

Health Canada
UNDERUTILIZATION OF THE ADVERSE REACTION
REPORTING SYSTEM
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FINAL REPORT

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EXECUTIVE SUMMARY

Research Objectives

The purpose of this research initiative was to collect qualitative information to help Health Canada understand why less than 10% of adverse reactions are reported by health care professionals and to explore ideas to increase reporting.

Approach and Methodology

Forty-eight one-on-one interviews were conducted with the following four groups: Medical doctors, Naturopathic doctors, Nurses, and Pharmacists. Twelve interviews were conducted with each of the target groups, each interview lasting approximately 30 to 40 minutes. The interviews were conducted between February 26 and March 12, 2007.

Sources of Post Market Drug Information

The most common sources for post market drug information used by the interview participants include the College of Physicians and Surgeons (CPS), journals (such as the New England Medical Journal), and personal interaction with colleagues in the industry either within the office, at a seminar or at a conference.

Awareness of the MedEffect website is fairly low. Of those who have heard of the MedEffect site, just half have visited the site while one respondent actually subscribed to the MedEffect e-notice.

Responsibility, Awareness and Use

Respondents were more likely to feel that physicians should be responsible for reporting adverse reactions over other health professionals in order to ensure the safety of the patient with the medication being administered. The main reason for this thinking is that the physicians are responsible for prescribing medication to patients and they are also the ones with the complete medical history of the patient.

Following physicians, pharmacists were the next most likely individuals to be identified as the person that should be responsible for post market drug safety. The key reason for believing pharmacists should be responsible is that they are the ones who bottle the medication and physically hand it to the patient. Very few participants felt that nurses are the health professionals who should be responsible for post market drug safety.

Reporting ADRs

Based on all interviews conducted, just three respondents have ever reported an adverse reaction (two pharmacists and one medical doctor). The majority of the medical doctors interviewed felt that there are six major factors affecting their willingness or ability to report: time, lack of knowledge about the reporting program, (lack of) severity of the reaction, previously known side effects, difficulty of analyzing symptoms, and the feeling that it is someone else's responsibility.

Pharmacists and nurses who were interviewed felt there were five major reasons for not reporting adverse reactions: lack of severity of reaction, lack of time, lack of knowledge, report to the doctor or drug company, and previously known side effects.

The differentiation between a perceived adverse reaction and a normal side effect was not clear to the participants. It was felt by most that there is no need to report what they would classify as a normal side effect such as a sniffle or a cough.

Due to an overwhelming workload, it is very important to keep the reporting system simple, easy to use, and convenient. Most professionals are not opposed to spending the time to fill out a report as long as the process is quick and easy to understand.

Interview participants indicated that a variety of reporting methods should be available. For example, some participants no longer have a fax machine in the office while some have limited or no Internet access. The method preferred by most participants was the Internet; however, many preferred the telephone as they do not appreciate impersonal means of communicating this type of information as it deals with a person's health.

There is a lack of awareness of how, why, what, and who should be reporting adverse reactions to Health Canada. Many participants feel that if this information were to be more effectively communicated then there would be an increase in reporting rates by health professionals. Participants indicated that they will refuse to report adverse reactions "just for the sake of reporting". However, if they were able to understand the value of their time and that it was being used for a greater good then they would be more likely to report.

Conclusions

There is a lack of awareness of the system in place for reporting adverse reactions to the Canadian Adverse Drug Reaction Monitoring Program. The positive news is that all health professionals interviewed agreed that there is some benefit in reporting adverse drug reactions to Health Canada for the better good of Canadians.

Health Canada needs to better communicate the definition of what constitutes an adverse reaction. Without the knowledge of what Health Canada defines as an adverse reaction and when they should be reported, health professionals can not be expected to increase their participation in the program.

Although there is no clear consensus on who should be reporting adverse reactions to Health Canada, it is clear that the physician who prescribes the medication is best suited to determine what is and is not an adverse reaction.

The majority of health professionals interviewed feel that appropriate communications will be enough to bolster their participation. It will be important for Health Canada to effectively explain the types of reactions that need to be reported, who should be reporting and when they should be reporting.

If the reporting process is kept simple and is easy to access, combined with effective communication, many of the interview participants indicated that they would likely start reporting adverse reactions on a more regular basis.

There are many health professionals that continue to prefer sending and receiving faxes or receiving letter mail, while others have become internet and computer savvy. Several interview participants feel that in-person communications at conferences or seminars is also a useful way of reaching health professionals. Since there is no single way to communicate with all health professionals, Health Canada should consider a multifaceted approach to any potential communications programs aimed at health professionals.

RÉSUMÉ

Objectifs de la recherche

Cette initiative de recherche avait pour but de recueillir des renseignements qualitatifs afin d'aider Santé Canada à comprendre pourquoi moins de 10 % des effets indésirables sont déclarés par les professionnels de la santé, de même que d'explorer des idées qui permettraient d'accroître le taux de déclarations.

Approche et méthodologie

Nous avons mené quarante-huit (48) entrevues individuelles auprès des quatre groupes suivants : médecins, naturopathes, infirmières et pharmaciens. D'une durée de 30 à 40 minutes chacune, douze entrevues ont été effectuées auprès de chacun des groupes cibles entre le 26 février et le 12 mars 2007.

Sources de renseignements sur les médicaments après la commercialisation

Les participants interviewés obtiennent des renseignements sur les médicaments après la commercialisation principalement auprès du Collège des médecins et chirurgiens, dans les revues médicales (comme le *New England Medical Journal*) et par l'intermédiaire des interactions qu'ils ont avec leurs collègues du milieu de la santé, que ce soit au travail ou lorsqu'ils participent à un séminaire ou un congrès.

