

## CURRICULUM VITAE

**Last updated:** March 2019

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**DATE & PLACE OF BIRTH:** Madrid, Spain (US Permanent Resident)

<b>EDUCATION</b>	<b>Date</b>	<b>Discipline</b>	<b>Degree</b>	<b>Institution</b>
	06/1995	Medicine	MD	Universidad Autónoma de Madrid
	06/1997	Public Health	MPH	Harvard School of Public Health
	06/2000	Epidemiology	DrPH	Harvard School of Public Health

<b>LICENSURE AND CERTIFICATION</b>	<b>Date</b>	<b>Type of license or certification</b>
	06/1995	Professional College of Physicians of Madrid

### PROFESSIONAL EXPERIENCE

<b>Dates</b>	<b>Title</b>	<b>Institution, Place of work</b>
1995-97	Research Fellow	Harvard School of Public Health, Boston, MA
2000-05	Assistant Professor	School of Public Health, Boston University, Boston, MA
2005-16	Senior Epidemiologist	Slone Epidemiology Center, Boston University, Boston, MA
2005- 08	Assistant Professor	Harvard School of Public Health, Boston, MA
2006-	Epidemiologist	Massachusetts General Hospital, Boston, MA
2008- 14	Associate Professor	Harvard School of Public Health, Boston, MA
2014-	Professor	Harvard School of Public Health, Boston, MA

### PROFESSIONAL SERVICE

#### Harvard University

2015- Member of Title IX Policy Review Advisory Committee and Harvard

#### Harvard School of Public Health

2005-2017 Director of the Pharmacoepidemiology Program  
2005-17 Leader, Admissions Committee, Pharmacoepidemiology  
2005-09 Member, Committee for Minority Student Diversity  
2005-11 Mentor, Summer Program in Quantitative Sciences for underrepresented minorities  
2005-10 Co-organizer, Epidemiology Seminar Series  
2008-2017 Member, Committee on Educational Policy  
2008-15 Member, HSPH NIEHS Center for Environmental Health  
2009 Member, Retreat Committee

- 2009 Member, Clinical Epidemiology Committee
- 2009-10 Member, Reproductive Epidemiology Committee
- 2009-10 Chair, Cancer Epidemiology Search Committee
- 2011-12 Member, Student Financial Aid Committee 2013-16  
Member, Faculty Council
- 2014 Organizer: “Development and Safety Management of Cancer Drugs” Symposium.
- 2014 Host and organizer of a “Symposium on Pharmacoepidemiology and Drug Safety”,  
cosponsored by the Program in International Pharmaceutical Engineering Management,  
Peking University.
- 2015 Chair, E. Fran Cook Promotion Committee
- 2015 Member, Funding Diversification & Sustainability Quad
- 2015 Organizer: “Patient Centered Benefit Risk Strategies in Oncology” Symposium.
- 2016 Organizer: “New Data and New Methods in Advancing Patient Care” Symposium.
- 2015-16 Member, Lifecourse Genetic Epidemiology / Development Search Committee
- 2016-17 Chair, Caroline Buckee Promotion Committee 2017  
Co-Chair, Committee on Educational Policy
- 2017-18 Chair, Epidemiology Search Committee
- 2018 Member, Environmental Health Search Committee
- 2018 Chair, Committee on Educational Policy

**International Society for Pharmacoepidemiology**

- 2001- Reviewer of Abstracts submitted to Annual Conference.
- 2002- Poster judge at Annual Conference.
- 2004-13 Member of Membership Committee
- 2004 Organizer of “The control of time-dependent confounding or why conventional methods  
may mislead us” symposium. Annual Conference, Bordeaux, France.
- 2006 Organizer and moderator of “Clinical trial simulation in pharmacoepidemiology”  
symposium, Annual Conference, Lisbon, Portugal.
- 2007 Organizer and moderator of “Selective Serotonin Reuptake Inhibitors and birth defects”  
symposium. Annual Conference, Quebec, Canada.
- 2007 Organizer, 2<sup>nd</sup> Meeting of the New England Regional International Society for  
Pharmacoepidemiology Group, Boston.
- 2007- Mentor for the Harvard Student Chapter.
- 2008 Speaker and discussant of “Self-controlled Study Designs” symposium. Annual  
Conference, Copenhagen, Denmark.
- 2009 Organizer of “Symposium – Assessment of drug safety during pregnancy: who is  
exposed?” Annual Conference, Providence, USA.
- 2010-2012 Chair of the Pregnancy Special Interest Group
- 2012 Organizer of “Symposium – Use of Databases to Asses Drug Safety during Pregnancy:  
who is exposed?” Annual Conference, Barcelona, Spain.
- 2013 Organizer of “Symposium – Welcoming Advanced Methods into the World of Pregnancy  
Research” Annual Conference, Montreal, Canada.
- 2013-15 Webinars for Student Chapter

