

The need for a generic form for spontaneous reporting of drug related problems

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Background

The WHO-QSM unit has recently received requests for a general WHO form to be used for spontaneous reporting of suspected adverse drug reactions. The demand has come from Public Health Programmes getting involved in the establishment of pharmacovigilance systems for new medicines in many countries around the world.

Current situation

There is currently only one internationally recognized reporting form for submission of ADR case information to national pharmacovigilance centres, the so called CIOMS-I form. It was developed in 1990 to allow marketing authorization holders (MAH) to submit ADR information to regulators using one and the same format in all countries. The form was not designed for soliciting case information from health professionals and would most probably not work for that purpose.

The WHO reporting form, developed in 1968 and revised in 1981 for submission of case information from national pharmacovigilance centres to the WHO database is international in scope but is not useful for collection of original data from health professionals. Since 2001 it is no longer accepted as a paper form within the WHO Programme, only as a format for electronic submissions.

Also the ICH-E2b format provides a standard for exchange of case information electronically between MAH and regulators on an international scale. The E2b format is very extensive and cannot be translated into a single-sheet reporting form.

Although all pharmacovigilance centres developed after the 1960s have had access to model reporting forms from established centres, they have all chosen to develop and use their own version. The book 'National Pharmacovigilance Systems' (Sten Olsson ed, 2nd edition 1999) contains an overview of the content of 40 reporting forms in use by the end of the 1990s. It demonstrates a great variation in data items asked for. Only 11 data elements were common to all forms and 20 elements occurred in a majority of forms (appendix 1). In total 65 different data items were represented on the 40 forms. Presently 98 countries are associated with the WHO International Pharmacovigilance Programme. They have all developed their own reporting forms.

Basic considerations

There are two main aspects of an ADR reporting form that are related but have to be considered separately

- Content
- Design

The content of the reporting form has to do with the data items being requested about the case. The design refers to the arrangement of tick boxes, fields to be filled in, the use of colours, logos etc.

Discussion

The form, whether paper based or electronic, provided to health professionals and/or patients for collection of case details about suspected drug related disease is a critical document, forming the basis for subsequent efforts in the creation of new knowledge. No specific guidelines exist on how a good form should be composed and designed. How to optimize the efficiency of the key document in the data collection process has been the subject of very little attention or systematic research.

Benefits of a generic reporting form

It would seem attractive to have a common, internationally accepted, form for ADR reporting that could be put to immediate use in the field whenever a system for spontaneous reporting is being introduced in a country or in a treatment programme. There would be less need for local pharmacovigilance competence in developing the form and the barrier for getting started might be lower. The generic reporting form would give guidance as to what data items are important to collect. If the form was adopted by WHO and carried the WHO logo it would be associated with status and credibility. The use of the same form for data collection in many countries and in different settings would facilitate uniformity of data. The data elements of the form could be made to comply with, and be a subset of, the E2b format. It would then be easy to transcribe data from such a form to an E2b compatible data base.

Reservations about having a generic reporting form

The aim and focus of spontaneous reporting systems are different depending on the local situation. The variability could be due to e.g

- *The type of data requested* e.g. adverse reactions, lack of efficacy, quality defects, poisoning, dependence, medication errors. Countries have different aims with their reporting programmes and are organized differently. Quality defects and ADRs might not be dealt with by the same authority. There might be a separate system for reporting poisoning for example. A generic form encompassing all possible needs might not be effective in meeting the local needs
- *The intended target group for reporting* e.g. community health workers, pharmacists, traditional healers, patients, physicians. The reporting form has to be adapted to the intended reporters. The same wording does not appeal equally to physicians and patients. Since countries choose different target groups for their reporting system a generic reporting form might not be well designed for any of their target groups.
- *Each treatment programme would have a need for specific information not requested by others* e.g.
 - CD-4 count and viral load in HIV/AIDS
 - diagnostic accuracy of disease in malaria and other parasitic infections
 - batch numbers, programmatic errors, strain specificity, cold-chain information in immunization programmes.

It would be difficult to accommodate the needs of all the various programmes unless you provide a lot of space for free text. With that solution you would miss the opportunity of prompting the reporter to the key data elements however.

The process of developing a reporting form is educational. You have to discuss the importance of requesting the various data items and weigh it against the feasibility of capturing the

information. A generic reporting form might request information that is unavailable or completely irrelevant in the local situation. If you have decided locally to include a certain data element on the form you are in a better position to give a justification to the potential reporter why it is important.

To be effective a reporting form needs to be available in the local language and have features relating to the responsible authority e.g. a logo, the address and contact details of the issuing institution. There might need to be a reference to a legal reporting requirement. A common WHO form provided in English would in very few instances be useful in its original form. It would need to be translated and adapted. This seriously reduces the benefit of having a generic WHO reporting form.

Reporting forms should be tested in a local community before general launch to find out what design solution works best in that community. It is not without reason that there are > 100 different reporting forms taken together in the countries (some have more than one) currently operating systems for spontaneous adverse reaction reporting. It would have been easier for the newcomers in the field to adopt a form being used in another country but they have all chosen to design their own.

We are totally dependant on the psychology of the various potential reporters and we have to adapt to the needs of the professionals or patients whom we want to encourage to report. If we start from the perspective of what is most convenient for the management of the pharmacovigilance programme we are bound to fail.

Conclusion and proposal

A generic WHO form for spontaneous reporting of drug related problems it not likely to be effective in any particular situation. WHO should however develop a set of guiding principles for the drafting and design of good forms for any setting, covering all the options, including minimum data needed for follow-up and other variables. The principles should apply to any setting, in any language. The WHO should also gather the best of the existing forms from a handful of different settings, improve and refine them, and offer them as models of best practice, which can then be modified and refined for particular situations

Note: The above discussion refers to forms for spontaneous reporting. Forms for use in active surveillance, e.g. cohort-event monitoring, have been suggested by WHO in the relevant context. General guidelines on how to design a good form would probably apply to them too however.

Appendix I

Overview of national reporting forms

Total number of reporting forms reviewed = 40

Data items occurring on all reporting forms (n = 39 or 40)

Patient data

Identity of patient (name, initials or civil registration number)

Sex

Age or date of birth

Exposure data

Name of suspected drug

Name of concomitant medication

Dosage schedule

Date of first administration

Date of drug withdrawal

Indication for drug treatment

Reaction data

Description of reaction

Date of onset

Additional items occurring on > 75% of reporting forms (n = 31 - 38)

Patient data

Patient's medical history

Exposure data

Route of administration

Other observations

Patient outcome

Additional information - free text

Additional items occurring on > 50% of reporting forms (n= 21- 30)

Patient data

Weight

Reaction data

Duration of reaction

Other observations

Treatment of reaction

Effect of rechallenge

Administrative

Origin of report

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