La connaissance du site Web *MedEffet* s'avère assez faible. Parmi les participants qui avaient entendu parler du site *MedEffet*, seulement la moitié avaient visité le site, et un seul participant était abonné à l'Avis électronique *MedEffet*.

Responsabilité, connaissance et utilisation

Les participants étaient plus enclins à dire que les médecins devraient avoir la responsabilité de déclarer les effets indésirables, plus que tout autre professionnel de la santé, afin d'assurer la sécurité des patients qui prennent des médicaments d'ordonnance. Cette opinion s'appuie sur le fait que ce sont les médecins qui prescrivent les médicaments aux patients et que ce sont également eux qui connaissent tous les antécédents médicaux des patients.

Après les médecins, ce sont les pharmaciens qui ont été le plus souvent signalés comme professionnels devant être responsables de l'innocuité des médicaments après leur commercialisation. L'opinion selon laquelle cette responsabilité incombe aux pharmaciens est justifiée par le fait que ce sont eux qui embouteillent les médicaments et les remettent aux patients. Très peu de participants croyaient que les infirmières devraient être responsables de l'innocuité des médicaments après la commercialisation.

Déclaration des effets indésirables des médicaments

Seulement trois participants, soit deux pharmaciens et un médecin, avaient déjà déclaré des effets indésirables. La majorité des médecins interviewés jugent qu'il y a six facteurs

importants qui influent sur leur volonté ou leur capacité de faire ces déclarations : le temps, le manque de connaissances quant au programme de déclaration, la gravité moindre de certains effets indésirables, la connaissance préalable de certains de ces effets, la difficulté de diagnostiquer certains symptômes et l'impression que cette responsabilité incombe à un autre professionnel.

Les pharmaciens et les infirmières interviewés ont cité cinq raisons importantes qui expliquent, à leur avis, pourquoi peu d'effets indésirables sont déclarés : la gravité moindre de certains effets indésirables, le manque de temps, le manque de connaissances, la déclaration faite auprès du médecin et de la société pharmaceutique et la connaissance préalable de certains de ces effets.

La distinction entre un effet indésirable perçu et un effet secondaire normal n'était pas évidente pour les participants. La plupart des participants croient qu'il n'est pas utile de déclarer des symptômes qu'ils considèrent comme des effets secondaires normaux, tels un rhume ou une toux.

Compte tenu de la charge de travail considérable des professionnels de la santé, il est très important que le système de déclaration soit simple, facile à utiliser et pratique. La plupart des professionnels ne s'opposent pas au fait de prendre le temps de remplir un formulaire de déclaration, pourvu que le processus soit rapide et facile à comprendre.

Les participants interviewés souhaitent que plusieurs méthodes de déclaration soient offertes. Par exemple, certains participants n'ont plus de télécopieur au bureau, alors que d'autres n'ont que peu ou pas d'accès à Internet. Le réseau Internet constitue la méthode privilégiée par la plupart des participants; toutefois, ceux-ci sont nombreux à préférer le téléphone, étant donné qu'ils n'aiment pas transmettre ce genre de renseignements sur la santé d'un patient en utilisant un moyen de communication impersonnel.

Les professionnels manquent de connaissances quant aux exigences de Santé Canada en matière de déclaration d'effets indésirables, notamment qui doit déclarer quoi, comment et pourquoi. De nombreux participants considèrent qu'une communication plus efficace de ces renseignements entraînerait une augmentation du taux de déclaration des professionnels de la santé. Les participants ont indiqué qu'ils refuseraient de déclarer des effets indésirables « simplement pour le fait de présenter des rapports ». Toutefois, ils seraient plus enclins à déclarer des effets indésirables s'ils étaient en mesure de comprendre l'importance du temps qu'ils y consacrent et comment cette base de données sur les effets indésirables sert l'intérêt public.

Conclusions

Le système actuel utilisé pour déclarer les effets indésirables au *Programme canadien de surveillance des effets indésirables des médicaments* est peu connu des professionnels de la santé. La bonne nouvelle, c'est que tous les professionnels de la santé interviewés reconnaissent qu'il y a des avantages à déclarer les effets indésirables des médicaments à Santé Canada en vue de mieux servir l'intérêt des Canadiens.

Santé Canada doit mieux communiquer la définition de ce qui constitue un effet indésirable. On ne pourra pas s'attendre à ce que les professionnels de la santé participent davantage à ce programme tant qu'ils ne connaîtront pas ce que Santé

Canada considère comme un effet indésirable ainsi que le moment auquel ils doivent le déclarer.

Bien qu'il n'y ait pas de consensus clair quant au professionnel de la santé qui devrait déclarer les effets indésirables auprès de Santé Canada, il est évident que le médecin qui prescrit le médicament est le plus qualifié pour déterminer ce qui constitue ou non un effet indésirable.

La majorité des professionnels de la santé interviewés considèrent que des communications appropriées seraient suffisantes pour améliorer leur taux de participation. Il sera important que Santé Canada explique efficacement quels types d'effets doivent être déclarés, qui devrait rédiger la déclaration et à quel moment.

Bon nombre de participants ont indiqué qu'ils commenceraient probablement à déclarer les effets indésirables sur une base plus régulière si, en plus de bénéficier de communications efficaces à ce sujet, le processus de déclaration demeurerait simple et facile d'accès.

