Recording and assessing medication errors within a spontaneous reporting system: first results from Germany

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Background

According to a German study, about 3 % of hospitalizations are due to adverse drug reactions (ADR). Of these, about 20 % were avoidable medication errors (ME) (1). As a consequence of the new European pharmacovigilance legislation, MEs are encompassed by the definition of ADR and must therefore be recorded within the national pharmacovigilance databases of EU member states (2). The Drug Commission of the German Medical Association (DCGMA) is a committee focused on drug-related matters. As a part of the German pharmacovigilance system, the DCGMA has developed a subsystem for recording and evaluating MEs within its spontaneous reporting system (3). Here we present the first results.

Aim

The aim of the project is to evaluate prospectively 1) the feasibility of recording and assessing MEs in the framework of the DCGMA and 2) the possibility of deducing risk minimizing interventions from the obtained case reports.

Methods

Healthcare professionals are invited to report MEs that harmed or might harm a patient's health. To comply with the special requirements of ME recording and assessment, the existing spontaneous reporting form was modified, taking into account the European Medicines Agency's Good practice guide on recording, coding, reporting and assessment of medication errors (GPG) (4). Case reports of MEs are assessed analogously to other spontaneous reports of ADRs within the established DCGMA structure. MEs are coded with MedDRA and forwarded to national and international institutions (ICH E2B format) (Figure 1).

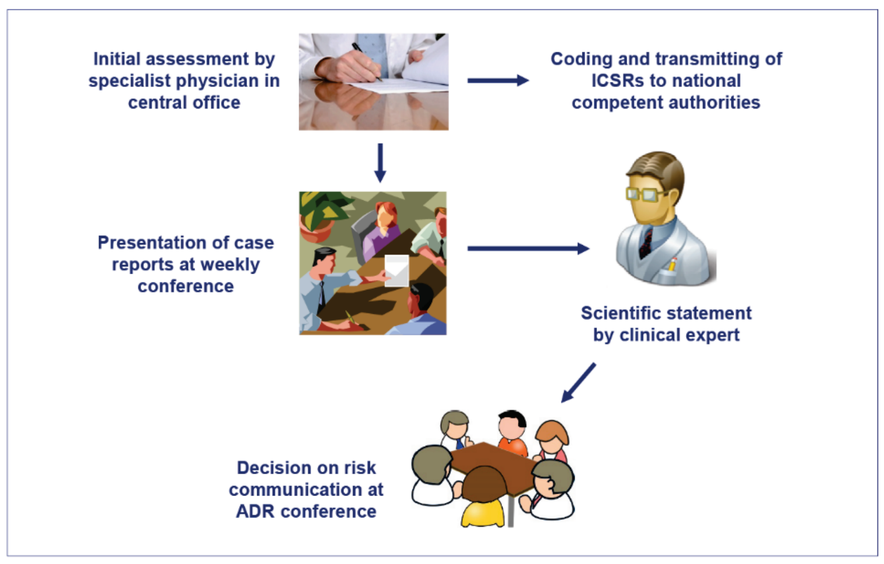

Figure 1: Assessment of case reports within DCGMA

For ME coding we used LLT MedDRA terms, which are allocated within the SMQ "medication errors". However, if the LLT was not allocated in this SMQ (e.g. "transfusion with incompatible blood"), a non-specific LLT ("medication error") was used in addition in order to facilitate searches for ME in our database. The data is currently being evaluated.

Results

From 4 January 2016 to 15 September 2017, over 6700 case reports of ADR were obtained by the DCGMA. Among these, there were 112 (1.7 %) case reports (55 male, 57 female) of ME which were coded and classified as ME after DCGMA appraisal. There were about 50 additional reports ("special cases") in which we suspected an ME but which were not classified as ME due to lacking information, e.g. about what happened exactly. Fifty-seven out of 112 (51 %) reports were considered serious (including 4 fatal cases). Administration errors were reported most frequently (n = 37), followed by prescribing errors (n = 29) and dispensing errors (n = 21) (Figure 2).

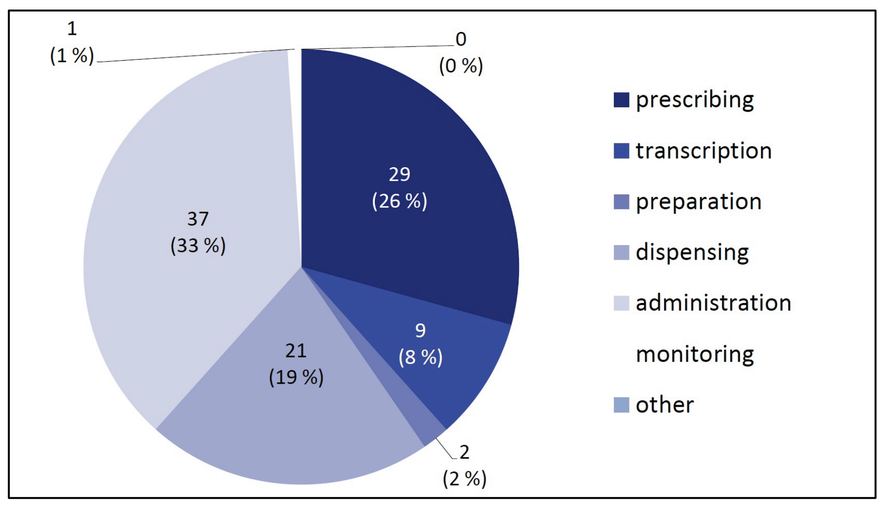

Figure 2: Reported medication errors: Affected step in medication process

Elderly patients (n = 62 of 112; 55 %) were the most affected group, followed by adults (n = 28). A significant number of case reports were related to children and adolescents (Figure 3).

