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# Farmakoepi-Nyt

September

Dansk Selskab for Farmakoepidemiologi's nyhedsbrev

2010

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No. 34

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### Dansk Selskab for Farmakoepidemiologi

Farmakoepidemiologi er en relativt ny gren af epidemiologien. Som navnet antyder, drejer det sig om anvendelse af epidemiologiske principper på lægemiddelrelaterede problemstillinger. Deskriptive undersøgelser af lægemiddelforbrug, kvalitative undersøgelser af holdninger til brug af medicin, farmakoøkonomiske vurderinger, og analytiske epidemiologiske studier af lægemiddelvirksomheder omfatter alle af farmakoepidemiologi og illustrerer dens bredde.

Formålet med Dansk Selskab for Farmakoepidemiologi er at fremme udviklingen af denne disciplin i Danmark. Selskabet er åbent for alle, som interesserer sig for farmakoepidemiologi inden for sundhedssektoren, de akademiske institutioner og industrien.

DSFE indgår sammen med Danmarks Farmaceutiske Selskab, Dansk Selskab for Farmakologi, Toksikologi og Medicinalkemi, Dansk Selskab for Klinisk Farmakologi og Dansk Selskab for Klinisk Kemisk Farmakologi i paraplyorganisationen Dansk Selskab for Farmakologi. Bestyrelsen for DSFE udpeger DSFEs repræsentanter i DSFs bestyrelse.

Selskabet afholder mindst ét årligt videnskabeligt møde, udgiver desuden et nyhedsbrev og samarbejder med tilsvarende udenlandske og internationale organisationer.

Vedtægter og indmeldelsesblanket kan rekvireres ved henvendelse til selskabets sekretariat; adresse ses på forsiden af Nyhedsbrevet. Årskontingentet er 250 kr.

Bestyrelsen består efter generalforsamlingen i april 2010 af overlæge, seniorforsker, ph.d. *Gunnar H. Gislason*, Kardiologisk afdeling P, Gentofte Hospital (formand); overlæge, ph.d. *Mette Nørgaard*, Klinisk Epidemiologisk Afdeling, Aarhus Universitetshospital (kasserer); Associate Principal, cand.pharm. *Henny Bang Jakobsen*, Nycomed (sekretær); post-doc, ph.d. *Helle Wallach Kildemoes*, Institut for Folkesundhedsvidenskab, Københavns Universitet og akademisk medarbejder, ph.d. *Maja Laursen*, Lægemiddelstyrelsen. Selskabets revisor er cand.oecon. *Kjeld Christensen*, Farum og revisorsuppleant er professor, ph.d. *Jens Søndergaard*, IST – Forskningsenheden for Almen Medicin, Syddansk Universitet – Odense.

**Redaktion:** *Maja Laursen*

Materiale, som ønskes optaget i nyhedsbrevet bedes sendt til adressen på forsiden, eller via mail til [hhorneberg@health.sdu.dk](mailto:hhorneberg@health.sdu.dk). Til samme

adresse stiles oplysninger om adresseændringer, indmeldelser og lignende.

### Farmakoepi-Nyt

Vi vil her benytte lejligheden til at efterlyse indlæg fra medlemmerne. Vi vil for eksempel gerne besvare faglige spørgsmål og formidle kontakter mellem medlemmer med nært beslægtede interesser. Kritik og forslag modtages også gerne.



### MEDDELELSER FRA BESTYRELSEN

#### Samarbejde med Institut for Rationel Farmakoterapi

Har du lyst til at kommentere på udkast fra IRF til omtale af epidemiologiske publikationer? Institut for Rationel Farmakoterapi (IRF) bringer løbende omtale af større videnskabelige undersøgelser af generel interesse for praktiserende læger og andre interesserede. Disse korte gennemgange med IRF's vurdering af undersøgelsens implikationer offentliggøres på IRF's hjemmeside ([www.irf.dk](http://www.irf.dk)).

Efter ønske fra IRF's styregruppe sendes disse studieanmeldelser til høring hos de relevante medicinske selskaber forud for offentliggørelse. Eventuelle kommentarer indarbejdes i IRF-omtalen eller nævnes i umiddelbar forlængelse af omtalen, hvor det også fremgår, hvilke sel-

skaber, der har været kontaktet. Som eksempel kan nævnes omtalen fra 5. juli 2010 af artikel i BMJ vedr. mortalitet i forbindelse med brug af hormonel antikonception, som DSFEs formand kommenterede på selskabets vegne.

DSFEs bestyrelse mener, at selskabet har en interesse i at bidrage her, og selv om antallet af henvendelser ikke er stort (3 indtil videre i 2010) **kan bestyrelsen kan ikke klare opgaven alene!** Vi opfordrer derfor selskabets medlemmer til at melde sig under fanerne, så vi kan etablere en mailgruppe af interesserede, vi kan kontakte, når behovet opstår.

