CONFERENCE REPORT

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Indicators of prescribing quality in drug utilisation research: report of a European meeting (DURQUIM, 13-15 May 2004)

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Abstract An invitational expert meeting on indicators of prescribing quality was held on 13–15 May 2004, bringing together—from 19 European countries, the US, Canada, and Australia—40 researchers specialized in the development and application of indicators. The meeting was organized by the European Drug Utilization Research Group (EuroDURG), the Belgian National Health Insurance Institute (RIZIV-INAMI), and the World Health Organisation Regional Office for Europe (WHO-Euro). The field of prescribing quality was defined and delineated from the medical error field. A conceptual grid for classifying quality indicators was discussed, combining two axes (a drug/disease/patient axis and a structure/process/outcome axis). In addition, available databases were listed for continuous monitoring of drug utilization in Europe, with a description of the content and the richness of the collected data, as well as the impact on the potential and limitations to develop quality indicators. The importance of the origin of data for validity assessment was stressed, as data on drug utilization may originate from physician sources (prescribing data), from pharmacist or health insurer sources (distribution data), or directly from patient sources (compliance data). The different aspects of validity and their methods of assessment were listed. An overview of

The DURQUIM Scientific Committee: Andersen M, Bergman U, Chapman S, de Joncheere CP, De Swaef A, Elsevier MM, Haaijer-Ruskamp FM, Hallas J, Mol PG, Vander Stichele RH, Vlahovic V, Wettermark B.

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De Pintelaan 185, 9000 Gent, Belgium E-mail: Robert.vanderstichele@ugent.be the (in)appropriate uses of indicators was given. The state of the art of the development and application of prescribing quality indicators in all represented countries was made, together with a first draft of a database of prescribing quality indicators, already subjected to validation procedures.

Keywords Drug utilization · Drug prescribing · Health care · Validity assessment · Quality indicators · Europe

Introduction

An expert meeting on indicators of prescribing quality was organised in Mechelen, Belgium on 13–15 May 2004, in a joint effort of the European Drug Utilization Research Group (EuroDURG), the Belgian National Health Insurance Institute (RIZIV-INAMI), and the World Health Organisation Regional Office for Europe (WHO-Euro).

In past decades, most European countries have developed data collection systems to monitor drug utilisation by measuring volume and expenditures of medicines on a national scale. For international comparisons, a drug classification system was elaborated by the World Health Organisation, namely the Anatomical Therapeutic and Chemical Classification with standardisation of the expression of drug consumption in Defined Daily Doses (the ATC/DDD system) [1]. A number of transnational studies comparing volume and expenditures of different countries have been published, culminating in recent pan-European comparisons [2, 3, 4]. Meanwhile, national drug utilisation monitoring systems have been increasingly used for measuring not only volume and expenditures of prescribing, but also the quality of prescribing. Hence, it is now time to pay attention to the opportunities and pitfalls in measuring prescribing quality using indicators derived from drug utilisation databases.

The Expert Meeting was labeled DURQUIM (Drug Utilisation Research Quality Indicators Meeting). From

19 different countries, 40 experts were invited to join the meeting, all of whom were researchers and/or policy-makers involved in specific European programs for quality indicator development. Three observers were present from the US, Canada and Australia.

The meeting focussed on four issues: a taxonomy of prescribing quality indicators, types of available data sources for working with indicators, the validity of indicators, and the possible (in)appropriate uses of prescribing quality indicators. Another objective of the meeting was to start a European catalogue of drug utilisation databases and of currently used prescribing quality indicators, including the status of validation of these indicators.

The meeting was prepared by a Scientific Committee and the Department of Clinical Pharmacology of the University of Groningen (The Netherlands), resulting in a background paper, with a complete literature review and a description of the "state of the art". This document is now available as a World Health Organisation publication [5].

At the start of the meeting, a representative of every country gave a short overview of data sources and examples of prescribing indicators available in his/her country (see EuroDURG web site http://www.eurodurg.com). These presentations clearly illustrated the existing differences among European countries. Then, the four major themes of the meeting were discussed. An introduction was given for each of the themes, followed by an intense group discussion in small working groups and a plenum. Experts from the US, Canada and Australia informed the group on specific projects abroad. In a closing session, a proposal for methodological and policy recommendations was refined and finalised (see Annex 1).

