Pilot project of recording and assessing medication errors within the German spontaneous reporting system

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Background

Worldwide, up to 10 % of hospital admissions are due to adverse drug reactions (ADR). About 20 % of these are preventable medication errors (ME)[1]. According to the new pharmacovigilance legislation, since 2012 all noxious and unintended responses to a medicinal product are considered as an ADR, including ME related adverse reactions. As a consequence, the national pharmacovigilance systems of the EU member states must be adapted so that ME may be recorded[2].

The Drug Commission of the German Medical Association (DCGMA), a committee of the German Medical Association focused on drug-related matters, is a part of the German pharmacovigilance system. The DCGMA is currently developing a system for recording and assessing ME within the established pharmacovigilance structures. This pilot project is being carried out in close collaboration with the Federal Institute for Drugs and Medical Devices (BfArM).

Aim

The aim of the project is to evaluate whether physicians are willing to report ME and whether a systematic analysis of ME is feasible within the existing structures of the DCGMA spontaneous reporting system. The possibility of deducing risk factors and intervention strategies will be investigated.

Here we present the results of the development of the ME report form, which takes into account the specific requirements for ME recording and assessment.

Methods

In this pilot project, ME reported spontaneously by ***physicians*** are assessed within the established hierarchical structures of the DCGMA (medical specialists working in the DCGMA's central office; committee members/clinical experts; ADR conference; for details see poster no. P 155). ME that have caused or may cause ***serious harm*** to the patient will be recorded. Data will be coded in a format in which they can be forwarded to national and international institutions (ICH E2B format). MedDRA codes are used as far as possible.

Using the existing spontaneous report form of the DCGMA as a basis, a report form for ME was developed which takes into account international experience (e.g. ISMP Canada) and the "Good practice guide on recording, coding, reporting and assessment of medication errors – draft" of the European Medicines Agency[3].

Results

A draft of an ME report form was developed which consisted of 16 items over several pages. After engaging in intensive discussions with clinical experts of the DCGMA, we decided to shorten the report form and to implement ***a two-step procedure*** for ME recording in order to avoid creating an unnecessary burden (Figure 1). The ME report form was split into two parts (Table 1): The basic report form (9 items) is to be filled in for each case report. As a second step, the additional report form (5 items) can be requested in cases of special interest.

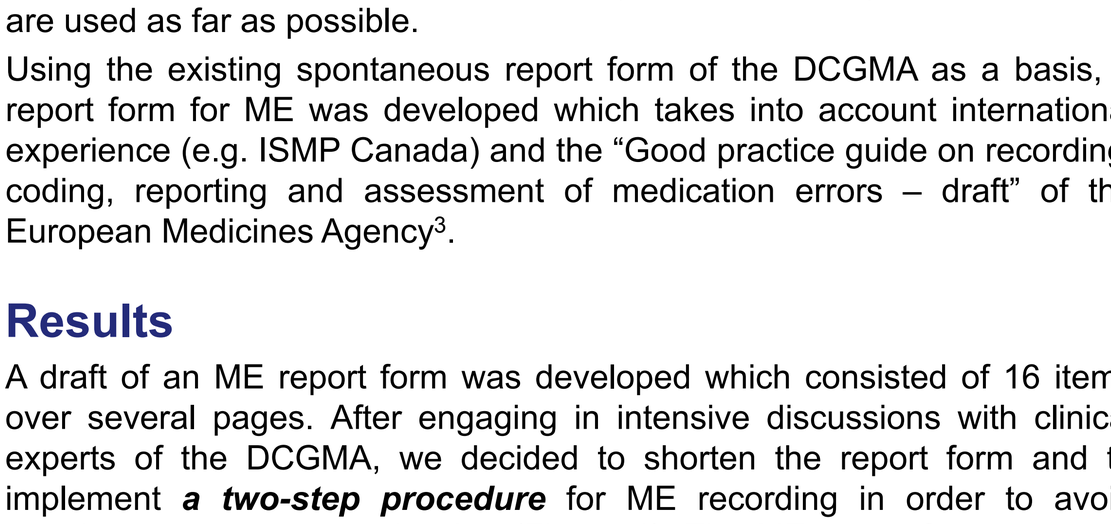

Figure 1: Development of the ME report form

Table 1: Two parts of the ME report form

Basic report form	Information about patient
	Information about reporter
	Suspected medicinal product
	Description of adverse drug reaction / type of medication error
	Comorbidity
	Seriousness
	Outcome
	Contributing factors
	Recommendations for future error prevention
Additional report form	Comedication
	Mitigating/ameliorating factors
	Response to dechallenge/rechallenge
	Setting where error occurred
	Stage of medication process where error occurred

The ***basic report form*** consists of information that is absolutely necessary for ME evaluation. Similar to routine ADR reporting, data on one identifiable patient, one identifiable reporter, at least one suspected adverse reaction, and at least one suspected medicinal product are required. But in the case of ME assessment, the type of ME should also be described in addition to the description of the ADR. Furthermore, contributing factors and recommendations for future error prevention are part of the basic report form (Table 2).

Table 2: Basic report form – ME specific information

Parameter	Description
Type of medication error	• Free text field
Contributing factors (select list)	Related to: • Drug • Patient • Staff • Work environment • Organisational factors
Recommendations	• Free text field

Case reports of special interest (e.g. fatal outcome; case reports related to children) will be followed up via the ***additional report form***. For ME assessment in particular, the setting and the stage of medication process where the error occurred should be recorded (Table 3).

Table 3: Additional report form - ME specific information

Parameter	Description
Setting (select list)	• Hospital • Emergency room • Office • Pharmacy • Dispensary • Rescue service • Nursing home • Domicile of patient • Other (please specify) • Unknown
Stage of medication process (select list)	• Prescribing • Transcription • Preparation for administration • Dispensing • Administration • Monitoring • Other (please specify)

Quantitative and qualitative analyses will be performed. Quantitative data (e.g. total number of ME cases; number of reports with fatal outcome) will be presented descriptively and according to absolute and relative frequencies. Qualitative data will be analysed on an individual basis before categories are formed. Intervention strategies will be derived from these analyses. Reporting physicians will receive a reply with information about the suspected medicinal product(s). Reporting ME is already promoted extensively, e.g. in medical journals and at conferences.

Conclusion

The pilot project of the DCGMA for recording and assessing ME is an effort aimed at improving patient safety. Existing structures need to be considered (e.g. coding) and adjusted if necessary (e.g. report form). Open questions with regards to the possibility of anonymous reporting, the systematic analysis within the existing database structure or the feasibility of the two-step reporting procedure will be addressed.

References

[1] Jha A. Summary on the evidence of patient safety: Implications for research. Geneva: WHO, 2008.

[2] Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use. Official Journal of the European Union 2010; L 348: 74-99.

[3] European Medicines Agency. Good practice guide on recording, coding, reporting and assessment of medication errors – draft: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/04/WC500185536.pdf. EMA/762563/2014; London, 14 April 2015. Last accessed: 13 October 2015.

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