Reporting vaccine-associated adverse events

Are family physicians aware of criteria and procedures?

Philippe Duclos, DVM, PHD Jamie Hockin, MD Robert Pless, MD Beth Lawlor, MD

ABSTRACT

OBJECTIVE To determine family physicians' awareness of the need to monitor and report vaccine-associated adverse events (VAAE) in Canada and to identify mechanisms that could facilitate reporting.

DESIGN Mailed survey.

SETTING Canadian family practices.

PARTICIPANTS Random sample of 747 family physicians. Overall response rate was 32% (226 of 717 eligible physicians).

MAIN OUTCOME MEASURES Access to education on VAAE; knowledge about VAAE monitoring systems, reporting criteria, and reporting forms; method of reporting VAAEs and reasons for not reporting them; and current experience with VAAEs.

RESULTS Of 226 respondents, 55% reported observing VAAEs, and 42% reported the event. Fewer than 50% were aware of a monitoring system for VAAE, and only 39% had had VAAE-related education during medical training. Only 28% knew the reporting criteria. Reporting was significantly associated with knowledge of VAAE monitoring systems and reporting criteria ($P < 0.01$).

CONCLUSION Physicians need more feedback and education on VAAE reporting and more information about the importance of reporting and about reporting criteria and methods.

RÉSUMÉ

OBJECTIF Déterminer le niveau de sensibilisation des médecins de famille face au besoin de pharmacovigilance et de déclaration des effets secondaires associés aux vaccins (ESAV) au Canada et identifier les mécanismes qui pourraient faciliter la déclaration.

CONCEPTION Sondage postal.

CONTEXTE Pratiques familiales canadiennes.

PARTICIPANTS Échantillon aléatoire de 747 médecins de famille. Le taux global de réponses fut de 32 % (226 des 717 médecins admissibles).

PRINCIPALES MESURES DES RÉSULTATS Accès à la formation sur les ESAV, connaissances des systèmes de pharmacovigilance des ESAV, critères de déclaration, formules de déclaration, méthodes de déclaration des ESAV, raisons de ne pas les déclarer et expérience actuelle avec les ESAV.

RÉSULTATS Des 226 répondants, 55 % disent avoir observé des ESAV et 42 % ont déclaré des incidents. Moins de 50 % étaient au courant d'un système de pharmacovigilance des ESAV et seulement 39 % avaient reçu une formation reliée aux ESAV pendant leur formation médicale. Seulement 28 % connaissaient les critères de déclaration. On a constaté que le niveau de déclaration était significativement associé au niveau de connaissance des systèmes de pharmacovigilance des ESAV et des critères de déclaration ($p < 0,01$).

CONCLUSIONS Les médecins ont besoin de formation et de feedback sur la déclaration des ESAV et d'être mieux renseignés sur l'importance de la déclaration et sur les critères et les méthodes de déclaration.

This article has been peer reviewed.
Can Fam Physician 1997;43:1551-1560.

← FOR PRESCRIBING INFORMATION SEE PAGE 1664

Drugs and vaccines approved for marketing in Canada have their safety and efficacy demonstrated in clinical trials and sometimes through experience in other countries. No product is completely safe, however, and unexpected adverse events do occur. With biological products, any new batch might not perform as previous batches have. Adverse events are often impossible to predict, but physicians should monitor for them.

The cornerstone of national postmarketing surveillance programs of licensed drugs and vaccines is voluntary reporting of adverse events that health care providers think might be due to administration of a drug. These reports are sent either to manufacturers (who must pass them on as directed by regulation) or directly to the national drug regulatory authority or other responsible agency.

Vaccine-associated adverse events (VAAE) generally are reported through well established provincial public health networks. Public health authorities are then kept informed of the performance of vaccines used in universal immunization programs and can provide feedback to vaccinators if required. Reports are simultaneously forwarded to the Division of Immunization at Health Canada's Laboratory Centre for Disease Control (LCDC) in Ottawa for aggregation and analysis.

