The WHO Programme for International Drug Monitoring, Its Database, and the Technical Support of the Uppsala Monitoring Center

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ABSTRACT. We describe the development of an international adverse reaction database. The operational responsibility for technical aspects of international drug monitoring are run by the Uppsala Monitoring Center (UMC). The system is based on interchange of adverse reaction information between national drug monitoring centers in 60 countries. Collectively these centers provide more than 150,000 individual reports annually of reactions suspected of being drug induced. The cumulative database constructed from these reports now comprises over 2 million records. Compatibility of different data collection systems that need to communicate with each other has been achieved through harmonization rather than standardization. The design of the new system was driven by the needs of existing and prospective users in terms of data fields and functionality. The data set required in the original WHO case reports form was the lowest common denominator consistent with being useful for signal generation and evaluation. The new database has an unlimited number of data fields. The WHO system relies on information being transferred, stored, and retrieved in a timely and secure way. Through the use of sophisticated exchange server technology, the Internet can be used as a transport medium for data and document transfer with guaranteed security and client authentication. (J Rheumatol 2001:28:1180–7)

Key Indexing Terms:
ADVERSE EVENTS
CLINICAL TRIALS
RHEUMATIC DISEASES
DRUG MONITORING

BACKGROUND

For over 30 years an international collaboration in monitoring adverse drug reactions, under the auspices of the World Health Organization (WHO), has been in operation. The program started in 1968 as a pilot project with the participation of 10 countries. The intent was to develop international collaboration to make it easier to detect adverse drug reactions not revealed during clinical trials. Some years later, the operational responsibility for technical aspects of the program and a WHO Collaborating Centre for International Drug Monitoring was transferred to Uppsala, now called the Uppsala Monitoring Center (UMC).

Now the system is based on interchange of adverse reaction information between national drug monitoring centers in 60 countries. Collectively these centers provide more than 150,000 to 200,000 individual reports annually of reactions suspected of being drug induced. The cumulative database that has been constructed from these reports now comprises over 2 million records.

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It is clear that there are 3 main aspects to this endeavor:

- timely receipt of reports
- efficient procedures for analysis of data
- communication of signals in such a way as to lead to appropriate action by health professionals and patients

To fulfill its role optimally, the UMC needs to develop tools and strategies continuously. It is important therefore to examine the current operation against what is possible today and in the foreseeable future.

Information technology (IT) solutions will not replace human minds and efforts; both are necessary for the assessment and interpretation of drug safety information. The use of new technology will, however, improve the speed and ease with which communication can take place, and it will provide the tools needed to create efficient and user friendly systems for data storage, retrieval, exchange, and security. Once a drug safety signal has been raised, the decision making process will also be aided by quick and easy access to relevant information. It is the aim of the UMC to meet these needs and to provide a single source for a wide range of services in the international drug safety area — now and in the future.

At the start of the Programme in 1968, a common case report format was agreed on, and guidelines for entering information were formulated. To ensure that the information would be recorded in a harmonized and structured way, the term *adverse reaction* was defined.

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Adverse reaction: a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function[1]

A terminology for adverse reactions and a drug classification system, both hierarchical, were elaborated. With these basic elements in place, a system for transmitting, storing, retrieving, and disseminating data was created.

The WHO Programme for International Drug Monitoring depends on a continuously developing, efficient, and up-to-date system for data collection, storage, retrieval, and analysis. Some of the recent projects and developments initiated and undertaken by the UMC will be discussed below, with an emphasis on technical advances. Before describing the development and functions of the new WHO surveillance system, it would seem appropriate to discuss some essential prerequisites.

Consistency and compatibility. To be widely accepted, a global drug surveillance system must reflect an international consensus as to what information it contains, the way in which the information is recorded, and how the information is communicated. There also must be a mechanism for achieving a correct understanding and interpretation of the information. There are a number of existing standards and conventions — all need to be considered when designing a computerized information system. An international system should be able to build on and link together the knowledge, experience, and information systems that have been developed over time and in different settings. Thus, there are a number of technical, linguistic, and cultural issues that need to be addressed. There are 2 possible methods of achieving working solutions: standardization or harmonization.