2014-15 Chair of the Strategic Planning Committee & President Elect 2015-16 President

2016-17 Chair of the Nominations, Awards and Fellowships Committee & Past-President

### **Society for Epidemiological Research**

2009 Organizer of “Symposium – Hot topics in pharmacoepidemiology”. Annual Conference, Anaheim, CA.

### **Society for Pediatric and Perinatal Epidemiologic Research**

2013-16 President-elect, President, Past-President

2015 Organizer of Annual Conference in Denver, Colorado

2018 Faculty at Advanced Methods Workshop “Epidemiologic evidence without p-values”

### **International Society for Epidemiological Research**

2014 Organizer of “Symposium – Problems and Paradoxes in Perinatal Epidemiology”. IEA World Congress of Epidemiology 2014, Anchorage, Alaska.

### **Teratology Information Services (TERIS)**

2017- Member of Advisory Board.

### **Scientific Journals**

1999- *Ad hoc* reviewer for multiple journals, including The New England Journal of Medicine, JAMA, Lancet, BMJ, Birth Defects Research, International Journal of Epidemiology, American Journal of Epidemiology, Drug Safety, Clinical Pharmacology and Therapeutics, Arthritis & Rheumatism, The Journal of Pediatrics, State of New York Department of Health Reports, Reproductive Toxicology, Teratology, Journal of Epidemiology and Community Health, The Medical Letter, and Preventive Medicine. 2007- Member, Editorial Board, *Epidemiology*.

2012- Member, Editorial Board, *Pharmacoepidemiology and Drug Safety*

2014-15 Associate Editor, Special Issue, *Birth Defects Research A*

### **External Thesis Reader / Opponent**

- Alex J Cole (graduation 2005, Boston University, US)
- Catherine Vasilakis-Scaramozza (graduation 2008, Boston University, US)
- Janneke Jentink (graduation 2010, Groningen University, The Netherlands)
- Mette Kalager (graduation 2012, University of Oslo, Norway)
- Marleen van Gelder (graduation 2012, Radboud University, The Netherlands)
- Gabriella Bröms (graduation 2015, Karolinska Institute, Sweden) □ Angela Lupattelli (graduation 2015, University of Oslo, Norway)
- Gwen Masclee (graduation 2016, Rotterdam University, The Netherlands)

### **Government agencies / Nonprofit institutions *National***

#### *Institutes of Health*

2004- Ad hoc Member, Study Sections. National Institute of Child Health and Development.

2009 Reviewer, Concept Clearance. National Institute of Child Health and Development.

- 2008, 2012 Reviewer, site visit to the Division of Epidemiology, Statistics, and Prevention Research (DESPR), National Institute of Child Health and Development.
- 2011 Reviewer, NIH Recovery Act Limited Competition: Director's Opportunity for Research in Five Thematic Areas.
- 2012 Reviewer, NIH Special Emphasis Panel/Scientific Review Group: AIDS Clinical Studies and Epidemiology.
- 2012 Reviewer, NIH Special Emphasis Panel: Population Sciences and Epidemiology: Chronic Disease Epidemiology and Genetics.
- 2013 Member, Committee "Towards earlier involvement of Children and Pregnant Women in Trials of New TB drugs". National Institute of Allergy and Infectious Diseases.
- 2014 Reviewer, Concept Clearance. National Institute of Child Health and Development.
- 2012-2015 Reviewer, NIH Special Emphasis Panel: Translational Research in Pediatric and Obstetric Pharmacology.
- 2016- Member Study Section, NICHD - Pediatric and Obstetric Pharmacology

*Food and Drug Administration*

- 2009 Advisor, ACR-FDA Fellowship Program Planning.
- 2010-15 Special Government Employee, Drug Safety and Risk Management Advisory Committee. [2 to 3 FDA Advisory Committees per year]
- 2015-16 Scientific Advisor, "A Guide to the Management of Opioid-Dependent Pregnant and Parenting Women and Their Children". SAMHSA.
- 2018- Chair of the FDA Drug Safety and Risk Management Advisory Committee (DSARM).

*Others*

- 2004 Reviewer, research grant applications, Action Research (charity foundation).
- 2012-16 Member, Steering Committee, Division of Birth Defects and Developmental Disabilities, CDC. Treating for Two; Safe Medication Use in Pregnancy Initiative
- 2012-15 Leader, European Academy of Cancer Sciences' taskforce on early detection of breast cancer through screening.
- 2017 Expert panel member, Birth Spacing and Adverse Health Outcomes, Office of Population Affairs (OPA). September 2017, Washington, DC.
- 2017 Member External Program Review, Department of Epidemiology at UNC-Chapel Hill

