

Title: A compilation of Research Working Groups on Drug Utilisation across Europe.

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ABSTRACT

Background: The assessment of the benefit-risk of medicines needs careful consideration of their patterns of utilization. Systems for the monitoring of medicines consumption have been established in many European countries, and several international groups have identified and described them. No updated compilation of European working groups has been published recently.

As part of the PROTECT project, as a first step in searching for European data sources on the consumption of five selected groups of medicines, we aimed to identify, describe and update the main characteristics of the existing collaborative European working groups.

Methods: Google and bibliographic searches (PubMed) of articles containing information on databases and other source data on the consumption of medicines were conducted. For each working group the main characteristics were recorded.

Results: Nineteen selected groups were identified, focusing on: a) general drug utilisation (DU) research (EuroDURG, CNC, ISPE'S SIG-DUR, EURO-MED-STAT, PIPERSKA Group, NorPEN, ENCePP, DURQUIM) , b) specific DU research: b.1) antimicrobial drugs (ARPAC, ESAC, ARPEC, ESGAP, HAPPY AUDIT), b.2) cardiovascular disease (ARITMO, EUROASPIRE), b.3) paediatrics (TEDDY), and b.4) mental health/central nervous system effects (ESEMeD, DRUID, TUPP/EUPoMMe). Information on their aims, methods and activities is presented.

Conclusions: We assembled and updated information on European working groups in DU research and in the utilisation of five selected groups of drugs for the PROTECT project. This information should be useful for academic researchers, regulatory and health authorities, and pharmaceutical companies conducting and interpreting post-authorisation and safety studies. European health authorities should encourage national research and collaborations in this important field for public health.

Keywords: pharmacoepidemiology, pharmacovigilance, European network, drug utilisation, drug consumption, national databases, review.

INTRODUCTION

Drug utilisation (DU) research is defined by the World Health Organization (WHO) as “the development, regulation, marketing, distribution, prescription, dispensing and use of medicines within a society, with special emphasis on the medical, social and economic consequences” [1]. A broad definition should also include the qualitative studies for assessing the appropriateness of DU and the intervention studies [2]. DU research plays a key role in understanding the use of medicines and evaluating the effect of interventions (such as policy changes, reimbursement policy and regulatory decisions) on drug use, thereby enhancing the quality of care and improving public health.

The Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium (PROTECT) study is a collaborative European project which aims to enhance the monitoring of the safety of medicinal products [3]. One of the specific objectives of PROTECT is to build and update an inventory of data sources on the consumption of medicines in the European Union as a tool to estimate the public health impact of several adverse drug events.

Efforts to collect information about the use of medicines in European countries date from the seventies. There is a wide international variability in DU documented in a WHO-Regional Office for Europe sponsored meeting [4]. In addition, information about the overall use of medicines across European countries is of interest to estimate the public health impact of adverse effects associated with the use of medicines [5,6]. As a first step in searching for European data sources for medicines consumption, we aimed to describe and update the main characteristics of the collaborative international European working groups, networks, and research projects related to DU.

METHODS

Search strategy:

1. Internet search. Its goal was to find institutions, networks and research projects related to DU in Europe in general and those focused on six groups of drugs, namely: 1) inhaled beta-2 agonists; 2) antibiotics; 3) antidepressants 4) benzodiazepines; 5) anticonvulsants, and 6) calcium channel blockers [3].

2. Bibliographic search: (1990-2010) in PubMed and SIETES (Sistema de Información Esencial en Terapéutica y Salud (<http://www.sietes.org>), an electronic drug information system in Spanish) Keywords: “databases”, “drug utilization”, “drug utilization research”, “Europe”, “international cooperation”, “international group”, “national databases”, “network”, “pharmacoepidemiology” and “working group”.

Group selection criteria:

Working groups were included if they were European groups, focused on DU and/or if they were involved in research on the medicines of interest for the PROTECT project . Groups studying a single condition and/or those focusing only on drugs of no interest for the PROTECT project, or based in a single European country, or not active at the time of search were excluded.