Selskabets sekretær, Henrik Horneberg, har påtaget sig at holde styr på mailgruppen og videresende henvendelserne fra IRF til gruppen. Den enkelte melder sin interesse for at gennemgå den enkelte artikel til Henrik, og hvis flere melder sig, informerer Henrik de tilmeldte og beder dem koordinere opgaven mellem sig. Svaret sendes via Henrik til IRF, og Henrik holder bestyrelsens formand informeret. Tilmelding til gruppen sker til: [hhorneberg@health.sdu.dk](mailto:hhorneberg@health.sdu.dk). På forhånd tak for hjælpen til gruppen og Henrik Horneberg.

### Formandens klumme

Danmark er et paradis for registerforskning i kraft af de nationale databaser og et enestående system med CPR-nummer samt lige adgang for forskere. Det bliver man også jævnt bekræftet i, da vores resultater bliver præsenteret uden for Danmark; fx da jeg sad og hørte en af vores dygtige Ph.d.-studerende præsentere sine resultater til Young Investigator Awards sessionen ved ESC (Den Europæiske kardiologi-kongres) i slutningen af august og en af tilhørerne i salen rejste sig og havde følgende kommentarer: "Are you telling me that you can link registers of hospitalization and drug claims from pharmacies for the whole population of Denmark without any restrictions? I'm impressed!". Det kan godt være, at vi synes det er en selvfølge, at vi har adgang til at anvende disse registre, men vi skal også forstå at vi har enestående vilkår og muligheder i forhold til andre nationer. Der foregår stor aktivitet på internationalt plan inden for registerforskning og flere og flere store registre og databaser bliver opbygget, så selvom vi i Danmark står helt i front lige nu angående muligheder for registerforskning kan det godt være, at vi snart bliver indhentet af andre. Derfor er det vigtigt at tænke fremad om nye muligheder og udvikling i registerforskning og samarbejde med myndighe-

der, så vi bedst kan udnytte de muligheder som ligger i Dansk registerforskning. Der synes jeg DSFE kan have en stor rolle som et samlingspunkt og ordfører for forskere som beskæftiger sig med registerforskning. Jeg synes DSFE skal være mere proaktivt og spille større rolle udadtil til at varetage forskernes interesser omkring registerforskning, fx mod Danmarks Statistik, Sundhedsstyrelsen og Lægemiddelstyrelsen? Som forsker har jeg selv stødt på mure og besværlige regler som vi har måttet bruge tid og kræfter på til at få gennemført projekter, og jeg er sikker på at mange har lignende historier at fortælle. Hvis vi står samlet under DSFE er jeg sikker på, at myndigheder vil være lydhøre over for nye ideer. Jeg vil invitere DSFE-medlemmer til debat og hvis I har en mening omkring ovenstående vil jeg gerne høre fra jer. Det er vigtigt at høre hvilket syn I har på, hvordan DSFE skal udvikle sig og hvilken rolle DSFE skal have i fremtiden.

*Gunnar Gislason  
formand*

### ORIENTERING

#### **Euro-DURG (Drug Utilization Research Group).**

Under ICPE holdes møder for grupper med interesse for specifikke områder inden for farmakoepidemiologi. Inden for disse interessegrupper (Special Interest Groups, SIG) er der dannet internationale farmakoepidemiologiske selskaber mhp. at facilitere internationalt projektsamarbejde

(<http://www.pharmacoepi.org/resources/sigscouncils.cfm>). I år blev den tidligere formand for DSFE, Morten Andersen, valgt som formand for interesse-Euro-DURG.

Man får løbende oplysninger om (jf. vedhæftede Euro-DURG bulletin), hvad der foregår i Euro-DURG ved at registrere sig med e-mail og interesseområder på:

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

Hvis du i forvejen er registreret som "medlem" men har fået ny e-mail adresse mv. kan informationer opdateres ved at skrive til Ria Benko: [benkoria@gmail.com](mailto:benkoria@gmail.com).

## Indtryk fra sommerens kongresser



### WorldPharma juli 2010, København

Fra 17. til 23. juli 2010 var Bellacentret i København rammen om den 16. IUPHAR World Congress on Basic and Clinical Pharmacology – en kongres med over 3.200 deltagere fra 80 forskellige lande, 700 mundtlige indlæg og over 2.000 poster. Det meget store udbud var ikke sådan lige at få overblik over, men der var heldigvis indlagt en række minikonferencer, der fokuserede på specifikke emner bl.a. farmakoepidemiologi under overskriften ”Pharmacoepidemiology – current controversies and opportunities”.