**OTHER PROFESSIONAL EXPERIENCE**

- 1996 Field supervisor, Center for Economic and Social Rights. Baghdad, Iraq
- 1997-99 Co-investigator, Physicians for Human Rights. El Salvador
- 1999 Co-investigator, El Colegio de la Frontera Sur. Chiapas, Mexico
- 2001-04 Member, Data Safety Monitoring Board, Novartis
- 2004 Member, Study Advisory Board, Serono
- 2002-05 Epidemiologist, Infant Outcomes Following Maternal Drug Exposure Study. FDAVanderbilt University

- 2005-10 Member, Scientific Leadership group and Elected Member of the Executive Committee. The Pediatric HIV AIDS Cohort Study, NIH
- 2007 Member, Study Advisory Board, Pfizer
- 2008-10 Member, Study Advisory Board, AstraZeneca
- 2009- Member, Scientific Advisory Board for the Atypical Antipsychotic Pregnancy Registry, Massachusetts General Hospital
- 2010-12 Member, Pregnancy Registry Advisory Board, Novartis
- 2011-14 Member, Pregnancy Registry Advisory Board, GSK
- 2014-15 Consultant, methodologic advisor, Pregnancy Cohort & offspring follow up, AstraZeneca
- 2014-16 Consultant, Pregnancy Registry Methods, UCB
- 2016 Consultant, Pregnancy Study Methods, Teva
- 2015-16 Consultant, Pregnancy Cohort in Electronic Medical Records, Boehringer-Ingelheim
- 2018- Consultant, Pregnancy Study Methods, Roche
- 2017- Member Academic Committee for the International Academic Program-Universidad Autónoma de Madrid (IAP-UAM)
- 2017- Member of the TERIS Advisory Board

## **TEACHING EXPERIENCE**

### **Harvard School of Public Health**

- 2004- Lecturer for “Advanced Reproductive Epidemiology” (2007- ), “Reproductive Epidemiology” (2006-), “Advanced Topics in Epidemiology” (2005-06), and “Advanced Topics in Pharmacoepidemiology” (2006-12), and “Introduction to Epidemiology: Methods I” (2008-2014) , “Measurement, Design, and Analysis Methods for Health Outcomes Research” (2016-).
- 2006 Co-Instructor of “Design of Cohort and Case-Control Studies”.
- 2008-14 Instructor of “Seminars on Drug Safety and Comparative Effectiveness. A case-based approach”. (Every other year)
- 2008-12 Instructor of “Principles of Screening”.
- 2012-15 Co-Instructor of "Topics in Medical Device Comparative Effectiveness Research" 2013-  
Co-Instructor of “Design of Cohort and Case-Control Studies”.
- 2015- Co-Instructor of “Effectiveness Research with Longitudinal Healthcare Databases” 2016-  
Co-Instructor of “Study Designs in Epidemiology” for On-line Master Program.
- 2017- Co-Instructor of “Introduction to Pharmacoepidemiology”
- 2017- Faculty Grant Writing Short Course

### **Boston University School of Public Health, Boston, MA**

- 2004 Developer and Instructor of “Advanced Topics in Epidemiology. Case Control Studies”.
- 2002-06 Lecturer for “Introduction to Epidemiology” and “Special Topics in Epidemiology”.

2013- Lecturer on “Pharmacoepidemiology in vulnerable populations” for Pharmacoepi.

### **National School of Public Health, Madrid, Spain**

1996-97 Course co-developer and co-director of “Design of Research Projects”.

1997-2003 Course co-developer and co-director of “Epidemiologic Assessment of Research Projects in International Health”.

2008 Short course developer and instructor on “Advanced study designs”

### **Short courses at other institutions**

2002 *Folic Acid Antagonists During Pregnancy and the Risk of Specific Birth Defects*. Human Teratogens Postgraduate Course. Massachusetts General Hospital, Harvard Medical School. Boston, MA.

2007 *Advanced topics in pharmacoepidemiology*. Midyear meeting International Society for Pharmacoepidemiology. Amsterdam.

2007-08 *Drug Safety during Pregnancy*. Pharmacoepidemiology course. Tulane University.

New Orleans. 2007-10 *Principles of Epidemiology*. Real Colegio Complutense & Rockefeller Brothers Fund.

Cambridge, MA.

2007 *Graphs for Causal Inference in Epidemiology*. Co-instructor. The Australasian Epidemiological Association. Brisbane, Australia.

2010-2018 Director of the Research Symposium for Spanish & Latin American Academics. Workshop on Clinical Research: From Randomized Trials to Data Science. Organized by IAP-UAM-DRCLAS at Harvard.

2010 Co-director of pre-conference course on “Assessment of perinatal outcomes; comparative validity of study designs and data sources”. Conference International Society for Pharmacoepidemiology. Brighton, UK.