Data abstraction

The characteristics of each working group were collected from their websites or from methods and acknowledgement sections in published papers.

These data were analysed in a descriptive manner.

RESULTS

Twenty-four European working groups on DU were identified, nineteen of which fulfilled our eligibility criteria. Additional information on excluded groups on (<http://www.icf.uab.es/EuropeanWG>).

The characteristics of the working groups are described in the table. Eight groups focused in promoting general DU research and eleven focused on specific fields.

DISCUSSION

As far as we know, no other updated compilation of European collaborative working groups and their sources of data on medicines utilisation have been published.

Nineteen European groups were selected: eight groups were interested in general DU research or PE, with the common objective of compiling information on data sources, either at European level (e.g., ENCePP in Europe) or at a more restricted geographical level (e.g., NorPen in the Nordic countries). The remaining eleven groups focused their research on specific fields, mainly antimicrobials, cardiovascular conditions, paediatrics, and mental health (e.g., ESAC: antimicrobials, EUOASPIRE: cardiovascular conditions).

Among the groups focussing on general DU the EURO-MED-STAT widened the initial EuroMedicines project and developed a European database of licensed medicines and their prices in twenty EU countries [7].

The CNC project offered a wide range of sources of medicines consumption data for eighteen countries. However, the information is not published but available on a website [8], and it is not clear whether the information has been kept updated.

EnCePP, led by the European Medicines Agency (EMA), was established to strengthen the postmarketing monitoring of medicines. Its website contains a voluntary register of the healthcare databases existing in all European countries including those monitoring drug consumption.

Our search identified several European working groups collecting information on the utilisation of the selected groups of medicines even though their main objective goes beyond the collection of drug consumption data.

As expected, we found wide heterogeneity in the nature and quality of the DU data among the groups. The main factors determining their heterogeneity were: a) variability in the population coverage, varying number of countries involved in each working group; b) differences in medicines coding systems, and c) source of the DU data (e.g., questionnaires to individuals, samples or registers of prescribed/dispensed medicines.). In addition, none of the groups, except ESAC has tried to validate DU data [9].

Inhaled beta-2 agonists and anticonvulsants did not appear in our search in relation to medicines consumption. This could be explained due to the fact that the groups working in those areas concentrate more on diseases risk factors rather than on exposure to medicines.

Most of the initiatives in this field have received public funding. As a consequence many good initiatives and efforts could have been lost when this funding ends. Funding is decisive in keeping these working groups research ongoing.

The strengths of our compilation are the standardised search and the categorising of the information as general and specific-related DU areas in Europe. The broad search let us find out the general groups on DU as well as those focusing on the selected PROTECT drugs. This paper highlights some of the benefits of international collaboration such as the possibility of sharing and transferring knowledge and the high number of participating countries. This international collaboration is also important for pharmacovigilance activities, to enable the regulatory institutions such as the EMA to obtain fast and reliable information for population benefit-risk assessment. It also facilitates regulatory decision-making and the assessment of the public health impact of the use of medicines [10].

Our research has some limitations. First, some working groups could have been missed because of the difficulty in understanding some non-English language websites. Second, although we conducted a complete search, part of the results refers only to the drugs of interest for the PROTECT project. Third, the information about the data on medicines utilisation available for each working group has been extracted from their website or from the methods section in the published references, which is sometimes summarised. Finally, the update of the information has been difficult because the websites are not updated regularly.

CONCLUSION

We assembled and updated information on European working groups in DU research and in the utilisation of five selected groups of drugs for the PROTECT project. A description of the main working groups and information on their data characteristics is provided. This information should be of value for academic researchers, regulatory authorities, health authorities and pharmaceutical companies conducting and interpreting post-authorisation and safety studies. European and member states' health authorities should encourage and support national research and European collaboration in this important field for public health.

