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Reporting of Adverse Drug Reactions by Poison Control Centres in the US

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Abstract

Background: Although US poison control centres manage approximately 30 000 adverse drug reactions each year, the extent of voluntary reporting of these events to the US Food and Drug Administration (FDA) MedWatch spontaneous surveillance programme is unknown.

Methods: A survey was mailed to directors of all 72 US poison control centres during April 1999 to determine their practices and opinions on reporting adverse drug reactions. The survey requested information on the poison control centre staff's practices in reporting adverse drug reactions to the FDA MedWatch programme during 1998.

Results: A total of 56 fully completed surveys were returned. Of the respondents, 30 had not directly submitted adverse drug reaction reports to the FDA, 22 had submitted 10 or less, and 4 had submitted a total of 47 during 1998. Reasons given for not routinely reporting adverse drug reactions included adverse drug reactions reporting is not part of the regular routine (20%), lack of time to complete forms (15%), inability to determine causality (13%), most reactions are already reported and not unique (10%), reporting to the FDA is too much work (9%), and responsibility rests with the attending physician (7%). Direct reporting to MedWatch of any cases of adverse drug reactions was more likely when the poison control centre was certified by the American Association of Poison Control Centers ($p < 0.05$; odds ratio = 5.1; 95% confidence interval 1.1 to 23.5); however, this practice was not associated with documenting deaths associated with adverse drug reactions, having more than 75% of the staff of the Poison Information Specialists composed of pharmacists or nurses, or managing greater than 20 000 or 34 000 human exposure cases during 1998. Approximately half of the poison control centres directly or indirectly reported some adverse drug reactions to the FDA by virtue of contacting the manufacturer or cooperating with postmarketing surveillance.

Conclusion: Poison control centres represent an underutilised source of reporting to MedWatch, but several internal and external obstacles limit the direct reporting of adverse drug reactions routinely.

During the last 3 decades, the problem of adverse drug reactions in the US has been characterised in hospitalised and outpatient populations. An 11% incidence of serious and nonserious adverse drug reactions has been estimated to occur in hospitalised patients with 0.3% of these patients experiencing fatal outcomes from adverse drug reactions. [1] During 1995, approximately 2 million physician office visits were attributed to adverse drug reactions. [2] The annual financial impact on healthcare

from adverse drug reactions has been estimated to cost US$77.6 billion in 1992. [3] Further, the problem of adverse drug reactions seems to be increasing with greater emphasis recently placed on detection and prevention. [4,5]

In the US, the Food and Drug Administration (FDA) conducts a postmarketing surveillance programme for medical products entitled MedWatch. [6] In this programme pharmaceutical manufacturers are required to report adverse drug reactions; in contrast, reporting is voluntary for healthcare professionals. The public may also submit reports. A suspicion of an adverse drug reaction is sufficient to trigger a report. Reporting by healthcare professionals has been estimated to be 1 to 6% of adverse drug reactions encountered in practice.[6-9] During 1996, MedWatch tabulated 159 504 adverse drug reactions with 91% of these reports originating from manufacturers.[10]

Poison control centres in the US are not part of the federal government and are associated through participation in a national organisation, the American Association of Poison Control Centers (AAPCC),[11] and contribution of case data to the Association's Toxic Exposure Surveillance System (TESS).[12] Since its inception in 1983 to 1998, TESS has accumulated a total of 24 803 585 human poisoning cases. During 1998, 65 reporting centres documented 2 241 082 human poison exposures in TESS with 31 601 of these exposures attributed to adverse drug reactions.[13] Although these cases of adverse drug reactions were reported to TESS, the extent of voluntary reporting of these adverse drug reactions by poison control centres to MedWatch is unknown. The purpose of this report is to survey US poison control centres on their practices for reporting adverse drug reactions to MedWatch and to determine characteristics associated with reporting cases of adverse drug reactions.

Methods

A survey was mailed to the directors of all poison control centres in the US during April 1999 based on the 1998 directory of the AAPCC.[11] The structured and open-ended survey requested information on the poison control centre staff's practices in reporting adverse drug reactions to the FDA MedWatch programme during 1998. If no routine reporting of adverse drug reactions was noted, it also asked for the respondents' opinion on reasons for not reporting. Basic questions about the level of activity of the centre during 1998, participation in TESS, and certification status by AAPCC were also ascertained. An adverse drug reaction as described in TESS is defined as an unwanted effect with prescribed, labelled or recommended use of a drug product attributable to an allergic, hypersensitive, or idiosyncratic response to the active ingredient, inactive ingredient, or excipient. This category does not include drug interactions, overdoses, drug abuse or 'therapeutic errors'. An adverse drug reaction is 1 of 18 classifications poison control centre personnel can select in TESS to categorise the reason for contacting the poison control centre.

