

EUROmediCAT News Archive

February 2017

World Birth defects Day

3 March is World Birth Defects Day. For the majority of medicines, there is too little information available on their safety in pregnancy. EUROmediCAT is working to prevent birth defects by improving the monitoring of safety of medicines used in pregnancy. EUROmediCAT is proud to be a partner of World Birth Defects Day.

December 2016

Latest Publications

Jordan S, Morris JK, Davies GI, Tucker D, Thayer DS, Luteijn JM, Morgan M, Garne E, Hansen AV, Klungsoyr K, Engeland A, Boyle B, Dolk H (2016). Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressants in Pregnancy and Congenital Anomalies: analysis of linked databases in Wales, Norway and Funen, Denmark. *Plos One* 11(12), DOI 10.1371/journal.pone.0165133.

September 2016

Latest Publications

Boyle B, Garne E, Loane M, Addor M-C, Arriola L, Cervero-Carbonell C, de Walle H, Gatt M, Lelong N, Lynch C, Nelen V, Neville AJ, O'Mahony M, Pierini A, Rissmann A, Tuckers D, Zymak-Zakutnia N, Dolk H (2016). The changing epidemiology of Ebstein's anomaly and its relationship to maternal mental health conditions: a European registry-based study. *Cardiology in the Young*. DOI:10.1017/S1047951116001025

Schurman L, Vinkel Hansen, A, Garne E (2016). Pregnancy outcomes after fetal exposure to antithyroid medications or levothyroxine. *Early Human Development* 101:73-77.

June 2016

Latest Publications

Charlton R, Klungsoyr K, Neville A, Jordan S, Pierini A, de Jong-van den Berg L, Bos J, Puccini A, Engeland A, Gini R, Davies G, Thayer D, Hansen A, Morgan M, Wang H, McGrogan A, Nybo Andersen A-M, Dolk H and Garne E (2016). Prescribing of Antidiabetic Medicines before, during and after Pregnancy: A Study in Seven European Regions. *PLoS ONE*, 11(5): e0155737. DOI: 10.1371/journal.pone.0155737.

Given J, Loane M, Luteijn J, Morris J, de Jong-van den Berg L, Garne E, Addor M-C, Barisic I, de Walle H, Gatt M, Klungsoyr K, Khoshnood B, Latos-Bielenska A, Nelen V, Neville A, O'Mahony M, Pierini A, Tucker D, Wiesel A and Dolk H (2016). EUROmediCAT Signal Detection: An Evaluation of Selected Congenital Anomaly-Medication Associations. *British Journal of Clinical Pharmacology*. DOI: 10.1111/bcp.12947.

April 2016

Latest Publication

Charlton RA, Pierini A, Klungsoyr K, Neville AJ, Jordan S, de Jong-van den Berg L, Thayer D, Bos HJ, Puccini A, Hansen AV, Gini R, Engeland A, Nybo Andersen A-M, Dolk H, Garne E (2016). Asthma medication prescribing before, during and after pregnancy: a study in seven European regions. *BMJ Open* 6. DOI: 10.1136/bmjopen-2015-009237.

November 2015

The EUROmediCAT Recommendations are published in Pharmacoepidemiology and Drug Safety

EUROmediCAT produced an extensive set of recommendations for European Pharmacovigilance concerning safety of medication use in pregnancy. These were first presented at the Poznan conference in February 2015, and have been endorsed by a range of experts in the field. Other stakeholders are welcome to contact us if they wish to endorse these Recommendations – they will then be listed on the EUROmediCAT website.

The Recommendations are for European and national medicines regulatory agencies, public health authorities and professional clinical bodies

- To improve future pharmacovigilance
- To inform future drug safety measures

relating to medication use in pregnancy and by women of childbearing age.

The recommendations are designed to help make better use of current data, networks and infrastructures in Europe, to achieve a more integrated system and better dissemination of knowledge and to raise the level of reproductive pharmacovigilance to meet women's reasonable expectations.

Dolk H, de Jong-van den Berg LTW, Pierini A, Morris J, Bakker M, Jordan S, Garne E, Klungsoyr K, Loane M, Charlton R, Luteijn JM, Sinclair M, Latos-Bielenska A (2015). EUROMediCAT Recommendations for European Pharmacovigilance concerning safety of medication use in pregnancy. *Pharmacoepidemiology and Drug Safety*, Volume 24, Issue S2, October 2015, Pages: 3–7. DOI: 10.1002/pds.3866
Article first published online : 23 September 2015

September 2015

New Publication - Improving information on maternal medication use by linking prescription data to congenital anomaly registers: A EUROMediCAT Study

Linkage of prescription databases to the congenital anomaly registries is a potentially effective method of obtaining accurate information on medicine use in pregnancies and the risk of congenital anomalies. Within the EUROMediCAT project we linked data from primary care and prescription databases to five EUROMediCAT congenital anomaly registries. The results are described in 3 deliverables and in a paper that will be published in *Drug Safety*.