Standardization can achieve a high level of consistency, accuracy, and transparency, which is particularly important in those areas where uniformity is required. This applies to the data elements recorded, the terminologies and classifications used, and the electronic transfer of data. However, the development of standards that cover everything is not usually possible, or even desirable, because of real differences in attitude, language, culture, and so on. Standards also introduce a rigidity that should be avoided when it is not absolutely necessary.

The aim of harmonization is to bridge the differences between systems that are conceptually and structurally related. It is possible to build a coherent system in which the integral parts can communicate. Instead of enforcing changes in existing systems that need to communicate with each other, compatibility can be achieved through harmonization.

Definitions. Both in the pharmacovigilance area and in computer science, there are a large number of established expressions and terms. Within a given setting, these might be understood and applied consistently, but when it comes to communicating between and outside certain confined areas, there is a possible risk of misunderstanding. One reason is that many terms are expressions of existing knowledge, or jargon, that is particular to certain groups or areas. Moreover, terms might not have the same meaning in different settings or cannot easily be translated between different linguistic and societal groups. To avoid confusion, it is essential to establish agreed-on definitions of terms and concepts used and referred to. A definition should be easy to understand and provide a concise and unambiguous description of a word or an expression. Any additional information or examples should not be part of the definition but be placed in a separate note. Accurate and clear definitions also facilitate translation and interpretation, which is particularly important in an international setting.

DATA REPRESENTATION

Terminologies, classifications, and controlled vocabulary. In a computerized pharmacovigilance system, information must be recorded in a structured way to allow for easy and flexible retrieval and analysis of the data. The information that goes into a database can be divided into 2 main categories: numerical data and alphabetical data (text or codes).

Numerical data are typically the result of counts or measurements and are recorded as the number of what is counted or the amount of what is measured. The unit of measurement should be added to the value. If a decision is made to only use a specific unit, the unit is not recorded.

Alphabetical data pose more of a problem, in that they are usually more complex and difficult to record in a systematic way. Some textual data fall into natural categories with clear divisions and a limited number of possible entries. However, consistency is not automatically achieved, in that there are many ways of expressing the same thing. Therefore, data entry must be restricted to a selection from a list containing only predefined, allowed terms, expressed as formatted text or codes.

A terminology is defined as a "set of terms representing the system of concepts of a particular subject field"[2]. The simplest form of a terminology is a straightforward enumeration of terms, commonly listed alphabetically (e.g., a list of countries or pharmaceutical dosage forms).

When a larger number of terms is involved, it should be considered whether the list could be organized in a more structured way. By grouping the terms and assigning them to classes or categories, a logical classification can be formed. If the classes can be ranked one above the other, the classification can be structured in a hierarchical way.

The advantage with a hierarchical classification is that it enables the use of different levels of precision and detail, both at data entry and retrieval. A complication occurs when a term belongs to more than one class. There are 2 ways of dealing with this: allowing poly-hierarchy (i.e., assigning or linking terms to more than one class) or choosing one "preferred" class for each term. The former structure can be

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useful for retrieval purposes (less chance of "missing" a term); however, in the presentation of results of calculations, one must be aware of the risk of the same term being included under several headings and, therefore, counted more than once. Using the second option, this risk is eliminated. Yet this method is more restricting, and there must be clear guidelines as to what goes where in the system.

It is not always feasible to use a controlled vocabulary approach — sometimes the use of free text fields is the preferred option. Free text fields are not limited in terms of how the information is expressed, and a large number of characters may be used. They allow storage of useful and detailed information in the form of comments and narrative descriptions. However, free text fields are less suitable for retrieval purposes or for the presentation of information and should be used as a complement to, not the replacement of, formatted fields.

THE NEW WHO DRUG SURVEILLANCE SYSTEM

With access to new technology a modern, comprehensive system has been designed that will meet the requirements of the international pharmacovigilance community for the foreseeable future.