Recipients were asked to return the questionnaires by mail or fax and were advised that the aggregate results may be subsequently reported. A second survey was mailed to those who did not respond within 2 weeks of the original mailing. Follow-up telephone interviews were conducted or messages were sent via e-mail to clarify incomplete or unclear responses.

Returned surveys were assessed for completeness and tabulated in a computerised relational database. Surveys that had incomplete descriptions of the poison control centre's characteristics were not included in data analysis. Statistical analysis included the chi square test with Yates correction and estimates of Bayesian probability.[14] Significance was accepted at $p < 0.05$. The study protocol was approved by the University of Tennessee Institutional Review Board.

Results

Of the 72 poison control centres that were mailed a survey, 61 were returned and 56 were complete or acceptable for analysis. One centre was no longer operational and 4 centres returned incomplete responses stating that information on cases during 1998 could not be provided. The most frequent respondent was the managing director (n = 47) with

reports also submitted by medical directors who also serve as managing director (n = 4), a medical director (n = 1) or others at the poison control centre (n = 4).

Only 1 poison control centre director reported that all adverse drug reactions are routinely reported to the FDA, but none were encountered during 1998. The remaining 98% of the respondents indicated that their practice was not to report all adverse drug reactions to MedWatch routinely. One director indicated that he or she did not recognise the name of the FDA MedWatch programme, and 12 respondents recognised the name but had no familiarity with report submission procedures.

In response to a question on the number of adverse drug reaction reports the poison control centre directly submitted to the FDA, 30 indicated none, 22 reported 10 or less and 4 reported greater than 10. For those reporting greater than 10, the total numbered 47 cases.

In response to a question of how many adverse drug reaction reports were indirectly submitted to the FDA as a consequence of the poison control centre contacting a drug manufacturer, 29 indicated none, 23 reported 10 or less and 3 reported greater than 10 and 1 did not respond. For those reporting greater than 10, the total numbered 130 cases.

In response to a question of how many adverse drug reaction reports were indirectly submitted to the FDA by virtue of the poison control centre contracting with a drug manufacturer to collect post-marketing drug surveillance reports, 45 indicated none, 6 reported 10 or less and 5 reported greater than 10. For those reporting greater than 10, the total numbered 545 cases. The indirect reporting practices assumed that the manufacturer would submit any applicable adverse drug reaction reports to the FDA.

For the 49 poison control centres that participated in TESS, respondents indicated that a total of 27 098 cases of adverse drug reactions were submitted to TESS out of 2 053 286 total cases of all types. Based on the practices of these 49 centres, the maximum number of cases of adverse drug reactions reported to MedWatch by direct or indirect reporting mechanisms is approximately 1232 which represents 5% of the cases reported to TESS. The maximum number of direct reports to the FDA was approximately 267 which represents 1% of the cases reported to TESS.

Table I. Characteristics of poison control centres and direct reporting of adverse drug reactions (ADRs) to the US Food and Drug Administration MedWatch spontaneous surveillance programme

Characteristics of poison control centre during 1998	Number	Percentage reporting
AAPCC certified centre	41	56[a]
Not AAPCC certified centre	15	20[a]
>75% of staff as pharmacists	15	63
<75% of staff as pharmacists	41	44
>75% of staff as nurses	31	48
<75% of staff as nurses	25	52
ADR-related deaths submitted to TESS	18	61
No ADR-related deaths submitted to TESS	31	45
Human poisoning exposures >20 000	39	49
Human poisoning exposures <20 000	10	60
Human poisoning exposures >34 000	26	46
Human poisoning exposures <34 000	23	57

a $p < 0.05$; others are not significant.

AAPCC = American Association of Poison Control Centers; **TESS** = Toxic Exposure Surveillance System.

Direct reporting of an adverse drug reaction to MedWatch was more likely when the poison control centre was certified by AAPCC ($p < 0.05$; odds ratio = 5.1; 95% confidence interval 1.1 to 23.5). The practice of direct reporting was not associated with documenting deaths associated with adverse drug reactions in TESS, having more than 75% of the staff full-time equivalents of the Poison Information Specialists composed of pharmacists, having more than 75% of the staff of the Poison Information Specialists composed of nurses, or managing greater than 20 000 or 34 000 human exposure cases in 1998 (table I).