Min personlige interesse ligger i epidemiologisk metode, så for mig var sessionen ”Methodological issues in pharmacoepidemiology” klart den mest interessante med flere inspirerende indlæg. Til Stürmer talte om ”Treatment decisions and propensity scores”, Robert J. Glynn sammenlignede udfordringerne ved analyser af forebyggende medicin med problemerne i ”the healthy worker effect” og Samy Suissa indskærpede, at en patients status på et givent tidspunkt aldrig må afhænge af noget der sker senere i forløbet – logik for burhøns, men Samy havde flere eksempler på publicerede artikler, hvor det forekom.

Kongressens tre sidste dage bød desværre ikke på mere farmakoepidemiologi. Til gengæld var

der en række mere eller mindre langhårede præsentationer inden for området ”Naturlige produkter”. Den gode nyhed er, at rødvin stadigvæk har gavnlige effekter på helbredet, den dårlige er at druesaft har helt samme virkning – i hvert fald når man ser på sagen molekylærbiologisk.

Næste IUPHAR verdenskongres foregår i Sydafrika, men først i 2014, så der er rigelig tid til at få bestilt billetter.

*Bine Bjerregaard  
DSFE-medlem*



### ICPE august 2010, Brighton

Den 26. ICPE, International Conference on Pharmacoepidemiology & Therapeutic Risk Management foregik i Brighton fra 19.-22. august. Fra klinisk epidemiologisk afdeling, Århus Universitetshospital var vi 8 deltagere, der havde i alt 11 præsentationer med (3 mundtlige og 8 poster).

Det var som sædvanlig en rigtig god kongres – både fagligt og socialt. Der var i år god mulighed for at fokusere på metodemæssige problemstillinger. Sessionen ”Matching on propensity Scores: Good practices and New directions” med Jeremy Rassen, Robert Glynn, Mark Lunt og Kenneth Rothman var for under tegnede et af de faglige højdepunkter. Der var dog flere interessante og inspirerende sessioner og diskussioner, og der var god mulighed at komme til at tale med kolleger fra nær og fjern.



Brighton er også stedet hvor Abba i 1974 fik deres store gennembrud ved at vinde det europæiske melodi-grandprix med sangen "Waterloo", og derfor var der lørdan aften arrangeret underholdning på Brighton Dome med kopi-bandet "Abba's angels". Denne danseglade musik lokkede rigtig mange af kongresdeltagerne på dansegulvet, hvor der blev danset med stor entusiasme og sveden sprang helt uafhængigt af faglig tyngde og H-index. Den 27. ICPE foregår 14.-17. august 2011 i Chicago – og jeg kan bestemt anbefale danske farmakoepidemiologer at deltage.

*Mette Nørgaard.  
DSFEs bestyrelse*

## AUTOREFERATER

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### Ph.d.-afhandling

**MSc, MPH Ramune Jacobsen**, Afdeling for Samfundsfarmaci, Institut for Farmakologi og Farmakoterapi, Det Farmaceutiske Fakultet, Københavns Universitet.

### **Patient-related barriers to cancer pain management with opioid analgesics and healthcare professionals' rationale to choose fentanyl for cancer pain patients**

Ph.d.-forsvaret fandt sted den 17. december 2009

### Vejledere

Professor Claus Møldrup, PhD, Københavns Universitet, Det Farmaceutiske Fakultet.

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Professor Per Sjøgren, MD, DMSc, Tværfaglig Smertecenter, Rigshospitalet, København.

Konsulent Lars Popper, PhD, Nycomed, Danmark.

### Bedømmere

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Seniorforsker Lene Jarlbæk, MD, PhD, Syddansk Universitet.

Professor Ulfe E. Konsgaard, MD, PhD, Oslo Universitets hospital.

## RESUMÉ

### Introduktion

Forekomsten af akutte og kroniske smerter hos kræftpatienter er høj: cirka 30% hos patienter med nyligt diagnosticeret kræft, 50-70% hos patienter i aktiv anti-cancerterapi og 60-80% hos patienter med langt fremskreden sygdom. Hos de fleste af disse patienter (op til 90%) kan tilstrækkelig smertelindring opnås, hvis adækvat behandling er iværksat, som foreslået i forskellige retningslinjer. Under behandlingen af kræft kan smerter være forårsaget af barrierer ved anvendelse af opioid analgetika. Det overordnede mål med ph.d.-projektet har været: 1) at beskrive og analysere patientrelaterede barrierer for smertebehandling ved kræft og 2) at beskrive det kliniske rationale ved valg af administrationsform med opioid Fentanyl.

### Materialer og metoder

Med henblik på at besvare forskningsspørgsmål i tilknytning til det første mål blev en spørgeskemaundersøgelse blandt kræftpatienter fra de danske smertecentre og smerteklinikker gennemført.

Med henblik på at besvare forskningsspørgsmål i tilknytning til det anden mål, blev to internetbaserede klassisk designede Delphi-undersøgelser gennemført af danske smertespecialister og danske smertesygeplejersker.

