief that that it is nearly impossible to determine if a drug is responsible for an ADR. Some of these beliefs and attitudes were significantly associated with under-reporting of ADRs by physicians ^[15]. Although most of these beliefs influence the reporting of the ADR, some of them can influence the physician's ability to recognize one. For example, if one believes that all medications are safe or that it is virtually impossible to determine if a medication has caused an adverse reaction, it is unlikely the physician will consider the possibility that a negative change in a patient's condition could be related to an ADR.

The purpose of the present study was to ascertain the barriers experienced or perceived by Canadian physicians in reporting ADRs, including knowledge; attitudes and beliefs; and the accessibility of the reporting system as the first step in understanding the problem of underreporting of ADRs. Few if any previous studies have explored the extent to which physicians engage in a dialogue about ADRs with their patients and if their office practice is structured to allow patient follow-up of an ADR. These two aspects were also assessed in our study population.

Methods

A survey was developed based on the instrument used by Figueiras et al ^[16]. The survey consisted of approximately 84 items and was designed to obtain information in the following areas; (1) about the physicians and their practice; (2) knowledge of and attitude toward ADR reporting in general; (3) barriers and facilitators to ADR reporting; (4) current ADR reporting profile; (5) sources of information on new medications; (6) interest in ADR education and support; and (7) technology use. Quantitative question format included: statement followed by: Strongly agree, Somewhat agree, Somewhat disagree, Strongly disagree and Unsure/Do not know, and participants were provided an opportunity to provide further explanations and comments.

The physician participant pool for this survey was generated from the University of British Columbia (UBC) Faculty of Medicine, Division of Continuing Professional Development (formerly CPD-KT) physician contact database. Approximately 4,300 of the physicians on the CPD-KT contact database that have an email address were sent an invitation letter by email that introduced the investigators of the survey, its purpose, a request for them to participate in the survey. Physicians were assured that the data would be held confidential and was coded to ensure confidentiality. After submitting their survey responses, the respondents were given an opportunity to provide their contact information if they would like to participate in a potential future study that would explore the efficacy of various educational strategies in improving ADR reports submitted to Health Canada. The survey was accessible on line between May and June 2008. The data was stored on a secure UBC Faculty of Medicine server. Ethics approval was obtained for the study from the UBC Behavioural Research Ethics Board.

Quantitative survey data was analyzed using the statistical software program SPSS version 17.0 (Chicago, IL, USA). Descriptive statistics such as variable frequencies and percentages were calculated. Responses to some questions were analyzed using cross-tabulation by whether the physician had ever reported an ADR using the chi-square test distribution. A difference of $p < 0.05$ was considered significant. Qualitative survey data was analyzed by two members of the research team to ensure inter-rater reliability surrounding interpretation of content. Qualitative findings were subsequently summarized, structured and reported according to thematic areas. Salient verbatim quotes that spoke clearly and succinctly about specific areas were included.

Results

Eighty-seven physicians completed the survey, yielding a response rate of approximately 2%. With this sample size, there is a 95% level of certainty that the quantitative results provided in this survey are within a sampling margin of error of plus or minus 10.5% ^[17].

The majority of physicians (62%) participating in the study have been practicing medicine in Canada for 20 years or less, while over one-third (39%) have been practicing more than 20 years (mean= 17.9 +/- 1.27 SE). Slightly over one-half (55%) of the participants were female. The large majority (79% and 87% respectively) graduated from a medical school and also completed their residency training in Canada; a higher percentage did so in faculties of medicine outside of BC. British Columbia is divided into 5 regional health authorities for managing the delivery of health care services. Most of the physician practices were located in the Vancouver Coastal/Providence Health Authority; and Fraser Health Authority (59%) with smaller numbers in the Vancouver Island Health Authority (16%); the Interior Health Authority (13%); and the Northern Health Authority (4%). The distribution of participating physicians approximates the population distribution in each health authority respectively: 60%; 16.9%; 16.5% and 6.5% as of 2008 ^[18]. Approximately two-thirds of the physicians were in full-time practice; 23% were in part-time practice, while another 12% said they were locums. With respect to practice setting, 33% worked in group practice, or in a tertiary care hospital (21%); while 13% were based in a community hospital; sole practice (8%) or an Emergency department (6%). Only 2% worked in walk-in clinics. Other practice settings were indicated by 16% of the participants. These included community-based offices e.g. cancer agency, mental health centre, or team-based practice. Some of the physicians that selected "Other practice setting" worked in academic, health unit-associated, home hospice, or hospital based HIV clinics.

