



Edwards IR, Lindquist M, **Bate A**, Norén GN. Data mining: A view from the Uppsala Monitoring Centre. In "Pharmacovigilance" 2<sup>nd</sup> Edition Publisher: Wiley edited by RD Mann and EB Andrews 2006

Edwards IR, Lindquist M, **Bate A**, Orre R. Data mining. in "Pharmacovigilance" 1<sup>st</sup> Edition Publisher: Wiley edited by RD Mann and EB Andrews 2002

#### **PEER REVIEWED REVIEW ARTICLES**

**Bate A**, Evans SJW. Quantitative signal detection using spontaneous ADR reporting. *Pharmacoepidemiology and Drug Safety*. 2009 18(6): pp 427-436

Hauben M, **Bate A**. Decision support methods for the detection of adverse events in post-marketing data. *Drug Discovery Today*. 2009. 14(7-8) pp 343-357

**Bate A**, Lindquist M, and Edwards IR. The application of knowledge discovery in databases to post-marketing drug safety: example of the WHO database. *Fundam Clin Pharmacol*, 2008. 22(2): p. 127-40.

**Bate A**, Edwards IR. Data mining in spontaneous reports. *Basic & Clinical Pharmacology & Toxicology* 2006; 98(3): 324-330

#### **PEER REVIEWED ORIGINAL RESEARCH PUBLICATIONS:**

##### *Applied*

Strandell J, **Bate A**, Hägg S, Edwards IR. Rhabdomyolysis a result of Azithromycin and statins: an unrecognized interaction. *British Journal of Clinical Pharmacology* 68(3) pp 427-434

Hägg S, Ståhl M, **Bate A**, Spigset O. Associations Between Venous Thromboembolism and Antipsychotics: A Study of the World Health Organization Database of Adverse Drug Reactions. *Drug Safety* 2009 31(8): pp 685-694

Sanz EJ, De-las-Cuevas C, Kiuru A, **Bate A**, Edwards IR. Selective serotonin reuptake inhibitors in pregnant women and Neonatal withdrawal syndrome: A database analysis. *Lancet* 2005; 365 (9458) pp 482-487

Spigset O, Hägg S, **Bate A**. Hepatic injury and pancreatitis during treatment with serotonin reuptake inhibitors. *International Clinical Psychopharmacology* 2003; 18(3): pp 157-161

Coulter DM, **Bate A**, Meyboom RHB, Lindquist M, Edwards IR. Antipsychotics drugs and heart muscle disorder in international pharmacovigilance: a data mining study. *BMJ* 2001; 322: 1207-1209

Hägg S, Spigset O, **Bate A**, Söderström TG, Myocarditis related to clozapine treatment. *J Clin Psychopharmacol* 21(4) 2001: pp 382-388

##### *Methodological*

Norén GN, Hopstadius J, **Bate A**, Star K, and Edwards IR. Temporal pattern discovery in longitudinal electronic patient records Data Mining and Knowledge Discovery. In Press

Hopstadius J, Norén GN, **Bate A**, and Edwards IR. Impact of stratification in adverse drug reaction surveillance. *Drug Safety*. 2008. 31(11): p. 1035-48.

Norén, GN, Sundberg R, **Bate A**, Edwards IR. A statistical methodology for drug–drug interaction surveillance. *Statistics in Medicine*. Stat Med, 2008. 27(16): p. 3057-70.

Norén GN, Orre R, **Bate A**, Edwards IR. Duplicate detection in adverse drug reaction surveillance. Data Mining and Knowledge Discovery. Data Mining and Knowledge Discovery 2007; **14**: 305-328.

Norén GN, Orre R, **Bate A**. Extending the methods used to screen the WHO drug safety database towards analysis of complex associations and improved accuracy for rare events. Statistics in Medicine. 2006; **25**(21): 3740-57

Orre R, **Bate A**, Norén GN, Swahn E, Arnborg S, Edwards IR. 2005 A Bayesian Recurrent Neural Network for unsupervised pattern recognition in large incomplete data sets. International Journal of Neural Systems. 15(3) pp 207-222

**Bate A**, Lindquist M, Orre R, Edwards IR, Meyboom RHB. Data mining analyses of pharmacovigilance signals in relation to relevant comparison drugs. European Journal of Clinical Pharmacology 2002; **58**(7): pp 483-490

van Puijenbroek EM, **Bate A**, Leufkens HGM, Lindquist M, Orre R, Egberts ACG. A comparison of measures of disproportionality for signal detection in spontaneous reporting systems for Adverse Drug Reactions. Pharmacoepidemiology and Drug Safety 2002; Volume 11( 1) pp 3-10.