The design of the new system was driven by the needs of existing and prospective users, in terms of data fields and functionality. The data set required in the original WHO case reports form was the lowest common denominator consistent with being useful for signal generation and evaluation. Although the data fields are still valid, they may be restricting in view of today's demands and possibilities for storage and electronic transfer of information. The new database builds on another philosophy: instead of a limited amount of data fields, the data model is exhaustive. It is up to the international community to define to what extent, and under which circumstances, the fields should be filled in.

In addition to the Adverse Drug Reaction (ADR) database, the system includes the following core parts:

- user interface for the ADR database
- document generator
- medicinal products database (MPD)
- user interface for the product database
- work-flow system to monitor and control processing of ADR reports
- system tools to maintain and update the database and to produce output documents
- exchange server for the transfer of data and documents.

The ADR database

The data model was based on the proposals made by the Council for International Organizations of Medical Sciences (CIOMS) 1A working group[3] and the recommendations by the ICH (International Conference on Harmonisation)[4]. This ensures that the database structure and content complies with internationally agreed on standards and definitions.

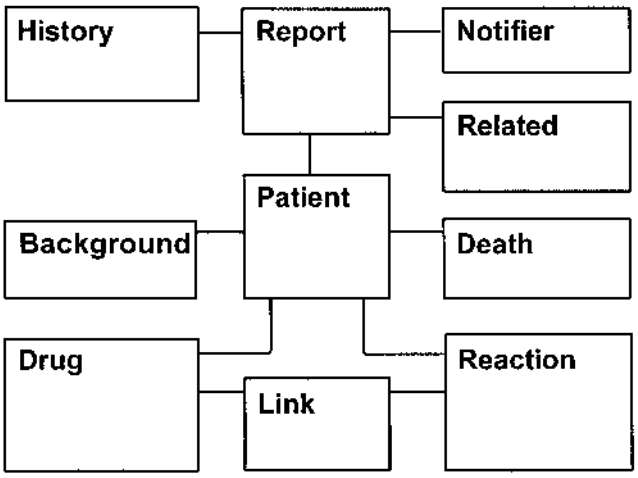

Figure 1. The ADR database. Unshaded panels are tables that exist in the current system.

The database model (Figure 1) can be run on all SQL based relational database management systems (DBMS). SQL is a standard language used to retrieve information and to request the relational DBMS to perform various actions. The WHO system will run on a server using the operating system UNIX (Uniplexed Information and Computing Service) and the relational DBMS Mimer. It is ODBC (Open Database Connectivity) compatible, and uses SQL for the database communication. This means that the database can be accessed and information retrieved using various mainframe or PC software systems.

The main tables are as follows:

Report: case identification, dates, classification
Patient: identification, age, sex, outcome, causality
Background: information on patient's previous illnesses/predisposing conditions
Death: cause of death, causality, and postmortem information
Related: link to and information on a related case
History: information related to reevaluation of a case
Notifier: identification of the reporter
Drug: medication information, including dosage, treatment dates, indication
Reaction: information on the adverse reaction, including onset date, date of resolution, seriousness
Link: causality assessment and information on de/re-challenge.

Some of these tables also exist in the current system (unshaded panels in Figure 1), although the amount of available fields has been expanded considerably. The other tables are completely new. Some new concepts that have been introduced warrant special mention, since they lead to major improvements compared with today's system. Any modification of a report is registered in an audit trail process, and the details of changes made are stored in the history table.

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Thus, previous versions of a report can be retrieved, and there is no loss of information.

An audit trail will also be implemented for the registration of external database accesses. This log will contain a full record of information that has been retrieved, by whom it was retrieved, and when.

The possibility to create a link between each adverse reaction and drug mentioned in a report is also new. This enables the reporter to make a causality assessment for any combination of drugs and reactions, and to record the outcome of each event. The result of de- and re-challenge is also recorded for each drug/reaction pair.

Finally, there is a table pointing to another case, designated as "related." This is used for example when a mother who has taken a drug during pregnancy bears a child who suffers an adverse reaction. In the table, data on exposure and pregnancy can be recorded.