Approximately one-half of the participants (52%) were specialists predominantly in 7 disciplines (psychiatry, emergency medicine, obstetrics and gynaecology, paediatrics, anaesthesia, internal medicine and dermatology). The next largest cohort was family physicians (36%) and general practitioners (11%). One-half (51%) of these physicians saw approximately 15-30 patients per day and 68% wrote less than 15 prescriptions per day. Only 4% did not write prescriptions. The survey revealed that 70% of the respondents had never reported an ADR. The reporting frequency of the remaining participants varied from once a year (21%) to once every six months (9%). The percent of physicians who had reported an ADR was similar among Family Physicians (33.3%), General Practitioners (33.3%) and specialists (26.2%).

Even though 70% of the physician participants had not reported an ADR, the majority (51%) of all physician respondents indicated that they always ask their patients to report to them any adverse reactions to the medications they prescribe, and 32% sometimes ask patients to report back as illustrated in Figure I. Only 12% said they never engage in this type of dialogue with their patients.

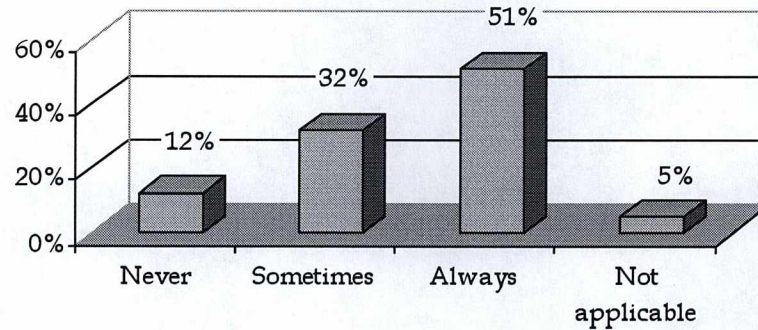


Figure 1. Percentage of physician participants who conduct a dialogue with the patient about adverse reactions and the need to inform the physician.

When asked if their office practice was structured to allow patient follow-up regarding adverse reactions, 64% of all physician participants answered yes. The physicians who had reported an ADR and those who had not were equally likely to respond yes to this question. Comments in response to this question included:

"Patients' are advised of possible adverse reactions and asked to report any to their physician directly, a [follow-up] appoint is arrange[d] for any patient starting new long term meds". - Physician

"I do explain to patients when prescribing something new that if there should be any side-effect/ADRs that the patients should return and have their condition and prescription reviewed by me." - Physician

One physician indicated they have a pharmacist on-site to assist ADR reporting, while others commented that their office waits until the patient's (those permanent to the practice) follow-up appointment to discuss ADRs. The feedback from these physicians suggests that some offices are structured to be more responsive in the event a patient called about an ADR.

"My group provides Team outpatient clinic care so there is always someone available to see a patient." - Physician

"Same day appointments available each day and after hours on call clinic doctor with access to EMR charts daily." - Physician

"I share an office with five other paediatricians. About 66% of my practice is consultations, the rest primary care. The primary care patients have access to one of us 6 days a week, and we share after-hours call for patients in our practice." - Physician

Thirty six percent of physician respondents mentioned a variety of reasons for why their office practice is not structured to allow patient follow-up regarding ADRs. Some said they do not have a follow-up procedure simply because they do not have a dedicated office space. Others said their office setting has not formalized a system for following up with patients regarding ADRs. For some physicians, the process is more ad hoc as they handle ADRs only when a patient happens to mention it during a subsequent visit, or they presume the patient will follow-up with their primary care provider if they happen to experience an ADR.