**Bate A**, Lindquist M, Edwards IR and Orre R. "A data mining approach for signal detection and analysis. Drug Safety 2002 Vol 25:6: pp393-397.

**Bate A**, Orre R, Lindquist M, Edwards IR. Explanation of data mining methods. BMJ website 2001; <http://www.bmj.com/cgi/content/full/322/7296/1207/DC1.html>

Orre R, Lansner A, **Bate A**, Lindquist M. Bayesian Neural Networks with confidence estimations applied to data mining. Computational Statistics and Data Analysis 2000; **34**(4): 473-493

Lindquist M, Ståhl M, **Bate A**, Edwards IR, Meyboom RHB. A retrospective evaluation of a data mining approach to aid finding new adverse drug reaction signals in the WHO international database. Drug Safety 2000;**23**(6):533-542

Lindquist M, Edwards IR, **Bate A**, Fucik H, Nunes A-M, Ståhl M. From association to alert - A revised approach to international signal analysis. Pharmacoepidemiology and Drug Safety 1999; **8**: S15-S25

**Bate A**, Lindquist M, Edwards IR, Olsson S, Orre R, Lansner A, DeFreitas RM. A Bayesian neural network method for adverse drug reaction signal generation. Eur J Clin Pharmacol 1998; **54**: 315-321

#### **PEER REVIEWED FULL PAPER CONFERENCE PROCEEDINGS:**

Norén GN, **Bate A**, Hopstadius J, Star K Edwards IR. Temporal Pattern Discovery for Trends and Transient Effects: Its Application to Patient Records. Proceedings of the Fourteenth ACM SIGKDD International Conference on Knowledge Discovery and Data Mining , Las Vegas 2008.

Caster O, Norén GN, Madigan D, **Bate A**. Large-Scale Regression-Based Pattern Discovery in International Adverse Drug Reaction Surveillance. Proceedings of the KDD Workshop on Mining Medical Data and KDD Cup August 2008

**Bate A**. BCPNN. Drug Safety, 2007 **30**(7): 623-625

Norén GN, Orre R, **Bate A**. A hit-miss model for duplicate detection in the WHO drug safety database 2005 Proceedings of the Eleventh ACM SIGKDD International Conference on Knowledge Discovery and Data Mining (**Awarded Best Application Paper at the SIGKDD annual meeting, Chicago 2005**).

**Bate A**, Lindquist M, Edwards IR and Orre R. A data mining approach for signal detection and analysis (The Proceedings of DSRU Signal detection meeting Southampton, 2001). Drug Safety 2002 Vol 25:6: pp 393-397

Orre R, **Bate A**, Lindquist M. Bayesian Neural Networks used to find adverse drug combinations and drug

related syndromes. Proceedings of the ANNIMAB ( Artificial Neural Networks in Medicine and Biology) conference Gothenburg 2000.

### **RESEARCH LETTERS:**

Karlsson J, Star K, Wallerstedt S, **Bate A**, Hagg S. Sudden cardiac death in users of second generation antipsychotics. J Clin Psychiatry In Press

Hopstadius J , Norén, GN, **Bate A**, Edwards IR Stratification for Spontaneous Report Databases. Drug Safety 2008; 31 (12): 1145-1147

Strandell J, **Bate A**, Lindquist M, Edwards IR Drug-drug interactions - a preventable patient safety issue? British Journal of Clinical Pharmacology 2008; 65(1):144-146

Edwards IR, **Bate A**, Lindquist M. Abacavir and increased risk of myocardial infarction. Lancet 2008; 372(9641):805.

**Bate A**, Lindquist M, Orre R, Edwards IR Violation of Homogeneity: A Methodologic Issue in the Use of Data Mining Tools: The authors' reply. Drug Safety 2003; 26(5): pp 364-366

### **THESES:**

**Bate A**. The use of a Bayesian Confidence Propagation Neural Network in Pharmacovigilance. PhD Thesis Umeå University, Umeå, Sweden 2003

**Bate A**. Studies of Acid-Base Catalysis by metal sulphide clusters in proteins. Masters Thesis, Oxford University, Oxford, UK 1995

### **CONFERENCE PAPERS:**

September 2009 - Pacific Drug Safety Summit, Invited Keynote presentation on: "Quantitative Safety Signal Detection: CIOMS Working Group VIII". San Francisco, USA.