Adverse reaction terminology. WHO Adverse Reaction Terminology (WHO-ART) has been developed and maintained within the WHO Programme for International Drug Monitoring to provide a tool for the rational coding of adverse reaction signs and symptoms. The terminology forms an integral part of the ADR database, but it is also an independent database. This means that regulatory authorities and pharmaceutical companies may implement and use WHO-ART as part of their own drug surveillance system.

The basic logic of the terminology is a hierarchical structure starting at the body system organ level, within which there are grouping terms (general/high level terms) that are useful for the broadest view of drug problems. The next level, consisting of specific "preferred" terms, allows precise identification of a reaction. Finally, WHO-ART includes a large number of "included" terms, which point to the closest preferred term available.

In recent years, an ICH initiative has been undertaken to develop a new international, multipurpose medical terminology (MedDRA). Because of the modular structure of the WHO ADR database, it will not be a problem to replace the existing terminology with a new one when it is available, provided that it has been adopted for use within the WHO Programme.

The ICD classification. The reason for drug treatment (indication), cause of death, and the patient's underlying diseases/predisposing conditions are all stored in the ADR database as ICD (International Classification of Diseases) codes. The ICD is maintained by the WHO in Geneva and is an international standard disease classification for general statistical use. The use of ICD versions 7–10 is allowed.

Tables for codes and text values. Many of the data fields in the ADR database are given codes rather than texts. Examples are: "country," "route of administration," "dosage form." The codes and their corresponding text values are in separate tables. These "lexicon" tables are language independent and easy to maintain.

Interface with the ADR database. To communicate with the database, an interface is needed between the user and the computer. Running in a Windows™ environment, the interface created for the ADR database provides a flexible instrument to update and retrieve information. The software can be configured to suit different users' needs, and it contains extensive search capabilities and graphical presentations of search results. The basic version is a client-server program installed in the user's PC (the client), which communicates with the mainframe computer (the server). The communication uses the TCP/IP protocol (Transmission Control Protocol over the Internet Protocol), which is an industry-standard set of rules allowing different types of computers to communicate with each other over the Internet. Access is made from a PC with a permanent IP connection [e.g., using a local area network (LAN)] or via direct dial-up connection using a modem. The application will run under any software that supports the standard for Windows™ TCP/IP applications, Windows Sockets.

Future developments include a planned conversion of the interface from the programming language Visual Basic to Java script. This means that the program will be available directly from the Internet, accessed through Internet browsers such as Netscape Navigator and Internet Explorer. The advantages are that there is no need for the user to install the client software and the latest version is automatically used.

The interface consists of an entry/update module and a search module.

The entry module. The entry module allows the user to edit information in a case report. It will be used by the UMC staff to edit received reports by correcting incoming reports that have not passed the syntax checks or when asked by the report custodian to modify the case information. All changes made are monitored by audit trail, which allows any previous version of a report to be recreated. Every report update must be signed off by the responsible person. The changes made and the sign off signature will be displayed in the audit trail window. It will also be possible to lock any version of a report so that no changes can be made to it. The right to make changes is determined by the user's predefined access level, which is part of the security system.

It is also intended to make a stand-alone version of the report entry module available to those reporting centers that do not have the facilities to submit reports by computerized media.

The search module. The search module provides a user friendly and flexible way of querying the database. The search results can be presented in a number of formats, including graphical data representation.

All data fields in the ADR database are searchable. The standard search window displays the most commonly queried field. A query is composed by selecting fields and entering search criteria. Instead of typing the whole field

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value, it is possible to use "wildcard" operators to replace characters. For some fields, there is a browse function, which displays the contents of the field and allows the user to select a value from the list. The search will be performed on cases that fulfil all of the specified search conditions (logical operator AND).

In the advanced search window, any field can be selected for querying. With the help of relational operators and the possibility to connect several search criteria with the logical operators AND/OR, complex search criteria can be created and saved.