A taxonomy of quality indicators of prescribing

This first theme was introduced by F.M. Haaijer-Ruskamp (Clinical Pharmacology, University of Groningen, The Netherlands).

The proposal for a taxonomy is based on the definition of prescribing quality, as agreed on by the WHO: "rational drug use means each patient receiving medication appropriate for his/her clinical needs, in doses meeting the related requirements, for an adequate period of time and at the lowest costs to them and to the community," with the element of including the patient's perspective as proposed by Barber [6, 7]. The definition of a prescribing quality indicator was given adjusted from the general indicator of quality of care, described by Lawrence and Olesen (1997): "a measurable element of prescribing performance for which there is evidence or consensus that it can be used to assess quality, and hence in changing the quality of care provided" [8].

Based on this definition, a taxonomy grid was proposed to categorize prescribing quality indicators, subdivided in process and outcome indicators on a first axis and on a second drug-, disease-, and patient axis. Drug-

oriented indicators include information solely on drugs. Disease-oriented indicators include information on drugs linked to diagnosis, where prescribing quality is seen as a part of the treatment quality. Patient-oriented indicators include information on individual clinical characteristics of the patient, e.g., severity of the disease. In a third separate axis, indicators can be included that describe documentation requirements, such as documentation of drug allergy on the medical chart.

It was proposed to limit the taxonomy to prescribing decisions and to include some aspects of medication error (limited to prescribing an inappropriate medicine, over- and under dosage, as well as suboptimal prescribing such as not prescribing an indicated medicine). Some problem areas were discussed such as the use of indicator sets as opposed to individual indicators and the inclusion of patient preference into prescribing. Also, the difference between a prescribing quality indicator and a comparator was emphasized; the latter is used to compare prescribing patterns at different levels, doctors, regions, countries, etc.

The nature of the available data sources

This second theme was introduced by J. Hallas (Clinical Pharmacology, Odense University, Denmark).

He emphasized the importance of using accurate data, i.e., the internal validity, and stressed the importance of recognizing the origin of the data, by proposing a grid along the lines of the prescribing and drug utilisation process: prescribing data (stemming from general practitioner databases); dispensing/purchasing/reimbursement data (stemming from pharmacy databases); and data on actual ingestion of medicines (stemming from patient observations).

Areas of major and minor uncertainty exist at all levels of the prescribing process. Discrepancy between different data sources was illustrated as well as its consequence for the use of quality indicators with examples derived from scientific literature. Lack of information on actual drug intake was considered a major problem. In general, the choice of the optimal data set is determined mainly by the problem studied. Is it the prescribing process? If so, GP data often provides the most complete information since these databases include information on the diagnosis. Is it drug exposure? If so, a pharmacy database may be better, although information on actual drug intake or health outcome requires information from the patient.

Validation of quality indicators of prescribing

M. Andersen (General Practice, University of Southern Denmark, Denmark) introduced this third theme.

He pointed out the necessity of having valid indicators and explained the concept of external validity. In the context of quality indicators, the concept of external validity demands evidence that the indicator is a good translation of the actual clinical situation or problem under study, and that changes in the value of the indicator are indeed related to changes in health. Different types of external validity were discussed, i.e., face-, content-, concurrent and construct validity. Definitions were given and further elucidated with examples to demonstrate the need for proper validation. To date, attention to validity has focused on content- and face validity. The few examples that have looked at concurrent validity indicate that content- and face validity may not be adequate, especially when indicating prescribing quality of complex diseases such as asthma. For adequate validity of indicators, involvement of stakeholders, in particular prescribers and patients, is important.

The use of quality indicators of prescribing

The last theme was introduced by S. Chapman (Medicines Management, Keele University, UK).

The essential issue in using indicators is asking the right questions with the right data and for the right reasons. In the UK, routinely available PACT (primary care alliance for clinical trials) data give information on expenditures and volume trends over time and are used to support GPs, to contain expenditures, for benchmarking and for identifying outliers. Issues of volume and expenditures are most often the primary focus, although they indicate little about prescribing quality. One of the problems is that PACT data lack information on diagnosis or indication. However, combining PACT data with data from a GP database, such as GPRD (General Practice Research Database), gives opportunities for more detailed prescribing quality measurement. Chapman identified barriers to Europe-wide indicators and wondered which minimum standards with regard to prescribing quality indicators could be applied across Europe.

