Drug-related problems: a cornerstone for pharmaceutical care

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Drug related problems are an essential term in the world of pharmaceutical care. Other terms can be used for the same concept, such as medication errors, but this term is different from drug related problems. The errors refer to the mistakes in the process that could lead to problems. Drug related problems can originate when prescribing, dispensing or taking/administering medicines. Drug use problems by the patient are probably the most frequent, but are not always noticed. There are several classifications for drug related problem, but in this article the classification of the Pharmaceutical Care Network Europe (PCNE) is used to clarify the concepts. Some of the known classifications seem difficult to be used in practice, and especially the reproducibility of the existing classifications should be researched further.

The concept of pharmaceutical care started developing in the early 1990s after the milestone publication of Hepler and Strand on this subject[1] and some years later Hepler depicted pharmaceutical care as a quality improvement process (a circle of Denning) in which the professional improves the outcomes of pharmacotherapy. During the quality improvement process, the causes that potentially lead to problems resulting from pharmacotherapy should be identified and corrected.[2] This philosophy around optimizing the outcomes of pharmacotherapy and pharmaceutical care lead to the concept of Drug Related Problems or DRPs, indicating some problem in the pharmacotherapy of the patients. DRPs therefore are defined as problems in the pharmacotherapy of the individual patient that actually or potentially interfere with desired health outcomes (definition PCNE 1999). The essential element of this definition is the impact of the problem on the health-outcome of the pharmacotherapy. If there is no potential impact, then there is no drug-related problem.

It would be much better to prevent drug related problems than to correct them, but this is not always possible because of the complexity of pharmacotherapy, lack of training and knowledge of health care providers and the behaviour of the medicine users. Also, some pharmacotherapy problems are the result of an unexpected reaction of the individual, like allergies, and cannot always be predicted. Therefore, even if one could analyse the medication and patient related factors during a medication review before a medicine is handed over to the patient, the evaluation of the pharmacotherapy after it has been initiated still remains necessary to detect DRPs and optimise outcomes.

A drug related problem is essentially different from a medication error. According to the NCC MERP a medication error is 'any preventable event that may cause or lead to inappropriate medication use or patient harm while medication is in the control of a health care professional, patient, or consumer'.[3] A medication error is much more process orientated than outcome orientated. If something goes wrong in the prescribing or dispensing *process*, then it is automatically regarded as a medication error whether or not there is an impact on patient outcome. Additionally, errors in medication use by patients seem not to be included but such errors can be causes for drug related problems.

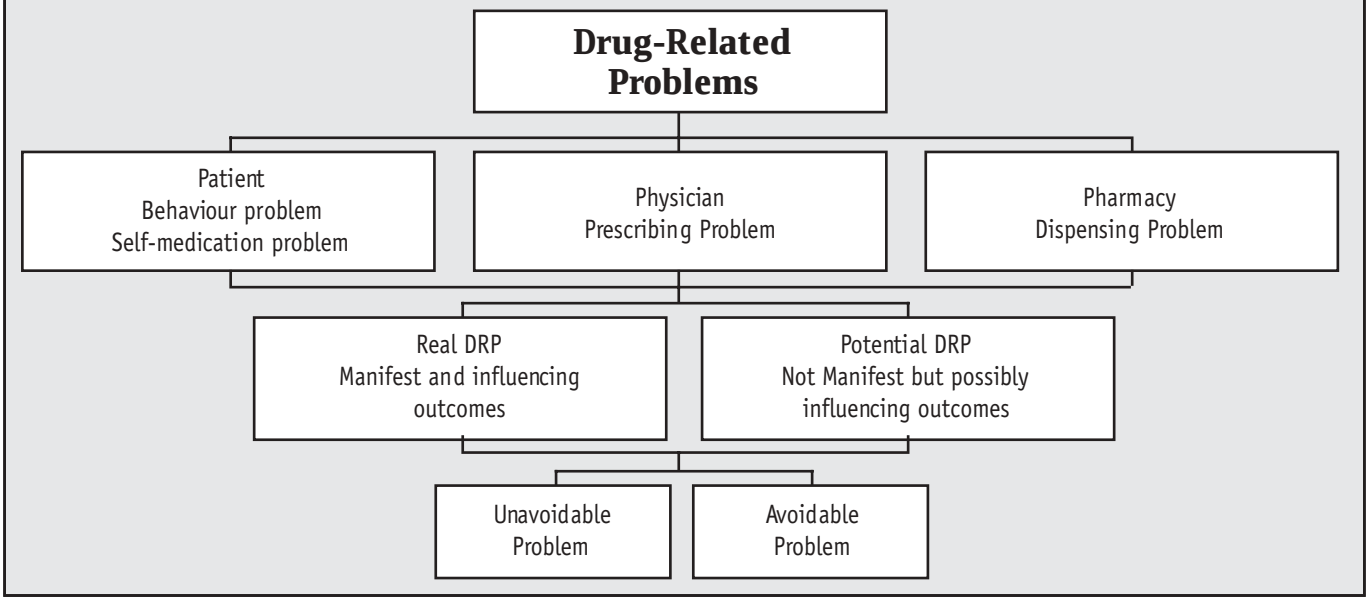
Terminology

The term 'Drug Related Problem' is not unique for a problem with pharmacotherapy. Other terms have been proposed. For instance 'drug-therapy problem' is often used too, and was introduced by the group of Cipolle, Morley and Strand.[4] Krska introduced the term 'Pharmaceutical Care Issue' in 2002. That term is sometimes used in the UK.[5]

