EuroDURG bulletin

No. 20 **January 2010**

NEWSLETTER OF THE EUROPEAN CHAPTER OF THE SPECIAL INTEREST GROUP OF DRUG UTILSATION RESEARCH (SIGDUR) OF THE INTERNATIONAL SOCIETY OF PHARMACOEPIDEMIOLOGY (ISPE)

Editors. *This issue was prepared by the following members of the Executive Committee of EuroDURG: Monique Elseviers, Robert Vander Stichele, Bjørn Wettermark, Elisabetta Poluzzi, Vera Vlahović-Palčevski Ria Benko.*
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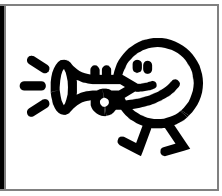
The Chair's message



Dear reader of this DUR Bulletin, Dear DUR friend,

For those of you who never heard about EuroDURG, we offer you a warm welcome to the readership of the EuroDURG bulletin. Especially for you, we will give a brief presentation of EuroDURG with an explanation why you receive this bulletin. For those who know EuroDURG, we hope this bulletin will serve as a pleasant reunion with the EuroDURG family.

This is the first time that we send the EuroDURG Bulletin directly to individual researchers interested in Drug Utilization Research (DUR) in Europe.
Based on lists of national DUR groups and DUR poster submissions of preceding years, completed with a literature research, we were able to identify more than 500 European DUR researchers.

EuroDURG

EuroDURG started its activities in 1987 inside the World Health Organisation. It became officially a European scientific non-profit organization with the registration of its constitutions in Spain in 1996.

European Drug Utilisation Research Group
EuroDURG

The mission of EuroDURG was and still is "to promote drug utilization research as a means to improve use of drugs by providing an international forum for communication and cooperation between people interested in drug utilization research". This mission was supported by national DUR groups of European countries.

Interested in EuroDURG? Please fill in our questionnaire at:

http://spreadsheets.google.com/viewform?formkey=dE9oeG94dHFwODFDUVhmUmlmakh1M2c6MA

It costs only 5 minutes of your time!

Not individual researchers but the national DUR groups registered as members of EuroDURG and proposed candidates for the executive committee.
During the last decade, the executive committee (ExCo) of EuroDURG managed to keep together a small but dynamic group of researchers, linked to regulatory authorities, universities and health insurers. The interest evolved from classical drug monitoring at national levels to quantitative research in drug use, and intervention research to improve the quality of prescribing with special focus on prescribing quality indicators.
You can find more information about our activities at the EuroDURG website: www.eurodurg.com

IN THIS ISSUE

EuroDURG as the European chapter of ISPE/SIGDUR

In 2006, the International Society of Pharmacoepidemiology (ISPE)

Board accepted a petition to create a special interest group (SIG) for Drug Utilization Research (SIG-DUR) with the full support of EuroDURG. The mission statement of the new SIG-DUR is "to create a global forum for discussion and cooperation between drug utilization researchers". It was decided that EuroDURG will continue as a regional chapter within SIGDUR, limiting its activities to the European scene. Last year, also Australia, Canada and the United States started to set up a regional chapter of SIGDUR.

As a consequence, EuroDURG will no longer focus on national membership, but will promote individual membership of ISPE in all European countries. ISPE has facilitated this by changing its policy rules and by reducing the annual membership fee for members from low and middle income countries to US$ 25. For further information about our 'umbrella' organisation ISPE and for ISPE membership, please visit the website at http://www.pharmacoepi.org
While registering as a member of ISPE do not forget to mark on the membership application that you are interested to join the Special Interest group of Drug Utilisation/ Health Service Research.

Next to this development, EuroDURG will try to identify and contact individual European DUR researchers, aiming to present our activities, to invite you for active participation and to offer a unique European-wide opportunity for DUR networking.

EuroDURG Activities 2008-2009

Despite important budgetary limitations, the EuroDURG Executive Committee succeeded to maintain its communication channels by the organization of teleconferences (bimonthly), the publication of the Bulletin and a regular update of the EuroDURG website. EuroDURG was actively involved in the European research project Happy Audit and took the lead in the SIGDUR initiatives on Cross-national comparison of drug utilization and the ATC browser (for details, see further in this issue).

What brings 2010?

EuroDURG will continue to actively support the Cross national comparison initiative focusing on the evaluation of drug utilization data in view of European national legislative initiatives. In 2010, EuroDURG will also participate in a new European FP7 project on drug-induced arrhythmias (ARITMO).