2012 Introduction to pharmacoepidemiology. ISPE Mid-Year Symposium. Miami, Florida

2012-18 Instructor of pre-conference course on “Pregnancy Registries”. ICPE Annual Conference, Barcelona, Montreal, Taipei, Boston, Dublin, Montreal)

2013 Web-seminar ICPE investigators: *Causality Assessment in Clinical Trials*.

2013-18 Co-director of pre-conference course on “Introduction to Pharmacoepidemiology” lecturing on “Case-control designs”. ICPE Annual Conference, Barcelona, Taipei, Montreal, Dublin, Prague.

2014 FDA one-day-course – Methodological Aspects in Drug Safety Studies during Pregnancy, September 2014, Silver Spring, MD

2018 Instructor of pre-conference course on “Advanced Methods for Pregnancy Safety Research”. ICPE Annual Conference, Prague.

2016- Instructor of “Screening methods” course on “Medical Research”. Harvard Medical School, Boston

- 2016- Lecture on “The VIOX case” within course on “Epidemiology”. Harvard Medical School, Boston
- 2019 Instructor on Pharmacoepidemiology course with Databases. Sessions on Proposal development and manuscript publication & Pregnancy. Karolinska Institute, Sweden

### **INVITED LECTURES Local**

*Impact of the Economic Embargo on Child Malnutrition in Iraq.* Real Colegio Complutense. February 1997. Cambridge, MA.

*Case-crossover, Case-time-control, and Exposed-case-series Designs in Birth Defects Epidemiology.* Slone Epidemiology Unit. Boston University School of Public Health. April 2002. Boston, MA.

*Use of case-crossover designs to study acute drug interactions: Antibiotics and oral contraceptive failure.* Pharmacoepidemiology Seminar Series. Department of Epidemiology. Harvard School of Public Health. February 2004. Boston, MA. *The birth weight paradox.* Dept Environmental Health, Harvard School of Public Health. February 2007. Boston, MA.

*Case Only Designs for Reproductive Epidemiology.* Advanced Methods Workshop. Society for Pediatric and Perinatal Epidemiologic Research Meeting. June 2007. Boston, MA.

*Risk factors for persistent pulmonary hypertension of the newborn.* Dept Neonatology, Beth Israel Hospital. November 2007. Boston, MA.

*Drug safety during pregnancy.* Seminar at the Summer Undergraduate Research Fellowship Program at the Massachusetts College of Pharmacy and Health Sciences (MCPHS). June 2009. Boston, MA.

*Comparative effectiveness and safety of Topiramate during pregnancy.* Boston University. May 2011. Boston, MA. *Case only designs in reproductive epidemiology.* March 2012. Boston University School of Public Health.

Boston, MA

*Safety of Antidepressants during Pregnancy: Sorting the Ever-Growing Data.* October 2014. Beth Israel Deaconess Medical Center, Department of Neonatology. Boston, MA

*Right and Left truncation in Pregnancy Studies.* November 2014. Maternal and Child Concentration Seminars, Harvard School of Public Health. Boston, MA

*Safety of Antidepressants during Pregnancy: Sorting the Ever-Growing Data.* January 2015. Department of Population Medicine. Harvard Medical School & Harvard Pilgrim Health Care Institute. Boston, MA

*Drug Safety during Pregnancy Methods and Application: Anticonvulsants.* November 2016. Beth Israel Deaconess Medical Center, Department of Neonatology. Boston, MA

*Methods to Assess Drug Safety During Pregnancy: The Topiramate Experience.* Department of Psychiatry, BWH. March 2018. Boston, MA.

*Drug Safety during Pregnancy: Ondansetron.* January 2019. Beth Israel Deaconess Medical Center, Department of Neonatology. Boston, MA

*Teratogenicity of Medications: Lessons Learnt in Pharmacovigilance.* Dept of Pediatric Newborn Medicine Grand Rounds, BWH. January 2019. Boston, MA.

## **National**

*Folic Acid Antagonists During Pregnancy and the Risk of Specific Birth Defects.* Center for Disease Control and Prevention. August 2000. Atlanta, Georgia.

*Non-Steroidal Anti-inflammatory Drugs and the Risk of Heart Failure.* Forth International Workshop on COX-2. San Juan, Puerto Rico. February 2001.

*Folic Acid Antagonists During Pregnancy and the Risk of Specific Birth Defects.* Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania. December 2001. Philadelphia, Pennsylvania.

*Pharmacoepidemiology: application of the technique to ART exposure surveillance.* PHACS Group Meeting. March 2007. Washington, DC.

*Methodological issues in the assessment of drug safety during pregnancy.* University of North Carolina School of Public Health. October 2008. Chapel Hill, NC.

Participant. Second Wave Workshop Toward the *Responsible Inclusion of Pregnant Women in Medical Studies.* Georgetown University. April 2009. Washington, D.C.

*Assessment of drug safety during pregnancy.* Post-Approval Drug Safety Strategies: Best Practices to Assess and Mitigate Risks throughout the Product's Life Cycle, 4<sup>th</sup> annual executive forum. November 2009. Philadelphia, PA.