De nombreux professionnels de la santé préfèrent encore transmettre et recevoir des télécopies ou recevoir des lettres par la poste, tandis que d'autres sont des adeptes d'Internet et de l'informatique. Plusieurs participants interviewés considèrent qu'une communication en personne à ce sujet dans le cadre de congrès ou de séminaires constitue un autre moyen efficace pour joindre les professionnels de la santé. Puisqu'il n'existe pas de moyen unique pour communiquer avec tous les professionnels de la santé, Santé Canada devrait envisager une approche multifacette pour tout programme de communication destiné aux professionnels de la santé.

1. BACKGROUND

Health Canada, through the Canadian Adverse Drug Reaction Monitoring Program, is responsible for monitoring health and safety risks related to the sale and use of chemicals, drugs and vaccines, food, pesticides, medical devices and certain consumer products. One of the methods used to monitor these health products is the Canadian Adverse Reaction (AR) Reporting System.

(http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index_e.html)

Consumers, manufacturers and health professionals alike are able to report adverse reactions directly to Health Canada through the online reporting tool, by fax, or by telephone. Upon identification of a safety issue, the Department can take the appropriate action.

Previous research conducted by Health Canada has determined that health professionals report less than 10% of adverse reactions, which is a cause for concern for the Department. This research study will assist senior management in the compilation of refinements to the system needed to encourage increased reporting and to help create marketing messages to the target markets.

RESEARCH OBJECTIVES

The purpose of this research initiative is to collect qualitative information to help Health Canada understand why less than 10% of adverse reactions are reported by health care professionals and to explore ideas to increase the percentage to an adequate level.

The specific research objectives for this study are to determine the following:

- Perceptions concerning health professional, patient, drug manufacturer and Health Canada responsibility in post-market drug safety;
- Awareness of the Adverse Reaction (AR) reporting system (e.g. who can report, how to report, what happens to information reported);
- Current AR reporting behaviour, including reasons why they may not be reporting and would they be willing to do so more in the future; and,
- Input in to what channels/tactics would be best used to reach health care professionals sources of information for new post-market drugs.

APPROACH AND METHODOLOGY

The approach for this research study was qualitative in nature. The Antima Group conducted a total of forty-eight (48) one-on-one interviews with the following four groups:

- Medical doctors;
- Naturopathic doctors;
- Nurses; and,
- Pharmacists.

Twelve interviews were conducted with each of the target groups, each interview lasting approximately 30 to 40 minutes. The interviews were conducted between February 26 and March 12, 2007. Three interviews were conducted in-person in the National Capital Region as a pre-test while the remainder were conducted over the telephone. The in-person interviews were conducted to ensure the clarity of the questioning prior to conducting telephone interviews.

Participant recruitment was conducted during February 2007 using a recruiting screener (attached as **Appendix A**) that was reviewed and approved by Health Canada. A discussion guide, which was developed with client input and approval, was used in all interviews to direct the flow of the discussions. The discussion guide is attached as **Appendix B**.

RESPONDENT PROFILE

Forty-eight interviews were conducted with health professionals across Canada. Overall tenure in their respective areas of specialization (i.e. nurse vs. doctor) ranged from less than two months to 35 years. Nearly all medical doctors interviewed had 18 or more years of experience with the exception of one relatively new doctor who had two years of experience. Each of the pharmacists we spoke with had a minimum of eight years experience, the naturopathic doctors each had less than ten years experience, while the range of experience among nurses varied from less than a year to more than ten years.

The key findings from the one-on-one interviews are presented in the following sections of this report. It is worth noting that responses were generally consistent across region and type of health professional. The one clear exception is among naturopathic doctors who feel they do not come across adverse drug reactions as part of their job due to the types of remedies they prescribe to their patients (i.e. herbal or natural medicines). Where differences exist among groups or regions they will be highlighted in the report.

Interpretative Note: Although qualitative research in general, and focus groups in particular, are highly valuable for providing insight into the needs, attitudes and opinions of an organization's customers and prospects, the results cannot be deemed to be representative of any wider group of individuals than those who participated.

2. SOURCES OF POST MARKET DRUG INFORMATION

The most common sources for post market drug information used by the interview participants include the College of Physicians and Surgeons (CPS), journals (such as the New England Medical Journal), and personal interaction with colleagues in the industry either within the office, at a seminar or at a conference. Some additional sources of post market drug information include:

- Association information (i.e. Pharmaceutical Association)
- Pharmaceutical Company communication (i.e. by mail or in person)
- Databases (i.e. natural medicine database, microdex)
- Educational sessions
- Internet/websites research (i.e. national library of medicine)
- Lunch and Learns
- Medical events
- Medical reviews
- Media (TV and Books)
- Memos from supervisors
- Prescribed letters
- Publications
- Subscription database (CD ROM)
- Text books

MedEffect

Awareness of the MedEffect website is fairly low as 38 of the 48 respondents indicated they have never heard of the site. Of those who have heard of the MedEffect site, just half have actually visited the site while one respondent has actually subscribed to the MedEffect e-notice. Additionally, few respondents (11 of 48) have heard of the Adverse Reaction Newsletter while even fewer have taken the time to read the newsletter. Those who have read the newsletter tend to agree that the information contained in it is very useful.

3. RESPONSIBILITY, AWARENESS AND USE

Prior to discussing the responsibility of reporting ADRs to Health Canada, most health professionals wanted to stress that they have little or no time to take on additional tasks. As a result, a standard practice of assuming someone else will take care of reporting the reaction has emerged.

*"I have no spare time to be doing this, so pharmaceutical companies should list the AR and take into consideration the interaction between drugs. Everyone else would in turn be responsible to inform the patient of the possible adverse reactions" -
Medical Doctor, Ontario*

However, among the health professionals interviewed, there seems to be an overwhelming predisposition to focus the responsibility on Physicians followed by Pharmacists.