Data from these reports become our first line of defence to ensure ongoing vaccine safety. Increasingly, the public and the media are questioning vaccine safety and are demanding not only safer products but also assurance that systems for detecting problems in a timely way are in place and functioning well. Although reporting VAAEs is mandatory only in Ontario, some people are calling for change in other provinces. It is important to remember that fear of VAAEs can affect the success of immunization programs.[1] Early detection of problems should counteract negative effects on health and immunization programs.

One important limitation of surveillance that relies on reporting is underreporting. In Canada, reporting rates vary among jurisdictions from one to nearly

Dr Duclos *is Chief of and* **Dr Pless** *is responsible for the vaccine-associated adverse events surveillance system in the Division of Immunization, Bureau of Infectious Diseases, at Health Canada's Laboratory Centre for Disease Control (LCDC) in Ottawa.* **Dr Hockin** *is an epidemiologist responsible for the Field Epidemiology Training Program at LCDC.* **Dr Lawlor** *practises in the Department of Pathology and Laboratory Medicine at the British Columbia Children's Hospital in Vancouver.*

Reporting and surveillance of adverse events temporally associated with vaccine administration in Canada

Robert Pless, MD

The vaccine-associated adverse events (VAAE) surveillance system was developed to maintain public confidence in vaccines and immunization programs. The system aims to identify uncommon illnesses that could be caused by vaccines, to monitor for unusually high rates of adverse events both with individual vaccines and individual lots of vaccine, to provide timely information for potential recipients and health care providers so they can weigh the risks and benefits of immunization, and to identify areas that require further epidemiologic investigation and research and problems that require immediate investigation.

The cornerstone of surveillance activities is having health care providers (mainly public health nurses and physicians) voluntarily report to local, provincial, and territorial public health authorities events they think are associated temporally with immunization. Health authorities, and to some extent vaccine manufacturers, forward all such reports to the Division of Immunization in the Bureau of Infectious Diseases at Health Canada's Laboratory Centre for Disease Control (LCDC).[1,2] Adverse events that have been cited in the literature are listed on a reporting form used (with modifications) by all provinces and territories. Health care providers also are asked to report other severe or unusual events they think might be due to administration of vaccines. The *Canadian Immunization Guide* provides information on adverse events that occur with specific immunizing agents.[3]

Epidemiologic and medical data from reports are entered into the database. To estimate rates of reported adverse events, the Division of Immunization obtains data from vaccine manufacturers on the number of doses of their products distributed across the country (an approximation of the actual number of doses of vaccine administered). Because of varying reporting practices, differences in lot-specific adverse event rates require cautious interpretation.

In addition to the case-reporting system, Canada also has an active surveillance system for serious events, vaccination failures, and certain infectious diseases, known as IMPACT (Immunization Monitoring Program ACTive).[4] The system is operated through a contract with the Canadian Paediatric Society and involves a network of 11 pediatric centres across Canada comprising more than 2000 beds and more than 85000 children admitted annually—more than 80% of all pediatric tertiary care admissions in the country. At each centre a nurse-monitor and clinical investigator do active casefinding based on a daily review of admission records. They are assisted by a network that includes admitting department staff, infection control nurses, neurology ward staff and physicians, infectious

Continued on page 1555

Newly revised form (front): *Local health departments can offer detailed instructions on how to report adverse events.*

Health Canada / Santé Canada

REPORT OF A VACCINE-ASSOCIATED ADVERSE EVENT

Protected when completed

In confidence to: Division of Immunization
L.C.D.C., Tunney's Pasture 0603E1
Ottawa, Ontario K1A 0L2
(613) 957-1340 1-800-363-6456 FAX (613) 998-6413

IDENTIFICATION

PATIENT IDENTIFIER	PROVINCE/TERRITORY	DATE OF BIRTH YEAR MONTH DAY	SEX ☐ Male ☐ Female	DATE OF VACCINE ADMINISTRATION YEAR MONTH DAY

VACCINES

VACCINE(S) GIVEN	NUMBER IN SERIES	SITE	ROUTE	DOSAGE	MANUFACTURER	LOT NUMBER

ADVERSE EVENT(S) *Events marked with an asterisk (*) must be diagnosed by a physician.* Report only events which cannot be attributed to co-existing conditions. Additional information for all events should be provided under SUPPLEMENTARY INFORMATION on reverse side. Record interval between vaccine administration and onset of each event in minutes, hours or days.