*Selection bias in the evaluation of prenatal exposures.* Colloquium at the Cancer Prevention and Control Colloquia Series. National Cancer Institute. January 2010. Bethesda, MD.

*Perils of birth weight.* Departmental Seminars Columbia University Mailman School of Public Health, Department of Epidemiology. March 2010. New York, NY.

*Comparative safety of drugs during pregnancy.* University of California in San Francisco (UCSF) and Kaiser Permanente. January 2011. San Francisco, CA.

*What Should Pregnancy Registries Use for a Comparison Group(s)?* Panelist at Pregnancy Registry Workshop. Teratology Society's 52nd Annual Meeting. June 2012. Baltimore, MD.

Frontiers of Research in Obstetric Therapeutics: *Drug Toxicity and Safety in Pregnant Women and the Fetus.* NICHD. Spring 2012. Rockville, MD

Medical Officer Safety Forum: *Causality Assessment in Clinical Trials.* National Institute of Allergy and Infectious Diseases. January 2013. Bethesda, MD

NIH Workshop - *Towards earlier involvement of Children and Pregnant Women in trials of new TB drugs.* Lecture on "Methods and approaches". NIAD. May 2013. Bethesda, MD

NIH Meeting on "Developing an interdisciplinary research agenda for genetics of birth defects". Topic "Are epidemiological approaches suitable for answering pertinent questions involving risk/preventive factors for human birth defects?" January 2014. Washington DC

Curricular Advances for Patient CER Meeting (Phrma, AHRQ and pcori). Topic "CER Educational Center of Excellence" January 2014. Washington DC

NIEHS, Epidemiology Branch Seminar "*Phthalates in medications and the risk of male genital malformations*", May 2014. North Carolina

RTI, Epidemiology Branch Seminar "*Two Stage Design*", May 2014. North Carolina



FDA public workshop – *Study approaches and methods to evaluate the safety of drugs and biologic products during pregnancy in the post-approval setting*, May 2014, Silver Spring, MD

*Weighing in on relative risks of fetal exposure to psychotropics and psychiatric disorders*. American Society of clinical psychopharmacology meeting. June 2014, Hollywood, FL.

*Use of Data Bases for Birth Defects Research*. NIH Think Tank on Birth Defects Meeting, February 2016. Dulles, Maryland.

*Methods to Study Vaccines in Pregnancy*. Global Alignment of Immunization Safety Assessment in Pregnancy Meeting. March 2016, Bethesda, Maryland.

*Workshop on the safety of Vaccines in Pregnancy*. Pfizer. May 2016, NYC, NY.

*Gestational Age at Enrollment*. Symposium on Pregnancy Registries. Teratology Society Annual Meeting. June 2016, San Antonio, Texas.

*Drugs and drug-environment interactions affecting the risk of oral clefts in humans*. NIH Meeting on “Gene-environment interactions in the etiology of oral clefts”. September 2016. Washington DC

*Safety of Topiramate: Sorting the Ever-Growing Data*. February 2017. John Hopkins University. Baltimore, ME

*Methods for Drug Safety in pregnancy*. November 2017. University of Florida. Gainesville, FL

*Methods for External Adjustment*. Lilly Expert Summit. May 2018. Lilly, Indianapolis, IN *Sample Size and Power Issues for Pregnancy Registries*. Panelist at Pregnancy Registry Workshop.

Teratology Society’s 58th Annual Meeting. June 2018. Clear Water, FL. *Pharmaco-*

*epidemiology/vigilance in Pregnancy*. PHACs / NIH Network Meeting, September 2018.

Bethesda, ME

### **International**

*Desnutrición infantil y tenencia de la tierra en Cuscatlán seis años después de los acuerdos de paz: un estudio epidemiológico*. Conferencia Nacional de Nutrición. San Salvador, El Salvador. January 1999.

*Folic Acid Antagonists during Pregnancy and the Risk of Neural Tube Defects*. Miguel Hernández University. July 1999. Alicante, Spain.

*Epidemiology of upper gastrointestinal side effects of non-steroid anti-inflammatory drugs*. Progress in the Field of selective COX-2 inhibitors. William Harvey Research Conferences. September 2001. Nice, France.

*Trimethoprim Teratogenicity*. Plenary Session. Teratology Society’s 44<sup>th</sup> Annual Meeting. June 2004. Vancouver, Canada.

*Assessment of teratogenic effects of drugs: what we need from databases*. Task-force in Europe for Drug Development for the Young. September 2006. Taormina, Italy.

*Case Only Studies for Reproductive Epidemiology*. Réseau québécois de recherche sur l’usage des médicaments. June 2007. Québec, Canada.

*Case Only Designs. Their relatives, their personality, their jobs*. Bern University. November 2007. Bern, Switzerland.

*Drug Safety during Pregnancy*. Murdoch Children’s Research Institute. July 2008. Melbourne, Australia

*Assessment of drug safety during pregnancy: what we need from databases.* Health Evaluation Research and Outcomes Network. July 2008. Sydney, Australia.