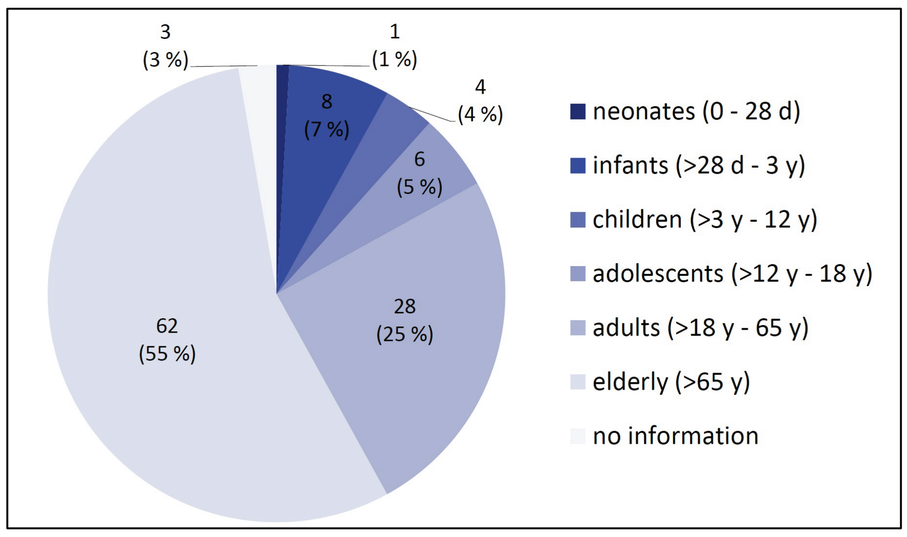

Figure 3: Age distribution of reported medication errors

The substances most frequently involved were apixaban (n = 7), phenprocoumon (n = 7) and human red blood cells (n = 6) (Table 1).

Substance	Number
apixaban	7
phenprocoumon	7
human red blood cells	6
metamizole	6
dabigatran	5
gabapentin	3

Table 1: Substances most commonly involved

The case reports related to apixaban and dabigatran often describe dose reductions carried out by patients without consulting their treating physician. With regard to phenprocoumon, most case reports describe bleeding complications / INR increases related to overdose, e.g. due to (drug name) confusion. Four out of six case reports on metamizol involved allergic reactions / agranulocytosis after re-exposition. The high number of transfusion errors triggered a DCGMA risk communication in the *Deutsches Ärzteblatt* (German Medical Journal).

At the PT level, the most frequently used terms are accidental overdose (n = 22), followed by drug prescribing error (n = 18) (Table 2).

Medication error	Number
accidental overdose	22
drug prescribing error	18
no adverse event	12
drug dispensing error	11
overdose	11
treatment noncompliance	10
medication error	9
drug administration error	8
transcription medication error	8
drug dose omission	6
transfusion reaction	6

Table 2: Most frequently used PT terms

Case reports of special interest were intensely discussed with experts of the DCGMA and the German drug authorities. The Federal Institute for Drugs and Medical Devices (BfArM) initiated regulatory measures in four cases. For example, as a consequence of a fatal case report involving an accidental overdose with colchicine, the maximum package size was reduced from 100 ml (= 50 mg) to 30 ml (= 15 mg). The DCGMA has published three announcements on medication errors in the *Deutsches Ärzteblatt*, like the above mentioned one on transfusion errors. Based on two "special cases" we used our newsletter *Drug Safety Mail* to communicate the risk of interactions.

Conclusion

Overall, ME recording and assessment within the existing structures of the spontaneous reporting system of the DCGMA are feasible. Some relevant aspects (e.g. information about risk factors), however, cannot be coded with MedDRA and cannot be forwarded in specific ICH E2B fields. In accordance with the GPG of the EMA (4), these data are recorded in the ICH E2B field "summary". To facilitate database inquiries, we have established a standardized approach with a defined text module in the local language (German).

Physicians reported fewer medication errors than expected. This might be due to a lack of awareness of the possibility of ME reporting or fear of legal consequences. However, the proportion of case reports that triggered risk minimizing measures was higher than in the usual spontaneous reports of ADR. ME recording and assessment are an important aspect of the pharmacovigilance system. Therefore, physicians and other healthcare professionals need to be encouraged to report MEs without fear of being blamed or punished.

References: 1. Rottenkolber et al.: Adverse drug reactions in Germany: direct costs of internal medicine hospitalizations. Pharmacoepidemiol Drug Saf 2011; 20: 626-634. 2. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Consolidated version : 16/11/2012): https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf (last accessed: 2 May 2017). Official Journal of the European Union 2012; 2001L0083. 3. Köberle et al.: Pilot project of recording and assessing medication errors within the German spontaneous reporting system. Poster at the 15th Annual Meeting of ISoP; Prag, 27–30 October 2015. 4. EMA, Pharmacovigilance Risk Assessment Committee (PRAC): Good practice guide on recording, coding, reporting and assessment of medication errors: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/11/WC500196979.pdf. Doc. Ref. No.: EMA/762563/2014, 23 October 2015.

Funding: Federal Ministry of Health (2015–2017; support code: GE 2014 0106. **Conflicts of interest:** The authors have no conflict of interest directly relevant to the content of this poster presentation.