September 2015

The retirement of Professor Lolkje de Jong van den Berg who devoted her working life to researching and improving medication safety in pregnancy

All of the EUROMediCAT participants wish Lolkje a happy retirement. She gave so much to the field of medication safety in pregnancy – we owe her a great debt. Lolkje's professional life spanned many developments – the increasing participation of women in the sciences; the huge impact of thalidomide yet the struggle thereafter to gain sufficient attention for pregnancy issues; the moves from collection of data on paper for hundreds of people, to electronic databases for thousands or millions, and then to realising in EUROMediCAT the potential for data linkage between congenital anomaly registries and pharmacy databases. Lolkje inspired many with her vision, enthusiasm, dedication, and integrity. And her legacy to EUROMediCAT will also be her insistence on the importance of the prior hypothesis!

Lolkje's professional life in a nutshell:

"In 1965 I started at the Groningen University to study 'Pharmacy', but not because I wanted to become a pharmacist. I liked the fields of Science and Mathematics, but no female students were present there in 1965, and my high-school teacher suggested Pharmacy.

Then I saw on the wall of the room of Prof Huizinga (Prof in pharmacotherapy) the picture of a softening baby, with a nice smile. We learned that the sleeping pill thalidomide had caused this anomaly. The story had a great impact on the way we evaluate the benefits and risks. Years later (1980), when I worked as a teacher at the School of Pharmacy, Prof Huizinga invited me to become member of the Dutch Drug Bulletin (Geneesmiddelenbulletin) a critical journal about the risk and benefits of medicines. Until 2006, I was involved in this independent Drug bulletin and learned a lot.

Around 1987, I started with a research project 'drug use in pregnancy'. I collected my information in 12 community pharmacies in the Northern Netherlands. I visit them monthly and collected all

information on paper. In addition I interviewed 300 pregnant women about experiences of their drug use. I completed my thesis in 1992.

After my thesis Martina Cornel (then registry leader of EUROCAT Northern Netherlands) and I worked together to improve the data collection on drugs in the NNL EUROCAT through data coming from the community pharmacies.

In the nineties I worked with Danish (Jorn Olsen) and Norwegian colleagues (Lorentz Irgens) on a FP5 project (drug use in pregnancy). The data were presented during a meeting in Cardiff in 1999 and there I met Helen (Dolk) for the first time. Helen had just started as Project Leader of EUROCAT: European Surveillance of Congenital Anomalies.

I became professor in 1998 and have supervised many PhD students on pregnancy related topics, among others Miriam Sturkenboom (acitretinoin), Corinne de Vries, Hermien de Walle, Jennita Reefhuis, Marian Bakker, Willemijn Meijer, Fokaline Vroom, Ineke Crijns, Priscilla Zetstra, Janneke Jentink.

At the same time I started to set up the IADB (InterAction DataBase stands for the interaction between scientists and community pharmacists). Instead of funds for a laboratory (which is normal in pharmacy) I asked for 2 extra persons to build and maintain the IADB: the lab for pharmacoepidemiological studies. Data from the IADB are also used in the drug utilization studies of EUROMediCAT WP6.

In 2003 I spent my Sabbatical at the department of Slone (Allen Mitchel) in Boston. Around the same time, I worked with Helen and the EUROCAT team in Belfast and in Groningen to evaluate the quality of drug information held in the EUROCAT database, introduce the ATC medication coding system to replace the old EUROCAT codes, and to prepare to use the data for the first projects on antiepileptic drug use. I had met Marianne Cunnington of GSK in Boston, and eventually this led to GSK funding for the first major pharmacoepidemiological project with EUROCAT – to investigate the signal of an association between lamotrigine and oral clefts.

And this was actually the start of the idea of EUROMediCAT.....and eventual EU FP7 funding starting in 2011.

At the final EUROMediCAT conference in Poznan in 2015, Geoff Adams-Spinks recognised my photo of a child with softenon exposure, inherited from Prof Huizinga.

The circle is now complete.