*Perinatal and Paediatric Special Interest Group breakfast session.* Australian Population Health Congress July 2008. Brisbane, Australia.

*Selection bias in the evaluation of prenatal environmental exposures.* Workshop at the Society for Environmental Epidemiology Conference. University College of Dublin. August 2009. Dublin, Ireland.

*Multiple comparisons in pharmacoepidemiological studies.* Plenary Session. European Medicine Agency Debate. August 2010. Brighton, UK.

*Causal inference: Selection bias.* Epidemiology Meeting. November 2011. Oslo, Norway.

*Study designs in epidemiology.* Public Health Department. November 2011. Oslo, Norway. *Causality assessment from clinical trials.* Uppsala Monitoring Centre Research Conference: Causality Assessment in an Evolving Pharmacovigilance Landscape. May 2012. Uppsala, Sweden.

*Breast Cancer Screening Task Force.* European Cancer Society. October 2012. Brussels, Belgium.

*Breast Cancer Screening. To do or not to do?* Bern University. January 2013. Bern, Switzerland.

*Early detection of breast cancer by screening.* Oncopolicy Forum, European cancer Congress. September 2013. Amsterdam, Netherlands. *Epidemiology of Preeclampsia.* Symposium Internacional en Ginecología y Obstetricia. May 2014.

Madrid, Spain

*Identifying and controlling for sources of bias in observational studies.* The 2nd International OTIS-ENTIS Conference. September 2014. Toronto, Canada

*Methods for drug safety during pregnancy.* 8th Workshop of the Work Group Pharmacoepidemiology of the German Society of Epidemiology. Bremen, Germany July 2015.

*Drug safety during pregnancy, methodological challenges.* Bayer. Berlin, Germany July 2015.

*Application of causal inference approaches to define confounding and selection biases in medication safety in pregnancy studies.* University of Oslo, School of Pharmacy. Oslo, Norway, September 2015.

*"Ser médico español en Harvard"* School of Medicine, UAM, Madrid, Spain, November 2015. *Structural management of biases in observational studies: Application to Pregnancy Research.* Madrid, Spain, November 2015. Universidad Autonoma de Madrid.

*Stimulant Drug Treatment of ADHD in Children: Age, Sex, and Academic Performance.* 9th Asian Conference on Pharmacoepidemiology. Thailand, November 2015.

*Status of the Pharmacoepidemiology.* Plenary Session. International Society for Pharmacoepidemiology Annual Meeting. August 2016. Dublin, Ireland.

*Lithium and cardiac malformations.* Invited Speaker. ASISA Annual meeting. June 2017. Leon, Spain.

*Enhanced Use of Electronic Health Records for Pregnancy Research.* Panelist and Speaker at Workshop. International Society for Pharmacoepidemiology Annual Meeting. August 2017. Montreal, Canada

*Application of Causal Inference Approaches to the Safety of medications in Pregnancy.* Norwegian Society of Pharmacology and Toxicology. December 2017. Oslo, Norway

Invited Plenary Speaker on “Prevalent users vs New user Design”. ICPE Annual Conference, Prague.

*Assessing Drug Safety for Pregnant Women: The Topiramate Experience*. Centre for Clinical Epidemiology – Jewish General Hospital. October 2018. Montreal, Canada.

*Banning p-value use, or misuse?* Department of Epidemiology Biostatistics, McGill University. October 2018. Montreal, Canada.

#### **ADVISING Doctoral students**

- Primary academic advisor, Pharmacoepidemiology, HSPH, Harvard University: Sengwee Toh (05/09), Andrea Margulis (07/11), Kristin Palmsten (10/12), Kelesitse Phiri (10/13), Qian Li (11/14), Yoon Young Park (12/17), Laura Schummers (14/18), Kazuki Yoshida (13/18), Sarah C. MacDonald (15/18), Katrina Mott (15/), Lidia Maria Moura (17/),
- Thesis committee member: Vera Ehrenstein (graduation 2007, Boston University), Molly Franke (2009), Meghan Baker (2011), Elisabetta Patorno (2011), Sonja Sawnsen (13/15), Katheryn Rough (2013/16), Ellie Caniglia (2014/16), Dominique Heinke (2015/18).
- Oral Exam committee member: Jereny Rassen (2007), Anshu P. Mohllajee (2007), Talia Zhang (2009), Jennifer Polinsky (2010), Joshua Gange (2010), John Jackson (2011), Lani Rapp Wegrzyn (2012), Sonja Swanson (2012), Peter Wahl (2012), Mariko Geiger (2012), SeoYoung Kim (2012), Travis Gerke (2014), Ellie Canniglia (2014), Dominique Heinke (2015), Katsiaryna Bykov (2016), Jenny Sun (2018), Getha Iyer (2018).
- Advisor Medical School-MD PhD: Chelsea Messinger (2016-)