The logical operator (LOP) AND/OR connects the different subconditions of a database query. *Relational operators* (ROP) define the comparison between the values that the expressions on either side of the ROP represent. Examples of relational operators are: "begins with," "less than," and "equal to." When a search is run, a summary of the search result is displayed in the search result list window. The following information is displayed:

- year when first/last report was received
- number of reports
- sex distribution
- number of reactions per causality assessment level
- number of reports per documentation grade
- number of fatalities.

Documentation grades:

1. Report contains date of onset of reaction and dates of treatment
2. (1) plus indication for treatment and outcome
3. (2) plus a positive re-challenge.

A list of the reports is displayed, showing the case identity numbers, country, sex, and age of the patient (the user may choose different attributes). From this list, one or more individual case reports may be selected for viewing. The selected reports can also be displayed graphically as a bar graph, showing the distribution of reports by main ADR groups (body system organ classes) or by drug groups (Anatomical Therapeutic Chemical, ATC, classification).

Alternative displays include distribution of selected reports by year, sex and age, outcome, seriousness, country. Graphs and screen displays can be printed, or the data can be sent to a file.

Document generator

The document generator can create a number of reports in different file formats, including ASCII (American Standard Code for Information Interchange) text files ("flat files") and SGML (Standard Generalised Markup Language, ISO 8879) documents.

The medicinal products database

Information on drugs has been entered into the WHO drug database since the start of the international program. All registered products from the participating countries are not included, however, since the drugs entered routinely by the UMC staff are those that have been mentioned in ADR reports. For each case report, however, information on all drugs is recorded, whether or not the drugs are suspected of having caused the reaction. Thus, the register covers a majority of the drugs used in the WHO Programme countries.

Again, the need for expansion has been recognized over the last several years. In connection with a general overhaul of the system, an extended medicinal products database (MPD) will be introduced, replacing the existing one. The data model complies with the European Committee for Standardization preStandard for medical product identification[5], which contains definitions of the concepts and descriptions of the characteristics and the relationships needed to identify each of these unambiguously, particularly for exchanging information between information systems. The advantages of adhering to this standard are that the naming of the data fields follows a standardized nomenclature, and the concepts and terms included in the database are defined.

The MPD model (Figure 2) that will be used for the WHO system is the core part of a general drug database model, which has been jointly developed with the UMC software supplier, PharmaSoft. The general model contains some tables for drug related information that is relevant only at a national or pharmaceutical manufacturer level. Compared with the existing database, the new MPD will provide a vast increase to the amount of information that can be stored on each product.

The main tables in the database are as follows:

Medicinal product: proprietary product and territory/country-specific information

Product group: information on the generic level, or on a group of medicinal products

Manufacturer: information on the product manufacturer

Product licence: information on the market authorization holder

Therapeutic group: therapeutic classification

Pharmaceutical product: pharmaceutical forms available for the product

Ingredient: quantity and identification of active ingredients

Substance: substance names and Chemical Abstracts Service (CAS) numbers.

ATC classification.

The therapeutic group will be designated using the ATC (Anatomical Therapeutic Chemical) classification, as in the existing database. The ATC system is a hierarchical classification, dividing drugs into different groups according to the main target body organ/system and their therapeutic, pharmacological, and chemical characteristics. It is maintained and updated by the WHO Collaborating Centre for Drug Statistics Methodology[6], Oslo, Norway. As one of the main users of the ATC system, the UMC takes an active interest