January 2009 - Drug Information Association (DIA) 8<sup>th</sup> conference on Contemporary Pharmacovigilance strategies, Invited oral presentation on: "Data mining of electronic patient records - recent advances." Washington DC, USA

December 2008 - DIA conference "Safety is Global: Contemporary Pharmacovigilance and Medical Product Risk Management Strategies". Invited oral presentation on: "Signal Detection, Case Assessment and Data Mining in Pharmacovigilance: Current State of the Art", Singapore.

November 2008 - DIA conference on "Data mining and signal detection." Programme committee member, chairman and speaker on: "Electronic patient records –screening for the unexpected" Washington DC, USA.

October 2008: - 31<sup>st</sup> Annual Meeting of Representatives of the National Centres participating in the WHO Programme for International Drug Monitoring. Invited presentations on: "Data mining of longitudinal patient records" and "CIOMS VIII – signal detection". Uppsala, Sweden

September 2008 – 3rd International Congress in Gender Medicine Invited oral presentation on: "Sex difference in suspected adverse drug reaction reports: data mining analyses of the four million record WHO database" Stockholm, Sweden.

July 2008 The IXth World Conference on Clinical Pharmacology and Therapeutics. Invited oral presentation on: "Safeguarding Patient Safety on Medicines: From Data to Useful Information" Quebec City, Canada.

June 2008 Invite only "think tank" meeting Pharmaceutical Research and Manufacturers Association (PhRMA) entitled: "Best practices in developing standards for data mining." Invited keynote speaker: "Spontaneous report mining – state of the art and future prospects" in Washington DC, USA

- March 2008 The DIA 20th Annual European meeting Oral presentation on: Signal management: the role of data mining patient records". Barcelona, Spain
- January 2008 - The DIA 7<sup>th</sup> conference on Contemporary Pharmacovigilance strategies, Invited Oral presentation: "Data mining of electronic patient records." Washington DC, USA
- October 2007 - 7<sup>th</sup> Annual Meeting of the International Society of Pharmacovigilance (ISOP). Two invited oral presentations: "Detecting signals for vaccines in the WHO database and "What is on the horizon/ in the future in quantitative signal detection?"– Bournemouth, UK
- June 2007 - DIA 43<sup>rd</sup> Annual meeting, Session Chair and presenter on: "Data Mining Patient Records v Spontaneous Reports – what can and cannot be done". Also invited discussant in session on "Data Mining: Perils, Pitfalls and Pragmatism". Atlanta, USA
- 4<sup>th</sup> Biennial Signal Detection & Interpretation in Pharmacovigilance conference. Invited Session Chair and presenter on: "Signal metrics and analytics explained" London, UK
- March 2007 - Presentation on "Data mining the WHO database of suspected adverse drug reactions" at International Biometric Society Eastern North American Region, Spring Meeting Atlanta, USA (invited speaker)
- October 2006: Presentation on "Knowledge Finding: Data Mining in Patient Record Data." At International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 9<sup>th</sup> Annual European Congress. Copenhagen, Denmark
- June 2006 - Presentation on "Knowledge Finding: Data Mining in Patient Record Data" at the 42<sup>nd</sup> Annual DIA meeting, Philadelphia, USA
- April 2006 - Presentation on "International data mining for signals of herbal ADRs" at conference on Pharmacovigilance of Herbal Medicines, London, UK (invited speaker)
- March 2006 - Presentation on "Bayesian Analysis of a Very Large Spontaneous Report Database: Successes and Future Prospects" at the 18<sup>th</sup> Annual European DIA meeting, Paris, France (invited speaker)
- September 2005 - Presentation on "BCPNN" at the 3<sup>rd</sup> biennial DSRU Signal generation conference, London, UK. (invited speaker)
- August 2005 - Leader and presenter of 90 minute workshop on "Misuses and Misunderstandings in data mining", In 21st International Conference on Pharmacoepidemiology, Nashville, USA
- June 2005 - Presentation on "Recent improvements in Data Mining at the UMC" at the 41<sup>st</sup> Annual DIA meeting, Washington DC, USA
- May 2005 - Presentation on "Data mining in spontaneous reports" at the 60<sup>th</sup> year anniversary symposium of the journal Basic and Clinical Pharmacology and Toxicology entitled: "Current Controversies in Pharmacoepidemiology". Kolding, Denmark (Invited speaker)
- March 2005 - Presentation on "Data mining and pattern recognition in post-marketing surveillance" at the European Federation for Pharmaceutical Sciences (EUFEPS) Expert Meeting on Drug Safety, Leiden (invited attendee and speaker at the closed meeting)
- September 2004 - Presentation on data mining at International Meeting on Pharmacovigilance in Psychiatry, Lausanne, Switzerland (invited speaker)
- December 2003 - Presentation at 2<sup>nd</sup> DSRU conference "Signal Detection and Interpretation - What's New?", London (invited speaker)
- November 2003 - Presentation at closed international meeting "Patient Safety: Proposals for Future International Collaboration", London, UK (invited speaker)
- March 2003 - Presentation on "signal detection: finding the needle in the haystack". Drug Safety and Pharmacoepidemiology Symposium, Basel, Switzerland (invited speaker)
- October 2002 - Presentation on the difference between Bayesian and Conventional Statistics at the 1<sup>st</sup> ISOP annual meeting, Amsterdam (invited speaker)
- September 2002 - Presented at the annual meeting of Swedish Medical Statisticians (FMS) on Risks and Benefits of Drugs and Food. Presented on: "Postmarketing surveillance" and "The WHO Collaborating Centre for International Drug Monitoring". Stockholm, Sweden
- August 2002 - "Understanding Quantitative Signal Detection Methods in Spontaneously Reported Data" In 18th International Conference on Pharmacoepidemiology, Edinburgh
- Nov 2001 - 1<sup>st</sup> Annual DIA meeting workshop In Japan For Global Pharmacovigilance on signal detection in the WHO database (invited speaker), Tokyo, Japan
- June 2001 - Umea 1<sup>st</sup> international summer conference on Adverse Drug Reactions (invited speaker)
- Presentation on data mining at the 1<sup>st</sup> biennial DSRU Signal generation conference DSRU signal detection conference, Southampton UK (invited speaker)
- November 2000 - Annual Conference of the Swedish Association of Learning Systems, Halmstad (invited speaker)

