

---

# Farmakoepi-Nyt

Februar

Dansk Selskab for Farmakoepidemiologi's nyhedsbrev

2008

---

No. 29

---

## MEDDELELSER FRA BESTYRELSEN

---

Formandens klumme ..... 2

## GENERALFORSAMLING 2007

---

Referat ..... 2  
Formandens beretning ..... 4  
Regnskab 2006 ..... 5

## AUTOREFERATER

---

Bente Glintborgs ph.d.-afhandling: *Medicinforbruget blandt akut indlagte medicinske patienter* ..... 6

Lise Aagaards ph.d.-afhandling: *Knowledge creation about adverse drugs reactions. Analysis of data from pre- and postmarketing file* ..... 7

## ABSTRACTS FRA ÅRSMØDE 2007

---

Se side ..... 9

## MØDER, KURSER og STILLINGER

---

Danmark ..... 11  
Udlandet ..... 11



### 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.

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 november 2007 af professor, dr.med. *Jesper Hallas*, Forskningsenheden for Klinisk Farmakologi, Syddansk Universitet - Odense (formand); seniorforsker, ph.d. *Morten Andersen*, Forskningsenheden for Almen Praksis, Syddansk Universitet – Odense; lektor *Birthe Søndergaard*, Institut for Farmakologi og Farmakoterapi, Det Farmaceutiske Fakultet, Københavns Universitet (kasserer); forskningsassistent, ph.d. *Pia Wogelius*, Klinisk Epidemiologisk Afdeling, Ålborg Hospital og *Betina Østergaard Eriksen*, Head of International Drug Safety, Nycomed. Selskabets revisor er afdelingschef, cand.oecon. *Kjeld Christensen*, AstraZeneca og revisorsuppleant er lektor, ph.d. *Jens Søndergaard*, Forskningsenheden for Almen Praksis, Syddansk Universitet – Odense.

**Redaktion:** *Betina Østergaard Eriksen*

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.

*Jesper Hallas*



### MEDDELELSER FRA BESTYRELSEN

#### Formandens klumme

Se formandens beretning lige efter referat fra generalforsamling 2007.

*Jesper Hallas*  
formand

#### GENERALFORSAMLING 2007

Referat fra generalforsamlingen i Dansk Selskab for Farmakoepidemiologi mandag den 19. november 2007:

Jesper Hallas bød velkommen til den 13. generalforsamling i Dansk Selskab for Farmakoepidemiologi.

Omkring 30 medlemmer af foreningen var til stede.

### 1) Valg af dirigent og referent

Ordstyrer: Jens Peter Balling

Referent: Helle Wallach Kildemoes

Jens Peter Balling konstaterede, at generalforsamlingen var lovligt indkaldt.

### 2) Formandens beretning om selskabets virksomhed det forgangne år

Jesper Hallas aflagde beretning. *(Red.: Er indføjjet i nyhedsbrevet lige efter dette referat).*

Beretningen blev godkendt.

### 3) Aflæggelse af rapport fra selskabets stående udvalg og råd.

Der er pt. ingen stående udvalg.

### 4) Fremlæggelse og godkendelse af det reviderede års regnskab

Da kasserer Birthe Søndergaard ikke var til stede pga. sygdom, gennemgik Jens Peter Balling det omdelte regnskab for 2006. Med et års resultat på +2277 kr. og balance mellem foreningens indtægter og udgifter, blev regnskabet godkendt efter et afklarende spørgsmål vedrørende de 4000 kr. til administration – sv.t. honorar til Henrik Horneberg. *(Red.: Regnskabsoversigten er indføjjet i dette nyhedsbrev).*

### 5) Valg af bestyrelse

Jens Peter Balling konstaterede, at der ikke var indkommet rettidige forslag til nye bestyrelsesmedlemmer. Forsamlingen genvalgte Morten Andersen og Betina Østergaard Eriksen. Jesper Hallas, Birthe Søndergaard og Pia Wogelius fortsætter uden valg i bestyrelsen.

### 6) Valg af revisor og suppleanter

Kjeld Christensen blev genvalgt til revisor, Jens Søndergaard til suppleant. Begge in absentia.

### 7) Forslag til vedtægtsændring

Tilføjelse af paragraf mellem den nuværende §8 og §9 blev godkendt. Dette betyder, at Dansk Selskab for Farmakoepidemiologi nu er tilknyttet paraplyorganisationen ”Danish Pharmacology”.

### 8) Nyhedsbrevet

Nyhedsbrevet udarbejdes alene af bestyrelsen. Der var positiv tilbagemelding på indholdet af

nyhedsbrevet. Jesper Hallas efterlyste evt. inputs samt ønsker til emner i nyhedsbrevet.