Since this year the ISPE conference will be organised again in Europe (Brighton (UK) from 19th to 22nd of August), EuroDURG will be more actively involved in the scientific programming as well as the advertisement of the conference among European DUR researchers. During the Brighton conference, election of a new EuroDURG chair, executive committee and ISPE liaison will be organized.
We look forward to meeting also you in Brighton. Do not miss this unique opportunity to receive all the latest information in the field of DUR, to present your research work and to meet your colleagues and friends.

ISPE CONFERENCE BRIGHTON, ENGLAND, UK
19-22 AUGUST 2010
Do not miss the opportunity to present the results of your DUR projects during the next ISPE meeting in EUROPE!

Submit your abstract at: www.call4abstracts.com/ispe10/
before **February 10, 2010**

Please start now to prepare your DUR abstract and do not miss the deadline for submission (10 February) (see further in this issue)!

May we kindly ask you to show us your interest in our activities by filling in a short questionnaire that you will find at the URL link:
http://spreadsheets.google.com/viewform?formkey=dE9oeG94dHFwODFDUVhmUmlmakh1M2c6MA

For you, it will only take five minutes of your time. It will offer you a new source of information on DUR and new opportunities for networking and dissemination of research results. For us, it will be very helpful to identify European DUR researcher and their special fields of interest. The information you provide will only be used for scientific purposes within our organisation.

We look forward to hearing from you for the start of a fruitful collaboration together with all other European DUR researcher!

With kind regards,
Monique Elseviers
Chair of EuroDURG

Conferences meetings

...Previous events

ISPE 2009 Mid-Year Meeting Stockholm, Sweden

The historical development and state-of-the-art of pharmacovigilance was in the focus of the meeting. Prof. Ralph Edwards (Director, WHO-Uppsala Drug Monitoring Centre (UMC)), presented an update on the WHO Programme for International Drug Monitoring. He informed us that currently the UMC gathers data on adverse drug reactions from 86 countries. This global ADR database, (Vigibase) contains almost four million ADR reports and receive quarter of million of case reports every year. He noted that New Zealand, the USA, and the Netherlands had the highest rates of ADR reporting. We could learn that nausea, rash, headache, dizziness and lack of drug effects were the most frequently reported suspected ADRs and that ethynylestradiolnorgestrel and rofecoxib are the medications most frequently cited in reports. He also explained how the automated data mining detect signals. (from almost 4 million case reports, this system filters only 5,000 drug-event combinations.)
The afternoon was devoted to a highly relevant area of pharmacoepidemiology, Comparative Effectiveness Research (CER). The methodological challenges in CER were critically evaluated.

Ria Benko

25th ICPE in Providence, Rhode Island, USA August 16-19, 2009

The 25th silver anniversary ISPE conference was a memorable event. The conference not only offered an outstanding scientific program to the highest number of participants ever registered, but particularly celebrated the 25th anniversary of ISPE with an exciting firework and a special conference song.

As part of the ISPE/SIGDUR, EuroDURG played a prominent role in the organization of the pre-conference educational DUR session and the DUR posterwalks.

Educational session

The course *Introduction to Drug Utilization/Health Services Research* started with a presentation of the methodological framework of DUR and the ATC/DDD classification system. DUR activities in the US were highlighted as well as the use of DUR data for cross-national comparison and the development of prescribing quality indicators. Statistical methods were offered to test interventions on drug utilization. More than 60 participants attended the session. Lecturers as well as participants expressed their interest in the additional organization of an advanced DUR course for next year.

Posterwalk

A new formula was tested for the organization of the DUR posterwalks. In place of one posterwalk for the entire group of DUR posters, the presentation of DUR posters was spread over the 3 days of the conference. A daily posterwalk was organized for a limited number of DUR posters, selected on the base of the original score assigned to the submitted abstract. Using this system, one poster price winner per day was selected resulting in a total of 3 winners.

Posterprice winners

Mahic M, Skurtveit S, Selmer R, Furu K. Department of Pharmacoepidemiology, Norwegian Institute of Public Health, Oslo, Norway: Prevalence and Persistence of TNF Inhibitors in Norway 2004-2008

Munson JC, Kreider M, Christie JD, Kimmel SE. University of Pennsylvania, Philadelphia, PA, United States: The Effect of Treatment Guidelines on the Initial Management of Idiopathic Pulmonary Fibrosis

Devold HM, Duong M, Tverdal A, Furu K, Meyer HE, Falch JA, Sogaard AJ. Department of Chronic Diseases and Institute of General Practice and Community Medicine, University of Oslo, Oslo, Norway: Anti-Osteoporosis Drug Use in Norway during 2004-2007

Congratulation to the winners!