Physicians

Respondents were more likely to feel that physicians should be responsible for reporting adverse reaction over other health professionals in order to ensure the safety of the patient with the medication being administered. The main reason for this thinking is that the physicians are responsible for prescribing medication to patients and they are also the ones with the complete medical history of the patient. Furthermore, they also have direct contact with the patient and should inform the patient of the possible effects of the medication before prior to prescribing it.

*"The doctor is the one who prescribed the medication, he is the only one who can un-prescribe it. I am not qualified to determine if this is actually an adverse reaction or not. It could be a mixture of medication causing the reaction" - Pharmacists,
Ontario*

"Doctors should only give out what they trust and know works well. Don't give out medication you don't know about" - Naturopathic Doctor, East

"They consult, diagnose, prescribe and should know the pros and cons of the medication" - Medical Doctor, Quebec

Pharmacists

Following physicians, pharmacists were the next most likely individuals to be identified as the person that should be responsible for post market drug safety. The key reason for believing pharmacists should be responsible is that they are the ones who bottle the medication and physically hand it to the patient. While those who feel pharmacists should be responsible for the reporting of adverse reactions agree with the importance of the doctor having the knowledge of the medication, they also feel it is the pharmacist who is most familiar with the chemicals contained in the drug. However, according to the pharmacists interviewed, they are constrained by the doctor's diagnosis and are not in a position to advise a patient to not take medication that has been prescribed by a

doctor. They are, however, in a position to raise red flags and report the incident to the prescribing physician.

"Pharmacists have programmes that alert them if there is a possible concern for mixing chemicals/medications" - Medical Doctor, West

"Pharmacists are a good check to the doctor's work" - Medical Doctor, East

"Pharmacists, because doctors are too busy, and pharmacists have the contact and are easily accessible for the patient" - Pharmacists, Ontario

"Pharmacists first and foremost because they have more time with the patient, however, they may not have all the proper information" - Pharmacist, East

"Pharmacists are more like dispensers, but they still shouldn't just give anything out to the patients" - Naturopathic Doctor, West

"Patients may not come and see the physician if there is an Adverse Reaction, they may go straight to the pharmacists. He should be letting the doctor know of the symptoms" - Medical Doctor, Ontario

Nurses

Very few participants felt that nurses are the health professionals who should be responsible for post market drug safety. In fact, the only group to feel this way were nurses themselves. Many of the nurses interviewed took it upon themselves to inform patients of the dangers relating to a specific medication. They feel that since they are responsible for giving, watching and treating anything that could go wrong with a patient while in their care, it becomes their responsibility.

"Physicians and nurses should be the ones who pay attention to what is being distributed to their patients, and warn the patient of the dangers of the medication. These are the first people they see and report to" - Nurse, East

"The nurse is the one who should know the background of the patient because he/she is the one who dealing with the patient on a personal basis. Sometimes the patient tells me things that they would not tell the doctor" - Nurse, Ontario

Health Canada and Drug companies

Of those who believed that post market drug safety resides in the hands of Health Canada and the drug companies, all felt that these two organizations have a responsibility to ensure that all medication is appropriately tested and that the proper information is delivered to the medical community.

" They should do enough testing, so that the drugs don't have severe side effects before it even makes it onto the shelves" - Naturopath, East

" Once the drug is approved, Health Canada should list the adverse reactions and take into consideration all the possible reactions with other medication. The doctor and pharmacists would then inform the patient of the possible adverse reactions" - Medical Doctor, Ontario

Based on the opinion of those we spoke to during the course of this study, it seems apparent that every health professional has some responsibility to ensure drugs are provided to patients in a safe manner. No two patients will ever behave in the same manner and all patients should be informed of the possible risks involved with taking a medication. It is also important that patients pose the right questions to their health professionals when being prescribed a new medication.

" Everyone has a responsibility. Manufactures at first (to ensure the drug is safe), Health Canada next (approves the drug for public uses), all health professionals to ensure everything is being taken correctly (dosages, mixing chemicals)" - Pharmacists, West

4. REPORTING ADRs

Based on all interviews conducted, just three respondents have ever reported an adverse reaction (two pharmacists and one medical doctor). When asked what proportion of adverse reactions they report, two respondents stated less than 10% while the third said less than 1%, in other words, they do not report regularly at all. This is due in large part to the fact that they do not feel many of the reactions they see are serious and therefore not worthy of submitting a report. However, if a serious reaction is encountered they claim to report closer to 75% of the cases.

Of those who have submitted a report, each felt the process was fairly simple and straightforward. Each person that has submitted an ADR report did so using a paper form and sending the report to Health Canada through the mail. These few participants had no difficulty locating the form nor did they experience any difficulty in completing the form. Additionally, they did not feel the process was onerous nor did it take too long to complete. They did however feel that the process could be improved if it was done online and that this functionality would probably increase the likelihood of their reporting.

Awareness of what is done with the data once an ADR is submitted is very low. In fact, the participants felt it would be beneficial to receive more detailed information from Health Canada regarding what happens after a report is submitted. The most effective method of communicating this additional information would be either by sending the health professionals a paper brochure through the mail or by providing them an e-mail explaining all aspects of the system.

HEALTH PROFESSIONALS LACK THE TIME REQUIRED REPORT

Medical Doctors

The majority of the medical doctors interviewed felt that there are six major factors affecting their willingness or ability to report:

- Time;
- Lack of knowledge about the reporting program;
- Severity of the reaction;
- Previously known side effects;
- Difficulty of analyzing symptoms; and
- The feeling that it is someone else's responsibility.