LOCAL REACTION AT INJECTION SITE

☐ **INFECTED ABSCESS** (tick one or both of the options below) — MIN. HOURS DAYS
(i) positive gram stain or culture ☐
(ii) existence of purulent discharge with inflammatory signs ☐

☐ **STERILE ABSCESS/NODULE** — MIN. HOURS DAYS
No evidence of acute microbiological infection

☐ **SEVERE PAIN AND/OR SEVERE SWELLING** (tick one or both of the options below) — MIN. HOURS DAYS
(i) lasting 4 days or more ☐
(ii) extending past nearest joint(s) ☐

☐ **SCREAMING EPISODE/PERSISTENT CRYING** — MIN. HOURS DAYS
Inconsolable for 3 hours or more; OR quality of cry definitely abnormal for child and not previously heard by parents

☐ **FEVER** — MIN. HOURS DAYS
Highest recorded temperature (Report only **39.0°C** (102.2° F) or above)
Temperature: _____ °C (or _____ °F)
Site: rectal ☐ oral ☐ axilla ☐ skin ☐ tympanic ☐
Temperature believed to be high but not recorded ☐
Should be supported by the presence of other systemic symptoms

☐ **ADENOPATHY** (tick one or both of the options below) — MIN. HOURS DAYS
(i) enlarged lymph node(s) ☐
(ii) drainage of lymph node(s) ☐
Site(s) _____

☐ **PAROTITIS** — MIN. HOURS DAYS
Swelling with pain and/or tenderness of parotid gland(s)

*☐ **ANAPHYLAXIS OR SEVERE SHOCK** — MIN. HOURS DAYS
Explosive, occurring within minutes after immunization, and evolving rapidly towards cardiovascular collapse AND requiring resuscitative therapy

☐ **OTHER ALLERGIC REACTIONS** (tick one or more of the options below) — MIN. HOURS DAYS
(i) wheezing or shortness of breath due to bronchospasm ☐
(ii) swelling of mouth or throat ☐
(iii) skin manifestations (e.g., hives, eczema, pruritus) ☐
(iv) facial or generalized edema ☐

☐ **RASHES** (other than hives) — MIN. HOURS DAYS
Lasting 4 days or more AND/OR requiring hospitalization
Generalized ☐ Localized (indicate site) ☐ _____
Specify characteristics of rash _____

☐ **ARTHRALGIA/ARTHRITIS** — MIN. HOURS DAYS
Joint pain/inflammation lasting at least 24 hours
If condition is an acute exacerbation of a pre-existing diagnosis, give details under **Supplementary Information**

☐ **SEVERE VOMITING AND/OR DIARRHEA** — MIN. HOURS DAYS
Must be severe enough to interfere with daily routine

☐ **HYPOTONIC-HYPORESPONSIVE EPISODE** (in children < 2 yrs, only) — MIN. HOURS DAYS
Characterised by all the features of: (i) generalized decrease/loss of muscle tone; AND (ii) pallor or cyanosis; AND (iii) decreased level of awareness or loss of consciousness
Should not be mistaken for fainting, a post-convulsion state, or anaphylaxis

☐ **CONVULSION/SEIZURE** — MIN. HOURS DAYS
Febrile ☐ Afebrile ☐
Past history of: A) Febrile seizures Yes ☐ No ☐
B) Afebrile seizures Yes ☐ No ☐
Omit fainting, seizures occurring within 30 minutes of immunization, and seizures occurring as part of encephalopathy or meningitis/encephalitis

