

MIPAL INTERNATIONAL

MEDICATIONS IN PREGNANCY & LACTATION

Issue's Birth Date: October 2024

MIPAL SIG NEWSLETTER

WELCOME

Dear friends and colleagues,
Welcome to the fifth MiPaL Newsletter!
This newsletter is meant to facilitate communication within the MiPaL SIG and the larger community of perinatal pharmacoepidemiologists. Please feel free to circulate this newsletter to anyone interested in pregnancy & lactation.

MiPaL stands for Medications in Pregnancy & Lactation (MiPaL), a Special Interest Group (SIG) from the International Society for Pharmacoepidemiology (ISPE). This SIG was established in 2006, with the mission to enhance communication, improve the quality of science, and expand knowledge related to the use and safety of the wide range of medications taken by pregnant and lactating people.

This newsletter was launched in September 2022 by Sandra Lopez-Leon and Andrea Margulis. Please send material for the next issue, as well as comments and suggestions, at MiPaLISPE@gmail.com

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CHAIR'S MESSAGE

While still gearing down from the exciting and successful 2024 ISPE Annual Meeting in Berlin and the celebration of the 18th birthday of this SIG, many interesting events and study updates related to medication use in pregnancy and lactation have been announced for the upcoming months. You will find more information in this issue of the MiPaL newsletter, as well as on the ISPE Exchange.

Speaking of the ISPE Exchange, the platform to connect to others involved in perinatal pharmacoepidemiology, it is clear that our SIG is still growing. Actually, it is one of the largest ISPE SIGs. At this moment, we have over 350 members, indicating the huge interest in our contributions to safe medication use in pregnancy and lactation. This was also reflected in the high number of abstracts related to these topics presented at the annual meeting as regular oral presentations, oral lightning presentations, symposia/workshops, spotlight posters, and 'regular' posters. But personally, my highlight was the Day 2 Plenary Session entitled "Role of Real World Data for Regulatory Science when Randomized Clinical Trials are Not Feasible: Lessons Learned from Perinatal Pharmacoepidemiology", in which many (methodological) studies performed over the last decade by MiPaL SIG members were showcased.

1 CHAIR'S MESSAGE (continued)

We were also happy to see many of you, including some new members, at the MiPaL Social Event. Many thanks to Sandra for organizing this evening. We hope to have a comparable event in Washington DC next year. You are already welcome to volunteer for organizing this 😊.

We would also like to congratulate Lin-Chieh Meng for winning the Andrew McAfee Award (researcher or student/post-doc living in a developing country who submitted the most highly rated abstract [“Paternal metformin use before pregnancy and risk of congenital malformations: a cross-national cohort study in Norway and Taiwan]) and Emma Cleary for winning the MiPaL SIG Spotlight Poster Award (“Associations between dose of prescribed opioid analgesic exposures during pregnancy and adverse birth outcomes and early mortality: a population-based study”).

Unfortunately, we have received the sad news that Dr. Helle Kieler passed away. We thank Carolyn Cesta and Sonia Hernández-Díaz for contributing the memorial that you can find in this Newsletter.

We asked Andrea Margulis to send us an summary of all the events related to pregnancy and lactation at the 2024 ISPE Annual Meeting and she reported the following:

The meeting in Berlin was exciting and fun; with 2,000 registrants, it was the largest ISPE meeting. The conference had 3 plenary sessions, 27 preconference courses, 28 workshops and symposia, 270 oral presentations and about 1,200 posters. Of these, 1 plenary session, 1 course, 1 workshop, 1 symposium, 26 oral presentations and over 130 posters focused on pregnancy and lactation. These presentations were well attended and generated interesting discussion. More than other years, target trial emulation had a strong presence in MiPaL-related research at the conference. The focus of MiPaL-related work was varied; at least 3 common data models were used; there were presentations on paternal exposures, policy impact, drug utilization, safety, vaccines, methods, digital data collection, regulatory activity, etc etc etc. Accepted research abstracts will be included in a supplemental issue of ISPE's journal *Pharmacoepidemiology and Drug Safety*, to be published in the coming weeks. Abstracts and some posters are available on the conference website without registration (<https://2024ispe.eventscribe.net/>). Conference registrants can download slides and posters by logging into the conference app. The photos of the conference are available at <https://www.flickr.com/photos/196557008@N08/albums/>. It's time to start preparing our submissions for next year!

We will have our next online quarterly meeting on Friday 22 November, 4 pm CET. Please stay connected for the details!