Nearly all doctors interviewed indicated that they simply have no extra time in a day to take on any additional tasks, nor do they have the resources required to hire additional staff to assist with the workload. Furthermore, medical doctors feel that the issue of adverse drug reactions can be treated at source, meaning the simple alteration of the medication and/or dosage is usually sufficient to cure the problem. Additionally, nearly all of their encounters with adverse reactions are not deemed serious enough to be worthy of reporting in their minds. Most medical doctors interviewed also felt they do not have enough knowledge on the reporting process, including who to contact or what adverse reactions should be reported. Most medical doctors also feel that most side

effects are already well known from previous testing and that reporting a known side effect is a waste of time (depending on the severity of the reaction). Some of the medical doctors feel that reporting adverse reactions is just not their responsibility. Finally, some of the medical doctors interviewed believe the process is too difficult. They feel that there is a lot more that goes behind reporting the adverse reaction than simply filling out a form. For example, they believe a lot of background research must be conducted.

"I did not know I was the one who was supposed to report it directly to Health Canada" - Medical Doctor, Quebec

"I will send it off to a specialist if it is severe" - Medical Doctor, Quebec

"I don't even know the telephone number" - Medical Doctor, Quebec

Other Health Professionals

Pharmacists and nurses who were interviewed felt there were five major reasons for not reporting adverse reactions:

- Severity of reaction;
- Lack of time;
- Lack of knowledge;
- Report to the doctor or drug company; and
- Previously known side effects.

Nearly all of the pharmacists interviewed stated that in their opinion they have never seen an adverse reaction serious enough to report. Most of the symptoms could be treated at source (by them or the prescribing doctor). In addition, many pharmacists interviewed claimed they simply do not have enough time to start reporting adverse reactions to Health Canada. Additionally, some pharmacists and most nurses interviewed felt they did not have enough knowledge on the matter to properly report the adverse reaction. For example, they are not aware of how, to whom or why they should be reporting an adverse reaction. Many pharmacists and nearly all nurses claimed if they happen to come across an adverse reaction that they would report the incident to the doctor or in some cases to the drug company. These participants feel this is justified as the doctors are the ones who must make the decision as to whether or not the symptoms are indeed indicative of an adverse reaction. Finally, the issue of previously known side effects about the certain medications reduces the likelihood that pharmacists will report to Health Canada.

"Side effects are already known, why report it again. If it was something new, I would refer it back to the doctor to diagnose" - Pharmacists, East

"I go to the physician and/or Drug Company if there is a problem. I would go to Health Canada if I felt they were not doing their job. However, there is no need to go over their heads, and all situations can be handled at their level" - Nurse, Ontario

As previously stated, Naturopathic Doctors typically prescribe herbs and natural medicines, and therefore experience a very low adverse reaction rate. It is also worth noting that Naturopaths from Quebec do not have to be licensed in order to practice natural medicine, therefore they have no medical rights to persuade patients to challenge doctors' orders regardless of the severity of the adverse reaction.

"I do not see any adverse reactions as a Naturopath; therefore I would not know the process to take to report a reaction. I have no medical right to remove someone from a prescribed medication" - Naturopathic Doctor, Quebec

"The tools I use have very low adverse reaction rates." - Naturopathic Doctor, East

PHYSICIANS SHOULD REPORT TO HEALTH CANADA

Nearly all respondents agreed that there could be some benefit if they were responsible for the reporting of adverse drug reactions that they come across. Many of those participants interviewed believe it to be primarily the physician's responsibility to report adverse reactions to Health Canada.

Physicians are the individuals who prescribe the medication to the patients; therefore, the other medical professionals have difficulty telling a patient to discontinue the use of a medication without having confirmed it with the prescribing physician. About half of all respondents feel that physicians have the majority of the responsibility of determining if a reaction is in fact an adverse one or perhaps a normal reaction to the medication.

"Physicians should be the ones reporting, because they are the ones seeing/treating the effects and are in contact with the patient" - (Medical doctor, Ontario)

"Physicians are the ones who can actually report whether this is actually an adverse reaction and not just an effect" - (Nurse, East)

As indicated by physicians, pharmacists and nurses alike, most physicians do not have enough time to commit to reporting adverse reactions. Due to this fact, many respondents feel that responsibility for reporting an adverse reaction could be delegated to the individual who initially encounters the reaction. The question again arises around who is in the best position to determine if a reaction is indeed an adverse one. Most agree that the physician is the only one qualified to make this judgment. Ultimately, most participants agree that regardless of position, either as a patient experiencing the

issues or a nurse assisting a patient in the hospital, everyone has a responsibility to ensure that this reaction does not affect anyone else in the country.

"Adverse reactions should be reported by doctors and pharmacists; because they are the ones who know the drugs and can properly diagnose and report it" - (Nurse, Quebec)

"I feel the prescribing physician should be the one to report the serious adverse reactions. However, if this was that serious the patient would likely have been brought to the emergency room. The ER specialist could have handled the report" - (Naturopathic Doctor, East)

"Everyone should be reporting it. It is important to let the pharmaceutical company know of the effects, because they are the ones who need to make the adjustments" - (Medical Doctor, Quebec)

Secondary to physicians reporting adverse reactions, some respondents feel that pharmacists are also qualified to identify and report an adverse reaction. They are the only people, other than doctors, who are familiar with the medications being prescribed. Also, they would likely have a better understanding of what is causing the effect than the nurse or patient would. However, pharmacists themselves don't believe they are able to make those types of judgements and ultimately refer the patient back to the doctor who prescribed the medicine in the first place.