*☐ **ENCEPHALOPATHY** — MIN. HOURS DAYS
Acute onset of major neurological illness characterized by any two or more of: (i) seizures; (ii) distinct change in level of consciousness or mental status (behaviour and/or personality) lasting 24 hours or more; (iii) focal neurological signs which persist for more than 24 hours

*☐ **MENINGITIS AND/OR ENCEPHALITIS** — MIN. HOURS DAYS
Abnormal CSF findings AND an acute onset of: (i) fever with neck stiffness or positive meningeal signs; OR (ii) signs and symptoms of encephalopathy (see ENCEPHALOPATHY above)
Results of CSF examination should be provided under **Supplementary Information**

*☐ **ANAESTHESIA/PARAESTHESIA** — MIN. HOURS DAYS
Lasting over 24 hours
Generalized ☐ Localized (indicate site) ☐ _____

*☐ **GUILLAIN-BARRÉ SYNDROME** — MIN. HOURS DAYS
Progressive subacute weakness of more than one limb (typically symmetrical) with **hyporeflexia/areflexia**

*☐ **PARALYSIS** (Do not code if Guillain-Barré Syndrome is coded) — MIN. HOURS DAYS
Limb paralysis ☐ Facial or cranial paralysis ☐
Describe _____

*☐ **THROMBOCYTOPENIA** — MIN. HOURS DAYS
Give lab results under **Supplementary Information**

☐ **OTHER SEVERE OR UNUSUAL EVENTS** — MIN. HOURS DAYS
Include any adverse event believed to be related to immunization, that does not fit any of the categories listed above and for which no other cause is clearly established
Report events of clinical interest which require medical attention, and particularly events that are (i) fatal, (ii) life-threatening, (iii) require hospitalization, or (iv) result in residual disability

DESCRIPTION

REPORTER'S NAME	TELEPHONE NUMBER ( )	ADDRESS (Institution/No., Street, etc.)
PROFESSIONAL STATUS: MD ☐ RN ☐ OTHER _____		
SIGNATURE DATE Year Month Day		City Province Postal Code

HC/SC 4229 (03-96) - 1

Canada

Newly revised form (back)

OUTCOME OF EVENT(S) AT TIME OF REPORT PLEASE FORWARD ANY FOLLOW UP INFORMATION	FULLY RECOVERED ☐	RESIDUAL EFFECTS (describe) ☐	FATAL ☐	LOST TO FOLLOW-UP ☐	PENDING ☐	
SOUGHT MEDICAL ATTENTION (Emergency room, clinic, family physician etc.)	NO ☐	YES ☐	(If yes, include relevant details of treatment under **Supplementary Information**)			
HOSPITALIZED BECAUSE OF EVENT(S)	NO ☐	YES ☐	**LENGTH OF STAY** (DAYS)		**DATE ADMITTED**	Year Month Day
CONCOMITANT MEDICATIONS (exclude those used to treat the adverse event) DRUG(S) GIVEN			**MEDICAL HISTORY** Please provide information on relevant medical history or concurrent illness (See detailed instructions on reverse)			

SUPPLEMENTARY INFORMATION

INSTRUCTIONS FOR COMPLETING REPORT OF A VACCINE-ASSOCIATED ADVERSE EVENT

1. Please use dark ink when completing form to improve legibility of copies.
2. Report only events which have a temporal association with a vaccine and which cannot be attributed to co-existing conditions. **A causal relationship does not need to be proven, and submitting a report does not imply causality.**
3. Events marked with an asterisk (*) must be diagnosed by a physician. Supply relevant details in the SUPPLEMENTARY INFORMATION box.
4. Record interval between vaccine administration and onset of each event in minutes, hours or days.
5. Provide relevant information, when appropriate, in the SUPPLEMENTARY INFORMATION box. Includes details of events diagnosed by physician (see 3 above), results of diagnostic or laboratory tests, hospital treatment, and discharge diagnoses where a vaccinee is hospitalised because of a vaccine-associated adverse event. If appropriate, and preferred, photocopies of original records may be submitted.
6. Provide details of medical history that are relevant to the adverse event(s) reported. Examples include a history of allergies in vaccinee, previous adverse event(s), and concurrent illnesses which may be associated with the current adverse event(s).