### 9) Temadage

Der var udbredt ønske om afholdelse af temadage.

Det blev foreslået, at næstkommende temadag skulle omhandle ”Fase 4 studier”/”Non-interventions studier”/anvendelsen af biomarkører.

Der var interesse for en temadag sv.t. den aflyste om de forskellige farmakoepide-miologiske miljøer i Danmark.

### 10) EuroDURG

Pro et contra for udmeldelse af EuroDURG blev diskuteret. EuroDURG er en ren europæisk organisation. På den anden side er organisationen ”døende” (ikke mange faglige aktiviteter – få betalende/aktive medlemmer). Fortællere for udmeldelsen mente, at den europæiske vinkel kunne varetages af interesse grupper under ISPE, f.eks. SIG DURG.

Udmeldelse af EuroDURG blev vedtaget med omkring 10 stemmer for og 1 imod, hvilket betyder, at selskabet betaler sidste kontingent i foråret 2008.

### 11) ISPE-kongres i København 2008

ISPE kongressen afholdes i Bella Centret 18-20/8. Jesper Hallas er i programkomitéen, mens Jens Peter Balling er i lokalkomitéen – en svensker, Anita Bäckmann, står for det praktiske.

- Program:

Der vil som på tidligere ISPE-konferencer være en vægtning mellem workshops, symposier og frie foredrag.

Ideer til workshops og symposier er velkomne. De indsendte beskrivelser vurderes af programkomitéen. Abstracts til frie foredrag vurderes af ISPE medlemmer.

Programkomiteen overvejer at lade Antidiabetica være Hot Topic. Mads Melbye er inviteret til foredrag om anvendelsen af de mangfoldige registre til farmakoepidemiologiske studier i Danmark.

- Selve arrangementet:

Den lave dollarkurs sætter begrænsning på valget af sted for konference-middag.

*Helle Wallach Kildemoes  
referent*

## Formandens beretning

### Bestyrelsens sammensætning

Ved sidste generalforsamling blev undertegnede valgt efter en obligatorisk pause sammen med Birthe Søndergaard fra Det Farmaceutiske Fakultet, Københavns Universitet. Morten Andersen, Pia Wogelius og Betina Østergaard Eriksen fortsatte. Vi konstituerede os med undertegnede som formand, Betina Østergaard Eriksen som sekretær, dvs. ansvarlig for ind- og udmeldelser og for vedligeholdelse af medlemsdatabasen og web-siden og Birthe Søndergaard som kasserer.

### Bestyrelsesmøder

Vi har holdt møde i alt 7 gange, deraf de 6 gange som telefonmøder.

### Nyhedsbreve

Der er udkommet et nyhedsbrev i det forgangne år: I juli, redigeret af Morten Andersen.

Vi planlægger at udgive et nyhedsbrev i november/december med referater fra årsmødet, abstracts mm.

Vi har valgt det gammelkendte serviceorienterede koncept med mødekalender, litteraturservice, autoreferater af væsentlige afhandlinger, beskrivelse af miljøer med farmakoepidemiologisk interesse og formandens klumme. Vi vil stadig gerne efterlyse input fra medlemmerne også mht valg af form. Det skal bemærkes, at alle nyhedsbreve siden 1995 kan downloades i pdf format fra vores web-side.

### Medlemmer

Selskabet har 116 medlemmer. Vi har netop fået materiale fra Lægeforeningens serviceafdeling, som administrerer kontingentopkrævning. Jeg kan med glæde meddele, at der er flere indmeldelser end udmeldelser, 10 vs 4 og ingen døde medlemmer i det forløbne år.

### Faglige aktiviteter

En stor del af vores faglige aktivitet har berørt den kommende internationale kongres i Bella Centeret i august 2008. Jeg vil henvise til særskilt indlæg. Der har ikke været afholdt fagligt forårssymposium i år. Vi vil gerne

opfordre medlemmerne til at komme med forslag til, hvad et forårssymposium for 2008 kunne indeholde.

### Sekretariatsfunktionen

En del af sekretariatsfunktionen - væsentligst korrespondance med medlemmerne - er forestået af lægeforeningens serviceafdeling, hvilket har fungeret yderst tilfredsstillende. Henrik Horneberg forestår stadig et stort praktisk arbejde, bl.a. indmeldelser, nyhedsbreve, hjemmesiden, opdatering af medlemsdatabasen, regnskab og arrangement af dette møde.

### Internationale relationer

Selskabet er tilknyttet European Drug Utilization Research Group (EURO-DURG). Som det fremgår af særskilt indlæg, er EURO-DURG under opløsning og dens aktiviteter forventes at indgå under ISPE som en "Special Interest Group". Vi har stillet i forslag, at vi formelt melder os ud af EURO-DURG.