"The doctor is the one who made the prescription, the pharmacists does not know what is trying to be cured" - Pharmacist, Ontario

Very few respondents feel that nurses should be responsible for the reporting of adverse drug reactions (only nurses themselves felt they have the knowledge required). Most nurses do not feel they are equipped or trained to determine whether a symptom is adverse or not and would refer the patient back to the doctor.

"Nurses should report because they are the ones who are dealing with the patient on a long term basis" - Nurse, Quebec

"Physicians should report because they are better equipped to determine if this is a sensitivity issue or an adverse reaction. Nurses support what the doctor says and takes his /her word for it" - Nurse, Ontario

It is also worth noting that some participants feel strongly that patients should not be the ones responsible for the reporting of adverse reactions. They feel this may skew the data collection as patients are typically not knowledgeable enough to make the determination of why they have experienced a particular reaction.

"The patient is not knowledgeable enough to make those kinds of reports. Everyone else should be reporting the effects" - Naturopathic Doctor, East

"Sometimes the change in colour or shape can lead a patient to believe that the medication is not doing what it is supposed to. It's a marketing issue and not the medication itself, because they have been on this medication for a year." - Pharmacist, Ontario

Finally, Naturopathic Doctors are not interested in reporting to Health Canada as they do not feel they are the ones prescribing the medication that is causing reactions to their patients.

"Doesn't happen with Naturopaths; let the doctor deal with it" - Naturopathic Doctor, East

Health Professionals are Not Sure What to Report

The differentiation between a perceived adverse reaction and a normal side effect was not clear to the participants. It was felt by most that there is no need to report what they would classify as a normal side effect such as a sniffle or a cough.

All health professionals interviewed agreed that the definition of an adverse reaction was unclear. There was unanimous agreement that the participants could benefit from a clear and precise definition of what is to be considered an adverse reaction and how to go about reporting the reaction. As it stands now, what might be considered an adverse reaction to one health professional may not be viewed as adverse to another. Therefore it is important to educate health professionals about what should be reported as it is clear that most health professionals have no time to report every symptom.

"If some take antibiotics and gets an upset stomach, I will not report this because it is a known side effect. Pros outweigh the cons" - Pharmacists, Ontario

"A definition would be helpful; they did it with the flu vaccine a while back" - Nurse, West

According to interview participants, an adverse reaction is defined as something serious and/or dangerous to the patient. Some of the more detailed definitions provided by respondents include:

- A reaction that is life threatening;
- A reaction that is considered uncomfortable or debilitating;
- A reaction that is deemed as unwanted or unexpected;
- A reaction that is permanent or irreversible;
- A reaction that is it considered harmful to the patient's health; and
- A reaction that "needs immediate attention."

Some respondents suggested that a severity scale could be created in order to compare symptoms against the definition of an adverse reaction.

"An adverse reaction is something that needs immediate attention. A symptom is something that we would take another approach to, like changing the dosage for example" - Nurse, Ontario

KEEP THE REPORTING PROCESS SIMPLE

Due to an overwhelming workload, it is very important to keep the reporting simple, easy to use, and convenient. Most professionals are not opposed to spending the time to fill out a report as long as the process is quick and easy to understand.

There were very few participants that claimed they would not start reporting adverse reactions if the system was simple and easy to use. Respondents indicated that they would spend anywhere between 5 minutes (maximum for physicians) and 20 minutes submitting a report, however, the shorter the time the more likely they are to submit.

"I have no time to do it. Have someone else do it for me. There is a lot more than just filling out a one page report, you have to research the background to determine what is the real cause of the reaction is" - Medical Doctor, Quebec

"It's a lot like recycling. If you had to travel across the city to do your recycling, would you? Probably not; however, if the government made it easy for you (i.e. going to your house to pick it up), you would be more inclined to participate. This is the same with reporting adverse reactions". - Pharmacists, West

Preferred Means of Reporting

Interview participants indicated that a variety of reporting methods should be available. For example, some participants no longer have a fax machine in the office while some have limited or no Internet access. The method preferred by most participants was the Internet; however, many preferred the telephone as they do not appreciate impersonal means of communicating this type of information as it deals with a person's health.

"I like to do things online, it's fast and convenient, and I don't have to wait for someone to get back to me like a phone call" - Medical Doctor, Ontario

"I like to use the phone because it ensures that the message was received and I can get more information out in 5 minutes by phone than I could by writing it. In addition, I get a person's name who I was talking to, in case I need to call back and speak with someone about the issue" - Naturopathic Doctor, Quebec

COMMUNICATION WILL LIKELY INCREASE REPORTING

There is a lack of awareness of how, why, what, and who should be reporting adverse reactions to Health Canada. Many participants feel that if this information were to be more effectively communicated then there would be an increase in reporting rates by health professionals. Participants indicated that they will refuse to report adverse reactions “just for the sake of reporting”. However, if they were able to understand the value of their time and that it was being used for a greater good then they would be more likely to report. It is important for Health Canada to make it clear that the reporting of adverse reactions is very important to the health of all Canadians. In addition, it is essential that a clear definition of adverse reaction be communicated. The health professionals interviewed are unclear of what needs to be reported and how severe a symptom needs to be in order to be worthy of a report.

There is no single method of communicating to all health professions regarding the reporting of adverse drug reactions. Some of the suggestions provided by participants included:

- Internet;
- Paper (i.e. brochure through the mail);
- In person (i.e. at seminars or conferences);
- Posters in the workplace;
- Through professional associations;
- Through medical journals and/or magazines; and,
- Television advisements.