Knowledge and Attitude Toward ADR Reporting

Attitude toward the reporting of ADRs was very positive and knowledge of the importance of the reporting of ADRs is documented in Table I. The majority (92%) of the physician respondents viewed the reporting of ADRs as a professional responsibility, and 67% supported the concept that ADR reporting by health professionals should be considered mandatory. Regarding who among the following: physicians, pharmacists, patients, nurses, medical office assistants (under the direction of a physician) have primary responsibility for reporting, 37% felt that physicians have a primary responsibility and 52% indicated that all health professionals share this responsibility. Most participants believed that it is possible to determine if a medication is responsible for a particular adverse reaction although about 50% agreed that they are unable to determine the role of the medication in the reactions they suspect are ADRs. Most of the physicians believe that reporting an ADR does not expose them to greater liability for the patient's outcome. Participants also demonstrated their knowledge of: a) patient biological diversity as a factor in response to medications; b) that the safety of a medication is not fully known at the time it is approved for marketing; and c) that individual physician reports of ADRs contribute to new knowledge. A significant majority of physicians (77%) said they did not know how the information was used by Health Canada. Seventy percent of the participants agreed that they would only report an ADR if they are sure it is related to the use of a particular medication.

Table I. Knowledge of adverse drug reactions and attitude toward ADR reporting.

| Knowledge or attitude | Agree* | Disagree** | Unsure/ Don't know |
|--|--------|------------|--------------------------|
| Patient biological diversity is a factor affecting the likelihood of having an ADR or responding to a medication | 98% | 0% | 2% |
| One adverse reaction that I may see in one of my patients cannot contribute to new medical knowledge (indifference) | 5% | 93% | 2% |
| I have a professional obligation to report ADRs | 92% | 6% | 2% |
| Reporting an ADR exposes me to greater liability for the patient's outcome (fear of litigation) | 8% | 85% | 7% |
| I do not know how the information reported to Health Canada is used | 77% | 17% | 6% |
| I would only report an adverse drug reaction if I am sure it is related to the use of a particular medication (diffidence) | 70% | 27% | 3% |
| It is nearly impossible to determine if a medication is responsible for a particular adverse reaction (insecurity) | 27% | 70% | 3% |
| ADR reporting by health professionals should be mandatory | 67% | 28% | 5% |
| Really serious adverse drug reactions are well documented by the time a medication goes on the market (complacency) | 39% | 57% | 4% |

Number of physician participants (n=87)

* sum of strongly agree and somewhat agree

** sum of strongly disagree and somewhat disagree

Barriers to Filing an ADR Report

As shown in Table II the major barriers to reporting an ADR are lack of clear guidelines, and a reporting mechanism that is perceived to be cumbersome and time-consuming. A significantly higher percentage of physicians who had reported an ADR agreed with the statement that the reporting process is too cumbersome ($p<0.01$). Although the physicians had differing opinions of whether they had time to report an ADR or to follow-up with Health Canada (HC), the majority of them disagreed with the statement that they did not have time to follow-up with a patient when they suspected an ADR had occurred. A significant number of physicians felt they required administrative support in completing an ADR report and some physicians felt there should be financial reimbursement for this aspect of patient care.

Table II Barriers to reporting adverse drug reactions (ADRs).

| Barriers to reporting ADRs | Agree* | Disagree** | Unsure/ Don't know |
|---|--------|------------|--------------------------|
| I would more likely report an ADR if there was an easier method | 75% | 19% | 6% |
| I am unsure of the reporting procedures and guidelines | 71% | 24% | 5% |
| I do not have time to follow-up with a patient when I suspect an adverse reaction has occurred (lethargy) | 26% | 71% | 3% |
| The reporting process is too cumbersome | 62% | 9% | 30% |
| I don't have time to complete an ADR report (lethargy) | 42% | 49% | 9% |
| I should be financially reimbursed for reporting an ADR (financial) | 31% | 48% | 21% |
| I don't have time for Health Canada to follow-up with me for more information on a particular report (lethargy) | 46% | 46% | 8% |
| I need administrative assistance to complete an ADR form (lethargy) | 43% | 31% | 26% |

Number of physician participants (n=87)

* sum of strongly agree and somewhat agree

** sum of strongly disagree and somewhat disagree

As shown in Figure 2, the majority of physicians were not familiar with Health Canada's online ADR form. More detailed analysis revealed that a higher percentage of physicians who had never reported an ADR were not familiar with the Online Health Canada form ($p<0.032$).

