EURO DURG bulletin

No. 10 **November 2000**

EUROPEAN DRUG UTILIZATION RESEARCH GROUP

Editors. *This issue was prepared by the following members of the Executive Committee of EURO DURG: Morten Andersen.*

Strategy for the realisation of the general objectives of "Mapping Europe"

EURO DURG has advocated since its inception, the use of validated scientific methods to construct monitor systems for drug utilization in the European countries:

• To be able to study drug utilization from the double perspective of cost and volume in a population-based approach, EURO DURG recommended the general use of the Anatomical Therapeutic Chemical Classification (ATC) and the Defined Daily Dose (DDD).

• EURO DURG has sustained the ongoing activities of the WHO-Collaborating Centre for Drugs Statistics Methodology in Oslo, to maintain and expand the ATC classification and DDD methodology, now under supervision of WHO at world level.

• EURO DURG scientists participated actively in a number of countries in the actual creation and maintenance of national monitoring systems, particularly in the northern countries and the Central and Eastern countries of Europe.

• EURO DURG has welcomed the initiatives of the European Commission for concerted action to create internationally validated national monitoring systems for antibiotics utilization, in response to the Copenhagen Recommendations, issued at the 1998 EU conference on the microbial treat.

However, it is obvious that the penetration of the scientific approach to drug utilisation monitoring in national monitoring systems (now set up in most countries, all over Europe) needs further support.

Moreover, a similar observation can be made in the different projects regarding drug information, tracking of drug regulatory activities, drug price policy and drug utilization monitoring at the European level.

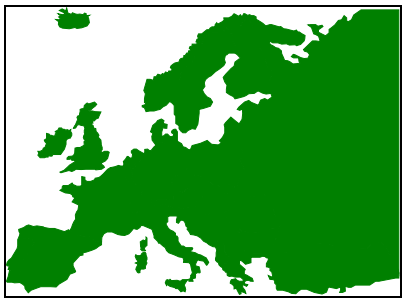
The strategic decision was therefore to take two initiatives:

1. To collect, in an exemplary way, data on antibiotics (project described in EURO DURG bulletin No. 9).

2. To propose a number of European projects in the Research programs of the European Commission.

These research projects pertain to the technological aspects (health telematics) of creating a European Database of registered and marketed Medicinal Products, to the implementation of the European Standard of Medicinal Product Identification of the CEN (European Committee for Normalisation), and to validated linkage procedures of unique identifiers of medicinal products on the national market to the internationally accepted classification systems (i.e. ATC).

Furthermore, the creation of this database is linked to a proposal for technical excellence in bringing independent drug information to physicians and patients, in cooperation with the national drug information centres and the competent national authorities.



One of these projects (MEPIRA) is already formally submitted in a consortium with Prof. G. Demoor (Health Informatics, Ramit), WHO-EURO, and an information technology company.

Granting of this project would make it possible to create a trans European network to validate and field test the structural specifications of a European database of Medicinal products, and to elaborate the functional analysis of a database maintenance tool for national authorities and national drug information centres.

R. Vander Stichele, B-DURG

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IN THIS ISSUE

Report from the EURO DURG General Assembly

The General Assembly was held at the Princess Sofia Intercontinental Hotel, Barcelona, 20 August 2000 from 11.00-13.30 and attended by about 40 persons.

Report of the Executive Committee

Flora Haaijer-Ruskamp and Marit Rønning presented the report of the executive committee concerning the activities in the period 1998-2000. The internal communication in the committee in between the EURODURG meetings has been via telephone conferences and e-mail. 13 telephone conferences have been arranged since the general assembly in Berlin in August 1998.

The following meetings have been arranged:
- The EURODURG annual meeting at the Dead Sea in October 1999. The main theme was: Improving the quality of drug utilisation – resources, methods and objectives. The report from the meeting is included in EURODURG bulletin no 8.
- A joint EURODURG/EACPT symposium was arranged in Jerusalem in October 1999 on the first day of the EACPT conference.
- A joint EURODURG/CPT symposium was arranged in Florence in July 2000.