List of abbreviations:

ARITMO: Arrhythmogenic potential of drugs

ARPAC: Antibiotic Resistance Prevention and Control

ARPEC: Antibiotic Resistance and Prescribing in European Children

ATC: Anatomical Therapeutic Chemical

CNC: Cross National Comparison

DDD: Defined Daily Dose

DG SANCO: Directorate-General for Health and Consumers

DRUID: Driving under the Influence of Drugs, Alcohol and Medicines

DU: Drug Utilisation

DURQUIM: Drug Utilisation Research Quality Indicator Meeting

EMA: European Medicines Agency

ENCePP: European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

ESAC: European Surveillance of Antimicrobial Consumption

ESEMeD: European Study of the Epidemiology of Mental Disorders

ESCMID-ESGAP: European Society of Clinical Microbiology and Infectious Diseases- Study Group for Antibiotic Policies

EU: European Union

EUROASPIRE: European Action on Secondary and Primary Prevention by Intervention to Reduce Events

EuroDURG: European Drug Utilisation Research Group

EURO-MED-STAT: European Medicines Statistics

HAPPY AUDIT: Health Alliance for Prudent, Yield, and Use of Antimicrobial Drugs in the treatment of respiratory tract infections.

ISPE'S SIG-DUR: International Society of Pharmacoepidemiology Special Interest Group of Drug Utilisation Research

NorPEN: Nordic Pharmacoepidemiological Network

PE: Pharmacoepidemiology

PROTECT: The Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium

SIETES: Sistema de Información Esencial en Terapéutica y Salud

UK: United Kingdom

TEDDY: Task Force in Europe for Drug Development for the Young

TUPP/EUPoMMe: The Users Perspective Project

WHO-DURG: World Health Organization Drug Utilization Research Group

COMPETING INTERESTS

Sabaté M, Pacheco JF, Ballarín E, Ferrer P, Laporte J-R, Ibáñez L, Hasford J and Rottenkolber M declared that they do not have anything to disclose regarding funding or competing interests with respect to this manuscript. Petri H was employee of Roche until April 2012. Schoonen WM is an employee of Amgen Ltd. Fortuny J is an employee at Novartis Farmacéutica. Costs related to their part in the research were carried by the respective company as in-kind contribution under the IMI JU scheme.

AUTHORS' CONTRIBUTION

MS participated in the conception and design, data collection, data analysis, interpretation of data and writing the paper. LI participated in the conception and design, interpretation of data, and writing the paper. JP participated in the data analysis, and revising it critically for important intellectual content. EB participated in the conception and design, data collection, interpretation of data, data analysis, drafting the article and revising it critically for important intellectual content. PF participated in the conception and design, data collection, interpretation of data, and drafting the article, and revising it critically for important intellectual content. All other authors participated in the conception and design, interpretation of data, and revising it critically for important intellectual content. All authors read and approved the final manuscript.

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Table . European working groups on general drug utilisation and on specific fields on drug utilisation