DSFE er ligeledes formelt tilknyttet ISPE. Der har ikke været formelle udvekslinger med denne organisation idet forløbne år.

Vi vil i øvrigt takke alle, der har deltaget i selskabets aktiviteter, for godt samarbejde. Og for at gøre vores arbejde så spændende som det er. Specielt vil vi takke vores sekretær Henrik Horneberg for en uvurderlig indsats.

*Jesper Hallas*  
*formand*

**Dansk Selskab for Farmakoepidemiologi**  
Sekretariatet

Klinisk Farmakologi  
Syddansk Universitet  
Winsløwparken 13, 3. sal.  
DK-5000 Odense C  
Tlf.: 6550 3788, fax: 6591 6089  
Giro: 091 2428

**Regnskab for 2006**

Indtægter: (Konto + rest)

100, Kontingent	25.750,00 kr.
130, Årsmøde, deltagergebyr	5.800,00 kr.
150, Renteindtægter	6,60 kr.
<b>Indtægter i alt</b>	<b>31.556,60 kr.</b>

Udgifter: (Konto + rest)

200, Bestyrelsesmøde	6.194,00 kr.
220, Årsmøde	10.213,52 kr.
230, Faglige møder	951,00 kr.
250, Kontingent, EURO-DLRG	3.977,56 kr.
280, Gebyrer	476,75 kr.
281, Gebyrer til Lægeforeningen	3.130,00 kr.
282, Porto	0,00 kr.
290, Godtgørelse til administratør	4.000,00 kr.
291, Andre udgifter	337,00 kr.
<b>Udgifter i alt</b>	<b>39.279,83 kr.</b>
<b>Årets resultat</b>	<b>2.276,77 kr.</b>

**AKTIVER**

Girokontosaldo pr. 31/12-2006	19.370,68 kr.
Checkkontosaldo pr. 31/12-2006	2.358,09 kr.
<b>Aktiver i alt pr 31/12-2006</b>	<b>21.728,77 kr.</b>

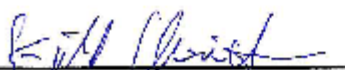
**PASSIVER**

Egenkapital 1/1-2006	19.452,00 kr.
Resultat 2006	2.276,77 kr.
<b>Passiver i alt pr 31/12-2006</b>	<b>21.728,77 kr.</b>

  
Birthe Søndergaard, kasserer  
BIRTHE SØNDERGAARD

16.11.07  
Dato

Overnævnte regnskab er revideret og beholdningen findes til stede

  
Kjeld Christensen, foreningens revisor

16/11 2007  
Dato

## AUTOREFERATER

---

### Læge Bente Glintborgs ph.d.-afhandling:

#### *Medicinforbruget blandt akut indlagte medicinske patienter.*

Forsvaret 18. januar 2008

Patienternes selvrapporterede forbrug versus receptdata og medikamentanalyser

En ufuldstændig medicinanamnese giver risiko for medicineringsfejl og mistolkning af symptomer. Formålet med afhandlingen var at vurdere nøjagtigheden af patienters selvrapporterede lægemiddelforbrug når data fra et struktureret interview blev sammenlignet med receptdata og medikamentanalyser. Afhandlingen udgår fra Klinisk Farmakologisk afdeling, Rigshospitalet, og patient-inklusionen foregik på akut medicinsk modtageafsnit, Bispebjerg Hospital.

Interviews blev foretaget blandt 500 akut indlagte medicinske patienter ved indlæggelsen og igen efter udskrivelsen i patientens eget hjem. Receptdata (PR) og medicinoplysninger fra hospitalsjournalen blev indhentet på alle patienter. Blod- og urinprøver indsamlet i relation til interviewene blev analyseret for udvalgte lægemidler (amlodipin, bendroflumethiazid, digoxin, glimepirid, simvastatin) og rusmidler (amfetamin, barbiturat, benzodiazepiner, cannabis, kokain, metadon, opiat), og resultaterne sammenlignet med patienternes selvrapporterede forbrug.