Three new national groups have been established in the period. The total number of national groups is now 17. Since 1998, Armenia, Bulgaria and Russia have been welcomed as new members.

An important information channel within the EURODURG network is the EURODURG bulletins. Four issues have been published in the period. Information about coming meetings and reports from meetings are included in the bulletins. The distribution procedure is that the bulletin is sent from the executive committee to the national chairs or contact persons and to all individual members. The national chairs are responsible for the further distribution to the members within each country. It was regretted from the executive committee that the bulletins sometimes have been delayed. The EURODURG website is still active even if there have been problems with the updates.

"The way ahead", a discussion document for general policy of EURODURG, has been prepared by the executive committee. This document was distributed to all national chairs in June.

Financial report

Emilio Sanz briefly presented the financial report for the period 1998-2000.

Report from the working groups

Emilio Sanz presented a brief report from two of the EURODURG working groups:
- TUPP – The User Perspective Project
- CHILDURG – Childrens use of Medications Study

Further information about these groups are available in EURODURG bulletin no 9

Robert Vander Stichele reported from the "Mapping Europe" project. A document explaining the strategy for the realisation of the general objectives of "Mapping Europe" is included elsewhere in this bulletin.

Hege Salvesen Blix reported from the collection of drug utilisation data on antibacterials. A brief outline of this project was presented in EURODURG bulletin no 9.

Reports of national DURGs

Svetlana Ratchina gave a presentation of the latest formalised national group, DURG Russia or the Russian Society of Pharmacoepidemiology.

There was no time for reports from other national groups.

"The way ahead"

The policy document was briefly discussed. It was concluded that the discussion should be continued in the national groups and that the executive committee should try to prepare some general policy "guidelines" in the next period, based on input from the members.

Future meetings

A separate EURODURG meeting will be arranged 7-10 June 2001 in Prague.

A joint EURODURG/EACPT symposium will be arranged in Odense in September 2001.

Election of the EURODURG executive committee 2000-2002

The nominating committee consisting of Annemarie Hoffmann (Germany), Ebba Holme Hansen (Denmark) and Nicola Montanaro (Italy) had received 13 candidates for the new executive committee (see EURODURG bulletin no. 9).

Votes were received from 11 countries.

The following eleven candidates were elected for the EURODURG executive committee 2000-2002:

John Ferguson - UK (chair)
Monique Elseviers - Belgium (new)
Karel Nemecek - Czech Republic (new)
Morten Andersen - Denmark
Joerg Hasford - Germany
Gyöngyvér Soós - Hungary (new)
Almar Grimsson - Iceland
Marit Rønning - Norway
Alfonso Carvajal García-Pando - Spain (new)
Christer Luthman - Sweden (new)
Lolkje T.W. de Jong-van den Berg - The Netherlands (new)

Election of nominating committee 2002

The following candidates for the new nominating committee were elected:

Flora Haaijer-Ruskamp - The Netherlands
Robert VanderStichele - Belgium
Ulf Bergman - Sweden

Closing remarks

The new chair, John Ferguson, welcomed the new members of the Executive Committee and thanked the former members of Executive Committee for the passed years. Special thanks were given to the former chair, Flora Haaijer-Ruskamp, for her strong commitment in building up the EURODURG as a scientific association.

Marit Rønning

Report from the ISPE/EURO DURG joint sessions in Barcelona

During the joint meeting of EURO DURG and ICPE on Monday 21st August in Barcelona there were two sessions with the issue: Drug use and Prescribing practice.

Morning session

During the first session on Monday-morning there were 6 presentations of which three regarding drug compliance and adherence.

The study of Peter Donnan from the University of Dundee was about adherence to prescribed oral hypoglycaemic medications. He concluded that one in three patients with type 2 diabetes had adequate adherence to their medications. One daily dosing and a lower number of comedications were associated with better adherence.