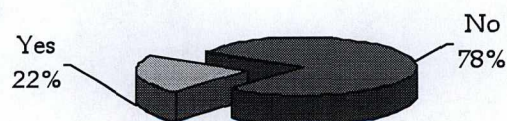


Figure 2. Physician familiarity with the online Health Canada Adverse Drug Report form.

A total of 41 physician respondents provided written responses when asked to identify other barriers (beyond those that were provided in the survey) to filing an ADR report. Qualitative analysis of responses revealed a few key barriers to reporting. According to several respondents the cumbersome nature of the ADR reporting process represents a significant barrier. Respondents described feelings of frustration associated with having to take multiple steps to complete this process such as remembering a complex URL and filling out several pages of data (at which point some respondents encountered

problems with the web-based system). Further, it was noted by some participants that the follow-up involved in the reporting process was too time consuming in cases where Health Canada required more information. They prefer that Health Canada take responsibility for the follow up.

“Having a website with a complicated URL which requires remembering some other site is doomed to failure” - Physician

Some physicians commented that if ADR reporting is an activity of significant importance then physicians should be paid to do it. A final barrier to ADR reporting is a lack of education around how to do so properly. Several physicians indicated that they were either not familiar with the process, unsure of where to get the forms, or not clear about what constitutes an ADR significant enough to warrant a report.

“When I attended xxx medical school, I was never told about reporting. It was years into my practice that I found out how to report...I think we need to educate new doctors early in their training.” - Physician

“The definition of adverse is not very clear to me. Physicians cannot distinguish between adverse, common or specific side effects of a drug” - Physician

Facilitators to Filing ADR Reports and Decision-Making Support

Almost 75% of all the physician respondents indicated that they would be more interested in reporting if they received feedback on the reports they submit. A significant majority of physicians (85%) indicated they would like access to decision-making support when they suspect the occurrence of an ADR.

As shown in Figure 3, a high percent of physician respondents indicated the need for support in finding and using an appropriate tool for ADR reporting. In addition, over half of physician respondents indicated they require support in identifying an ADR; finding time to report; and require support to complete the report correctly. A lower percentage felt they needed support in describing the adverse drug reaction. Physicians were also given an opportunity to select various resources they would like to use for learning about ADR reporting. The only two resources that over one-half of the physicians selected were: an ADR reporting website (68%) and information on Health Canada's website (54%).

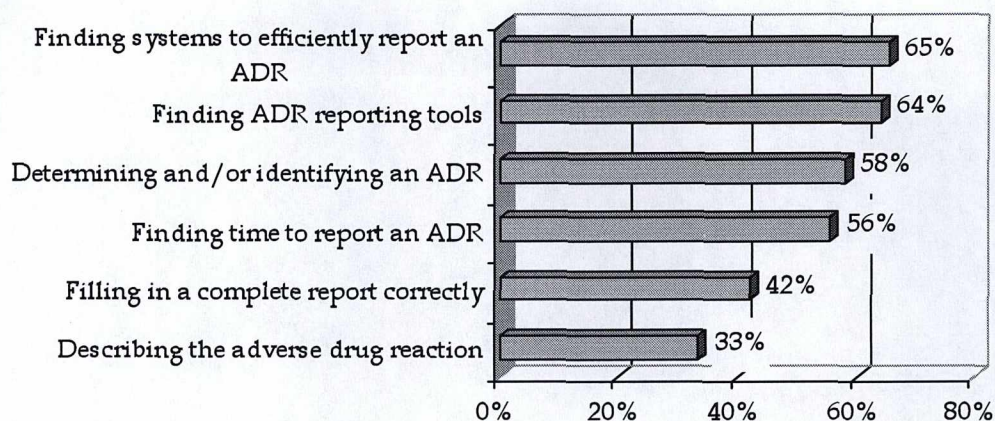


Figure 3. Support related to reporting ADRs.