- August 2000 - "Validating" automated signal detection methods used in spontaneous reporting systems. In 16th International Conference on Pharmacoepidemiology, Barcelona, Spain
- May 1999 - Invited speaker at IIR conference: "ADRs '99" London, UK
- August 1998 - "Identifying and quantifying signals automatically" In 14th International Conference on Pharmacoepidemiology, Berlin, Germany
- May 1998 - Pharnasoft conference on drug safety. Invited speaker. Dublin; Ireland
- April 1998 - Läkmedelsverket (Swedish Medical Product Agency) annual pharmacovigilance day - - invited speaker Uppsala, Sweden

### **PUBLISHED CONFERENCE ABSTRACTS:**

Star K, **Bate A**, Meyboom RH, Edwards IR. 2009 A temporal association between prescriptions of antipsychotic drugs and pneumonia in electronic health records Drug Safety 32(10) pp 931

Star K, **Bate A**, Caster O and Edwards IR. Dose variations in NSAID prescriptions for children – an analysis of electronic patient records Pharmacoepidemiol Drug Saf 18: S208 478 Suppl. 1 AUG 2009

O Caster, J Strandell, **Bate A**, and Edwards IR. Automatic Extraction Of Adverse Drug Reaction Terms From Medical Free Text” Proceedings of the ISCB 2009

**Bate A** Sex difference in suspected adverse drug reaction reports: data mining analyses of the four million record WHO database. Gender Medicine 5 (3) 300-301. (2008)

Santanello N, Sacks S, **Bate A**, Gould AL, Ryan P, Stang P, Walker AM. Identifying potential safety concerns in claims and electronic health record (EHR) databases. Pharmacoepidemiol Drug Saf 17: S132 299 Suppl. 1 AUG 2008

Strandell, J; Noren, NG, **Bate A**; et al. Drug- drug- ADR screening in spontaneous reports as a tool for detecting clustered reporting and brand name confusion Pharmacoepidemiol Drug Saf 17: S17 038 Suppl. 1 AUG 2008