### Resultater

Den første undersøgelse har valideret danske udgaver af hhv. "Medication Adherence Report Scale", "Patients' Perceived Involvement in Care Scale" og "Barriers Questionnaire-II", og vi fandt, at skalaerne giver et troværdigt og

validt mål for henholdsvis compliance til smertebehandlingsregimer, patient-professionel kommunikation i relation til cancersmerte og for kognitive barrierer mod opioid-behandling. Undersøgelsens resultater viste, at smerteintensiteten som blev rapporteret af patienterne i undersøgelsen var betydeligt lavere end de gennemsnitlige smerteintensiteter rapporteret i "European Pain in Cancer"-undersøgelsen. De fleste af patienternes bekymringer var relateret til fysiologiske konsekvenser af opioidbrug. Niveauerne for depression og angst hos kræftpatienterne svarede til det gennemsnitlige niveau i den europæiske undersøgelse. Andelen af patienter som stoppede medicinindtagelse på grund af bivirkninger var forholdsvis lille. Det blev vist, at en psykologisk-emotionel status hos patienterne signifikant forklaret oplevet smerteintensitet, mens patienternes holdning til betydningen af smertebehandling med opioid analgetika signifikant forklaret opfattelse af smertelindrings niveau.

Resultaterne af de to Delhi-undersøgelser viste, at hvis det var umuligt eller vanskeligt med oral indtagelse af analgetika, var det den vigtigste grund til at administrere Fentanyl-plastre, mens patienter med dermatologiske problemer og oprindelig neuropatisk smerte var de vigtigste grunde til ikke at administrere Fentanyl-plastre. Fentanyl-slikkepinde blev af både læger og sygeplejersker set som en alternativ administrationsform til at bryde kræftsmarter i tilfælde af ineffektiv oral administration. En beskædiget mund, de høje omkostninger og den energi, der kræves for administrationen af denne medicin blev rapporteret som de vigtigste årsager til, at Fentanyl-slikkepinde kun sjældent blev ordineret til kræftsmertepatienter i Danmark.

### Konklusion

Indgreb i kræftpatienters følelsesmæssige nød og bekymringer kunne muligvis resultere i bedre smertebehandlingsresultater. Yderligere studier af flere og mere forskelligartede kræftpatienter skal øge generaliserbarheden af disse konklusioner.

Forventningerne med hensyn til anvendelsen af Fentanyl-plastre var indfriet med hensyn til effektivitet, bekvemmelighed og anvendelighed af denne administrationsform til kræftpatienter med særlige kliniske forhold, f.eks. umulighed eller vanskelighed med oral indtagelse af medicin. Imidlertid blev forventningerne med hensyn til anvendelse af transmucosale Fentanyl-systemer (slikkepinde) ikke indfriet, navnlig med hensyn til komfort og anvendelighed

af denne administrationsform for palliative kræftsmertepatienter. Undersøgelsen bidrog med et nyt kendskab til litteratur og kan potentielt påvirke skabelse eller revision af retningslinjer og protokoller for ordinerings af langtidsvirkende og øjeblikkelig smertestillende opioid-behandling.

### Ph.d.-afhandling

**MSc. (pharm) Anne-Mette Lilleøre**, Research & Development, Denmark  
CMC Biopharm Analysis & Formulation  
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### **Knowledge Creation Processes in Research and Development – a Case Study in the Pharmaceutical Industry**

Ph.d.-forsvaret fandt sted den 19. marts 2010

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### RESUME

### Introduktion

Gennem de sidste årtier har lanceringen af nye produkter fra den farmaceutiske industri været aftagende. En tilgang, hvormed lægemiddelud-

viklingen i den farmaceutiske industri kan stimuleres, er gennem videnedelse; en disciplin som blandt andet omfatter videndannelsesprocesser i organisationer. Dette projekt havde til formål at forstå videndannelses-processer i farmaceutisk R&D.

#### Metode

Studiet var designet som et enkelt, eksplorativt case studie i novo Nordisk R&D. En fænomenologisk tilgang blev valgt til at guide dataindsamling, analyse og fortolkning. Data blev indsamlet som producerede dokumenter (47 deltagere) og som semi-strukturerede interviews (19 informanter). Interviewene blev båndet og transskriberet ordret. Indsamlede data blev analyseret og fortolket ved hjælp af kodninger efterfulgt af temadannelse samt udarbejdelse af memoer og koncepter.

#### Resultater

**Delstudie I:** Vigtige katalysatorer og barrierer i relation til videndannelse blev identificeret i den farmaceutiske R&D organisation. Akademikere og laboranter havde forskellige holdninger til at engagere sig i videndeling. Katalysatorerne, som blev identificeret, anerkendte brugen af tavs viden.