At least two-thirds of physician respondents indicated they need the following types of support for new medications: finding accurate information, accessing up-to-date safety information, as well as determining the benefit versus harm issues for specific patients (Figure 4). A high percentage of physicians indicated they would like to refer to the Health Canada website (65%) as well as receive regular safety/ADR reports from Health Canada (55%).

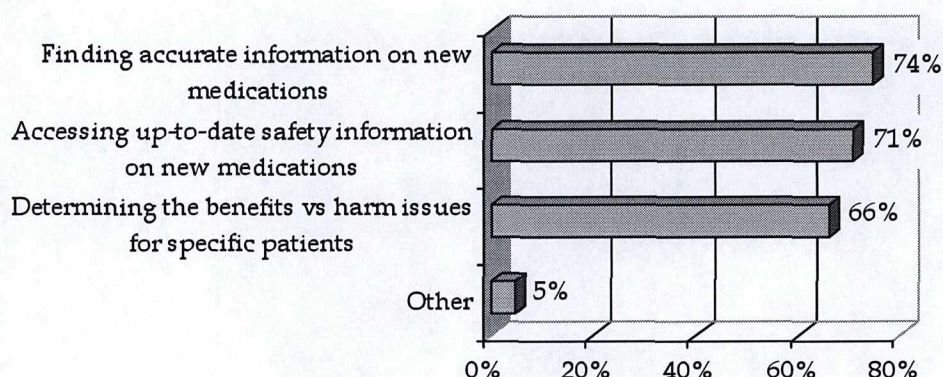


Figure 4. Support needed in education about new medications.

Other areas identified from the qualitative data that require more support with new medication prescribing include: a) a system to estimate denominator (i.e. exposure data); b) number needed to treat for benefits; c) safety in pregnancy; and d) being kept up to date on new medications as they are released to the public (e.g. via email or newsletter).

Physicians Who Had Reported ADRs

The following findings were obtained from 30% of the physician participants who had reported an ADR in the past. Similar percentages of family physicians (33%), generalists (33%) and specialists (26%) indicated they had reported an ADR. Most of these physicians reported about once per year (69%) and the remaining physicians reported ADRs every six months. Over 77% of the participants file reports for prescription medications, with smaller numbers reporting ADRs for biologics (12%), natural health products (8%), non-prescription drugs (8%) or other agents (23%) (e.g. vaccines, hormones). More physicians were prompted to report an ADR for serious reactions (or worsening of symptoms) (69%), unexpected reactions (not consistent with product information) (65%) and reactions in response to newly marketed drugs (27%). Most of the physicians observed ADRs in adult patients (81%) with about 20% reporting ADRs respectively in infants, children and young adults. Consistent with the literature^[19], a high percentage (42%) of the physicians also indicated that more elderly patients experience the ADRs that they report. Approximately three-quarters (76%) submitted the ADR report to Health Canada. Only a few (12%) had reported ADRs to pharmaceutical companies. Other centres that physicians reported ADRs to include BC Centre for Excellence in HIV/AIDS Pharmacovigilance Program, as well as BCAS adverse event data. Only two physicians had a pharmacist forward the ADR. The reports were submitted using one of the following: mail (39%), Health Canada's online form (35%), faxing (23%), or phoning a regional Health Canada monitoring office (4%). The majority (51%) of these physicians indicated a preference for utilizing an online Health Canada report form with 12% preferring mail, 20% preferring fax, 0% preferring phone, and 16% preferring other means (e.g. pharmacist reporting).