Jakobsson M, Noren NG, Hopstadius J, **Bate A** and Edwards IR. Choice of comparison and impact of stratification in vaccine pharmacovigilance Pharmacoepidemiol Drug Saf 17: S182 415 Suppl. 1 AUG 2008

Strandell J, **Bate A**, Lindquist M, et al. Ongoing spontaneous reporting of established drug-drug interactions Pharmacoepidemiol Drug Saf 16: S29-S30 060 Suppl. 2 AUG 2007

Noren GN, Sundberg, R, **Bate A**, et al. A new quantitative method for drug-drug interaction screening in collections of individual case safety reports Pharmacoepidemiol Drug Saf 16: S72-S73 151 Suppl. 2 AUG 2007

**Bate A**, Noren NG, Star K, et al. Results from data mining in IMS disease analyzer patient records Pharmacoepidemiol Drug Saf 16: S256-S256 539 Suppl. 2 AUG 2007

Strandell J, **Bate A**, Lindquist M, et al. Drug interaction signal detection in spontaneous reports Pharmacoepidemiol Drug Saf 16: S256-S257 540 Suppl. 2 AUG 2007

Hopstadius J, Noren NG, **Bate A**, et al. Issues in confounder adjusted adverse drug reaction surveillance Pharmacoepidemiol Drug Saf 16: S257-S258 542 Suppl. 2 AUG 2007

Noren GN, **Bate A**, Orre R, Edwards IR. A statistical approach to duplicate detection in adverse drug reactions monitoring Pharmacoepidemiol Drug Saf, 15: S113-S113 241 Suppl. 1 AUG 2006

Spigset O, **Bate A**, Stahl M, et al. Venous thromboembolism during treatment with antipsychotics Pharmacoepidemiol Drug Saf 15: S223-S223 478 Suppl. 1 AUG 2006

Strandell J, **Bate A**; Eiermann B; et al. Can WHO-Database of suspected ADRs be used to support existing information on pharmacokinetic drug interactions? DRUG SAFETY, 29 (10): 930-930 33 2006

**Bate A**, Ericsson J, Farah M. International data mining for signals of herbal ADRs Drug Safety 29 (4): 353-353 2006 (abstract for invited oral presentation)

**Bate A**, Evans SJW Misuses and Misunderstandings in the Data Mining of Spontaneous ADR Data Pharmacoepidemiol Drug Saf, 14: S76 149 Suppl. 1 AUG 2005 (Abstract for workshop)

**Bate A**, Noren GN, Orre R, Edwards IR Recent Improvements in the BCPNN Method for Data Mining the WHO Database. Pharmacoepidemiol Drug Saf, 14: S141 284 Suppl. 1 AUG 2005

**Bate A**. Principles of Signal Detection and Data Mining and their Application to Psychotropic Drugs Pharmacopsychiatry 38(1) 2005 (Abstract for invited oral presentation).

Norén N, **Bate A** et al. Improved Bayesian dependency derivation in the WHO adverse drug reactions database. 2004 Proceedings of the International Society of Clinical Biostatistics (ISCB) 25th annual conference, Leiden, The Netherlands

**Bate A**, Noren GN, Orre R, Lindquist M, Edwards IR. Pattern detection for celecoxib and rofecoxib in the WHO database. Pharmacoepidemiol Drug Saf, 13:S323 640 Suppl. 1 AUG2004 (Abstract for poster presentation at ICPE 2004)

**Bate A**, Edwards IR, Edwards J, Swahn E, Norén N, Lindquist M. Knowledge finding in IMS disease analyser Mediplus UK database – effective data mining in longitudinal patient safety data. Drug Safety, 2004, 27(12): 917-918.

**Bate A** Lindquist M Edwards IR. Understanding quantitative signal detection methods in spontaneously reported data. Pharmacoepidemiol Drug Saf S214 443 11(S1) 2002 (Abstract for oral presentation at ICPE 2002)

Orre R, Bate A, Lindquist M, Edwards IR. Recurrent Bayesian neural network applied to finding complex associations in the WHO database of adverse drug reactions. In Proceedings of the 22nd Annual Conference of the International Society for Clinical Biostatistics, Stockholm, Sweden, August 2001.

Bate A, Orre R, Lindquist M and Edwards IR Signal Detection using Neural Network Based Data mining. in 1st Umeå International Summer Conference on Adverse Drug Reactions. 2001. Umeå Sweden. (Abstract for oral presentation.)