**Delstudie II:** Tre, kontekst-specifikke praksisser i relation til videndeling blev identificeret, som kombineret førte til videndannelse. Disse blev betegnet: 'reaktive', 'rutine' og 'transfer'. De praksisser, der vedrørte 'rutine' og 'transfer' var en del af de daglige rutiner, hvorimod de reaktive praksisser fremkom som et respons, når kritiske episoder opstod. Tavs viden fremkom som den underliggende ressource. Møder, fysisk nærhed til kollegaer, sociale relationer og flytning af en medarbejder blev identificeret som fundamentale katalysatorer i forhold til anvendelse af tavs viden og dermed effektiv videndeling.

**Delstudie III:** Den organisatoriske kontekst, som omfattede følgende elementer: Eksterne omgivelser, mål, deltagere, social struktur og teknologi, var alle associeret med videndannelse. Det fremkom, at eksterne omgivelser, deltagere og social struktur havde en tosidet associering til videndannelse, da disse organisatoriske elementer fungerede både som katalysatorer og barrierer.

#### Konklusion

Dette kvalitative studie har resulteret i en forståelse for, hvordan viden dannes i farmaceutisk R&D. Det blev demonstreret, at essensen af videndannelse i farmaceutisk R&D omhand-

ler deling af viden, hvor erfaringsbaseret viden spiller en afgørende rolle. Vigtige katalysatorer og barrierer i relation til videndeling og videndannelse blev identificeret i organisationen. R&D ledere bør derfor være opmærksomme på værdien af videndeling, og at denne størrelse er kritisk, når ny viden skal dannes.

#### Ph.d.-afhandling

**Cand.pharm. Søren Ilsøe-Kristensen**, Farmaceutisk Fakultet, Københavns Universitet

#### **Cross-Sectorial Communication and Drug Management after Hospital Discharge - An Observational Study of Heart Failure Patients**

Ph.d.-forsvaret fandt sted den 3. juni 2010

#### Vejledere

Professor Mette Rasmussen, Farmaceutisk Fakultet, Københavns Universitet  
Institutchef Steffen Thirstrup, Institut for Rationel Farmakoterapi

#### Bedømmere

Lektor Birthe Søndergaard, Farmaceutisk Fakultet, KU  
Professor Jens Søndergaard, Forskningsenheden for Almen Praksis, Syddansk Universitet  
Overlæge Stig Ejdrup Andersen, Klinisk Farmakologisk Afdeling, Bispebjerg Hospital

#### RESUMÉ

#### Background

At hospital discharge, the transfer of patients to primary care is sensitive to unintentional transfer-related deficiencies in patient drug management. Clinical practice often shows a de facto separation of treatment responsibilities between hospitals and primary care. Specialists in hospitals prescribe drugs according to specific areas of expertise while leaving other areas to the prescribing habits of primary care practitioners. Optimal continuation of discharge medications is therefore dependent on satisfactory communication between the sectors. However, several studies have shown that this communication is often inadequate and that patients experience various inappropriate changes in drug treatment. The objectives of the present PhD study were:

**Study I:** To describe and evaluate the information provided for general practitioners (GPs) in

hospital discharge summaries regarding timely data, discharge medication and directions for follow-up.

**Study II:** To describe medication changes and patient primary non-compliance upon transfer of patients between hospitals and primary care.

#### Methods

**Study I:** We did a retrospective descriptive observational study of all available discharge summaries from patients identified through a heart failure outpatient clinic at a university hospital in Copenhagen, Denmark. Discharge summaries were collected by contacting the GPs presently and previously associated with eligible patients. Data collected included: index date of admission and discharge of the patient, index date of despatch to and date of receipt in primary care, treatment summary, follow-up plans and medication prescribed at discharge.

**Study II:** We did a retrospective descriptive observational study of patients affiliated with three outpatient heart failure clinics in Denmark. Patients were recruited from two hospitals in the Region of Southern Denmark and one hospital in the Capital Region of Denmark. Out-patient prescription drug use was collected from hospital medical records, primary care case notes and pharmacy dispensing data available through the Personal Electronic Medicine profile. Individual patient medication changes and primary non-compliance following discharge were observed during a 6-month follow-up period.

#### Results

**Study I:** From the 284 eligible patients contacted to participate in the study, 135 (48%) signed an informed consent form and were screened for available data. Complete study data according to inclusion criteria were obtained for 88 of screened patients. From 593 collected discharge summaries, we found that 98% were transmitted electronically using a standardised information protocol (EDIFACT). Median delay of receipt in primary care was 0 days from the day of discharge. A discharge, medication status was reported in 30% of all discharge summaries. Potential omission and commission errors happened frequently during patient discharge. Full agreement in daily dose was found in 40% of comparisons between hospital medical records and discharge summaries. Drug strength and dosage were missing in 13% and 12%, respectively, of all drugs

listed. Details on follow-up plans were specified in 73% of sampled discharge summaries.