TO BE COMPLETED BY MEDICAL HEALTH OFFICER RECOMMENDATIONS FOR FURTHER IMMUNIZATION		
NAME: _____ PHONE: _____	**SIGNATURE**	**DATE** Year Month Day

continued from page 1552

diseases staff, and medical records technicians. The IMPACT system was set up to enhance VAAE surveillance, particularly for children's most serious reactions.

Other organizations

In addition, an external multidisciplinary advisory committee assists with evaluation of all cases involving serious events and helps identify signals for in-depth investigation.[5] The LCDC is also a contributor to the World Health Organization's International Drug Monitoring Program and is a reference centre for vaccine-related events. The WHO program aggregates case reports from more than 43 countries and is uniquely placed to analyze worldwide adverse reaction data. Collaboration is also active on a technical level among many national and international agencies, in particular the Canadian Paediatric Society and public health authorities in all provinces and territories.

Although the Division of Immunization is available to respond to queries and concerns, since immunization programs are the responsibility of each province, local public health authorities should be contacted initially for information.

Guidelines for reporting adverse events

Timely reporting of vaccine-related events is crucial. All health care providers, whether they immunize or not, should be alert to the range of adverse events and their temporal relationship to vaccines. History taking, therefore, should elicit any recent vaccination received.

The form reproduced here is a newly revised version of the national VAAE reporting form. Provinces may have different versions, or may use this form with their own logos and addresses. It is important to contact local health departments to verify their method of reporting. Reporting instructions are on the form. Minor reactions are of interest if the reporter thinks they are occurring with unusual frequency. More serious reactions that are thought to be related to immunization are always of interest, especially if they are unexpected or thought to be extremely rare (such that the product monograph was not helpful in anticipating the reaction). Supporting information, such as case summaries or the results of laboratory tests, are always useful. This is especially true for reactions that might be reviewed by our advisory committee.

References

1. Division of Immunization. Vaccine-associated adverse events in Canada, 1992 report. *Can Commun Dis Rep* 1995;21(13):117-28.
2. Duclos P, Pless R, Koch J, Hardy M. Adverse events temporally associated with immunizing agents. *Can Fam Physician* 1993;39:1907-13.
3. National Advisory Committee on Immunization. *Canadian immunization guide.* 4th ed. Ottawa: Canadian Medical Association; 1993.
4. Morris R, Halperin S, Dery P, Mills E, Lebel M, MacDonald N, et al. IMPACT monitoring network: a better mousetrap. *Can J Infect Dis* 1993;4:194-5.
5. Pless R, Duclos P, Advisory Committee on Causality Assessment. Reinforcing surveillance for vaccine-associated adverse events: the Advisory Committee on Causality Assessment. *Can J Infect Dis* 1996;7(2):98-9.

100 per 100 000 doses distributed.[2] Reporting appears better in provinces where vaccination programs are delivered mostly through public health clinics. In provinces with private and public health delivery, most reports emanate from public clinics. Physicians have many reasons for not reporting or being reluctant to report VAAEs.[3-9] We believe, however, that no other study in Canada has described why physicians do and do not report VAAEs. This survey sought to determine how aware family physicians were of how and when to report VAAEs and to better understand why physicians do or do not report them, with the aim of implementing activities or structures to facilitate reporting.