Bate A, Orre R, Lindquist M, Edwards IR. Pattern recognition using a recurrent neural network and its application to the WHO database Pharmacoepidemiol Drug Saf, 10:S163 380 Suppl. 1 AUG2001 (Abstract for poster at ICPE 2001)

Lindquist M, Edwards IR, Ståhl M, Brown E, Pettersson M, Bate A, Kiuru A. The effect of different strategies of signal finding in WHO International ADR data. Proceedings of the ISOP annual conference, Tunis, September 2001

Bate A, Lindquist M, Edwards IR, Orre R. Automated evaluation of signals as group effects or drug specific using the WHO database. Proceedings of the European Society of Pharmacovigilance (ESOP) 2000. (Abstract for poster).

Van Puijenbroek EP, Bate A, Egberts ACG, Lindquist M, Leufkens HGM. Measures of Disproportionality in Spontaneous Reporting Systems of Adverse Drug Reactions - How Do They Relate to Each Other? Pharmacoepidemiol Drug Saf, 9:S76 207 Suppl. 1 AUG 2000. (Abstract for poster at ICPE 2000).

**Bate A**, Lindquist M, Orre R, Edwards IR. Identifying and quantifying signals automatically. Pharmacoepidemiol Drug Saf, 7:S99 47 Suppl. 2 AUG 1998 (Abstract for oral presentation at ICPE 1998)

## **TEACHING ON ACCREDITED COURSES (in Uppsala, Sweden; unless otherwise stated):**

Nordic School of Public Health course: "Register-Based Epidemiology", Gothenburg. (January 2009). Lecture on: Exploratory data analysis in drug safety: "Data mining" and "Why statistics and some statistical issues in register based epidemiology".

Annual DIA Conference for Contemporary Pharmacovigilance and Risk Management Strategies, tutorial on "Signal detection, case assessment and data mining in pharmacovigilance: Current State of the art". A DIA training course (3.5 hours). (January 2009 and January 2008).

Uppsala University "Läkemedelsbiverkningar och farmakovigilans" (Adverse Drug Reactions and Pharmacovigilance.) 5Point undergraduate course, present regularly on "Systems complementary to spontaneous reporting" (60 minutes). (November 2008, Spring 2008, November 2007, February 2007, October 2006, March 2006)

Seminar on Signal detection in the WHO database and patient records to the department of Clinical Pharmacology, Umeå University (October 2008)

Member of teaching faculty for the European Center of Pharmaceutical Medicine (ECPM) Course Module 4: "Confirming Trials: Methodology and Biostatistics" Lecture on 'Data mining' (45 minutes) Workshop Series – Frontiers in Drug Development, course cycles VIII (in September 2005) and IX (in September 2008). Basel Switzerland

Member of teaching faculty for London School of Hygiene and Tropical Medicine. Certificate in Pharmacoepidemiology and Pharmacovigilance. Lecture on: "Spontaneous reporting systems – overview of WHO functions & signal detection" 90 minutes each time (April 2008, April 2007, June 2006, February 2005). London UK.

Uppsala Monitoring Centre (UMC) training course "Pharmacovigilance – The Study of Adverse Drug Reactions & Related Problems" : Teach "Systems complementary to spontaneous reporting".

Uppsala Monitoring Centre (UMC) training courses: Teach "Systems complementary to spontaneous reporting" November 2006, September 2005 (special courses for a Chinese delegation).

Training course at ICPE: "Introduction to Spontaneous reporting." Lisbon, Portugal August 2006

Uppsala Monitoring Centre at the Therapeutics Goods Administration (TGA), Canberra Australia – training course "Pharmacovigilance - The Study of Adverse Drug Reactions" November 2004: Principles of data mining techniques used in signal analysis, The UMC process for signal identification and Analysis, The process from signal generation to decision making, Pharmacovigilance into the future, Use of sales data as a denominator, Systems complementary to spontaneous reporting

"Therapeutic Drug Monitoring (TDM)-dagarna" teaching on "UMC combination database som redskap till att hitta biverkningssignaler" and "Exempel på biverkningssignaler från UMC combination database." Umeå University (september 2003)

Lecture on "Data mining the WHO database for side effects of pharmaceutical drugs." Kurs I informationsutvinning ( Course in data mining), 4 point undergraduate course. Inst. för Informationsteknologi, avd. för Datologi (Computer science department at the Institute for Information technology. November 2000

## **SUPERVISORY RESPONSIBILITY FOR THESESES:**

### **Formal (co-) supervisor:**

PhD thesis:

Strandell J. Expanding the use of spontaneous reporting databases in pharmacovigilance Gothenburg University. (Thesis ongoing, Resigned as supervisor on relocation to US in August 2009)

Masters theses:

Caster O. 2007 Mining the WHO drug safety database using Lasso Logistic Regression. Department of Mathematics. Uppsala, Uppsala University.