Fernandez-Llimos *et al.* recently proposed 'pharmacotherapy failure', corresponding to negative clinical outcomes resulting from the use or the lack of use of medicines. Those pharmacotherapy failures then include necessity, effectiveness and safety problems.[6]

All these terms may stand for similar concepts as drug-related problems and therefore it remains important to define the concept properly before using it in research or publications.

Figure 1: The scenery of drug-related problems



How and where do DRPs originate

In the entire course of installing pharmacotherapy there are three main processes where a drug-related problem can be generated: the prescribing, dispensing and drug use process as illustrated in Fig.1

DRPs can also be split into real and potential DRPs. Additionally some of those problems cannot be avoided without reducing the effect of the pharmacotherapy, e.g. nausea as a side effect of oncolytic medicines, or interactions between different medications for AIDS.

Prescribing problems originate usually behind the physicians' desk, or sometimes at the bedside. Usually negligence or lack of knowledge may cause such problems, sometimes lack of information regarding the full therapeutic profile of the patient, and at times possibly also missing laboratory data. The physician can also be influenced by external entities, such as the pharmaceutical industry, and may not prescribe the most appropriate medicine. Nurses may also cause DRPs by wrongly copying the physicians' instructions on a chart or order form, or by not providing medication as intended.

Dispensing problems also are often a result of negligence. Misinterpreting the physicians' handwriting, not performing a drug use review, taking the wrong box or bottle may all cause DRPs.

Drug use problems by the patient probably occur very frequently, but are not always noticed. In general, half of the patients do not adhere to the pharmacotherapy. This leads to a significant amount of drug related problems, but only part of those problems are detected e.g. when the patient is taken to the emergency department of a hospital for not taking insulin.

Example of a Drug Related Problem - Case study

Mrs A, an 87 year old lady, has been taking digoxin 0.25 mg daily for her atrial fibrillation for 3 years. Recently you have noticed that she is getting increasingly frail and may have lost weight. On a Saturday morning she presents a new prescription for digoxin. While you prepare the prescription, she tells you that she has been having visual disturbance and wonders if she needs her glasses replaced. You recognise the possible side effect of the digoxin and tell her not to take the digoxin for one day and to go to her GP on Monday to explain her symptoms.

There clearly is a DRP, a problem with the pharmacotherapy, because the visual disturbance is most probably due to high plasma levels of the digoxin. The probable cause of the problem is too high a dose as a result of a lack of therapeutic drug monitoring.

If this problem must be documented or registered, a classification that is especially designed for DRPs can be used. The PCNE-DRP classification is an example of such a documentation tool. The global outline of this classification is illustrated in Table 1

In the case of the woman with the digoxin, P1 and C1 plus C2 would be the appropriate coding choices because the patient suffers from an adverse drug event, caused by an issue in the drug use process. However, this description does not provide much information. Therefore, in the PCNE classification, a second more detailed information level is available. Then the coding would read as P1.3, C2.4, I2.3 and I3.5 (see also Table 2).

One will also need some extra patient and drug data in order to document a drug related problem like gender and age and ATC-code.* A form to document drug related problems is illustrated in Figure 2.

* A coding system for medicines compiled by the WHO: the Anatomic Therapeutic Classification.

Table 1: The first level domains of the PCNE-classification V. 5		
	Code	**Domains**
Problems	**P1**	**Adverse reaction(s)** Patient suffers from an adverse drug event
	P2	**Drug Choice Problem** Patient gets or is going to get a wrong (or no drug) drug for his/her disease and/or condition
	P3	**Dosing problem** Patient gets more or less than the amount of drug he/she requires
	P4	**Drug Use/Administration Problem** Wrong or no drug taken/administered
	P5	**Interactions** There is a manifest or potential drug-drug or drug-food interaction
	P6	**Other**
Causes	**C1**	**Drug/Dose Selection** The cause of the DRP can be related to the selection of the drug and/or dosage schedule
	C2	**Drug Use Process** The cause of the DRP can be related to the way the patient uses the drug, in spite of proper dosage instructions (on the label)
	C3	**Information** The cause of the DRP can be related to a lack or misinterpretation of information
	C4	**Patient/Psychological** The cause of the DRP can be related to the personality or behaviour of the patient.
	C5	**(Pharmacy) Logistics** The cause of the DRP can be related to the logistics of the prescribing or dispensing mechanism
	C6	**Other**
Interventions	**I0**	**No intervention**
	I1	**At prescriber level**
	I2	**At patient (or carer) level**
	I3	**At drug level**
	I4	**Other**
Outcome of intervention	**S1**	**Problem totally solved**
	S2	**Problem partially solved**
	S3	**Problem not solved**