“ They should show us that this is having an impact on someone’s life. Prove to us that we are not just filling out forms for the sake of filling out forms” - Nurse, West

“ Sometimes I have no time to return calls, sometimes I don’t check my e-mail, a lot of mail goes to the junk pile, and I don’t have time to go to an online site everyday. So it is important that you through a variety of communication mediums at me to ensure that I get the message” - Naturopathic Doctor, East

“ It’s important that you focus on our associations and less on each professional themselves.” - Naturopathic Doctor, East

The use of an Internet site where health professionals can go get more information is very important. This allows the health professional to access information or print out the necessary forms at their convenience. Respondents also stressed the important that the site be as simple as possible to access and even easier to use otherwise they will not continue. Some creative marketing tools to advertise an Internet site were mentioned by participants including:

- A sticker that can be placed on the side of the computer
- A magnet for a fridge
- A clip on the side of the computer that could hold your paper when you type, and

- A calendar that they could use to keep track of their appointments.

Some participants also suggested that communicating the definitions and the importance of adverse reaction reporting be done on a continuous basis (i.e. quarterly communications). This would eliminate the potential of health professionals forgetting the importance of reporting adverse reactions due to their busy work life. One suggestion was to create a monthly newsletter that outlines a “*drug of interest*”. In addition, it was recommended by respondents that the reporting tools be simple and quick to use as they have no time to figure out how to fill out a form.

Another alternative suggested by several participants was to provide health professionals with some sort of incentive to report; however, not all agreed with this approach as some feel it is not ethical to be paid for something that is really part of the job. Those who did feel this was a viable option felt so as they currently have time to report during office hours and would be reporting on their own time.

*“I’m pretty sure that Veterans Affairs does something like this (paid incentives)” -
Medical Doctor, East*

“You have to be very careful with providing cash incentives to people for reporting, because eventually people become dependent on this source of income and people could start reporting bogus reports, just to make a quick buck. Maybe companies will make it a quota to report 10/week, for accounting purposes” - Pharmacist, East

Consequently, the idea of providing non-monetary incentives was suggested. For example, a nurse suggested something as simple as providing a pin that can be fastened to their uniform. Another nurse suggested a “lunch and learn” for those that who have reported adverse reactions as a thank you, as well as to provide more details about the program. Finally, a pharmacist recommended sending a plaque that they could place on the wall to show their clients how seriously they take adverse reactions.

It is also worth noting that participants feel dentists should also be informed of adverse reactions as they also provide patients with medications and anaesthetics. Should dentists witness an adverse reaction, they should have access to the appropriate reporting tools.

5. CONCLUSIONS

Lack of Awareness

Many health professionals interviewed were not aware of the Canadian Adverse Reaction Reporting System. There seems to be a lack of communication between Health Canada and the health community regarding the reporting of adverse drug reactions. Even among those who have heard of the system, most have limited knowledge about the reporting method and even fewer have actually reported an adverse reaction. The positive news is that all health professionals interviewed agreed that there is some benefit in reporting adverse drug reactions to Health Canada for the better good of Canadians.

Define ADRs

Without the knowledge of what Health Canada defines as an adverse reaction and when they should be reported, health professionals cannot be expected to increase their participation in the program. It will be important to communicate a clear and concise definition to health professionals. Furthermore, as suggested by an interview participant, a severity scale may be a beneficial tool to health professionals when trying to determine if a particular reaction should be reported or not.

Physicians Are Best Suited to Report ADRs

Although there is no clear consensus on who should be reporting adverse reactions to Health Canada, it is clear that the physician who prescribes the medication is best suited to determine what is and is not an adverse reaction. However, it is not as simple as just placing the responsibility on the physicians as they are already overworked and do not have the time required. The reporting of adverse reactions should be marketed as a shared responsibility among all health professionals who interact with patients.

Communication is the Key to Increasing Participation

The majority of health professionals interviewed feel that appropriate communications will be enough to bolster their participation. It will be important for Health Canada to effectively explain the types of reactions that need to be reported, who should be reporting and when they should be reporting. It will also be necessary to ensure the health professionals that the process is not onerous and that they have multiple options for submitting a report such as the internet or over the telephone. Health professionals will also become more likely to begin reporting adverse reactions if Health Canada provides information regarding the outcomes of reported adverse reactions. The health professionals we spoke with made it clear that they do not want to report “just for the sake of reporting.”

Keep it the Reporting Process Simple

If the reporting process is kept simple and is easy to access, combined with effective communication, many of the interview participants indicated that they would likely start reporting adverse reactions on a more regular basis. It will be important to communicate to the health professionals the amount of time that will be required to submit a report as if they feel a task should be five minutes and it takes longer, they will simply not complete the task.

A Multifaceted Communications Approach is Necessary

There are many health professionals that continue to prefer sending and receiving faxes or receiving letter mail, while others have become internet and computer savvy. Several interview participants feel that in-person communications at conferences or seminars is also a useful way of reaching health professionals. Since there no single way to communicate with all health professionals, Health Canada should consider a multifaceted approach to any potential communications programs aimed at health professionals.

APPENDIX A – RECRUITING SCREENER

Adverse Reaction Study – Executive Interviews, Health Canada

Hello, my name is _____ and I am calling from Research House Inc, a market research firm. We are calling on behalf of Health Canada, which is currently conducting research with health professionals regarding the reporting of adverse reactions to medication. We are calling today to invite you to participate in an executive interview discussion. Your participation in the research is completely voluntary and your decision to participate or not will not affect any dealings you may have with Research House Inc. All information collected, used and/or disclosed will be used for research purposes only and administered as per the requirements of the Privacy Act. The interview will last approximately 30 to 40 minutes and we will schedule a time that is convenient to you to conduct the interview. In appreciation for your time and participation, we will provide you with either a cash honorarium or make a donation in your name to a charity of your choice. May we have your permission to ask you some further question to see if you qualify to be part of our study?