The most common reasons cited by the respondents for not directly reporting cases of adverse drug reactions to MedWatch included that it was not part of the regular routine, there was a lack of time to complete the reporting forms, and there was an inability to determine the cause of the adverse drug reaction. Several other reasons were also cited (ta-

Table II. Reasons given by directors of poison control centres for not directly reporting adverse drug reactions (ADRs) to the US Food and Drug Administration MedWatch spontaneous surveillance programme

Reason for not reporting to MedWatch	Percentage of responses[a]
Not part of the regular routine	20
Lack of time to complete forms	15
Inability to determine cause of the ADR	13
Cases are not unique, most reactions have already been reported	10
Reporting to MedWatch is too much work	9
Unaware of the type of ADRs to report	7
Responsibility resides with the physician, not poison control centre	7
Never seriously considered reporting before	7
Unaware of reporting procedures and process	5
Only serious or unusual cases are reported	3
Reporting forms are unavailable or difficult to obtain	2
Fear of litigation	1

a Percentage of 187 responses; respondents could have cited several reasons.

ble II). In response to open-ended questions, several respondents cited the personnel costs associated with reporting adverse drug reactions and that this expense should be reimbursed by the FDA. Others indicated that the FDA could purchase the information reported to TESS from the AAPCC and thereby tabulate the cases reported to poison control centres.

Discussion

In this survey of US poison control centres, approximately 50% of the 56 responding centres reported at least 1 adverse drug reaction directly or indirectly to MedWatch during 1998. During this period, 49 of these poison control centres internally documented 27 098 cases of adverse drug reactions, but at most only 1% were directly reported to MedWatch. This extent of reporting is consistent with the rate reported for other healthcare professionals.[6-9] Many of the reasons cited by poison control centre managers emanate from the absence of the culture, time and personnel to report these events to MedWatch. Many of these same reasons have also been reported for other healthcare professionals (table III).[6-9,15,16] Several of the earlier reports[6,15,16] referred to the spontaneous reporting system that was the predecessor of FDA MedWatch, but many of the same reasons, such as not being a routine part of practice, lack of time, and inability to determine causality, apparently persist with MedWatch as reported in this survey and by others.[8]

One of the features envisioned for TESS is to provide a means to perform postmarketing surveillance of newly introduced drugs.[12,17] A shortcoming exhibited by TESS, and any voluntary spontaneous reporting system, involves the inability to determine the true incidence of a reaction since the total number of people exposed to an agent, i.e. the population at risk or the denominator, is not known.[17,18] Spontaneous reporting systems can provide information on the types of problems that occur, identify risk factors, and serve as an 'alerting system' to identify potentially new adverse reactions.[17]

Table III. Reasons given by US healthcare professionals for not spontaneously reporting adverse drug reactions (ADRs) in alphabetical order

Reason for not reporting ADRs	Reference
Ambition to publish a case series	15
Drug-induced disease not considered in diagnosis	6
Fear of litigation or disciplinary action	7, 8, 9, 15
Forms are not available	8, 9
Forms are too much trouble	9
Guilty feelings about patient harm	15
Ignorance about value of reporting	7, 15
Inability to determine causality	8, 15
Indifference to contributing to body of knowledge	15
No professional obligation to report; responsibility of someone else	8, 9
Not important to report	9
Not part of routine or professional culture to report	6, 8, 9
Only safe drugs are approved for marketing	15
Reaction was expected and already reported	8, 9
Reaction was minor	8, 9
Reluctance by nonphysician to report an incident involving a physician	15
Reluctance to interact with a governmental agency	9
Reporting method not easy	9
Too much time required to report	7, 9
Unfamiliar with reporting procedures	6, 7, 8, 9, 15, 16

Table IV. Examples of published adverse drug reactions reporting efforts of US poison control centres

Problem examined by poison control centres[a]	Time span	Number of cases	Reference
β-Blockers: comparative toxicity of agents with characterisation of more dangerous agents (1995)	11 years	52 156	19
Childhood poisoning: hazard analysis to characterise the most dangerous agents (1989)	5 years	3 810 405	20
Cimetidine: clinical features of toxicity (1985)	5 years	881	21
Poisoning in the elderly: characterisation of products and circumstances (1997)	5 years	322 423	22
Gamma-hydroxybutyrate: multistate outbreak of sentinel cases of poisoning and adverse events (1990)	6 months	57	23
Iatrogenic poisoning fatalities: characterisation of drugs and types of errors (1997)	13 years	41	24
Loperamide: characterisation of the clinical features of poisoning and overdose cases (1993)	5.3 years	216	25
Medication errors: relationship of dosing errors from dosing cups and paediatric poisoning (1991)	8 days	34	26
Methylphenidate: characterisation of the clinical features of toxicity in adults and children (1997)	5 years	18 151	27
Nicotine transdermal patches: characterisation of the clinical features of self-poisoning of adults (1994)	2 years	9	28
Nicotine transdermal patches: characterisation of the clinical features of childhood poisoning (1994)	2 years	36	29
Polysaccharide iron: characterisation of human toxicity (1998)	9 years	810	30
Quetiapine: characterisation of the clinical features of poisoning and adverse events (1998)	1.5 years	871	31

a Year or last year of study in parentheses.