Ved indlæggelsen rapporterede patienterne et medianforbrug på 3 receptpligtige lægemidler (POM), hvoraf 6% ikke var registrerede i patienternes PR. Sammenlagt undlod patienterne at rapportere 19% af de POM, som ifølge deres receptdata var indkøbt i ugen op til indlæggelsen. Ved hjemmebesøget var det tilsvarende antal 11%. Hjertemedicin (ATC gruppe C) var den medicintype, som blev rapporteret i højest overensstemmelse med PR. Specielt ældre patienter rapporterede i uoverensstemmelse med receptdata. Overensstemmelsen mellem lægemiddelanalyser og selvrapporteret forbrug af de 5 lægemidler var generelt høj (kappa for alle lægemidler >0,79). En screening for urinindhold af rusmidler blev foretaget blandt 100 tilfældigt udvalgte patienter ved indlæggelsen. Ingen patienter havde positiv screening for amfetamin eller kokain. I alt 12 patienter (12%) havde en screening po-

sitiv for stoffer, som ikke var blevet rapporteret ved interviewet (cannabis: 5 patienter, benzodiazepin: 7 patienter). Patienterne var generelt troværdige, når de benægtede brug af de enkelte stoffer (negativ prædiktiv værdi >92%).

Receptdata tyder således på, at der på trods af strukturerede lægemiddelinterviews sker en betydelig underrapportering af lægemiddelforbruget - selv når interviewene foretages i patientens hjem. Dette taler for anvendelse af receptdata i klinikken, specielt blandt ældre patienter. For behandlende læger er patienternes receptdata umiddelbart tilgængelige via [www.medicinprofilen.dk](http://www.medicinprofilen.dk). Lægemidler med misbrugspotentiale og illegale stoffer anvendes kun af få patienter. Imidlertid underreporteres brugen af benzodiazepin og cannabis ofte, og rusmiddel-analyse kan eventuelt overvejes ved diagnostisk uafklarede patienter.

Forf.s adresse: Hybenvej 46, DK-2830 Virum.

E-mail: [glintborg@dadlnet.dk](mailto:glintborg@dadlnet.dk)

Forsvaret finder sted den 18. januar 2008, kl. 14, Dam Auditoriet, Panum Institutet, Nørre Alle, København

Bedømmere: Christian Torp-Pedersen, Jesper Hallas, Birgitte Brock

Vejledere: Kim Dalhoff, Henrik Enghusen Poulsen

*Afhandlingen bygger på følgende publikationer:*

Glintborg B, Poulsen HE, Dalhoff K.

The use of nationwide on-line prescription records improves the drug history in hospitalized patients.

British Journal of Clinical Pharmacology, offentliggjort online august 2007

Glintborg B, Hillestrøm PR, Olsen LH, Dalhoff K, Poulsen HE.

Are patients reliable when self-reporting medication use? Validation of structured drug interviews and home visits by drug analysis and prescription data in acutely hospitalised patients.

Journal of Clinical Pharmacology, 2007 Nov;47(11):1440-9

Glintborg B, Olsen LH, Linnet K, Poulsen HE, Dalhoff K.

The reliability of self-reported use of amphetamine, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone and opiates

among acutely hospitalised elderly medical patients.

Juli 2007 accepteret til publikation i Clinical Toxicology.

### **Lise Aagaards ph.d.-afhandling**

#### ***Knowledge creation about adverse drugs reactions. Analysis of data from pre- and post-marketing files***

Forsvaret 24. januar 2008

**Background:** Effective systems to quickly capture new knowledge about undetected serious adverse drug reactions (ADRs) arising after product launch are crucial to public health. Thus in 1968, Denmark, in keeping with other countries, introduced a reporting system inspired by the thalidomide case around 1960. Despite the more stringent requirements regarding the reporting of drug safety, new cases of serious ADRs continue to appear. This questions the ability of existing systems to capture relevant knowledge about ADRs.

**Aim:** The overall aim of this project is to uncover how knowledge about ADRs is created and used in drug surveillance. Specific aims were to:

**I:** Explore how the system has reacted to the collected data and how the information has been converted into new knowledge.

**II:** Investigate whether it would have been possible to foresee serious ADRs based on information reported in the clinical trials before marketing of the drugs.

**III:** Review the occurrence of ADRs in three therapeutic cases and to explore the knowledge produced about ADRs.

**IV:** Analyse characteristics of ADRs reported by consumers as compared to ADRs reported by health care professionals.

**V:** Explore the organizational structure and processes of the Danish and Australian spontaneous reporting systems with a special view to information creation about new ADRs.

Each research question corresponds to an empirical sub-study (I-V).

**Theoretical frame of reference:** Nonaka & Takeuchi's theory of knowledge creation was

chosen to guide the analyses because it deals with knowledge as a process involving learning and problem solving, and provides the opportunity to reflect on the assumptions that support this knowledge and changes in it.

**Methods:** The empirical analyses in this thesis were based on ADR data from the Danish ADR register and other documentary sources, including registration files, files from the archives of The Danish Medicines Agency, published articles and publications from the National Committee for ADRs, as well as observations in the Danish and Australian ADR systems.

**Results:** Main findings of the sub-studies were:

**I:** The spontaneous reporting system lacked the potential to capture available and relevant knowledge about ADRs. ADR reports have been of limited value and significance in the process of creating scientific knowledge.