Use of Technology

All of the participating physicians use computers in their office practice and homes and most did not use or prefer not to use other handheld devices. Almost all (95%) reported an interest in using technology to access information on ADRs and new medications.

Discussion

We sought to explore a number of factors that may contribute to the under reporting of ADRs by Canadian physicians. These factors were: the knowledge of and attitude toward ADRs; patient dialogue about ADRs and structure of the clinical practice; access to the report form, knowledge about if and what needs to be reported and educational support required for ADR reporting and for new medications in general. The study population was comprised of approximately equal numbers of generalists and specialists (seven major clinical disciplines) and nearly equal numbers of male and female physicians. Almost all of the participants completed medical school (79%) and residency (87%) in Canada. Only about one-fifth of the physicians are practicing medicine in a tertiary care facility with the majority based in group practice, a community hospital, emergency room or sole practice setting. Our physician population was actively engaged in patient care and prescribed medications on a daily basis. Others (15) have shown the lack of association between the age, gender, number of patients seen and prescriptions written/day and the rate of ADR reporting. Few if any previous

studies have explored the extent to which physicians engage in a dialogue about ADRs with their patients and if their office practice is structured to allow patient follow-up of an ADR. These two aspects are as important as physician attitudes toward reporting. The majority of physicians in our study population reported discussing ADRs with their patients (83%) and that their office practice was structured to permit follow-up with suspected ADRs.

Herderio et al ^[15] found that there was an inverse correlation between the following attitudes/beliefs and the behaviour of ADR reporting: a. complacency, b. insecurity, c. diffidence, d. indifference and e). ignorance. A recent systematic review of the literature ^[14], found that a) ignorance; b) lethargy; c) diffidence; d) insecurity and e) complacency were associated with under-reporting in 45 studies conducted in 16 countries. In contrast to an earlier report based on a much larger number of physicians^[7], our select physician population showed a very positive attitude toward reporting ADRs; 92% agreed that they have a professional obligation to report and a significant number would support a mandatory system of reporting. Similar to the literature, a significant number (70%) believed that one should only report if there is certainty that it is linked to the medication, i.e. diffidence; and smaller numbers believed that only safe medications are marketed (39%), i.e. complacency; and, that it is virtually impossible to determine if a drug is responsible for an ADR (27%), i.e. insecurity. The rationale suggested by Inman ^[12] underlying the belief of diffidence is that physicians would not want to appear ignorant in the eyes of those receiving the report of a suspected ADR. It is likely that physicians do not report a suspected ADR when they are not certain (they do not have sufficient evidence) that it can be attributed to a specific medication is due to a belief that they should only report when they are certain. In contrast to the findings of Herdeiro ^[15], our population showed little evidence of indifference with 93% disagreeing with the statement: "One adverse reaction that I may see in one of the my patients cannot contribute to new medical knowledge". The results indicate there is little concern about fear of litigation or having a greater liability for the patient's outcome. In contrast to other physician populations, our physician participants understand that the benefit vs harm profile of new medications is not fully known at the time the medication is licensed; that the reporting of ADRs is one mechanism of providing this safety data; and acknowledge that reporting ADRs is their professional responsibility. In comparison to an earlier study of Canadian physicians ^[20], our results show that physicians in BC recognize the need to report ADRs to Health Canada and the majority (76%) of those who filed an ADR, submitted the report to Health Canada.

Despite the positive attitude toward reporting ADRs, 70% of the physician participants had never reported an ADR. The results of our study of motivated physicians indicate that difficulties in the actual mechanism of reporting ADRs rather than negative physician attitude toward reporting these events contribute to the underreporting of ADRs in physicians in British Columbia. Some of the key challenges include:

- Online submission of the completed form was not always possible: At the time our survey was conducted, the form had to be downloaded and either faxed or mailed to Health Canada. The MedEffect Canada website is the main portal to access the online report form ^[21].