Summing up

Prof. J. Avorn (Harvard Medical School, Boston, USA) discussed the meeting results from an American viewpoint. He presented the RAND template for rational prescribing. This template uses the "if (health problem)—then (drug)—because (clinical trial data)" terms to identify the underlying logic of a prescription. Avorn concluded with a two-sided implementation of quality indicators, through educational outreach and political buy-in (see Euro DURG Web site).

Information on Australian projects was brought by Jane Robertson. Colleen Metge reported on the Canadian experiences.

The participants concluded the meeting by stressing the relevance of developing European indicators of prescribing quality to be based on international evidence. Such European indicators are valuable in identifying the main problems in prescribing within the European countries. Shared problem areas, such as the use of cardiovascular drugs, antibiotics, and anti-asthmatics should be used as a focus in developing Europewide indicators.

The meeting ended with a set of recommendations, supported by the participants, on the four aspects of quality indicators discussed. These recommendations focus on methodological aspects and on policy making (see Annex 1)

It was decided that, in the following years, this meeting on quality indicators in general will be followed by a number of meetings on specific drug classes, such as cardiovascular drugs, antibiotics, and anti-asthmatics.

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Annex 1: Recommendations of the drug utilisation research quality indicator meeting (DURQUIM), held in Mechelen, Belgium, 13–15 May 2004

Recommendations on methodology

On taxonomy it is recommended

- To define a prescribing quality indicator as a measurable element of prescribing performance for which there is evidence or consensus that it can be used to assess quality and, hence, be used in changing the quality of care provided
- To adopt and test a taxonomy in research programs categorizing indicators as drug-, disease-, and patientoriented indicators of prescribing quality at process and outcome level for quality indicator development
- To develop indicators of prescribing quality
- To develop disease-oriented quality indicators
- To develop indicators that include the patient preference

On the use of *databases*, it is recommended

- To be conscious and explicit about limitations of data sources.
- To conduct comparative studies on specific prescribing quality indicators within data sources on different levels (physician, pharmacy and patient).
- To develop a catalogue of all available databases within Europe. In particular, the availability of clinical data and treatment objectives must be considered.
- To further explain the use and ownership of such a database.

On the validity it is recommended

- To consider validation as an integral part of the development and implementation of indicators
- To consider requirements on validity in relation to the type of indicator (taxonomy) and the purpose it is used for (context)
- To provide an explicit and clear evidence base, e.g., what part of the guidelines is referred to and the extent the guidelines are up to date (content validity)
- To assess consensus procedures in relevant target groups, both in development and validation of indicators (face validity)
- To compare indicators of prescribing quality with another (gold) standard for both disease- and patient oriented indicators, especially if indicators include proxies of indications, co-morbidity, or disease severity (concurrent validity)
- To start with a catalogue of prescribing indicators used across Europe with information on validation, use and references to guidelines, studies, and reports

On the use of indicators, it is recommended

- To have common standards of data collection
- To have common general principles for generating indicators
- To have common evidence base for quality indicators on all levels (individual to national)
- That in most cases quality indicators need information on drug as well as diagnosis or indication

Recommendations on policy

On taxonomy it is recommended

- To include or develop indicators of prescribing quality
- To include both drug- and disease-oriented quality indicators
- To promote development of disease-oriented quality indicators
- To support the development and implementation of a robust and valid methodology to select prescribing quality indicators
- To harmonise the development and/or inclusion of indicators of prescribing *quality* in sets of performance indicators

On databases it is recommended

 To organise and maintain a catalogue of major data sources across Europe, using EURO-MEDSTAT as a starting point

- To use a common form for description of databases
- To facilitate access to and linkage between relevant data sources
- To strengthen existing administrative drug databases on volume and expenditures by supplementing with clinical data and/or a clinical database from a population sample

On use of indicators it is recommended

- To measure prescribing quality in key disease areas on a national level and to empower prescribers
- To differentiate between quality indicators and comparators (relative markers)
- To let quality indicators lead to a payback to healthcare systems, either in saving money or better health.
- To share individual country-generated indicators when in context

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