A study presented by Philip S. Wang of the Harvard Medical School identified factors, including modifiable psychosocial and behavioural characteristics of patients, associated with poor adherence with antihypertensive therapy. He concluded that depressive symptoms may be an underrecognized but modifiable risk factor for poor antihypertensive compliance. Patient knowledge of hypertension, health beliefs, and poor psychosocial variables do not appear to consistently affect adherence.

Yola Moride from the Faculty of Pharmacy of the Montreal University presented her study of predictors of adherence to antidepressive treatment She evaluated whether the recommended at least 6 months treatment was maintained in a fixed cohort of 1301 GP's and 236 psychiatrists. She found that only 55% of treatments initiated by GP's were more than 6 months versus 73% for psychiatrists. Factors that significantly decreased adherence were among others urban practice, age of the patient and increasing co-morbidity. She concluded that since patients who initiate treatment from GP's are less likely to follow guidelines, interventions should be targeted towards GP's especially in urban regions.

All these studies looked at factors influencing compliance and these findings are important for those who are planning interventions to improve drug compliance in every day medical and pharmaceutical practice.

Lolkje T. W. de Jong-van den Berg

Afternoon Session

Several of the afternoon presentations dealt indirectly with the problem of accessing knowledge at the right time. We have a lot of knowledge of how to treat and how to use the pharmacological toolbox, but sometimes there seems to be a discrepancy between evidence based medicine and the everyday reality, examplified during the afternoon. The reason for this discrepancy might have to do with a lack of coordination of medical and pharmacological information and perhaps also a lack of feedback to the prescriber. If this is the case, treatment, outcome and adverse effects should be properly recorded and accessible in the right situation to the benefit for the patient. A task for the future would be to agree upon a minimum level of an infrastructue for informatics within the healthcare systems. So, in the glorious tomorrow the patient will not be a hazard to an otherwise perfect heath care system.

In the first presentation the striking difference in therapeutic tradition between Denmark and Italy of antibiotic use in children was shown. In Italy the broad-spectrum antibiotics are dominating whereas in Denmark the narrow-spectrum penicillins and macrolides are. The big difference in resistance patterns, the most severe one in Italy, was also illustrated. In Denmark, however, antibiotic resistant pneumococci are still extremely rare.

The second presentation showed that in the UK, contrary to the terapeutic guidelines, the use of combined oral contracepties did not decrease among women with the diagnosis lupus erythematosus (SLE).

The third presentation illustrated a positive result, how the use of newer and more efficient pharmaceuticals for treating early symtoms of lower urinay tract symtoms (LUTS) now postpones surgery. The postponement of surgery was associated with earlier treatment and the increase of use of newer, more effective products such as finasteride and new alfa-blockers. At this point of the afternoon it felt releaving to hear how knowledge can be used to the benefit for the patients.

In the fourth presentation we were told about the use of contraindicated drugs, in this case NSAIDs, to people with previously proved gastriontestinal problems. But during the discussion it became clear that ASA was used in low dosage as an antithrombotic agent.

The fifth presentation was from Denmark and described the influence of risk factors, as day care attendance, on use of systemic antibiotics in kids. The conclusion was that there are no difference in risk for the kids between these forms of day care for receiving systemic antibiotics – at least not in the studied age group 0-2 years old. A conclusion, though not so well documented, was that a longer maternity leave would decrease the use of antibiotics. This is a very important socio-economical point.

The sixth presentation "Patterns of Hormone Replacement Therapy in the UK" with focus on women with and without hysterectomy. The adherence is 88% which is high in comparison to other drug groups. A substantial proportion of women still receive unopposed estrogens; they should also receive prostagens to reduce their risk of endometrial cancer.