Best regards,
Marleen

www.pharmacoepi.org/communities/sigs/pregnancy/



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Estrel Waterfront, Berlin, 26 August 2024



Role of Real World Data for Regulatory Science when Randomized Clinical Trials are Not Feasible: Lessons Learned from Perinatal Pharmacoepidemiology (plenary session), 27 August 2024. Source: ISPE Annual Meeting photos: <https://www.flickr.com/photos/196557008@N08/albums/>

What	OHDSI Global Symposium
When	October 22-24, 2024
Where	New Brunswick, NJ, USA
Link	https://ohdsi.org/ohdsi2024/
Information	OHDSI Perinatal and Reproductive Health Group (PRHeG) work group meeting: October 24, 8 -10 EDT (12-14 UTC). Presentations will be available following the symposium to PRHeG members. ISPE MiPAL members are welcome to join PRHeG using this form: link.

What	ConcePTION The Next Generation: A Force for Change
When	November 21, 2024
Where	Brussels, Belgium
Registration/ Information	https://form.jotform.com/242203984172354 This is ConcePTION's year-end event; please see section Networks and Initiatives

What	FDA-organized public workshop on optimizing pregnancy registries
When	March 28-29, 2025
Where	Hybrid at FDA and online
Note	Information will become available in January

What	RheumaPreg	
When	April 8-10, 2025	
Where	Vienna, Austria	
Link	rheumatology-update-europe.eu	

What	SPER (Society for Pediatric and Perinatal Epidemiologic Research) Annual Meeting
When	June 9-10, 2025
Where	Boston, MA, USA
Link	https://sper.org/annual-meeting-2/

What	Society for Birth Defects Research & Prevention Annual Meeting
When	June 28 - July 1, 2025
Where	Denver, CO, USA
Link	https://birthdefectsresearch.org/meetings/2025/

What	2025 ISPE Annual Meeting
When	August 22-26, 2025
Where	Washington DC, USA
Link	https://www.pharmacoepi.org/meetings/annual-conference/

3 SOCIAL MEDIA



Edit profile

Medications in Pregnancy & Lactation

@ISPEMiPaL

ISPE Medications in Pregnancy & Lactation. Follow our list: twitter.com/i/lists/153101...

Joined May 2022

Twitter: Follow this List:

<https://twitter.com/i/lists/1531015319346630656>

It includes worldwide Twitter pages related to pregnancy and lactation (see below)



EUROmediCAT
@euromedicat



BSACP
@BSACP



BRIDGE Project
@projectbridge_



UKTIS bumps
@medsinpregnancy
Follows you



All Source Pregnancy
@PregnancyAll



P&P Epidemiology
@PPE_Journal



ACOG Pregnancy
@ACOGPregnancy



MedsPregnancyJC
@MedsPregnancyJC



MotherToBabyUT
@MotherToBabyUT



MotherToBaby
@MotherToBaby



IMIConcePTION
@IMIConcePTION
Follows you



Society for Birth Defects
@SocBirthDefects



FDA Women
@FDAWomen



Centre for Reproductive Health
@CRRC_BPAS



AJOG
@AJOG_thegray



JAMA Pediatrics
@JAMAPediatrics



Harvard Perinatal & Reproductive Sciences
@h4p_research



NIH Women's Health
@NIH_ORWH



MotherToBaby CA
@MotherToBabyCA



Curemus
@curemus



HER Foundation
@HGmoms



ECHO Child Health Research Network
@ECHOChildHealth



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What To Expect
@WhatToExpect

4 OPEN POSITIONS

11 vacancies for PhD and postdocs: <https://cordis.europa.eu/project/id/101169127>

A PhD looking at "Safety of antibiotics prescribed for urinary tract infections in pregnancy using electronic health records" will shortly be advertised based at St George's, University of London jointly with London School of Hygiene and Tropical Medicine; the start date will be October 2025. Urinary tract infections are the most common infections during pregnancy, yet data on the safety for mother and fetus of some of the antibiotics used is incomplete because pregnant women are often excluded from drug trials. This PhD will assess the safety of antibiotics for urinary tract infections used in pregnancy using routinely collected NHS data. The student will work on defining and validating outcomes, performing cohort studies including quantifying potential biases, and addressing confounding by indication. Candidates will develop their methodological expertise in Health Data Science while answering a clinically important question for the health of mothers and infants.