**Study II:** From the 867 eligible patients contacted to participate in the study, 476 (55%) signed an informed consent form and were screened for available data. Complete study data according to inclusion criteria were obtained for 164 of screened patients. Included heart failure patients were discharged with an average of 7.0 prescriptions. During six months follow-up, the GPs prescribed 6.5 drugs per patient, while patients purchased 8.5 drugs per patient at pharmacies. The majority of patients were allocated to various cardiovascular drug combination regimens. We showed that approximately 24% of patients were primarily non-compliant with one or more cardiovascular drugs prescribed at the heart failure clinics. Additionally, we showed that despite patient enrolment at the clinics, GPs were involved in continuing cardiovascular therapy for 77% of patients. However, GPs appeared only to continue selected drug treatment and frequently change drug regimens prescribed at the clinics. Kappa analyses showed pronounced differences in agreement between drug information in hospital medical records, primary care case notes and pharmacy dispensing data.

#### Ph.d.-afhandling

**Cand.med. Kaare Dyre Palnum**, Klinisk Epidemiologisk Afdeling, Århus Universitets-hospital.

#### **Implementation of clinical guidelines regarding acute treatment and secondary medical prophylaxis among patients with acute stroke in Denmark**

Ph.d.-forsvaret fandt sted den 17. september 2010

#### Vejledere

Søren Paaske Johnsen, MD, PhD, Associate Professor, Dpt of Clinical Epidemiology Aarhus University Hospital  
Grethe Andersen, DMSc, Associate Professor, Dpt of Neurology, Aarhus University Hospital, Aarhus Hospital, Denmark

### Bedømmere

Birgitta Stegmayr, Professor, MD, Unit of Epidemiology, National Board of Health and Welfare, Sweden

Gudrun Boysen, Professor, DMSc, Department of Neurology, Bispebjerg Hospital

Steen E. Husted, DMSc, Associate Professor, Department of Medical Cardiology, Aarhus University Hospital.

### RESUMÉ

Omfanget og implikationerne af mulige alders- og kønsrelaterede forskelle i akut og sekundær profylaktisk behandling og pleje efter apopleksi er et omdiskuteret emne. Flere studier antyder, at patienter med apopleksi måske modtager forskelsbehandling på baggrund af alder og køn, og at disse forskelle kan have alvorlige kliniske konsekvenser for patienterne. Derudover eksisterer der kun sparsomme data vedrørende effektiviteten af sekundær medicinsk profylakse efter iskæmisk apopleksi. For yderligere at undersøge dette emne, blev der foretaget fire studier på basis af data fra danske registre. Målet med de første to studier var at klarlægge om der er alders- og kønsrelaterede forskelle i den akutte apopleksibehandling i Danmark, og i så fald, om disse forskelle eventuelt bidrager til alders- og kønsrelaterede forskelle i dødeligheden efter apopleksi. De to sidste studier havde som formål at undersøge potentielle alders- og kønsrelaterede forskelle i brugen af sekundær medicinsk profylakse efter iskæmisk apopleksi samt effektiviteten af medicamenterne i forhold til dødelighed, risikoen for akut myokardieinfarkt og ny apopleksi. Alle studierne var baseret på data fra Det Nationale Indikatorprojekt (NIP), som er et nationalt initiativ til at monitorere og forbedre kvaliteten af behandling iblandt udvalgte sygdomme, inklusiv apopleksi. Projektet gør dette ved at udvikle og implementere evidensbaserede indikatorer for behandlingskvalitet. Data fra NIP blev koblet med oplysninger fra Landspatientregistret, Lægemiddelsstyrelsens lægemiddelstatistikregister og CPR-registret samt den Integreerede Database for Arbejdsmarkedsforskning for at indhente informationer vedrørende patienters udskrivningsdata, vitale status, indløste recepter og socioøkonomisk status. De første to studier inkluderede ca. 30.000 patienter indlagt med apopleksi fra 2003 til 2005 mens de to sidste studier inkluderede ca. 29.000 patienter indlagt med iskæmisk apopleksi fra 2003 til 2006. Studierne blev designet som landsdækkende populationsbaserede follow-up studier. Data blev analyseret ved brug af logistisk re-