Name, Website ^a and Funding	Information
Working groups promoting general DU research	
CNC <i>Cross National Comparison</i> 2008–ongoing http://www.pharmacoepi.org/eurodurg/workgr/cross_national.cfm	Specific project Objective: Collect worldwide information on the state-of-the-art of national drug utilisation monitoring systems Data: received by questionnaire to key informants and contact persons <ul style="list-style-type: none"> • Poster presentation on drug consumption data (2000-2007) • DDD, € or \$ <i>Data source:</i> dispensing or prescribing <i>Codification system:</i> ATC <i>Units of measure:-</i> <i>Setting:</i> outpatient <i>Period: -</i> <i>Drugs of interest:</i> Proton Pump Inhibitors (A02BC), Statines (C10AA), and clopidogrel (B01AC04) antibacterials (J01). <i>Covered population: -</i>
DURQUIM <i>Drug Utilisation Research Quality Indicator Meeting</i> 2004–ongoing https://pharmacoepi.org/eurodurg/durquim.cfm Funds: WHO/EuroDURG, RIZIV	Expert meeting Objective: To analyse the patterns of drug use and to implement strategies for improving the prescribing and use of drugs, and constructing prescribing quality indicators. Data: Power Point presentation of participating countries with the available European databases (administrative, prescription, reimbursing, health assurance, ...). <i>Source, Codification system, Units of measure, Setting, Period, Drugs of interest, Covered population:</i> no applicable.
ENCEPP <i>European Network of Centres for Pharmacoepidemiology and Pharmacovigilance</i> 2006–ongoing http://www.encepp.eu/ Lead by the EMA	Network Objective: To bring together the available expertise and research experience in the fields of pharmaco-epidemiology and pharmaco-vigilance scattered across Europe in a Network of Excellence. Data: Registry of EU data sources (research and medical-care centers, healthcare databases, electronic registries and existing networks) in the field of pharmacoepidemiology and pharmacovigilance. <i>Source, Codification system, Units of measure, Setting, Period, Drugs of interest, Covered population:</i> no applicable.
EuroDURG <i>European Drug Utilisation Research Group</i> 1993–ongoing EuroDURG bulletins http://www.pharmacoepi.org/eurodurg Funds: WHO European Office	Non-profit organization Objective: To provide an international forum for cooperation and communication to promote DU research, to work on: DU research methodology, cooperate with international and national drug regulatory authorities. Data: <i>Source, Codification system, Units of measure, Setting, Period, Drugs of interest, Covered population:</i> no applicable. Working groups: DRUID HAPPY AUDIT TUPP DURQUIM

Name, Website ^a and Funding	Information
EURO-MED-STAT 2002–ongoing http://ec.europa.eu/eahc/projects/database.html?prjno=2003133 Funds: European Commission	Specific project Objective: To establish an inventory of national medicines data sources and a survey of available data, to assess data reliability and comparability between countries. Data: <ul style="list-style-type: none"> List of medicines data sources (available on-line) Competent authorities of each country list of licensed medicines per country.
ISPE's SIG-DUR <i>Special Interest Group of Drug Utilisation Research</i> (2006–ongoing) http://www.pharmacoepi.org/resources/sigs_research.cfm	Network Objective: To create a forum for discussion and cooperation between drug utilization researchers. Data: International ATC/DDD browser. <i>Source, Codification system, Units of measure, Setting, Period, Drugs of interest, Covered population:</i> no applicable. MTI Methods for Testing Interventions. PCI Prescribing Quality Indicators. RHI Relationship with the Health Insurers
NorPEN <i>Nordic Pharmacoepidemiological Network</i> 2008–ongoing http://www.nhv.se/customer/templates/InfoPage_1619.aspx?epslanguage=EN Funds: NordForsk (<i>Nordic research board operating under the Nordic council of Ministers</i>)	Network Objective: To facilitate pharmacoepidemiological research initiatives promoting safer and more efficient drugs and drug use in a public health perspective. Data: Database prescription drugs dispensed (for each country) <i>Source:</i> prescriptions <i>Codification system:</i> ATC/DDD methodology <i>Units of measure:</i> - <i>Setting:</i> ambulatory care (in Denmark also in-patient) <i>Period:</i> - <i>Drugs of interest:</i> All drugs <i>Covered Population:</i> 25 million people
PIPERSKA GROUP 2008–ongoing http://www.piperska.org/home	Network Objective: to ensure robust systems in place in Europe, to enhance the rational use of drugs , including new expensive drugs, to improve health. Data: <i>Source, Codification system, Units of measure, Setting, Period, Covered population:</i> no applicable. <i>Drugs of interest:</i> New expensive drugs
Working Groups focused on specific fields	
ARITMO <i>Arrhythmogenic potential of drugs</i> (Jan. 2010–Dec. 2012) http://www.aritmo-project.org Funds: FP7	Specific project , network Objective: to analyse the arrhythmic potential of drugs. Data: <i>Source:</i> review of literature and variety databases. Prospective case-control surveillance (planned). <i>Codification system:</i> - <i>Units of measure:</i> - <i>Setting:</i> outpatient <i>Period:</i> - <i>Drugs of interest:</i> antipsychotics, anti-infectives (antibacterials, antimycotics and antivirals) and H1-antihistaminics. <i>Covered population:</i>