Please contact Liza Bowen (lbowen@sgul.ac.uk) or Joan Morris (jmorris@sgul.ac.uk) for more details.

5 PREGNANCY RESEARCH NETWORKS AND INITIATIVES

These are some of the pregnancy networks and initiatives that have been shared with us. Please see the previous issue for information on other initiatives. If you have more information, please send it to MiPaLISPE@gmail.com

Call for manuscripts! Frontiers in Drug Safety and Regulation

The Journal Frontiers in Drug Safety and Regulation is calling for papers research topic on drug safety in the perinatal period. Deadlines: manuscript summary submission: 31 October 2024; manuscript submission: 30 November 2024. <https://www.frontiersin.org/research-topics/63210/drug-safety-in-the-perinatal-period>.



FDA's report on public workshop on Optimizing Postapproval Pregnancy Safety Studies

As part of its PDUFA VII (Prescription Drug User Fee Act) commitments, FDA published a report on the public workshop on Optimizing Postapproval Pregnancy Safety Studies held September, 2023, available at the following webpage: <https://healthpolicy.duke.edu/events/optimizing-use-postapproval-pregnancy-safety-studies>

FDA: Demonstration projects to develop framework in pregnancy safety studies

As part of its PDUFA VII commitments, FDA is working on demonstration projects to inform the development of a framework to optimize postapproval pregnancy safety studies. Information is available at the following link: [FDA Demonstration Projects to Inform Development of a Pregnancy Safety Study Framework | FDA](#)

ConcePTION: updates and invitation to year-end meeting

Invitation to *ConcePTION The Next Generation: A Force for Change*

We are delighted to invite you to ConcePTION's year-end event, taking place on Thursday 21st November, at the EGG in Brussels, from 11.00am to 4.00pm CET.

ConcePTION's notable achievements to date

Since its launch in 2019, the IMI ConcePTION Consortium has been dedicated to building a trusted ecosystem to drastically improve the provision of accurate and reliable information on the safety of medicines, used before and during pregnancy, and when breastfeeding. You can find out more by [visiting the ConcePTION website](#).

This vital work mustn't stop here

Although ConcePTION has made notable progress, the Consortium formally disbands at the end of 2024, and their overarching aim is to gain your valuable input on how you can work in partnership to realise their ambition of achieving 10 goals that will have significant impact 10 years from now. Key discussions will focus on ConcePTION's policy proposals and how they bring their vision to life.

Working together to be a force for change

We do hope you can join ConcePTION at what will be a landmark event in addressing this urgent need, and in meeting a fundamental societal obligation for the next generation.

Please kindly RSVP by completing [this registration form](#).

6 NEW PUBLICATIONS

Pharmacoepidemiology & Drug Safety Journal

- Albano JD, Scheuerle AE, Watts DH, Beckerman KP, Mofenson LM, Pikis A, et al. The Antiretroviral Pregnancy Registry: Three decades of prospective monitoring for birth defects. *Pharmacoepidemiol Drug Saf.* 2024 Jun;33(6):e5801. doi:<http://dx.doi.org/10.1002/pds.5801>.
- Ankarfeldt MZ, Søltoft-Jensen A, Salinas CA, Lupattelli A, Pukkala E, Bolin K, et al. Effectiveness of Baricitinib Risk Minimization Activities in Patients With Rheumatoid Arthritis-A Cohort Study in Four Nordic Countries. *Pharmacoepidemiol Drug Saf.* 2024 Sep;33(9):e70010. doi:<http://dx.doi.org/10.1002/pds.70010>.