Hopstadius J. 2006 Methods to control for confounding variables in screening for association in the WHO drug safety database. Department of Statistics. Uppsala, Uppsala University

Bachelors thesis:

Star K. 2007 Events after Off-Label NSAID Prescriptions and Dosages among Children. Department of Public Health and Caring Sciences, Uppsala University

**Other thesis supervision:**

PhD thesis:

Norén GN. 2007 Statistical methods for knowledge discovery in adverse drug reaction surveillance, in Department of Mathematics. PhD thesis Stockholm, Stockholm University

Masters theses:

Jakobsson M. 2008 Vaccine pharmacovigilance in the WHO database. [Masters thesis]. Uppsala: Uppsala University,

Norén, GN. 2002 A Monte Carlo Method for Bayesian Dependency Derivation. Masters thesis. Department of Mathematical Statistics, Chalmers University of Technology, Gothenburg.

**DIRECT INVOLVEMENT IN GRANT APPLICATIONS:**

Steering Committee member of RIGHT (Research Into Global Healthcare Tools). A UK collaborative research project (>1 million pound research grant) involving leading research scientists from five universities including Cambridge. (2007 to date)

By invitation participated as one of seven work package leaders in the proposal for a five year 21 million Euro IMI funded grant project proposal to call topic Number 6: Strengthening the Monitoring of Benefit/Risk. I was the WHO Centre's lead scientist in the proposal. The consortium won the grant award.

Was responsible for WHO Centre research activity in the 2 million euro grant awarded by the European Commission in response to the 7th Framework Programme call from EU. The project is submitted under the title "Monitoring medicines - Optimizing drug safety monitoring to enhance patient safety and achieve better health outcomes."

**OTHER RESPONSIBILITIES:**

Member of Editorial Board of International Journal "Drug Safety" (2007 to 2009)

Member of the Scientific Advisory Board of OMOP ((Observational Medical Outcomes Partnership), an FNIH coordinated public-private partnership to help improve the monitoring of drugs for safety. (2009 to date)

Expert adviser to the Committee for Medicinal Products for Human Use (CHMP), European Agency for the Evaluation of Medicinal Products (EMA), UK (2003 to 2009)

By invitation represented WHO in the Council for International Organizations of Medical Sciences (CIOMS) In Working Group VIII on adverse drug reaction detection. This is an international collaboration between senior scientists from drug regulatory authorities, pharmaceutical companies, WHO and academia.

Have reviewed articles for the following international journals: British Medical Journal, Clinical Pharmacology and Therapeutics, European Journal of Clinical Pharmacology, , American Statistician, Journal of the American Statistical Association (JASA), Statistics in Medicine, Information Fusion, Expert Opinion in Drug Safety and the Journal of Clinical Pharmacology

Member of PhD examination board for: Lindbom L “Development, Application and Evaluation of Statistical Tools in Pharmacometric Data Analysis”. Department of Pharmacy, Uppsala University. Uppsala, 2006

Reviewed a grant application for an Intermediate Clinical Fellowship on behalf of the Wellcome Trust.

Overall responsibility for the organisation for a UMC 30<sup>th</sup> year Anniversary Symposium on “Impacting patient safety : Adverse drug reaction signal detection. Quantitative and qualitative approaches in screening healthcare data” in Uppsala, Sweden, in October 2008. Additionally acted as conference chair.

Frequent invited presenter to health related research groups, regulators and organisations throughout Europe, US and Asia. Presentation audiences have included the FDA, the Singapore regulatory authority (HSA), the Danish Council on Adverse Drug Reactions and the Swedish regulatory agency. In addition to patient safety, presentation subjects have included: data mining, drug safety, data analysis, vaccine surveillance, herbal surveillance, statistical methods (including Bayesian) and the need for novel IT tools in healthcare. Also presented regularly to international visitors to the WHO Collaborating Centre.

**REFERENCES:**

References available on request