Monique Elseviers

Meeting on cross national study on drug utilization

Mechelen, Belgium
November 26-27

A meeting was held in Mechelen to discuss potentials and pitfalls of cross-national comparisons (CNC) on drug utilisation and expenditure. The objective of the meeting was to bring together data providers from more than 15 countries for validation as well as review and discussions around the rationale behind the substantial differences observed in the utilisation of proton pump inhibitors (PPIs), statins/ ezetimbe, newer anti-depressants and ACE inhibitors/ Angiotensin receptor blockers (ARBs) between European countries 2001-2007. In addition, areas of concern with drug utilisation studies were reviewed, e.g., DDDs for combination products, measures of expenditure in cross national comparison (CNC) studies and quality indicators. Frank May was also invited to help give a global perspective. Feedback was also sought from this predominantly health authority/ health insurance audience of the benefits of a future training programme/ meeting for health insurer and health authority personnel. Some individual country data have already been published in scientific papers and cross-national comparisons are now being planned. A potential poster session in ISPE in Brighton will be discussed further through EuroDurg.

Brian Godman

Upcoming conferences…

ISPE 2010 Mid-Year Meeting

The 2010 Mid-Year meeting of the International Society for Pharmacoepidemiology (ISPE) will be held in Raleigh, North Carolina, USA between the 10th and 12th of April at the Marriott Raleigh City Centre.

ISPE 2010 Annual conference

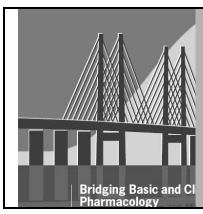
EuroDURGers and all people interested in pharmacoepidemiology are cordially invited to attend the 26th International Conference on Pharmacoepidemiology and Therapeutic Risk Management. The meeting will be held August 19-22, 2010 at the Hilton Brighton Metropole, in Brighton, a beautiful city at the south coast of England.

The preceding day of the conference (August 18) and on

the first day of the conference (August 19) special educational courses will be organized in the following topics:

- Introduction to Pharmacoepidemiology
- Pharmacogenetics I
- Student Skills Workshop
- Regulatory Pharmacoepidemiology
- Introduction to Drug Utilization
- Comparative Effectiveness
- Pharmacoepidemiology for the Pharmacist
- Reproductive Epidemiology
- Risk Management
- Advanced Topics in Pharmacoepidemiology
- Advanced Drug Utilization Research

All these require separate registration. Further information about the scientific program soon will be uploaded to the ISPE website http://www.pharmacoepi.org/meetings/26thconf



WorldPharma 2010 - Copenhagen, Denmark

The International Union of Basic and Clinical Pharmacology (IUPHAR) invite you to attend the 16th World Congress of Basic and Clinical Pharmacology in July, 17-23.

WorldPharma 2010 will provide in depth treatment of the hottest topics in basic and clinical pharmacology, while at the same time offering the broad perspective of how drugs affect the living organism, which is the foundation of our subject.
The scientific programme is available at: http://www.worldpharma2010.org/scientificprogramme.php

21st Annual Scientific Meeting

The Drug Utilisation Research Group of United Kingdom and Ireland organize their 21st Annual Scientific Meeting in London at the Royal Society of Medicine (, 1 Wimpole Street). The title is" Medicines Utilisation from national databases across Europe" The one-day meeting will be on the 4th of February 2010.

Ria Benko

ISPE educational conference for European Health Policy makers and Insurers Spring 2011

The Special Interest Group on Drug Utilisation Research within ISPE has envisioned holding a 2 days educational conference on pharmaceutical policy and prescribing quality. The project is now supported by the ISPE Educational Committee, WHO Europe, and the WHO Collaborating Centre for Pharmacoepidemiology and Pharmaceutical Policy Analysis in Utrecht, and the Belgian Health Insurance Institute. The meeting will probably be held in Belgium in the spring of 2011. A programme will be ready by the ISPE conference in Brighton.