#### **Master students**

- Academic advisor for MPH students, Quantitative Methods concentration, HSPH: Taiki Yamaji (05), Jude Herbert Koomson (05), David Ezriel Katz (05/06), Binta Sultan (07), Aneasha Shetty (07), Gustavo Velazquez (07), John Berry-Candelario (08), Cecilia Ganduglia (08), Kuei-Yu Lin (08), Douglas Pugliese (08), Young-Hee Rho (09), Hsin-Hsiao Wang (09), Churl-Su Kwon (09), Katherine Almendinger (10), David Rho (10), Zarif Jabbar-Lopez (11), Siri Lillegraven (11), Brian Bateman (11), Jiun-Shiou Lee (12), Adler, Joel T (13/15), Sarah C. MacDonald (13/15), Robert A. Ravinsky (13), Konrad H. Stopsack (13), Kristin Dwyer (14/17), Federico Angriman (15/16), Mona El Smaili (15/16), Anamarie Uhgly (15/16), Youyou Duanmu (16/18), Candace Wu (16/17) Hsuan Yen (16/17), Ye Liu (17/18), Paulina Tolosa Tort (17/18), Veronica Ventura (17/18), Daphney Clermont (18/19), Andrew Enslen (18/19)
- Academic advisor for MS students, pharmacoepidemiology concentration, HSPH: Shan Cai (07/08), Wei Liu (06/09), Qian Li (08/10), Katsiaryna Bykov (10/11), Andrew Rothman (11/13), Lina Goez Mogollon (15/17), Wan-Ting Hsu (17/), Alexandra Sosinsky (18/)

#### **Post-doctoral trainees**

- Elvira Masso Gonzalez, 2008.
- Kuei-Yu Lin, 2009-2010.
- Wai Ping Yau, 2009-2010.
- Lucia Cea Soriano, 2011-2012
- Sara Oberg, 2011-16
- Gabriel Sanf elix-Gimeno, 2011-2012
- Jaqueline Cohen 2015-18
- Alice Panchaud 2015-17
- Mollie Wood 2016-18
- Mar Martinez 2017

- Milada Mahic 2017-18
- Gabriella Bröms 2017-18
- Szu-Ta Chen 2018-2019

## HONORS AND DISTINCTIONS

- 1989-90 Spanish Ministry of Education scholarship – Academic scholarship for medical studies at Autónoma University of Madrid.
- 1996-98 Real Colegio Complutense Scholarship – Academic scholarship for graduate studies at Harvard University
- 1999 15<sup>th</sup> Annual Conference on Pharmacoepidemiology – Oral Presentation Prize.
- 2000 Lilienfeld Student Prize – Awarded at the Society for Epidemiologic Research meeting
- 2004-10 Elected Board Member of the International Society for Pharmacoepidemiology
- 2004 Kenneth Rothman Prize Award - Awarded by *Epidemiology* for the manuscript “A structural approach to selection bias”. (Hernan et al)
- 2006 Kenneth Rothman Prize Award – Awarded by *Epidemiology* for the manuscript “*Transient exposure to coffee as a trigger of a first nonfatal myocardial infarction*” (Baylin et al)
- 2008- Elected Fellow of the International Society for Pharmacoepidemiology
- 2010-12 Elected Chair of the Pregnancy Special Interest Group, International Society for Pharmacoepidemiology
- 2012 Elected Fellow of the European Academy of Cancer Sciences
- 2013 Kristin Palmsten (doctoral student) wins the Lilienfeld Student Prize – Awarded at the Society for Epidemiologic Research meeting
- 2013 Elected President of the Society for Pediatric and Perinatal Epidemiologic Research
- 2014 Elected President of the International Society for Pharmacoepidemiology
- 2015 Top 10 Clinical Research Achievement Award winner from the Clinical Research Forum
- 2015 Alumni Award Universidad Autónoma de Madrid (Alma Mater)
- 2017 Teaching Award, Harvard TH Chan
- 2017 Mentorship Award, Harvard TH Chan
- 2017 Poulsson medal/award by the Norwegian Society of Pharmacology and Toxicology

## RESEARCH SUPPORT (does not include training grants)

### Past:

*Risk of Neural Tube Defects and Gestational Hypertension associated with Methyltetrahydrofolate Reductase Polymorphisms.* (PI: Hernández-Díaz) Charles E Culpeper Biomedical Pilot Initiative Grant. Rockefeller Brothers Fund. 2001-2002. Role: PI.

*Endocrine Disruptors and Male Genital Malformations* (PI: Hernández-Díaz) Hood Foundation Child Health Research Grant. Charles H. Hood Foundation. 2004-2005. Role: PI.