METHODS

We surveyed by mail a simple random sample of 747 physicians selected from a complete list of family physicians currently in practice across Canada (from the Southam–Canadian Medical Association master file). We needed a sample size that allowed us to be 95% confident that estimates of proportions would not differ from true proportions by more than 5 percentage points. We assumed some proportions would be about 0.5 and that the response rate would be about 50%. The questionnaire was pilot tested and distributed in both English and French. It requested information to validate the eligibility of study participants (current clinical activity, occupation, and care provided to immunized patients whether currently providing immunization or not). Other questions asked about physicians' province of practice; observation of VAAEs; education about VAAEs; knowledge of VAAE monitoring systems, reporting criteria, and forms; perception of the obligation to report VAAEs; current experience and procedures for reporting VAAEs; and what procedures might make reporting easier for them. They were also asked for comments. Data on current hospital-related work and university and year of graduation were abstracted from the 1993 *Canadian Medical Directory.*

Analysis was performed using Epi Info (version 6.0). Uncorrected χ^2 values were used to test for statistical significance of the difference between two proportions. We calculated 95% confidence limits for proportions by the exact binomial method.

RESULTS

Of 747 questionnaires sent, 256 (34.3%) were returned completed; 30 were ineligible because the

Table 1. Family physicians sampled by province

PROVINCE	TOTAL NO. OF FAMILY PHYSICIANS	NO. SAMPLED	NO. OF RESPONDENTS	RESPONSE RATE %
Alberta	773	81	29	36
British Columbia	793	125	34	27
Ontario	2925	277	87	31
Quebec	1365	123	41	33
Others	841	141	35	25
TOTAL	6697	747	226	30

Table 2. Self-reported knowledge and practices of respondents (n = 226)

KNOWLEDGE AND PRACTICES	% (95% CI)
Access to VAAE education	
• Independent readings	42 (36-49)
• During medical training	39 (33-46)
• Meetings and conferences	30 (24-37)
• No VAAE education	24 (19-31)
Knowledge of VAAE monitoring systems	
• Aware of the provincial system	39 (33-46)
• Aware of the national system	10 (6-14)
• Aware of both	3 (1-6)
Knowledge of VAAE criteria and reporting form	
• Know formal reporting criteria	28 (23-35)
• Know reporting form	18 (13-23)
• Know both reporting criteria and form	14 (10-19)
Method of reporting VAAE (n = 52)	
• Telephone to local department of health	71 (57-83)
• Written report to local department of health with or without telephone report	19 (10-33)
• Telephone to provincial or other authorities	19 (10-33)
Reasons for not reporting (n = 172)	
• Had never observed a VAAE	52 (45-60)
• Did not know reporting was expected	16 (11-22)
• Event did not seem serious enough	14 (9-20)
• Did not know reporting procedure	10 (6-15)
• Did not know whether they had seen a VAAE or not	2 (0.4-5)
• Did not think reporting was crucial	1 (0.1-4)
• Thought reporting procedure was too tedious	0.6(0.1-3)
• No reason specified	5 (2-10)

physicians were not seeing immunized patients (27 were in a subspeciality not pertinent to this survey and three had retired). Overall response rate was 32% (226 out of 717 eligible).

Of the 226 eligible physicians, 80% had acquired their medical degrees from Canadian schools (median year of graduation was 1977, range 1938 to 1991), 79% administered vaccines, and 43% were certificants of the College of Family Physicians of Canada. **Table 1** shows the provincial distribution of eligible respondents compared with the total number of practising physicians. Asked whether they had ever observed a VAAE, 55% said yes (95% CI 49 to 62): 42% of them reported the event. Overall, 23% indicated ever reporting VAAEs (95% CI 18 to 29): 24% in Alberta (95% CI 10 to 44), 32% in British Columbia (95% CI 17 to 51), 21% in Ontario (95% CI 13 to 31), 18% in Quebec (95% CI 7 to 33), and 26% in the other provinces combined (95% CI 13 to 43).

Knowledge and reporting practices of respondents are shown in **Table 2**. **Table 3** presents associations between reporting practices and various characteristics of family physicians.

In Ontario, 36% of physicians thought reporting was mandatory, 11% thought it was not mandatory, and 52% did not know versus 27%, 22%, and 52%, respectively, for physicians outside Ontario. Among the 141 physicians who indicated observing VAAEs in the past, reporting was more frequent among those who thought reporting was mandatory (59%) than among those who thought reporting was not mandatory (32%) (P = 0.04) or who did not know whether reporting was mandatory or not (38%). Among other variables examined, only awareness of the VAAE reporting system and awareness of formal criteria for reporting had a statistically significant association with reporting if P=0.05 (**Table 3**). Results were similar when only those observing VAAEs were included in the analysis.