**II:** Registration material contained observations/data on serious ADRs which have not been followed up with further clinical trials or other form of documentation and not been published. The registration material contained certain data/information about the ADR profiles of the drugs in sub-populations, such as patients with liver and kidney disease.

**III:** Analyses of three cases showed that knowledge about new ADRs only originated from case reports. Other approaches at a higher level in the evidence hierarchy did not provide such information, but rather information about the relative risk of already detected ADRs.

**IV:** The reporting patterns of consumers and non-consumers differed with regard to seriousness, organ classes and ATC level. Consumers reported information about ADRs that was not reported by non-consumers.

**V:** A comparison of the Danish and Australian ADR systems showed that the systems differs with regard to reporting requirements, report handling, resources spend and information exchange with the environment. The analyses did not provide information of the ability of the systems to produce information about new ADRs.

**Conclusion:** Systems that can capture new information about potential ADRs and convert it into new knowledge have not yet been established. In their absence, we will have to continue to base drug surveillance on

published case reports and spontaneous reporting systems, as well as on any other method that can lead to reliable information at reasonable cost and speed. The challenges in the future drug surveillance are to strengthen the scientific evidence, respond faster to new ADR signals, integrate pre- and post-marketing reviewing, enhance post-marketing safety monitoring, conduct confirmatory drug safety and efficacy studies and take better advantage of information reported during clinical trials.

**Keywords:** Pharmacoepidemiology, Adverse Drug Reactions, Denmark, knowledge creation, Nonaka, spontaneous reporting systems

*Lise Aagaard Ph.d.-studerende (pharm.), HD (O)*

.....  
*Consumer Safety Division  
Danish Medicines Agency  
Axel Heides Gade 1  
DK-2300 København S  
T: 44889611  
E-post: [lia@dkma.dk](mailto:lia@dkma.dk)*



## ABSTRACTS FRA ÅRSMØDET 19. NOVEMBER 2007

### CARDIOVASCULAR EFFECTS OF LETIGEN. A CASE-CROSSOVER STUDY

*Jesper Hallas, Lars Bjerrum, Henrik Støvring og Morten Andersen.*

**Background:** Ephedrine and herbal ephedra preparations have been shown to induce a small to moderate weight loss. Owing to a large number of spontaneous reports on serious cardiovascular events they were banned from the US market in 2004. There are no large controlled studies on the possible association between prescribed ephedrine/caffeine and cardiovascular events in general.

**Methods:** We linked data from four different sources within the Statistics Denmark, using data on 259,326 users of prescribed ephedrine/caffeine. Data were analyzed by use of a case-crossover technique with a composite end-point of death outside hospital, myocardial infarction and stroke. In order to account for the effects of chronic exposure and for effects in naïve users, we performed a secondary case-control study nested within the cohort of ephedrine/caffeine ever users.

**Results:** Among 2,316 cases, 282 (12.2%) were current users of ephedrine/caffeine. The case-crossover analysis yielded an OR of 0.84 (95%-CI: 0.71; 1.00), and 0.95 (CI 0.79; 1.16) after adjustment for trends in ephedrine/caffeine use. Sub-group analyses revealed no strata with significantly elevated risk. In the case-control sub-study, there was no increased risk among naïve users, or among users with large cumulative doses.

**Conclusion:** Use of prescribed ephedrine/caffeine is not associated with an increased risk of adverse cardiovascular outcomes.

### PHARMACISTS WORKING WITH PATIENTS TO ENHANCE COMPLIANCE

*Charlotte Rossing. Pharmakon, Danish College of Pharmacy Practice, Milnersvej 42, 3400 Hillerød, Denmark*

Based on EuroPharm Forum programmes on diabetes and hypertension, Pharmakon and Danish pharmacies have developed practice models and carried out compliance demonstration projects within these areas.

The hypertension program has been tested in 12 Danish pharmacies from February 2006 through January 2007. The diabetes program has been tested in four Danish pharmacies from January through June 2007. The pharmacies worked with the implementation, testing and validation of the program. A number of 250 patients, half of which were showing signs of non-adherence, were included in the hypertension study. A number of 80 type 2 diabetics, all of which were showing signs of non-adherence, were included in the diabetes study. The patients were assigned to either a comprehensive or a basic version of the multidimensional intervention program. Selected preliminary results will be presented at the conference.

#### Intervention outline:

1. Quick screening for non-adherence and identification of problem types
2. Patient story-telling as the key starting point
3. Assessment and possible adjustment of drug therapy
4. Finding resources in the patient-system
5. Individual coaching, in order to tailor solutions to individual needs and resources
6. Offering relevant reminder technology and/or patient instruction/education
7. Follow up
8. Close collaboration with the patient's GP

Results from the two studies will be presented and compared during the presentation.