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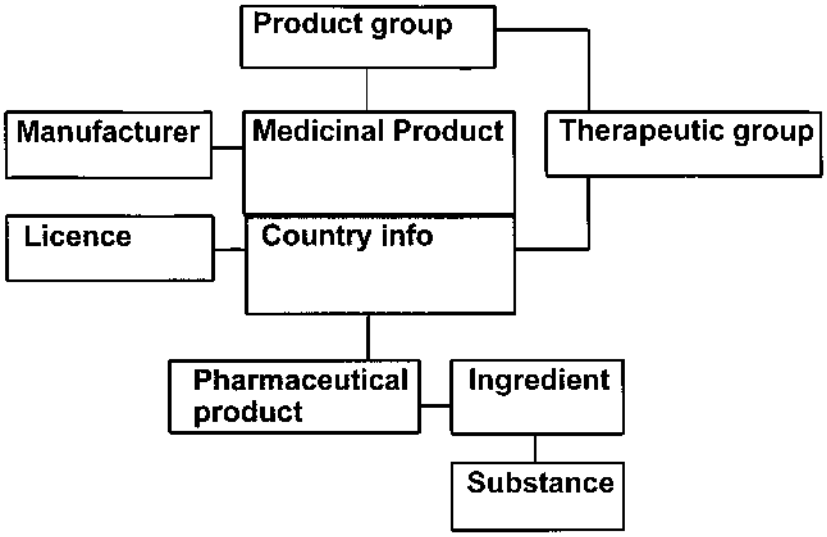

Figure 2. The medicinal products database. Shaded panels indicate information not included in the current system

in the development of the classification, and it is represented in the international ATC/DDD (Defined Daily Doses) working group.

The ATC codes are assigned on a generic level (products containing the same ingredient/combination of ingredients will have the same ATC code/s), but also on the proprietary product level (which is not the case today), which allows for different ATC codes depending on the form or the strength of a product. For example, there are several possible ATC codes for prednisolone products; the form and indication will determine the ATC code for a particular product. Thus, a prednisolone cream indicated for topical use will have a "dermatological" code, a suspension for use in the eye will have an "ophthalmological" code, and so on.

Interface with the MPD

The interface for the MPD is similar to that for the ADR database. It is a graphical, Windows™ application that allows the user to update the information in the database and to make searches.

One of the major challenges is to provide the MPD with correct and up-to-date information on medicines registered worldwide. To improve the speed and accuracy of data entry, the center encourages companies to assist in providing the necessary information on their own products. This process will be aided by user friendly software made available for external use, allowing distributed data entry. Advanced security features are necessary with this approach, and any information entered from outside the UMC will be labelled as provisional until checked and approved.

SYSTEM TOOLS

A number of programs are needed for routine database operations and maintenance. These programs — system tools — are only for internal use at the UMC and are run by authorized persons at the center. Special security categories are implemented on the program levels.

Batch data entry. To allow processing, ADR reports sent to the UMC must be in a predefined file format. In addition to ASCII text files, which currently is the only accepted electronic format, the new system will also handle data transfer using EDIFACT (Electronic Data Interchange for Administration, Commerce and Transportation) and SGML (Standard Generalised Markup Language). EDIFACT (ISO 9735, EN 29735) is an electronic messaging format standard, and SGML (ISO 8879), a generic language for the representation of documents, is an international standard that has become the norm for the exchange of formatted information within and between systems. EDIFACT and SGML are the standards recommended by the ICH for Electronic Data Interchange (EDI). The advantage with EDI transfer of reports is that the format and quality of the reports can be checked at the point of submission. Reports in incorrect format will be rejected at the sender's side. Also, the submitter can receive acknowledgment reports on the status of the transmission.

All incoming reports that have not yet been approved for entry into the ADR database are stored in a temporary buffer database. For a report to be accepted into the ADR database, it has to pass an extensive error checking procedure involving the following: syntax check, inter-field coherence check, check for duplication, check of drug names and adverse reaction terms.

In the syntax check, the technical correctness of each field is controlled against predefined validity checks (e.g., the field "amount" must not contain letters) and lexicon tables containing all approved codes.

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The coherence check compares the values in certain fields against those in related fields. For instance, the date of starting drug treatment should be less than or equal to the date of stopping treatment, and the outcome on the case level cannot be less than the worst outcome of any of the adverse reactions mentioned. Some values are calculated automatically (e.g., if the date of birth of the patient is stated, "age" is calculated from this date and the date of onset of the first reaction).

The duplicate control checks the reporter's case ID number against case ID of reports already stored in the database. This check might be extended in the future to include a check of a number of significant fields. Before such a check is introduced, criteria for what should be considered a "suspected duplicate" must be developed and tested.