gression og Cox proportional hazards regression. Det første studie viste, at ældre patienter (>80 år) modtog en ringere kvalitet af behandling og pleje end yngre patienter (≤65 år); dog lod forskellene ikke til at kunne forklare den højere dødelighed blandt ældre patienter. Det andet studie fandt, at der ikke var væsentlige kønsrelaterede forskelle i den akutte hospitalsbehandling, og at den lavere kort-tidsdødelighed hos kvinder derfor sandsynligvis skal forklares af andre faktorer. Det tredje studie viste, at ældre patienter (>80 år) havde en langt mindre sandsynlighed for at modtage sekundær medicinsk profylakse efter en iskæmisk apopleksi sammenlignet med yngre patienter (≤65 år). Ældre patienter som påbegyndte brug af sekundær profylakse havde også en mindre sandsynlighed for at fortsætte behandlingen, og forskellene i brugen af sekundær medicinsk profylakse bidrog til den højere dødelighed som kunne observeres blandt ældre patienter. Det fjerde og sidste studie fandt, at brug af sekundær medicinsk profylakse efter apopleksi var associeret med en lavere dødelighed, og i nogen grad lavere risiko for myokardieinfarkt og recidiv apopleksi. Effekten af den sekundære medicinske profylakse som i første omgang er blevet påvist i nøje kontrollerede kliniske forsøg på selekterede patientgrupper ser således ud til at kunne genfindes i den kliniske hverdag på uselekterede patienter.



## MØDER, KURSER og STILLINGER

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### *Danmark:*

**Det Farmaceutiske Fakultet, Københavns Universitet udbyder følgende enkeltkurser:**

**Non-Clinical Safety and Toxicology**, 11.-15. oktober 2010.

(Ansøgningsfrist 1. august 2010)

**Evidensbaseret lægemiddelanvendelse i praksis**, 15.-17. november 2010 + 18.-20. januar 2011.

(Ansøgningsfrist 1. september 2010)

**Drug Formulation and Delivery**, 6.-10. december 2010.

(Ansøgningsfrist 1. oktober 2010).

[www.farma.ku.dk/enkeltkurser](http://www.farma.ku.dk/enkeltkurser)

Kataloget for efterårets efter- og videreuddannelseskurser som udbydes af Det Farmaceutiske Fakultet, Københavns Universitet er nu tilgængeligt. Hent eller bestil kursuskataloget på

[www.farma.ku.dk/kursuskatalog](http://www.farma.ku.dk/kursuskatalog)

### *Nærmere oplysninger:*

Kontaktperson for kursustilmelding er Lone Lundgaard Jensen 3533 6389

[master@farma.ku.dk](mailto:master@farma.ku.dk)

**Afdeling for Klinisk Epidemiologi, Aarhus Universitet udbyder følgende 5-dages kursus:**

**Logistic Regression and Survival Analysis in Epidemiologic Research**

*Undervisere:* Stanley Lemeshow, PhD og David W. Hosmer, Jr, PhD

*Tid:* 4.-8. oktober 2010

*Pris:* 9.000 kr.

*Kontaktperson:* Vera Ehrenstein:

[ve@dce.au.dk](mailto:ve@dce.au.dk)

**Dansk Selskab for Farmakoepidemiologi inviterer til tema-møde om anvendelse af Propensity Score i farmakoepidemiologiske studier**

*Tid:* 16. november 2010

*Sted:* Center for Sundhed og Samfund, Øster Farimagsgade 5, 1014 København K, Bygning 22, auditorium 22.0.19.

Kontrol af konfounding er formentlig den største udfordring i vores observationelle studier. Indenfor farmakoepidemiologi vil der i studier, hvor en medicinsk behandling ikke tildeles randomiseret, altid være en risiko for at personer, der får behandlingen, grundlæggende har en anden risiko for et givet outcome, end personer, der ikke får behandlingen ("Confounding by indication"). I de seneste år har brug af propensity score vundet tiltagende indpas som en måde af kontrollere denne konfounding. Propensity score er et mål for en given persons sandsynlighed for at blive tildelt en given behandling – men hvordan udvælger man i praksis de variable, der skal med i beregningen af denne score - og er vi i det hele taget sikre på at brug af propensity score fører til estimater af medicineffekter, der er mindre biased, end de estimater vi får i vores traditionelle multivariate metoder? Disse spørgsmål er baggrunden for at vi i DSFEs efterårsmøde har valgt at fokusere på propensity score. Vi håber på et meget spændende og oplysende møde.

[Se invitation senere i dette nyhedsbrev.](#)

### Kommende møde:

Tema: Measuring quality of prescribing in chronic diseases and in the elderly. Marts 2011, Odense.

**Udlandet:****Møde i NorPEN-netværket**

*Tema:* Medicine use in children

*Tid:* 14.-15. oktober 2010

*Sted:* Reykjavík

Se mere om NorPEN i et tidligere nummer af Farmakoepi-Nyt

[http://www.farmakoepi.dk/nyhedsbreve/EPIFY\\_T31.pdf](http://www.farmakoepi.dk/nyhedsbreve/EPIFY_T31.pdf)

og

[http://www.nhv.se/customer/templates/InfoPage\\_1619.aspx?epslanguage=SV](http://www.nhv.se/customer/templates/InfoPage_1619.aspx?epslanguage=SV)

**ENCePP information day**

*Tid:* 26. november 2010, kl. 8-17

*Sted:* London.