## EXPOSURE TO ANTIEPILEPTIC DRUGS AND RISK OF HIP FRACTURE: A CASE-CONTROL STUDY

Ioannis Tsiropoulos<sup>1,2</sup>, Morten Andersen<sup>3</sup>, Tine Nymark<sup>4</sup>, Jens Lauritsen<sup>4,5</sup>, David Gaist<sup>1</sup>, Jesper Hallas<sup>2,6</sup>

*Institutions*

*Departments of <sup>1</sup>Neurology, <sup>4</sup>Orthopaedic Surgery and <sup>6</sup>Internal Medicine, Odense University Hospital,*

*Research Units of <sup>2</sup>Clinical Pharmacology, <sup>3</sup>General Practice and <sup>5</sup>Epidemiology, Institute of Public Health, University of Southern Denmark.*

**Purpose:** To investigate whether use of antiepileptic drugs (AEDs) increases the risk of hip fracture.

**Methods:** We performed a case-control study using data from the Funen County (population 2004: 475,000) hip fracture register. Cases (n= 7,557) were all patients admitted to county hospitals with a hip fracture during the period 1996-2004. Controls (n= 27,575) were frequency matched by age and gender. Information on use of AEDs, other drugs and hospital contacts was available from local registers. Odds ratios (ORs) with 95% confidence intervals (CI) for hip fracture were estimated by unconditional logistic regression.

**Results:** Fracture risk was increased with ever use of any (OR, 1.31; 95% CI: 1.16 to 1.48), but not with use of only liver enzyme inducing AEDs (OR, 1.06; 95% CI: 0.88 to 1.28) or only non inducing AEDs (OR, 1.07; 95% CI: 0.81 to 1.40). Current and recent use, as well as daily and cumulative dose, but not treatment duration or previous use, increased fracture risk. The risk was decreased in analysis stratified by the presence (OR, 1.29; 95% CI: 0.77 to 2.18) or absence (OR, 1.08; 95% CI: 0.94 to 1.24) of an epilepsy diagnosis. In monotherapy with specific AEDs, only current and recent use of phenobarbital and current use of oxcarbazepine increased fracture risk.

**Conclusion:** Use of antiepileptic drugs modestly increases the risk of hip fracture. The risk increase may be more associated to a dose dependent effect on CNS with current and recent use, than to a direct effect on bone tissue.

**Keywords:** case-control, fracture, antiepileptic drugs, epilepsy, prescriptions

## COMPLIANCE TIL ORDINERET MEDICIN HOS TYPE 2 DIABETIKERE

*Sofie Gry Pristed. Aarhus Universitet*

**Baggrund:** Prævalensen af type 2 diabetes er stigende på verdensplan, og sygdommen kan medføre en lang række komplikationer. Det er kendt at suboptimal compliance til ordineret medicin er medvirkende til progression af komplikationerne. Compliance defineres forskelligt og der findes ingen standard metode til kvantificering af compliance.

**Formål:** At undersøge studiepopulationens compliance til ordineret medicin og dernæst at undersøge om der er forskel på compliance til perorale antidiabetika og kolesterolsænkere samt anti-hypertensiva.

**Materiale og metode:** Tværsnitsundersøgelse hvor 79 type 2 diabetikere med tilknytning til Medicinsk Endokrinologisk Afdeling, Aalborg Sygehus deltog i interviewundersøgelse vedrørende compliance til ordineret medicin.

**Resultater:** Studiepopulationens compliance til perorale antidiabetika, insulin, anti-hypertensiva og kolesterolsænkere var høj med range fra henholdsvis 78,6 – 100 %, 57,1 – 100 %, 85,7 – 100 % og 78,6 – 100 %.

**Konklusion:** Andelen af compliant patienter var stor for alle medicingrupperne. Ved cut-off på 90 % var 98 % af patienterne compliant til anti-hypertensiva, 96 % af patienterne var compliant til insulin, 91 % var compliant til perorale antidiabetika og 90 % var compliant til kolesterolsænkere.

Studiepopulationens compliance til anti-hypertensiva var signifikant højere end compliance til perorale antidiabetika (p: 0,035). Der var ikke signifikant forskel på studiepopulationens compliance til perorale antidiabetika og kolesterolsænkere.

Glemsomhed var den hyppigste årsag til reduceret compliance for samtlige medicingrupper.

**MØDER, KURSER og STILLINGER****Danmark:****Danish Clinical Intervention Research Academy Courses (DIRAC-kurser)**

*Tid:* Afvikles løbende hele året.