All drug names and ADR terms given in a report are tested against those already stored in the MPD and in WHO-ART. Any name or term that is not recognized is rejected by the system.

A modified version of the ADR interface will be used for correcting reports that have not passed the checks. Each report will be shown in a window, and technical errors detected in the syntax check will be highlighted. The program will notify the user if the same incorrect field value occurs in more than one report in the checked batch. In this case, all reports with the same error can be corrected in one operation.

Any rejected product name must be checked and corrected and/or entered into the MPD, and any ADR term not included in WHO-ART is similarly corrected/entered into the WHO-ART. When all the checks/corrections are completed, the reports are cleared by the system. When signed off by an authorized person at the UMC, they are transferred from the buffer database to the ADR database.

NEW METHODS FOR DATA SCREENING AND ANALYSIS

Two new developments for the improvement of ADR signal detection and analysis, undertaken by the UMC, deserve special mention.

The ASAP methodology. The main purpose of the ADR Signal Analysis Project (ASAP), funded by the European Union Biomedical and Health Research (BIOMED) concerted action, was to examine the use of the WHO ADR database, the IMS drug utilization databases, and international demographics for the investigation of drug safety signals. The objective was to develop a methodology that would provide a set of relevant denominators for spontaneously reported ADR data to meet a wide range of ADR issues and to permit the analysis of subsets of a drug product's total use to isolate higher risk situations.

Although no definitive algorithms could be applied to every analysis, a number of standard tabulations were developed, together with methods to concatenate the data and recalculate sales and prescription figures into internationally comparable measurements. Some of the results have been published in medical journals[7-10]. The analyses showed that the methodology can be used for a wide range of drug safety problems and that it is a cheap and quick way of analyzing international ADR signals.

The Bayesian neural network. The dilemma of spontaneous reporting is that, to make as sure as possible that nothing is missed, we ask for all (serious) ADR suspicions to be reported. This philosophy means that the "haystack" must be large to incorporate all the possible ADR "needles." The actual reporting requirements vary from country to country, and include direct patient reporting in some countries. The result is that national regulatory and pharmaceutical industry databases are crowded with ADR associations that have little value in raising new general concerns — the "haystack" is indeed massive. Information technology has now made it possible to share information in the different databases throughout the world easily. This has the potential to increase the problems with duplicate reports.

The problem of getting early and useful ADR signals out of this huge haystack is one that has taxed the WHO Programme members since its inception. However, the UMC has developed a data mining tool based on Bayesian, mutual information logic within a neural network (Bayesian Confidence Propagation Neural Network, BCPNN)[11-13] that allows the strength of all drug/ADR data associations to be quantified. Effectively the whole database is being used as the control, so that any new positive drug/ADR association highlighted implies a significant difference from the global reporting experience: in this case the haystack size becomes an advantage!

The BCPNN allows analysis of complex variables, so that the contribution of other medicinal products than the target one, age range, other disease, and indeed any other recorded variables can be evaluated.

The BCPNN has been evaluated for its basic performance and is in routine use within the WHO Programme, as a support for human review, which will always remain essential for complete analysis of a safety signal. New evaluations of performance in different applications are being made[14,15].

EXCHANGE OF INFORMATION

The WHO system relies on information being transferred, stored, and retrieved in a timely and secure way. Through the use of a sophisticated exchange server technology, the Internet can be used as a transport medium for data and document transfer with guaranteed security, authenticity, and client authentication. Internet technology is also used for the exchange of information through E-mail discussion groups. Recently, a dedicated discussion group for pharmacovigilance issues, VigiMed, was set up by the UMC. It is open to all participating centers and serves as a forum for the communication of current drug safety issues.

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Plans are well under way at the UMC for the establishment of advanced IT solutions to access information on the World Wide Web. The use of a neural network for this purpose will allow intelligent searching of the Web in a way that is supplemented by the experience of the neural network in matching the users' given characteristics with information and data sources. The neural network will also be capable of "learning" and "remembering" experience gained from any user's interaction with the Web, so that future use should be even more precise and useful to the user.

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