The last presentation of the afternoon was about the "High Failure Rates of Presumptive Helicobacter Eradication Therapy in General Practice". A prescription database in Ireland was used to determine success rates. They found a 56% failure rate and even higher in the age group over 65. This is over 5 times the reported failure rate in controlled hospital-based trials. This seemed as a consequence of bias, because the outcome measure was inappropriate.

Christer Luthman
Gyöngyvér Soós

Results of poster evaluation

First authors and titles of posters awarded in the ISPE/EURO DURG poster sessions are listed.

1st prize: Nana Thrane. Individual use of antibiotics and prevalence of beta-lactam resistance among bacterial pathogens from middle ear fluid.

2nd prize: Lisa G. Pont. Asthma and asthma medication – a database study of asthma treatment in general practice.

3rd prize: Fabrizio de Ponti. Exposure to non-cardiac QT-prolonging drugs in the community – comparison among seven countries.

Awards for each session:
E. Soler Company. Patterns of analgesic drugs utilization during the postoperative period in a Spanish hospital.

Jose C. Domingues. Therapeutic profile of antihypertensive drug use by Portuguese sentinel GP.

Lars Bjerrum. Increasing prescription rate of lipid lowering drugs after introduction of guidelines on cardiovascular risk.

Jens-Ulrik Rosholm. Use of antidepressants from 1992 to 1997 with focus on duration of treatment and age-related prevalence.

Kirsten Schæfer. Psychopharmacology and general practice. A quality improvement project in the County of Roskilde, Denmark.

Björn Beermann. Prescription based study on the use of orlistat.

Lisa G. Pont. Relevance of interventions to reduce polypharmacy.

Hedvig Nordeng. Drug use in early pregnancy – the impact of maternal health and sociodemographic factors.

Morten Andersen

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EURO DURG meeting, Prague, Czech Republic 7-10 June 2001

Integrating drug utilization studies in a wider Europe

Venue: State Institute of Drug Control

A central issue of the meeting is the construction of a European data base with information on pharmaceuticals, and tools for editing and disseminating independent information on medicines to health professionals, patients and the lay public at the national level. We will also focus on the topics of health technology assessment, meta-analysis, drug information, guideline development, promotion of rational drug use, drug classification, implementation of research and the effect of pharmacovigilance findings on the decision process guiding drug prescribing and drug taking.

http://congress.cls.cz/eurodurg/

5th Congress of the EACPT Odense Denmark 12-15 September 2001

EURO DURG joint sessions on 14-15 September.

Session A.3 - Drug use in the paediatric population in Europe

Chair: E. Sanz (Spain)
Co-chair: G. Pons (France)

1. Drug use research in children. The project CHILDURG (E. Sanz, Spain)

2. Drug use in children in Eastern Europe (S. Rachina, Russia)

3. Drug use in children in EU (A. Peiré, Spain)

4. The use of population databases to explore the use of drugs by children (J. Straand, Norway)

5. Qualitative studies on drug use in children: what do children think about health, disease and the use of medicines. A multidisciplinary, cross-cultural research to study drug use. The COMAC and ASPSRO1 and ASPSRO2 projects (D. Trakas, Greece)

Session A.4 - Quality indicators in drug use

Chair: M. Andersen (Denmark)
Co-chair: N. Montanaro (Italy)