When asked which of the specified options would make reporting VAAEs easiest in their practices, 61% of responders indicated a 1-800 number for phoning in reports; 29% a 1-800 fax number; 39% information sheets; 27% self-addressed stamped envelopes; and 12% an improved form.

Twelve physicians volunteered the following comments on ways of making reporting easier; each comment was mentioned by one or two physicians: periodic feedback and didactic information, a comprehensive pamphlet for parents at the birth of their child, a pamphlet for immigrants at entry into Canada, guidelines for hospital emergency settings,

FOR PRESCRIBING INFORMATION SEE PAGE 1653 →

Table 3. Reporting practices and characteristics of respondents

CHARACTERISTICS	% REPORTING VAAES: RESPONDENTS WITH CHARACTERISTIC	% REPORTING VAAES: RESPONDENTS LACKING CHARACTERISTIC	P
Current CCFP certification (n = 98)	27	21	0.30
Hospital-based practice (n = 135)	27	17	0.09
Current immunization provider (n = 177)	22	29	0.27
Had VAAE-specific education (n = 167)	25	16	0.21
Aware of VAAE monitoring systems (n = 113)	35	11	0.00003
Aware of formal VAAE reporting criteria (n = 63)	35	19	0.009
Aware of forms for reporting VAAE (n = 40)	33	21	0.12
Knew reporting was mandatory (n = 69)	25	22	0.8

prompt communication when changes in VAAE reporting procedures or forms occur, access to the Internet for reporting, and payment of a fee for reporting.

DISCUSSION

Results of this survey must be interpreted with caution due to the low response rate. Although such a response rate is not unusual for mailed surveys, reminders, such as those proposed by Dillman,[10] would likely have increased it. Nevertheless, this study provided valuable lessons for the future direction of our efforts in monitoring VAAEs. Several interpretations of the data are possible. Perhaps those who did respond are the most sensitized to, and concerned with, vaccine safety. If this is so, our results actually overestimate physicians' awareness of the necessity to report VAAEs. The low response rate, however, might indicate that physicians have little interest in surveillance of VAAEs. We hope this is not true.

Results do suggest, in any case, a low level of perceived awareness and knowledge about reporting VAAEs. Only 50% of the physicians were aware of a monitoring system. Clearly, we should improve our feedback and education efforts and work with medical schools to teach VAAE monitoring better. A previous survey on reporting adverse events to drugs showed that the most effective interventions for improving reporting were feedback, presentations at hospital rounds and continuing medical education events, and a newsletter.[6]

The most frequently cited reasons[3-5,7,11] for not reporting VAAEs were:

- lack of understanding of the objectives and mechanisms for reporting and lack of reporting forms;
- lack of time or loss of time required to report;
- uncertainty about causality between vaccine and event;
- perception that minor, common, or well-known events are not worth reporting;
- fear of litigation;
- feeling guilty about the reaction; and
- perception that reports are merely filed away somewhere.

The apparent importance of each of these factors has varied from one study to another.

As in other studies, the wording of our questions might have limited the range of reasons physicians gave for not reporting VAAEs. It is likely, however, that an important common barrier would have been detected through the open question that asked for reasons other than the ones listed on the form. It appears, nevertheless, that the main reason for not reporting was that a respondent genuinely thought he or she had never observed a VAAE. To a lesser extent, physicians reported that events observed did not seem serious enough, that reporting was not expected, or that they did not know the reporting procedure. It is gratifying at least that only one respondent indicated that reporting was too tedious. In our study, the only two factors significantly associated with a higher reporting rate were awareness

← FOR PRESCRIBING INFORMATION SEE PAGE 1670

of a monitoring system and knowledge of reporting criteria. The latter undoubtedly will help define what an adverse event is. Perception that reporting was mandatory did not seem to be much of an incentive to report.