*Nærmere oplysninger:* [www.diracforsk.dk](http://www.diracforsk.dk)

**Safety & Pharmacovigilance - Module 1**

*Tid:* 22.-23. april 2008

*Sted:* Strødamvej 50 A, 2. sal, 2100 København Ø.

*Nærmere oplysninger:*  
<http://www.lif-uddannelse.dk/sw32770.asp>

**ISPE 24th International Conference on Pharmacoepidemiology & Therapeutic Risk Management**

*Tid:* 17.-20. august 2008

*Sted:* København

*Nærmere oplysninger:*  
<http://www.pharmacoepi.org/meetings/24thconf/index.cfm>

**Safety & Pharmacovigilance - Module 2**

*Tid:* 7.-8. oktober 2008

*Sted:* Strødamvej 50 A, 2. sal, 2100 København Ø.

*Nærmere oplysninger:*  
<http://www.lif-uddannelse.dk/sw27575.asp>

**Udlandet:****McGill Pharmacoepidemiology courses  
Department of Epidemiology and Biostatistics**

McGill University, Montreal, Quebec, Canada

Summer session in Epidemiology and Biostatistics 2008.

3 courses, each given intensively over a 4-day period.

June 2-5: Pharmacoconomics (Dr Jaime Caro)

June 9-12: Introduction to Pharmacoepidemiology (Dr Jean-Paul Collet)

June 16-19: Advanced Pharmacoepidemiology (Dr Samy Suissa)

The courses will present state of the art methods discussed around the current very hot topics dealing with drug use, benefit, risk and economic impact. The classes attract a mix of students from academia, industry and regulatory agencies.

Application deadline for May/June courses is March 1st.

<http://www.mcgill.ca/epi-biostat-occh/summer/>

**European Educational Programme in Epidemiology**

21st Residential Summer Course in Epidemiology

Florence, Italy, from 23 June to 11 July 2008, three-week main course

The courses are taught in English by lecturers mostly from European Universities and Research Institutes and are held in residential form in the "Studium" centre on the hills close to Florence.

The main three week course offers in the first two weeks five general modules on epidemiological study design and statistical analysis of epidemiological data. In the third week six special modules, ranging from cancer epidemiology and cardiovascular epidemiology to the impact of changes of global climatic environment cover topics of current relevance for

health (students can choose which modules to follow).

The morning and afternoon sessions include lectures, computer based analyses (using the “Stata” package), exercises and discussion sessions. To follow profitably this course, students are expected to possess some knowledge of epidemiological and statistical methods at introductory level.

Applications can be submitted from December 1, 2007 to May 7, 2008. An early application will count as a priority element for admission. Successful applicants will be requested to confirm attendance by paying a non-refundable advance of 1000 Euros at the latest fifteen days before a course starts.

The inclusive fee, covering registration, course materials, books and full board and lodging in rooms for two students at the "Studium" centre from the Sunday night preceding the course to the Friday ending the course. The inclusive fee for the three week main course taking place from June 23 to July 11, 2008 is 3200 (three thousand and two hundred) Euros. The number of participants is limited to seventy residents. Applications to this course are also accepted from students wishing to attend on a non-residential basis only the special modules of the third week.

<http://www.eepe.org/courses.html>



*For the second time, on behalf of the European Association of Clinical Pharmacology and Therapeutics (EACPT) and in collaboration with EMEA, the Division of Clinical Pharmacology, Karolinska Institute, Karolinska University Hospital, Stockholm, arranges the course:*

# Pharmacovigilance

## *principles and practice*

**The course will take place in Stockholm, Sweden, April 7 – 11, 2008**

and starts on Monday April 7 at 13:00 (1 pm). It ends at 12:00 (noon) on Friday April 11. The course is directed to clinical pharmacologists, other clinical specialist or health care professionals engaged in clinical, regulatory, scientific or public health oriented aspects of adverse drug reactions and drug safety.

### Venue

The course will be held at the Division of Clinical Pharmacology, Karolinska University Hospital (Huddinge), located some 20 km south of Stockholm.

One day will be spent in Uppsala at the Medical Products Agency and the WHO Collaborating Centre for International Drug Monitoring (UMC- the Uppsala Monitoring Centre)

### Included in the course fee is:

Full curriculum and documentation, beverages during breaks and lunches.

Local public transportation including travel between Stockholm and Uppsala.

### Not included:

Travel expenses to Stockholm, per diem, insurances, as well as accommodation is paid by the participant. Tours and excursions are not included. Information about suitable accommodation (hotels with special rates for Karolinska Institutet course participants available on a first come basis) will be sent with the application for. For further information, please contact Ms Sissi Myllyniemi.