Table 2: PCNE V 5.01 codes for the example case		
	Code	**Description Subdomain**
Problems	**P1.3**	**Toxic effects suffered**
Causes	**C1.2**	**Inappropriate dosage selection**
	C2.4	**Therapeutic drug level not monitored**
Intervention	**I2.3**	**Patient referred to prescriber**
	I3.5	**Drug stopped**

Classifications

There are many classifications available to code drug related problems (see also Table 3) but not all those classifications are easy to use. Van Mil *et al.* published an overview of such classifications in 2004.[7]

A practical classification should at least have the following characteristics:

- Focus on the problem itself not on its cause or consequence;
- Problems should be clearly and uniquely defined;
- The classification should be valid and the coding reproducible

Some additional properties would make a classification extra attractive:

- Preferably enable coding for both practice and research;
- Suitable for the documentation needed for the remuneration of cognitive services;
- Open structure, enabling introduction of additional coding levels without the need to change the basic structure;
- Offer an option to classify the intervention.

Selection and validity issues†

The issue of definitions becomes once again important when choosing a valid classification for documenting DRPs. What does one consider a DRP to be? In a publication by Paulino *et al*, the uncertainty or lack of knowledge about the aim or function of the drug was considered to be a drug related problem.[8] For others it could be the cause (potential cause) of a problem, but not a problem in itself.

Not many DRP-classifications have been tested for validity and reproducibility. For both the PCNE Classification and Westerlund system testing is almost continuous. Some usability data are also available for the Revised Granada Consensus, in comparison with the PCNE classification.[9] But for other classifications such data cannot be retrieved.

† This section is partially based upon a document of the National Centre for Health Outcomes Development at the University of Oxford. Source original document: http://phi.uhce.ox.ac.uk/, last accessed 12-07-2004.

Table 3: List of DRP classifications[7]

ABC system
ASHP classification
Cipolle *et al.*
Granada consensus
Hanlon
Hepler/Strand
Krska *et al.*
Mackie
PAS
PCNE Classification
PI-doc
SHB-SEP
Westerlund classification

Figure 2: DRP-Registration Form V5.01 (PCNE Classification)

Patient number _____

Age of patient _____ ☐ Male ☐ Female

Name of medication _____ ☐ R_x ☐ OTC

Main active substance _____ ☐ New ☐ Refill
(ATC-Code(s))

N° of drugs taken _____ ☐ According to patient
☐ According to medication record

Problem discovered ☐ by patient ☐ by pharmacy ☐ by physician Date:_____

Description & comments: Time spent on evaluation and intervention: min _____

TYPE OF PROBLEM *(Code for max. 1 problem)*

CAUSE OF DRP *(Max. 3 codes)*

TYPE OF INTERVENTION *(Max. 3 codes)*

OUTCOME OF INTERVENTION *(Only one code)*

Like for other classification or instruments, for DRP classifications it is also important that users can consider different aspects of the instruments. There are eight criteria that should be considered in the selection of drug related problem classification and those criteria in the mean time also constitute criteria for validation.

Appropriateness: is the classification content appropriate to the questions which the application seeks to address?

Acceptability: is the classification acceptable to pharmacists and researchers?

Feasibility: is the classification easy to use and process?

Interpretability: how interpretable are the codes of the classification?

Precision: how precise are the codes of the classification?

Reliability: does the classification produce results that are reproducible and internally consistent?

Validity: does the classification document what it claims to measure?

Responsiveness: does the classification offer options to follow interventions and outcomes of interventions?

These criteria are not uniformly described in the literature; nor can they be prioritised in terms of importance, rather they should be considered in relation to the proposed application of a DRP classification.

Conclusion

The concept of drug related problems is essential for pharmaceutical care, and the pharmaceutical care process. Nevertheless, documenting DRPs systematically in practice or for research is difficult. There are a number of instruments available. But the available validation data for some instruments show poor reproducibility. There seems to be a difference in how different professionals assess the drug treatment process, and identify the problems. This difference in skills is enhanced by varying levels of actual knowledge.

Documentation systems for other professions also pose problems in practice. The quality and correlates of medical records in the ambulatory care setting are debatable too.[10]

It is certain that actual and potential drug related problems occur, and can be corrected in order to improve the outcome of pharmacotherapy. But there seems to be little agreement on how to name and classify these problems between both researchers and practitioners alike.

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