Name, Website ^a and Funding	Information
<p>ARPAC <i>Antibiotic Resistance Prevention and Control</i> 2002–2005 http://www.abdn.ac.uk/arpac (not updated) <i>Funds:</i> European Commission</p>	<p>Specific project, network Objective: to develop strategies for control and prevention of antibiotic resistance in European hospitals. Data: <i>Source:</i> published data on antibiotic hospital use. Cross-sectional survey study (questionnaire survey). <i>Codification system:</i> ATC <i>Units of measure:</i> DDD/100 bed-days. <i>Setting:</i> inpatient (170 hospitals) <i>Period:</i> 2001 to 2005 <i>Drugs of interest:</i> antibiotic subgroups (4th ATC level) <i>Covered population:</i></p>
<p>ARPEC <i>Antibiotic Resistance and prescribing in European Children</i> 2010–ongoing http://www.arpec.sgul.ac.uk/ <i>Funds:</i> DG SANCO of the European Union</p>	<p>Specific project Objective: to improve the quality of antibiotic prescribing for children in Europe and to reduce the prevalence of antimicrobial resistance in bacterial infections in children. Data: hospital point prevalence survey <i>Source:</i> European community prescribing databases. Questionnaire to hospital pharmacists. <i>Codification system:</i> ATC/DDD methodology <i>Units of measure:</i> novel paediatric defined daily dose <i>Setting:</i> in and out-patient <i>Period:</i> - <i>Drugs of interest:</i> antibiotic <i>Covered population:</i></p>
<p>ESGAP <i>ESCMID Study Group for Antibiotic Policies</i> 1998–ongoing http://www.escmid.org/research_projects/study_groups/antibiotic_policies/ Official recognition from the ESCMID</p>	<p>Study Group Objective: to improve antimicrobial prescribing policies and practices, to improve patient care and prevent/reduce the development of resistances Data: <i>Source:</i> questionnaire distributed to hospital pharmacists <i>Codification system:</i> ATC/DDD methodology <i>Units of measure:</i> ABC Calc: to measure hospital antibiotic consumption in number of DDD/ 100 bed-days (available on the website). <i>Setting:</i> hospital <i>Period:</i> - <i>Drugs of interest:</i> antibiotic <i>Covered population:</i></p>
<p>ESAC <i>European Surveillance of Antimicrobial Consumption</i> 2001–ongoing http://app.esac.ua.ac.be/public/ <i>Funds:</i> DG SANCO of the European Union, European Centre for Disease Prevention and Control ECDC</p>	<p>Specific project Objective: to provide information on the consumption of antimicrobials and developing indicators and guidelines to help managing the risk of infections and resistances. Data: <i>interactive database available online</i> <i>Source:</i> distribution or reimbursement data (out-hospital) Questionnaire to hospital pharmacist (in-hospital) <i>Codification system:</i> ATC <i>Units of measure:</i> DDD/1000 inhabitants/d <i>Setting:</i> out and Inpatient and nursing homes <i>Period:</i> annual reports by chemical group (ATC classification) since 2006–2008. <i>Drugs of interest:</i> anti-infectives (J) ATC level 2 to 4. <i>Covered Population:</i> population coverage: out-hospital <25-100%, In-hospital 9 countries sample data, the rest 85-100%.</p>