**Course fee** (reduced fee before March 1, 2008)

€ 650 Academic affiliation or governmental employment

€ 950 Employees of the commercial sector

### Application Form

**The Application Form will be provided to anyone that announces his/her interest by sending an E-mail or message to Ms Sissi Myllyniemi**

[sissi.myllyniemi@karolinska.se](mailto:sissi.myllyniemi@karolinska.se)

Fax: +46 8 585 810 50

Participants will be accepted on a first come basis. The 2005 course was completely signed up.

Welcome with an application

[Anders.Rane@ki.se](mailto:Anders.Rane@ki.se)

[Ulf.Bergman@karolinska.se](mailto:Ulf.Bergman@karolinska.se)

Professor & Chairman/Course leader

Professor/Director of studies

Karolinska Institutet, Division of Clinical Pharmacology, SE-141 86 Stockholm, Sweden





## Copenhagen Compliance & Concordance Conference

**30 May 2008**

The Copenhagen Compliance & Concordance Conference aims at creating a profound insight in patient compliance through input from a variety of stakeholders in patient compliance in order to work towards a common solution.

CCCC gathers a number of leading experts and stakeholders active in the field of patient compliance, adherence and concordance:

- Jakob Axel Nielsen** Danish Minister of Health and Prevention
- Brian Haynes** Professor, Clinical Epidemiology and Biostatistics, McMaster University, Ontario, Canada
- Sabina DeGeest** Professor of Nursing, University of Basel, Switzerland
- Alejandra Mørk** CEO, KLIFO A/S, Denmark
- Jim Kierans** Member, the Danish Diabetes Association
- Rob Horne** Professor, School of Pharmacy, University of London; Member NICE Concordance Project Team, National Institute for Health and Clinical Excellence, United Kingdom
- Hanne Herborg** Director of R&D, Pharmakon, Denmark

CCCC takes place in the elegant premises of Danish Design Centre in the heart of Copenhagen.

For detailed information on **speakers, programme, venue, accommodation, transportation and registration** please visit the conference web-site:

<http://www.farma.ku.dk/CCCC>

The deadline for registration is **20 March 2008**. As seats are limited make sure to register as soon as possible. Registration will be on a first come first served basis. The conference fee is €200 (PhD-students €100).

CCCC is organised by the University of Copenhagen and Bang & Olufsen Medicom with participation from the Research Centre for Quality in Medicine Use (FKL).

**29 May 2008**

In association with the conference a mini-symposium is conducted on Thursday May 29. Registration will be on a first come first served basis with a preference for PhD students (Registration on [www.farma.ku.dk/CCCC](http://www.farma.ku.dk/CCCC)). Participation will be free of charge.





## Vacancy announcement

# PhD position in pharmacoepidemiology

The Nordic School of Public Health, NHV, is a Nordic institution for education and research within public health science. NHV is situated at the entrance to the Port of Göteborg in the grounds of the previous naval base Nya Varvet, and more than 700 students from all the Nordic countries study here every year. Along with some 40 other Nordic institutions, NHV has the Nordic Council of Ministers as its principal and is jointly financed by the five Nordic countries.

We are looking for a research assistant to join a research project aimed towards investigating statistical characteristics of existing methods for register-based pharmaceutical studies, as well as developing new methods.

The project will be organised in a project group consisting of research assistant/PhD student and experienced supervisors with medical, pharmaceutical and statistical backgrounds. The successful candidate will also be part of the research group for pharmacoepidemiological research at NHV, which comprises several different projects within the field. The project will commence during the spring of 2008; planning and execution is estimated at four years.

**Job description** The position entails, via analytical studies and computer simulations, to identify statistical characteristics of current and newly developed methods for population studies of pharmaceutical use based on pharmaceutical drug sales registers in the Nordic countries. The work is to be performed in close contact with applied research projects. The position also includes developing an individual PhD research plan. Once the individual research plan has been approved, the position will develop into a PhD position with the aim of obtaining a PhD degree.

**Qualifications** The successful candidate should have either a statistical or epidemiological background, alternatively a pharmaceutical or medical background with knowledge in statistics. Experience from the pharmaceutical field with focus on pharmaceutical drug use is considered an asset. We welcome applicants from all the Nordic countries, especially from outside Sweden. The position requires proficiency in Swedish, Norwegian, Danish or English.

**Contact details** For questions please contact Max Petzold (phone +46-(0)31-693972, mobile +46-(0)703-867077).

**Application** Please send your written application to the Registry, NHV, Box 12133, SE-40242 Göteborg, quoting reference number A12/08:10. The application deadline is **March 15 2008**.



Nordic School of Public Health  
Gothenburg, Sweden



norden  
Nordic council of Ministers