Se invitation og flere oplysninger på

<http://www.ENCePP.eu>

**Kommende møde:**

Tema: Monitoring safety.

Oktober 2011, Stockholm.



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Dansk Selskab for FarmakoEpidemiologi

*Sekretariat:* Klinisk Farmakologi  
Syddansk Universitet, Winsløwparken 19, 2. sal, 5000 Odense C  
Tlf.: 6550 4237. Fax: 6591 6089. Giro: 091-2425  
[www.farmakoepi.dk](http://www.farmakoepi.dk)

## **Dansk Selskab for Farmakoepidemiologi inviterer til Temamøde om anvendelse af Propensity Score i farmako- epidemiologiske studier**

Tid: Tirsdag den 16. november 2010, kl. 14:00-17:00

Sted: Center for Sundhed og Samfund (CSS)  
Københavns Universitet  
Øster Farimagsgade 5  
1014 København K  
Bygning 22, Auditorium 22.0.19  
Kort over CSS: <http://www.ifsv.ku.dk/kontakt/alle.jpg>

### **PROGRAM**

- 14.00-14.10 **Velkomst**  
*Gunnar Gislason*, formand for DSFE
- 14.10-14.45 **Generel introduktion til Propensity Scores**  
*Per Kragh Andersen*, professor, Biostatistisk afdeling, IFSV, Københavns Uni-  
versitet
- 14.45-15.15 Spørgsmål og diskussion af oplæg
- 15.15-15.30 DSFE byder på kaffe, te, vand og sandwich
- 15.30-16.00 **"Healthy user bias" i statin-studier – er brug af Propensity Score  
løsningen?**  
*Reimar Thomsen*, afdelingslæge, ph.d., Klinisk Epidemiologisk Afdeling,  
Århus Universitetshospital
- 16.00-16.15 Spørgsmål og diskussion af oplæg
- 16.15-16.45 **Er der en reel klinisk interaktion mellem clopidogrel og protein-  
pumpehæmmere, eller forklares det hele ud fra confounding-by-  
indication? Et eksempel på brug af Propensity Score-analyse på  
danske lægemiddeldata**  
*Gunnar Gislason*, overlæge, ph.d., Gentofte Hospital
- 16.45-17.00 Spørgsmål og diskussion af oplæg
- Afrunding

**Tilmelding:** Deltagelse er gratis, men af hensyn til forplejning bedes tilmelding ske senest  
tirsdag den 9. november 2010 til sekretær Henrik Horneberg: [hhorneberg@health.sdu.dk](mailto:hhorneberg@health.sdu.dk).

**Bliv medlem af DSFE; kig forbi [www.farmakoepi.dk](http://www.farmakoepi.dk). Medlemskab koster kun 250 kr. årligt.**

# EuroDURG bulletin

No. 20

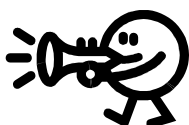
January 2010

NEWSLETTER OF THE EUROPEAN CHAPTER OF THE SPECIAL INTEREST GROUP OF DRUG UTILISATION 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.

Send reactions to: [benko@clph.szote.u-szeged.hu](mailto:benko@clph.szote.u-szeged.hu) OR [benkoria@gmail.com](mailto:benkoria@gmail.com)

*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](http://www.eurodurg.com)

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## EuroDURG as the European chapter of ISPE/SIGDUR

In 2006, the International Society of Pharmacoeconomics (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/](http://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 ethynylestradiol/norgestrel 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**

### 25<sup>th</sup> ICPE in Providence, Rhode Island, USA August 16-19, 2009

The 25<sup>th</sup> 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 25<sup>th</sup> 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/ ezetimibe, 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...*



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.



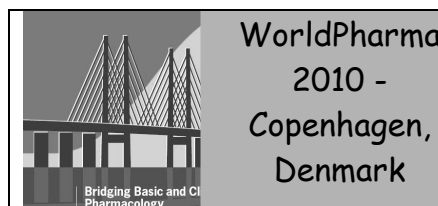
EuroDURGers and all people interested in pharmacoepidemiology are cordially invited to attend the 26<sup>th</sup> International Conference on Pharmacoepidemiology and Therapeutic Risk Management. The meeting will be held August 19-22, 2010 at the Hilton Brighton Metropole, in Brighton, a beautiful city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

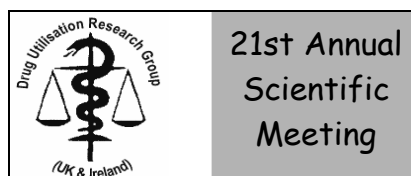


The International Union of Basic and Clinical Pharmacology (IUPHAR) invite you to attend the 16th World

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>



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*



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.



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](mailto: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 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](http://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](mailto:monique.elseviers@ua.ac.be)

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2008-2010**

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