1. How to implement general indicators for the quality of drug use in clinical practice (U. Bergman, Sweden)

2. Poor quality of drug treatment observed in patients entering the clinical trials in cardiology (P. Lechat, France)

3. Measuring changes in quality of drug use in intervention studies (M. Maclure, Canada)

4. Quality aspects in NSAID use (J.R. Laporte, Spain)

5. Indicators for the quality of asthma treatment (P. Denig, L. Pont, Netherlands)

http://www.sdu.dk/med/homepages/eacpt/eacpt5.html

Challenges in drug utilization research – Karl Kimbel in memoriam

The Contergan (thalidomide) catastrophe required an explanation free from the specific interests of the pharmaceutical industry and demanded methodically reliable and scientifically independent studies into medication risks, in particular after admission to the market. As the Contergan experience showed, there are severe risks that then become obvious only when the drug is used in outpatient care. These considerations motivated the constitution of the Drug Utilisation Research Group (DURG) at the European WHO Office (1964). The founding members came from those countries whose health system is organized nation wide. In these countries, which include Great Britain, Germany and its Nordic neighbors, the well-being of the citizens has priority to commercial interests. These countries have data for their health systems at their disposal which form a suitable basis for drug utilization research. The first drug utilization studies that became models for this kind of research were published in the Nordic countries [Baksaas 1980, Gross and Inman 1977]. Germany was represented in the DURG (WHO) by Karl Kimbel and Hans Friebel.

In 1996 the EURO DURG was established as an independent society in Balaton, Hungary and as the umbrella organization for all the national societies. The "Gesellschaft für Arzneimittelanwendungsforschung (GAA)" (Society for Drug Utilization Research) was one of the co-founders.

Already in 1992 Karl Kimbel had taken the initiative in founding the GAA. In its constitution the Society defined the following aims and tasks: It supports scientific research into the utilization of drugs; in particular, it is concerned with the influences on drug use and prescribing behavior and the study of benefits and risks of drug therapy. It is engaged in the distribution of research results. It supports international co-operation in these fields.

In setting these aims the GAA adopts an important position – as a Public Health Discipline – in relation to pharmacoepidemiology whose focal point lies in research into the effects and side-effects of drugs, primarily in clinical studies.

Karl Kimbel thought the following questions should guide the research activities of the EURO DURG:
- What evidence-based information is available concerning medication and drug utilization?
- What characterizes medication used by the patient, what characterizes drug utilization by the doctor?
- Do medication and drug utilization meet quality criteria?

In his opinion, the results of such studies, should form the basis for research in the following context:
- Which social, mental and cultural patterns influence the patients' demand and put prescribing pressure on the doctor?
- Can medically necessary drug use be separated from medically unnecessary use? If so, how can the dividing line be set in a practical manner?
- Which contraindications against the use of particular drugs must be considered? For example, interactions, ADR, introduction of new drugs without sufficient experience.

The data base used to examine these questions should be, according to Kimbel, the implementation of documents from statuatory health insurance or state-financed health care, as is the case in the Nordic countries, Great Britain, Canada and Italy. In Germany the statutory health insurance (GKV) data is most suitable. Such data are a reliable basis for epidemiological statistics concerning mortality, morbidity and care, if they can be made widely available and be analyzed both on a population and on an individual level. These data are then particularly suitable for drug utilization research. Just last year Karl Kimbel intensified his efforts in public statements to resume research on a random sample of insured persons in the GKV. He engaged in the campaign promoting patient-related research within the limits set by the data protection laws.

Likewise he was involved in the demand for the unrestricted publication of the Drug Prescribing Report 1997 (Arznei-Verordnungs-Report 1997) against legal objections of the pharmaceutical industry. Kimbel's aim was to provide a neutral ground for uncensored drug reports.

Karl Kimbel regarded close co-operation of national and European research as important. Joint projects which must be borne in mind are: the Mapping Europe project – an international comparison of drug use in Europe. Kimbel made an effort to establish an internationally defined daily dose (DDD) and ATC (WHO drug coding system), used commonly in all participating countries, as a technical prerequisite for international drug utilization research.

With respect to quality assurance and optimization of drug therapy Kimbel was convinced that it is hard to determine the deviding lines between necessary and unnecessary use which are not clear, above all, to the general practitioner. Therefore, he regarded the definition of "necessary" and "unnecessary use" as the most crucial problem for research, since the GP urgently needs this information for everyday prescribing.

All of us who work in the field of drug utilization research are very thankful to Karl Kimbel for having laid the most important milestone for our research. We can best show our appreciation by putting his ideas into practice.

PD Dr. med. L. von Ferber
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An update of National DURGs in Europe

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