Robert Vander Stichele

European projects

HAPPY AUDIT project

The European "HAPPY AUDIT" project and its intervention programme is aimed to reduce the occurrence of bacterial resistance

- by reducing prescribing of unnecessary antibiotics for respiratory tract infections
- by improving the use of appropriate antibiotics in suspected bacterial infections
- by improving the quality of diagnostic procedures for RTIs in general practice

HAPPY AUDIT project: "Health Alliance for Prudent Prescribing, Yield And Use of Anti-microbial Drugs In the Treatment of Respiratory Tract Infections"

The project started in 2007 with the involvement of six countries (Denmark, Sweden, Spain, Russia, Lithuania, and Argentina) and will end this year, in March. EuroDURG is a partner in the project.
In 2008 the participating GPs (N=618) registered all patients with respiratory tract infections. After the interventions tailored to GPs (e.g. workshops, training courses, guidelines) and patients (e.g. patient brochures) a second registration period took place in 2009 with the involvement of 511 GPs. Overall around 30,000 patient contacts were registered during each of the two (3 –weeks long) registration periods. With this high number, it is probably until now the largest study in a primary health care setting involving so many GPs from so many different countries. Presently most of the deliverables have been completed; the projects soon will be finalised. Presently the statistical analysis is going on. From the results one can conclude, that the project reached its goals: after the interventions the rate of patients treated with antibiotics decreased. The results of the project will be published in numerous articles. In the last stages WONCA (World Organization of Family Doctors) will play a crucial role: they are the leaders of developing materials for media campaigns and they will organize a working conference. EuroDURG will also have a role in the last stage of the project: we will help in the wide dissemination of project results.

Ria Benko

ESAC project

ESAC is a European project managed to develop and maintain a continuous, comprehensive and comparable database on antibiotic use in Europe. ESAC started in 2001 November, and presently the third ESAC- project is running.

- ESAC I (2001-2004)
- ESAC II (2004-2007)
- ESAC II extension ECDC
- ESAC III (2007-2010)

Presently all the 27 EU member states, 3 EEA/EFTA and 3 candidate countries (Croatia, Former Yugoslavian Republic of Macedonia and Turkey) are participating.

ESAC "European Surveillance of Antimicrobial Consumption"

Many papers were published from the project's results. At the projects website: http://www.esac.ua.ac.be you can reach further information on the project and have free access to the interactive database.
In the future the European Centre for Disease Prevention and Control (ECDC) will be the coordinator of the project (the ESAC Scientific Advisory Board met in November 2009 to agree on a plan for the take-over of ESAC by ECDC). In order to facilitate the take-over, the ESAC project will be extended for 4 months (September - December 2010; ESAC-4). The ESAC-5 project will be run by ECDC as of January 1, 2011, and the management team will be located in Bologna. The scientific advisory board (SAB) agreed upon a timeline to make the take-over a success. Consensus was reached on take-over by ECDC of:

- Core data collection•
- Regional data collection•
- Interactive database
- Ambulatory Care Protocol
- A• Hospital Care point prevalence survey (pps) (ECDC already decided to combine this PPS with health care associated infections)
- Economics database

Robert Vander Stichele

ARITMO project

The ARITMO project, aimed to analyse the cardiac safety profile of antipsychotics, anti-infectives and H1-anti-histamines, was just approved for funding by the 7th Frame Program of EU and will start in early 2010. The project is coordinated by Professor Sturkenboom, from the Erasmus Medical Centre (Rotterdam). The University of

Bologna is one of the ARITMO partners. The objectives of the project include some specific issues for which the collection of drug utilisation data is needed. In particular:

- To assess the reporting rate and relative risk (disproportionality) of QTc prolongation, TdP, ventricular fibrillation and sudden death from regional and international pharmacovigilance databases.
- To assess the rate and relative risk of symptomatic QTc prolongation, TdP, ventricular fibrillation and sudden death during use of study drugs.

The University of Bologna is planning an agreement with EuroDURG to collect drug utilisation data on antipsychotics (ATC N05A), anti-infectives (antibacterials (J01), antimycotics (J02) and antivirals (J05)) and H1-antihistamines (ATC R06) from as many as possible European countries.

It is expected that the University of Bologna will assign a 12-month scholarship to a PhD student in Drug Utilisation. The student may come from any European country and must have previous experience in drug utilisation. He/she will perform this activity in connection with the CNC (Cross National Collaboration project) researchers, many of which belonging to EuroDURG.

Elisabetta Poluzzi

SIG-DUR projects

As reported in the Bulletin 2007 and in this issue, within the ISPE the Special Interest Group – Drug Utilization Research (SIG-DUR) was formed.
Summary and updates on two SIG-DUR projects with special involvement and contribution of ExCo members are presented here:

International ATC Browser

The aim of this project is to create a web application to browse therapeutic arsenals from different countries, using the ATC classification. We try to locate the scientific team in each country, who is responsible for allocating ATC codes and for calculating the number of DDDs in the available medicinal product packages in the country, identified by the local unique identifying number. We ask this team to transform the national data into a predefined format and to send the updates once a year to a central web master, who will then enter these national data into an international system. The aim of the project is to assist in cross validation of classification of drugs in different countries, to facilitate cross national comparison of therapeutic arsenals, and to help research teams in other countries to construct valid links between national drug databases and the international classification ATC/DDD.