In several longitudinal and short term studies, the TESS programme has been used to describe risk factors, characterise adverse events, and identify sentinel events (table IV) involving drug products.[19-31] Detection of sentinel toxic events, such as those involving gamma-hydroxybutyrate[23] and an aerosol leather conditioner,[32] suggests a powerful and perhaps sensitive mechanism for safety surveillance. Although these reports are inherently valuable, the present survey indicates these findings are not routinely integrated in the larger body of adverse drug reactions compiled by the FDA.

One potential benefit of contributing to the larger body of adverse drug reactions is the integration of experiences with national efforts of the FDA and international surveillance programmes of the World Health Organization to which the FDA contributes data.[33] These efforts are increasingly reliant upon the submission of all suspected adverse drug reactions to form a baseline of events from which to detect signals.[34,35] The evolution of signal detection promises to provide a powerful complementary tool for pharmacovigilance that does not rely on determining absolute causality of individual cases.[35] With increasing numbers of similar observations of suspected events, the statistical likelihood of false positive events is lessened and the value of widespread spontaneous reporting of any suspected adverse event is thereby increased. The spontaneous nature of reporting to poison control centres has great promise to aid signal generation. In May 1999 the FDA released a task force report which describes several recommendations to improve postmarketing surveillance for adverse drug reactions that would place greater emphasis on use of signal detection in broad-based databases in addition to sentinel reporting sites and prospective product use registries.[36]

The electronic submission of adverse drug reactions reports by pharmaceutical manufacturers to the FDA is an active work-in-progress. Besides the obvious advantages of reducing paper transactions and speeding submission rates, there is hope for global electronic exchange of postmarketing safety data.[37] Logistical obstacles noted by poison control centre directors involve the time and resources needed to report suspected adverse drug reactions. The TESS report format used by poison control

centres could be modified to produce an electronic facsimile of the MedWatch report form in order to submit adverse drug reactions with greater efficiency. By 1998, 77% of US poison centres utilised an electronic case management system to submit data to TESS; this capability was anticipated to increase to 93% by 1999.[11] Further, there are plans to link US poison control centres through an electronic network. An electronically linked, dynamic surveillance system, such as TESS, could enhance the ability to detect sentinel events and characterise national trends at the time of case closure from reporting sites throughout the nation.

Poison control centres in the US can serve as valuable sources of adverse drug reaction reporting based, in part, on the following characteristics:[38]

- ready availability in the community for the public and health professionals;
- continuous telephone access 24 hours a day;
- staffing with specially trained pharmacists or nurses with ready access to physicians for back-up consultations;
- staff orientation in clinical toxicology and pharmacology;
- skills in history taking, risk assessment, referral and documentation;
- utilisation of computerised case management systems for record keeping, reporting and electronic data export.

In addition to improving the logistical obstacles to efficiently report adverse drug reactions, other approaches may also need to be considered. In addressing the general problem of errors in healthcare, the Institute of Medicine of the US National Academy of Sciences issued a report in November 1999 that suggested several recommendations to improve reporting of errors and adverse events by healthcare professionals.[39] These recommendations included policies and incentives to foster a culture of reporting adverse events such as creating a national centre to foster research and reporting of errors, encouraging voluntary efforts to report errors, creating a national reporting centre with mandated reports from hospitals, raising standards of oversight bodies, group purchasers and professional groups to expect safety protocols, identifying and implementing safe practices in the delivery of care, and passing legislation to extend peer review protection to data related to patient safety and quality improvement. Implementation of many of these principles may also improve the reporting of adverse drug reactions to poison control centres by healthcare professionals and the subsequent reporting to MedWatch by poison control centres.

Conclusion

Poison control centres in the US represent an underutilised potential reporting source of adverse drug reactions to MedWatch. Several internal and external obstacles limit direct reporting of adverse drug reactions to MedWatch. By overcoming barriers to direct reporting through awareness, technology and support, poison control centres may increase reporting to MedWatch that could aid the overall understanding of adverse drug reactions.

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