P50 HL067669-05, CFDA 93.838 NIH/NHLBI (PI: van Marter) *Response of the Preterm Lung*. 2005-6. Role: Co-Investigator

HSPH NIEHS Center Pilot Project. (PI: Hernández-Díaz). *Phthalates in Medications and Male Genital Malformations*. 2007-2008

NIH R21 HD055479-01 (PI: Setoguchi) *Use of Health Care Utilization Databases to Studying Drug Safety During Pregnancy*. 2006-2009. Role: Co-Investigator

NIH U01 HD52104-01. NICHD. (PI: Van Dyke) *Pediatric HIV/AIDS Cohort Study (PHACS) – Coordination Center*. 2005-2011. Role: Co-Investigator.

NIH R01. (PI: Hernan) *Pooling HIV Cohorts to inform clinical decision making*. 2007-2010.

NIH R01 HD056940-01A2. (MPI: Hernández-Díaz) *Assessment of Infant Outcomes after in utero Exposure to Antiretroviral Therapy*. 2009-2012. Role: PI.

HSPH-Initiative. *Case-crossover design to study triggers of preterm labor*. (PI: Hernández-Díaz) 2011-2012. Role: PI.

NIH R01 HD046595-01A1. National Institute of Child and Human Development. (PI: HernándezDíaz) *Teratogenicity of Drugs Commonly Used in Pregnancy*. 2005-2013.

NIH R01 HD059861. National Institute of Environmental Health Sciences. (PI: Hernández-Díaz) *Phthalates in Medications and the Risk of Male Genital Malformations*. 2009-2014. [\$558,145]

AHRQ R01 HS018533. (MPI: Hernández-Díaz) *Comparative Effectiveness and Safety of Depression Treatments during Pregnancy*. 2009-2014. Role: PI. [\$423,778]

PhRMA Fndtn 6259936-01. (PI: Hernández-Díaz) *Training Program in Comparative Effectiveness Research*. 2013-2015 [\$250,000]

Ministry of Health and Care Services – Norwegian Institute of Public Health 240197/H10 (Handal, M.) *A Scandinavian cohort of pregnant women in opioid maintenance treatment during pregnancy: long term consequences for the child*. 01/01/16 – 12/31/17

GlaxoSmithKline LLC (PI: Hernández-Díaz) *Observational Cohort Study To Assess Maternal Diabetes During Pregnancy*. Protocol development. 2016-2017.

Pfizer, Inc. Grant number N/A (Bateman, B.). *Using Claims Data to Define Opioid Misuse and Abuse* 07/20/16 – 07/19/22

NIH/NIMH R01 MH100216. (PI: Hernández-Díaz) *Comparative Safety and Effectiveness of Psychotropic Drugs in Pregnant Women*. 5/01/14-4/30/18. [\$510,231]

GlaxoSmithKline LLC (PI: Hernández-Díaz) *Observational Cohort Study To Assess Maternal Asthma During Pregnancy and Fetal Outcomes*. 2016-2018.

Patient-Centered Outcomes Research Institute (PCORI) ME-1503-28119 (PI: Hernan, M) *Causal Inference Guidelines for Pragmatic Randomized Trials* 03/01/16 – 02/28/19

**Current [Current Year direct Costs Awarded]:**

MGH5271486 *North American Antiepileptic Drug (AED) Pregnancy Registry*. (PI: Holmes) Multiple Sponsors – pharmaceutical companies. 2006- . Role: Co-Investigator [\$18,553 per year]

NIH R01 AI102634 (PI: Hernan). *Dynamic Strategies for the Clinical Management of HIV Disease*. 2012-2018. Role: Co-Investigator [\$185,093]

PCORI Grant (PI: Mittleman, Murray A.). *Stratified Regression Models for Case-Only Studies* 08/01/16 – 07/31/21

NIMH R03 Research Grant (PI: Huybrechts, K.). *Ondansetron and risk of congenital malformations* 04/01/17 – 03/31/19

R21HD092879 (PI Hernandez-Diaz, S) *Pregnancy Registries nested in international pooled health care databases*. 9/17 – 6/19

R01MH116194 (PI: Huybrechts) *In-utero exposure to psychotropic medications and the risk of neurodevelopmental disorders*. 6/18 – 5/23

FDA contract HHSF223201400043I (PI: Huybrechts) *Developing the Capability of Using National Medicaid data for FDA Post-Marketing Surveillance to Assess Medication Safety During Pregnancy* 9/17 – 9/20

R01DA044293-01A1 (PI: Brian Bateman) *The Impact of Prescription Opioid Use on Pregnancy Outcomes* 7/17-6/21

PCORI- Grant (PI: Hernan, M.) *Causal Inference Guidelines for Pragmatic Randomized Trials*. 3/16 – 2/19

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ORIGINAL ARTICLES (\* = Primary advisor of first author)

1. Hernández-Díaz S, Rhomberg L. The Sperm-Count Debate. *Risk in Perspective* 1997;5:1-4.
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