About half the physicians who wrote comments requested periodic feedback and didactic information. Several items were identified: a comprehensive pamphlet for new parents, a pamphlet for immigrants at entry into Canada, guidelines for hospital emergency rooms, and prompt communication of changes in VAAE procedures or forms. Our study clearly indicated a need for more communication and feedback to practitioners. It is worth mentioning that, although Alberta has consistently had the highest reporting rates for VAAEs, routine vaccines are administered almost exclusively by public health nurses and reporting is done mainly by these same nurses through the public health system. The low reporting rates of Alberta family physicians might indicate that, although information is circulating within the public health network, it is not reaching private physicians.

The first step in reporting a VAAE is to identify that the problem is worth monitoring. We noted that a large part of the problem is identifying something worth reporting. Our survey was not designed to determine the sensitivity or specificity of recognizing a VAAE, but efforts to improve reporting must take this into consideration.

CONCLUSION

Our sample of family physicians across the country had a low rate of reporting VAAEs. The main reasons cited were that physicians did not believe they actually had seen a VAAE, that the event was too trivial to be reported, and that they did not know reporting was expected.

Postmarketing surveillance of VAAEs is an integral part of immunization programs and plays an important role in ensuring continued public confidence in those programs. It is of the utmost importance that all countries have independent governmental surveillance programs. Although the efficiency of such programs depends on the will and conscience of health professionals in the field, we at the Bureau of Infectious Diseases must play our part and provide feedback and demonstrate the value of physicians' efforts in reporting, efforts that contribute not only to maintaining vaccine safety but to the public's confidence in immunization programs.

Correspondence to: *Dr P. Duclos, Division of Immunization, Bureau of Infectious Diseases, Laboratory Centre for Disease Control, Health Canada, Ottawa, ON K1A 0L2*

References

1. Duclos P, Bentsi-Enchill A. Current thoughts on the risks and benefits of immunization. *Drug Safety* 1993;8:404-13.
2. Duclos P, Pless R, Koch J, Hardy M. Adverse events temporally associated with immunizing agents. *Can Fam Physician* 1993;39:1907-13.
3. Scott HD, Rosenbaum S, Waters WJ, Colt AM, Andrews LG, Juergens JP, et al. Rhode Island physicians' recognition and reporting of adverse drug reactions. *R I Med J* 1987;70:311-6.
4. Milstien JB, Faich GA, Hsu JP, Knapp DE, Baum C, Dreis MW. Factors affecting physician reporting of adverse drug reactions. *Drug Inf J* 1986;20:157-64.
5. Rogers AS, Israel E, Smith CR, Levine D, McBean AM, Valente C, et al. Physician knowledge, attitudes, and behavior related to reporting adverse drug events. *Arch Intern Med* 1988;148:1596-600.
6. Rosenbaum SE, Thacher-Renshaw A, Green M, Waters WJ. Interventions to increase physician participation in a voluntary reporting system. *Clin Res Regul Affairs* 1992;9:261-75.
7. Belton KJ, Lewis SC, Payne S, Rawlins MD, Wood SM. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. *Br J Clin Pharmacol* 1995;39:223-6.
8. Scott HD, Thacher-Renshaw A, Rosenbaum SE, Waters WJ, Green M, Andrews LG, et al. Physician reporting of adverse drug reactions: results of the Rhode Island Adverse Drug Reaction Reporting Project. *JAMA* 1990;263:1785-8.
9. Wallace SM, Suveges LG, Gesy KF. Adverse drug reaction reporting. Part I. A survey of pharmacists and physicians in Saskatchewan. *Drug Inf J* 1995;29:571-9.
10. Dillman A. *Mail and telephone surveys: the total design method.* New York: John Wiley and Sons; 1978.
11. Duclos P. La surveillance des effets secondaires des vaccins après leur commercialisation. *Rev Epidémiol Santé Publique* 1994;42:425-33.

...

FOR PRESCRIBING INFORMATION SEE PAGE 1665 ➔