1. Are you or is any member of your household or immediate family employed in or by, or ever been employed in or by:

	No	Yes
Market Research	()	()
Marketing	()	()
Public Relations	()	()
Any media (Print, Radio, TV)	()	()
Health Canada	()	()
Public Health Agency of Canada	()	()

IF YES TO ANY OF THE ABOVE – THANK AND TERMINATE

Record Region (need approximately 12 in each region)

West (BC, AB, SK, MB)	1
Ontario	2
Quebec	3
East (NS, NB, PEI, NL)	4

2. Are you a...? (RECRUIT 12 PER GROUP)

Medical Doctor	1
Naturopathic Doctor	2
Nurse	3
Pharmacist	4
None of the above	9 → THANK AND TERMINATE

3. How many years experience do you have in your profession? (Need a good mix)

Less than five years 1
Five of more years 2

4. Can you please tell me where you are located? (ask only if in 613 area code)

National Capital Region 1 (ASK Q.5)
Other 2 (SKIP to Q.7)

5. Would you be willing to participate in an in-person interview?

Yes 1 (Need two to three - should be scheduled first)
No 2 (SKIP to Q.7)

6. Record address.

7. We would like to invite you to participate in the interview. The interview will last no longer than 45 minutes and will take place at over the telephone. A representative from the Antima Group will contact you directly. As an appreciation for your participation in this research, you will be offered an honorarium. (Doctors and Naturopathic Doctors \$125, Nurses and Pharmacists \$75) Would you be interested in participating in the interview?

Yes 1 → INVITE
No 2 → THANK AND TERMINATE
Don't know / need to confirm 3 → SCHEDULE CALL BACK

8. Record Gender (About a 50/50 mix)

Male 1
Female 2

Confirm

Name:

Occupation:

Telephone Number:

Date of interview:

Time of interview:

Mailing address (to send incentive):

Appendix B – Interview Guide

Health Canada – Adverse Reaction Reporting Interview Guide – Draft

Name:

Region:

Occupational Group: Medical Doctor, Naturopathic Doctor, Nurse, Pharmacist

Date:

Introduction (Study Objectives)

Health Canada plays an integral and active role in ensuring Canadians have access to safe and effective drugs and health products. One of the ways Health Canada monitors the safety, effectiveness and quality of health products after they reach the marketplace is by routinely evaluating adverse reaction (AR) reports submitted by health professionals, manufacturers and consumers. If a safety issue is identified through these reports, appropriate action is taken, which may include distributing new product safety information to the public and the health care community, recommending changes to the product's labelling or requesting the removal of the product from the market.

A current threat to this safety system is that, according to previous research done by Health Canada, only app. 10% of adverse reactions are reported by health care professionals. This research seeks to understand why this percentage is so low and what could be done to raise it.

Profile

1. Do you specialize in a particular area of health care?
 - If yes, what?
2. How long have you been in the health care profession?

Sources of Information

3. What are your main sources of new post-market drug information?
4. Have you ever heard of:
 - Health Canada's (MedEffect) web site?
 - i. Do you visit the MedEffect web site as a source of new post-market drug information?
 - Health Canada's electronic bulletin, (MedEffect e-notice)
 - i. Do you subscribe to MedEffect e-notice?
 - the Canadian Adverse Reaction Newsletter?
 - i. Do you subscribe to this newsletter either as part of the Canadian Medical Association Journal, or on its own?
 - ii. Do you read this newsletter?
 - iii. How useful is it as a source of information of ADR?

Responsibility, Awareness and Use

5. What responsibilities do health professionals, patients, drug manufacturers and Health Canada have with respect to post market drug safety? In your opinion who among this group is most responsible for post-market drug safety, why?
6. Are you aware that medical professionals and the public can report adverse drug reactions to Health Canada?
7. Have you ever or do you currently report ADRs to Health Canada?

ASK Q8 TO Q12 OF USERS ONLY

8. On average, what proportion of the ADRs you have come across do you report? If not all, how do you determine which to report?
9. Do you submit the report or do you have someone do it on your behalf? If someone else, who?
10. Can you describe to me the process you (or the person who submits it) go (goes) through when reporting an ADR?
 - How is the report submitted (e.g. telephone, online, etc.)?
 - In your opinion is the process complicated or onerous?
 - Do you have suggestions on how it can be improved?
11. **(IF ONLINE NOT MENTIONED)** Were you aware that you can now report an ADR online?
 - If yes, has this changed your reporting habits?
 - If no, will this change your reporting habits?
12. Do you know what happens to the information after an ADR is reported?
 - Would you like to have more information about this?
 - How would you prefer to receive any additional information?
 - Would you say this is the best way to reach most people in your profession?

ASK Q13 TO Q16 OF NON USERS ONLY

13. What are the reasons you do not report ADRs to Health Canada?
 - Do you not believe there is a benefit?
 - Time consuming? If so, how much time would you be willing to spend reporting ADRs?
 - Is the process unclear?
 - Are you unsure of the information that should be reported? In your opinion, what criteria should be used to determine whether an ADR should be reported?
14. Assuming that you do report ADRs to Health Canada, what would be your preferred way of doing so (e.g. online, telephone, etc.), and why?
15. What could Health Canada do to encourage health professionals to report ADRs?

16. What would motivate you to start reporting ADRs in the future?

Conclusion

17. What is the best way of communicate information to health professionals regarding adverse reactions?

18. Do you have any final comments or suggestions that you feel would increase the number of medical professionals that report adverse reactions?

Thank and end interview