- Chaudhary V, Kumari S, Khurana N, Azharuddin M, Singh AP, Devi V, et al. Prevalence of self-medication practices among pregnant women in India: A systematic review and meta-analysis. *Pharmacoepidemiol Drug Saf.* 2024 Apr;33(4):e5791. doi:<http://dx.doi.org/10.1002/pds.5791>.
- Christensen J, Trabjerg B, Dreier JW. Correlation of drug dose estimated from national prescription registers with mean blood level of antiseizure medication in pregnancy. *Pharmacoepidemiol Drug Saf.* 2024 Jun;33(6):e5811. doi:<http://dx.doi.org/10.1002/pds.5811>.
- Karlsson P, Gembert K, Esslinger S, Geldhof A, Gissler M, Leinonen MK, et al. Pregnancy and Infant Outcomes After Prenatal Exposure to Golimumab in Denmark, Finland, and Sweden 2006-2019. *Pharmacoepidemiol Drug Saf.* 2024 Aug;33(8):e5878. doi:<http://dx.doi.org/10.1002/pds.5878>.
- Kelty E, Hansen M, Randall S, Gratton D, Baynam G, Preen DB. Use of privacy-preserving record linkage to examine the dispensing of pharmaceutical benefits scheme medicines to pregnant women in Western Australia. *Pharmacoepidemiol Drug Saf.* 2024 Jun;33(6):e5845. doi:<http://dx.doi.org/10.1002/pds.5845>.
- Meng LC, Lin CW, Chuang HM, Chen YY, Shang CY, Wu CY, et al. Prescription Patterns and Predisposing Factors of Benzodiazepine and Z-Hypnotic Use During Pregnancy: A Nationwide Cohort Study. *Pharmacoepidemiol Drug Saf.* 2024 Jun;33(6):e5847. doi:<http://dx.doi.org/10.1002/pds.5847>.
- Muschett MR, Ewig C, Morris E, Adkins LE, Goodin A, Brown J. A Review of Concordance and Quality in Clinical Guidelines for Hormonal Contraceptives to Mitigate Drug-Drug Interactions in Women With Epilepsy. *Pharmacoepidemiol Drug Saf.* 2024 Aug;33(8):e5861. doi:<http://dx.doi.org/10.1002/pds.5861>.
- Nordeng H, Lupattelli A, Engjom HM, van Gelder M. Detecting and Dating Early Non-live Pregnancy Outcomes: Generation of a Novel Pregnancy Algorithm From Norwegian Linked Health Registries. *Pharmacoepidemiol Drug Saf.* 2024 Sep;33(9):e70002. doi:<http://dx.doi.org/10.1002/pds.70002>.
- Strangfeld A, Meissner Y, Weiß A, Rudi T, Zink A, Ellmann T, et al. Rhekiss-The German Register for Child Wish and Pregnancies in Inflammatory Rheumatic Diseases. *Pharmacoepidemiol Drug Saf.* 2024 Aug;33(8):e5867. doi:<http://dx.doi.org/10.1002/pds.5867>.

Other New Publications

- Bahri P, Genov G, Arlett P, Sarinic VM, Korakianiti E, Nolte A, et al. The STAR Compass to Guide Future Pharmacovigilance Based on a 10-Year Review of the Strengthened EU System. *Drug Saf.* 2024 Oct;47(10):941-56. doi:<http://dx.doi.org/10.1007/s40264-024-01451-3>.
- Lyons JG, Shinde MU, Maro JC, Petrone A, Cosgrove A, Kempner ME, et al. Use of the Sentinel System to Examine Medical Product Use and Outcomes During Pregnancy. *Drug Saf.* 2024 Oct;47(10):931-40. doi:<http://dx.doi.org/10.1007/s40264-024-01447-z>.

8 IN MEMORIAM: HELLE KIELER

Helle Kieler, professor emeritus at Karolinska Institutet (KI) in Sweden, died on 1 September 2024 at the age of 68 years. During her 17 years as the scientific leader of the Centre for Pharmacoepidemiology at KI, Professor Kieler made a lasting mark on the field with her dedication to creating sustainable Nordic and international research collaboration.

Throughout her career, Professor Kieler made outstanding contributions to the field of drug safety in pregnancy. In 2008, she initiated a collaboration with researchers from the 4 other Nordic countries (Norway, Iceland, Denmark, Finland) with the aim of creating the first-ever pooled dataset of individual level Nordic register data including drug exposure information. While it took some years to navigate these uncharted waters, the result was a Nordic cohort of over 1 million pregnant women and their children, from which a number of high impact publications on SSRIs and adverse pregnancy and neonatal outcomes were produced. This endeavor led to the formation of the Nordic / International Pregnancy Drug Safety Studies consortium (NorPreSS/InPreSS) which continues to provide training and research opportunities to the next generation of reproductive pharmacoepidemiologists. Helle was also faculty in the Modern Pregnancy preconference course at the ISPE Annual Meeting from its inception in 2015 to 2017.

Professor Kieler was a steadfast leader, a pioneer in her field, and an inspiration to many. She will be remembered fondly and deeply missed by colleagues and friends throughout the Nordics and around the world.



Photo Credit: Creo Media Group

THANKS FOR READING!

Please send any thoughts, reactions, comments, or ideas to MiPaLISPE@gmail.com for the next edition.