- A guide to Adverse Drug Reaction reporting is present on the website i.e., “Guidelines for reporting suspected adverse reactions by health professionals”, however, it is not easily accessible to aid physicians while in the process of completing an ADR report.
- Locating the on line reporting web portal is challenging: As of July 2009, accessing the web page for online reporting is several clicks away from the main page. Alternatively, directly accessing the online report form requires entering a specific but complicated URL ^[22].
- ADR reporting is not “one stop shopping”: The online form can be used to report suspected adverse reactions to prescription and non-prescription pharmaceuticals, biologics including blood products, therapeutic and diagnostic vaccines, natural health products and radiopharmaceuticals. But, reporting adverse reactions involving preventative vaccines, medical devices or any other products not listed on the page must be made through different sites. While the links to these three other sites are provided, the online report forms for them are not operational and the ease of finding the appropriate form differs.

Even though only 22% of all of the participants were familiar with Health Canada's Online ADR form about half of the physician participants indicated an interest in online reporting on the Health Canada website. Educating physicians to use the online report form would conceivably improve ADR reporting rates.

Beyond improving access to and function of the ADR online report form, our survey results also point to significant gaps in physician knowledge about adverse drug reactions and the subsequent reporting process. For example, our physician participants are cognizant that the full safety profile of new medications is not known at the time they licensed, however the issue of determining the role of the medication in the generation of what is suspected to be an adverse reaction is seen as difficult. The Health Canada guide on reporting ADRs is clear that all suspected reactions should be reported even if causality has not been established. Over 85% of the physicians indicated they would like access to decision making support when dealing with a suspected ADR. Specific and timely educational support about if and what to report particularly when the physician is not sure if the ADR is due to the medication may help address the problem of under-reporting. An educational strategy could also address the gaps in knowledge on how to complete an ADR form for specific types of patients and reactions. The provision of an educational intervention has been shown to be effective in increasing the reporting of ADRs ^[23].

Our survey results further suggest that letting physicians know how Health Canada uses the ADR information would improve reporting. Dissemination of drug safety information derived from ADRs to prescribing physicians and actions of drug regulatory agencies have been shown to influence drug prescribing practice and the incidence of adverse reactions associated with these medications ^[24]. Most physicians indicated a preference for frequent updates from Health Canada on the status of ADRs reported for the medications they prescribe rather than annual summaries. As indicated by our participants, provision of specific feedback to physicians on the ADRs they submit

would likely improve engagement and facilitate physicians in ADR reporting. The results of our study also point toward a need to provide educational resources on new medications including up-to-date safety data and resources to assist physicians in determining the benefit vs harm profile for specific patients.

Limitations

The low participation rate of the physicians who received the request to complete the survey (2%) may limit the generalisability of the results in this study. However, one may also argue that the physician participants in our study would likely be described by most investigators as more “motivated” than average physicians, evidenced by their participation in the survey. The views expressed in our survey – the reporting of ADRs as an essential physician competency and a professional responsibility; supporting a system of mandatory reporting – further support this notion. Therefore, given that our physician participants: a) are motivated to report an ADR, b) engage in the discussion with their patients on ADRs and c) have an office practice that is structured to allow patient follow-up, strengthens this study’s observations that the barriers reported by our participants and the need to support this group of enthusiastic physicians are highly relevant and must be effectively addressed if the system is ever to attract the average physician to engage in ADR reporting. Another potential limitation of our study is over-reporting of intentions or activities. Even though a large number of physicians responded that they follow up with their patients on ADR, we cannot verify that they actually perform these tasks as we did not actually audit their practices. Therefore, our data may cause skewing towards a bias for action, but the actual level of activity might not match the intentions.

H. Conclusion

Conclusion

Our findings reveal a need to improve a) access to an efficient reporting mechanism and, b) knowledge of what and how to report an ADR in order to engage and promote the reporting of ADRs by the greater physician population. This study will inform the development of resources for decision-making support when dealing with a suspected ADR; assistance in finding up-to-date safety information; and access to accurate information on new medications including support in determining a particular medicine’s benefit vs harm profile for specific patients.

4853 word count does not include the abstract-

I. Footnotes

None

J. Reference list (Vancouver style)

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