The first phase of the project (visible at http://atc.ramit.be:) has been completed with 4 consecutive years of Belgium.

Work has continued during 2009 with developing a version 2 of the prototype showing data from Belgium, Italy, and Sweden, in 4 languages (English, French, Dutch, Italian, Swedish). This version will be completed by the Brighton meeting. The application allows to see the medicinal product packages available on the national market with the national coding into the ATC system and package size expressed in DDD.

Funding of the project is assured in the Heymans Institute of Pharmacology (University of Gent, Belgium). Interested researchers can contact robert.vanderstichele@ugent.be

Robert Vander Stichele

Cross National Collaboration Survey

The first aim of this survey was to collect as much information as possible about the state of the art of drug utilization research (DUR) and to obtain drug consumption data for some selected drugs in different countries by using a structured questionnaire designed for the study and performed by the members of the EuroDURG and ISPE SIG-DUR. We received responses and filled questionnaires from more than 20 countries. Results were presented in a

dedicated poster session at the ICPE in Copenhagen in August 2008. The project demonstrated high variability in sophistication of available DUR data, limiting possibilities for international comparison of drug consumption.

From 2009, the Cross-National Comparison project is fused with another EU project (DU generic policy project) and continued under the leadership of Brian Godman and Bjorn Wettermark. Data providers from 26 countries (predominantly European) met in Mechelen, Belgium to validate results and to discuss further consolidation of this project (see further information at the Mechelen meeting).

Several publications focussing on single countries and on one of the 4 topics (Statins; PPIs; antidepressants;ACE inhibitors and ARBs) are accepted, or under revision.

Vera Vlahović-Palčevski and Monique Elseviers

News from national DURGs

Sweden

"4 years with the Swedish Prescribed Drug register - opportunities for pharmacoepidemiological research"

An international seminar was recently arranged by the Swedish National Board of Health and Welfare and the Swedish Society for Pharmacoepidemiology (SLEF) to celebrate the 4th anniversary of the Swedish Prescribed Drug register. The register was founded in July 2005 and contains unique identifiers of all dispensed drugs to the entire Swedish population. Every year more than 6 million Swedish citizens purchase prescribed medicines at the pharmacies and are thus included in the register. More than 40 studies have until now been published or are in press. The seminar gathered around 130 participants and started with of a number of lectures focusing on various aspects such as an overview of scientific studies conducted so far, the use of registers to monitor the quality of prescribing and socioeconomy and drug use. Some international experience was also brought in by Bert Leufkens, Utrecht University who shared his experience of pharmacoepidemiologic research in the Netherlands. The lectures were followed by four parallel interactive workshop discussions on measuring exposure with register data on dispensed drugs, monitoring quality of prescribing in health data registers, inequity in drug consumption and pharmacoepidemiologic study Designs. Presentations from the meeting and publication lists are available through the website of the Swedish Society for Pharmacoepidemiology - www.pharmacoepi.se

Björn Wettermark

Italy

In the recent years, drug utilisation activities have been highly increased in Italy. In particular, during the last year 3 main events had concerned this field.

(1) The annual Conference on drug use and safety of drugs (La valutazione dell'uso e della sicurezza dei farmaci: esperienze in Italia) organised by the Italian Institute of Health has reached his 28th Edition and hundreds participated both from Universities and Health Authorities. Each December, it represents an annual date for epidemiologists, pharmacists and pharmacologists to discuss experiences and to obtain useful suggestions for future research approaches. The main topics of the last Conference were represented by drug utilisation and appropriateness, and assessment of drug safety.

(2) On October 14-17, the 34th Conference of Italian Pharmacology Society (SIF) took place in Rimini. Three sessions were focused on pharmacoepidemiology both in terms of drug safety and drug utilisation. Many contributions concerned methods for the evaluation of drug use appropriateness, and also several focused on the exposure to drugs during pregnancy.

(3) A specific meeting on drug use appropriateness, especially in cardiovascular risk, was organised last 18 and 19 of December in Florence, with main speeches of Professors of the University of Florence and

Milan. The main topic of this meeting was the assessment of non adherence to treatments and its clinical and economics consequences.

Finally, a specific SIF meeting on drug misuse in Italy and their consequences in terms of drug safety has been planned for next June by the University of Bologna.

Elisabetta Poluzzi

We invite other national DUR groups to inform us about their activities!
Please send your summary to monique.elseviers@ua.ac.be

EuroDURG ExCO 2008-2010

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