Name, Website ^a and Funding	Information
<p>ESEMeD <i>European Study of the Epidemiology of Mental Disorders</i> (2001–2003) Not website <i>Funds:</i> European Commission, WHO/World mental Health 2000 Initiative, GSK laboratories.</p>	<p>Specific project Objective: to collect data by a cross-sectional survey, on prevalence, risk factors, health-related quality of life and use of services associated with common mental disorders. Data: published data Source: cross-sectional patients interview survey. Sample of the adult Codification system: - Units of measure: presented in % of the total sample Setting: outpatient Period: 2001-2003 Drugs of interest: psychotropic drug Covered population: -</p>
<p>EUROASPIRE <i>European Action on Secondary and Primary Prevention by Intervention to Reduce Events</i> 1994–2007 <i>Funds:</i> European Society of Cardiology registries. http://www.escardio.org/guidelines-surveys/ehs/prevention/Pages/ehs-on-prevention.aspx</p>	<p>Specific project Objective: to determine if cardiovascular risk factors are recorded in patients' medical records, to measure the modifiable risk factors, to describe therapeutic management after hospitalization in patients with coronary heart disease. To determine whether Joint European Guidelines on CV prevention are followed in every day clinical practice. Data: published data Source: review of medical records, and patient interviews. Codification system: - Units of measure: - Setting: outpatient (at least 6 months after hospital admission) Period: 1995-1996,1999-2000, 2006-2007. Drugs of interest: antiplatelet, beta-blockers, ace inhibitors, calcium channel blockers, lipid-lowering drugs and anticoagulants by groups. Covered Population: selected geographical area with a defined population and all hospitals serving this population</p>
<p>DRUID <i>Driving under the Influence of Drugs, Alcohol and Medicines</i> (2006–2011) http://www.druid-project.eu/cln_031/nn_107542/Druid/EN/home/homepage_node.html?_nnn=true 6th FP</p>	<p>Specific project Objective: to combat the scourge of drink-driving and find answers to the question of the use of drugs or medicines that affect people's ability to drive safely. Data: published data. Final report 1/8/2012. (Information is not available currently) Source: data provided by national agencies, institutes of public health, insurance companies, community pharmacies, ministries of health. Codification system: ATC/DDD methodology Units of measure: - Setting: outpatient Period: 2000-2005. Drugs of interest: anxiolytics, hypnotics, sedatives, antidepressants Covered Population: 100% for 6 countries</p>
<p>HAPPY AUDIT <i>Health Alliance for Prudent, Yield and Use of Antimicrobial Drugs in the treatment of respiratory tract infections.</i> (2007-2010 planned) http://www.happyaudit.org 6th FP</p>	<p>Specific project Objective: to improve the antibiotics prescription in respiratory tract infections in primary health care in Europe through development of intervention program targeting general practitioners (GPs), parents of young children and healthy adults. Data: report of the results (available on-line). Source: according to the APO (<i>Audit Project Odense</i>): auditing GP. Sample of GP Codification system: - Units of measure: antibiotic use in % by respiratory tract indication Setting: outpatient Period: - Drugs of interest: antibiotics Covered population: -</p>

Name, Website ^a and Funding	Information
<p>TUPP/EUPoMMe <i>European User's Perspective on Mood-modifying Medicines</i> (1997–ongoing) http://www.pharmacoepi.org/eurodurg/workgr/tupp/index.htm (not updated)</p>	<p>Specific project Objective: to frame a protocol for pan-European research on the user perspective on mood-modifying medicines. Data: <i>Source:</i> sample patient interview <i>Codification system:</i> - <i>Units of measure:</i> - <i>Setting:</i> - <i>Period:</i> - <i>Drugs of interest:</i> mood-modifying medicines <i>Covered population:</i> -</p>
<p>TEDDY <i>Task Force in Europe for Drug Development for the Young</i> (2005–2010 planned) http://www.teddyyoung.org/index.php <i>Funds:</i> FP6</p>	<p>Network, specific project Objective: to promote the availability of safe and effective medicines for children by integrating existing expertise and good practices. Data: publications <i>Source:</i> data sources containing information on medicines used in male/female children, out-patient data, prescription or drug dispensing data (Netherlands, Italy and UK). <i>Codification system:</i> - <i>Units of measure:</i> prevalence drug of use by age and therapeutic level (ATC 2nd level) <i>Setting:</i> outpatient <i>Period:</i> 2000-2005 <i>Drugs of interest:</i> all drugs <i>Covered population:</i> 2.9-100%</p>

^aLast accessed for all websites 16/09/2013