

CURRICULUM VITAE

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

EDUCATION

Date	Discipline	Degree	Institution
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

LICENSURE AND CERTIFICATION

Date	Type of license or certification
06/1995	Professional College of Physicians of Madrid

PROFESSIONAL EXPERIENCE

Dates	Title	Institution, Place of work
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- Director of the Pharmacoepidemiology Program (gap 2017-2020)
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", co-sponsored 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, 2nd 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 Assess 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.
- 2020 Panelist of “Professional Development Session – Learning how to become a leader”. Annual Conference, Online.

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*
- 2020- Member, Editorial Board, *American Journal of Epidemiology*

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.
- 2016-20 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. FDA-Vanderbilt 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
- 2019- Consultant, Pregnancy Study Methods, UCB
- 2019-20 Consultant, Pregnancy Study Methods, GSK
- 2017- Member Academic Committee for the International Academic Program-Universidad Autónoma de Madrid (IAP-UAM)

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” (2016-18), “Effectiveness Research with Longitudinal Healthcare Databases” (2019-)
- 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”.
- 2015-19 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”
- 2017-19 Faculty Grant Writing Short Course

Short courses or lectures at Harvard

- 2016-20 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

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.

2010-2019 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.

2019 Instructor on Pharmacoepidemiology course with Databases. Sessions on Proposal development and manuscript publication & Pregnancy. Karolinska Institute, Sweden

2020 Instructor of pre-conference course on “COVID-19 Diagnostic Test Performance”. ICPE Annual Conference, Berlin (online).

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.

Use of health care data to generate real world evidence. Committee on University Resources (COUR) Annual Symposium. Harvard University. April 2019. Cambridge, MA.

Careers in Academia. One example: Epidemiology. Symposium ECUSA-BOSTON. Massachusetts Institute of Technology. October 2019. Cambridge, 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, 4th 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

Observational cohort Studies based on healthcare utilization databases. The Safety of Asthma Medications during Pregnancy: Research Priorities and Methodology. FDA – White Oak Campus. November 2019. Washington DC

Phenotypes in Epidemiology: read between the arrows. Key Note Speaker. Society for Epidemiological Research Meeting. March 2020. Salt Lake City. Utah.

Evaluation of drug safety during pregnancy: Methods and application. Harry Guess Memorial Lecture. UNC Gillings School of Global Public Health. September 2020. Chapel Hill. NC (online)

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 44th 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.

Drug Safety for Pregnant Women. Karolinska Institute. Sweden, March 2019.

Keynote Speaker. *Data Science Applications to Birth Defects Surveillance*. Karolinska Institute’s Epidemiology and Biostatistics Event. Stockholm. Sweden, May 2020

Invited speaker. ISPE Medications in Pregnancy and Lactation Special Interest Group Webinar. *The International Registry of Coronavirus Exposure in Pregnancy (IRCEP)*. Sep 2020

Drug Safety in Pregnancy: Challenges and Solutions in the Modern Era of Pharmacoepidemiology. Semi-Annual Meeting Canadian Network for Observational Drug Effects Studies. Nov 2020 (online)

Invited lecturer. *Target Trial Emulation to Study the Effects of Treatments and Vaccines during Pregnancy*. Karolinska Institute’s Epidemiology and Biostatistics Event. Online, February 2021

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 (15/20), Lidia Maria Moura (17/21),
- 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), Louisa H Smith (16/21).
- 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 (2016-2020)

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), Aneesha 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 (17/19), Jennifer Yland (17/19), Alexandra Sosinsky (18/20), Julien Heidt (18/21)

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  lix-Gimeno, 2011-2012
- Jaqueline Cohen 2015-18
- Alice Panchaud 2015-17
- Mollie Wood 2016-20
- Mar Martinez 2017
- Milada Mahic 2017-18
- Gabriella Br  ms 2017-18
- Szu-Ta Chen 2018-2020
- Carolyn Cesta 2020-2022

HONORS AND DISTINCTIONS

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|---------|---|
| 1989-90 | Spanish Ministry of Education scholarship – Academic scholarship for medical studies at Aut  noma University of Madrid. |
| 1996-98 | Real Colegio Complutense Scholarship – Academic scholarship for graduate studies at Harvard University |
| 1999 | 15 th 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 <i>Epidemiology</i> for the manuscript “A structural approach to selection bias”. (Hernan et al) |
| 2006 | Kenneth Rothman Prize Award – Awarded by <i>Epidemiology</i> for the manuscript “ <i>Transient exposure to coffee as a trigger of a first nonfatal myocardial infarction</i> ” (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	Poulsen medal/award by the Norwegian Society of Pharmacology and Toxicology
2020	Committee on the Advancement of Women Faculty (CAWF) Mentoring Award
2020	Master of Science (SM2) mentor award

RESEARCH SUPPORT (does not include training grants)

Past:

Risk of Neural Tube Defects and Gestational Hypertension associated with Methylentetrahydrofolate 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.

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.

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

NIH R01 HD046595-01A1. National Institute of Child and Human Development. (PI: Hernández-Díaz) *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]

NIH R21 HD081271(PI: Brogly). *Comparative Safety of Buprenorphine vs. Methadone in Pregnancy*. 9/14-7/16

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

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* 07/16 – 07/19

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

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

Eli Lilly (PI: Huybrechts) *Observational Studies to Assess Maternal and Fetal Outcomes Following Exposure to Duloxetine* 4/16 - 9/18.

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

Shire (Takeda). (PI: Hernandez-Diaz, S) *Observational Study to Assess Maternal and Fetal Outcomes Following Exposure to Prucalopride during Pregnancy* (protocol development). 5/19 – 12/19

Current [Current Year direct Costs Awarded]:

MGH5271486 *North American Antiepileptic Drug (AED) Pregnancy Registry*. (PI: Holmes) Multiple Sponsors – pharmaceutical companies. 2006- .

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

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 – 3/21

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

R01HD097778 (PI: Hernandez-Diaz) *Comparative Safety of Non-Insulin Agents in Pregnant Women with Pregestational Diabetes*. 9/19 – 6/24

R01HD088393 (PI: Hsu, J. and Hernan, M.). Long Term Impact of Fertility Treatments (LIFT) Study. 09/2/17 – 5/30/2022

R01DA049822 (PI: Huybrechts, K, J. and Bateman, B.) The Comparative Effectiveness and Safety of Pharmacotherapies for the Treatment of Opioid Use Disorder in Pregnancy 04/12/20 – 12/31/2023

PUBLICATIONS

ORIGINAL ARTICLES (* = Primary advisor of first author)

1. Hernández-Díaz S, Rhomberg L. The Sperm-Count Debate. *Risk in Perspective* 1997;5:1-4.
2. Rhomberg L, Hernández-Díaz S. Testicular Cancer Trends: What's Going On? *Risk in Perspective* 1997;5:1-2.
3. Brentlinger P, Hernán MA, Hernández-Díaz S, Azaroff L, Martin M. Childhood malnutrition and post-war reconstruction in rural El Salvador six years after the cease-fire. A community-based survey. *JAMA* 1999;281:184-90.
4. Hernández-Díaz S, Peterson KE, Dixit S, Hernández B, Parra S, Barquera S, Sepúlveda J, Rivera JA. Association of Maternal Short Stature with Stunting in Mexican Children: Common Genes vs. Common Environment. *European Journal of Clinical Nutrition* 1999; 53: 938-945.
5. Brentlinger P, Hernán MA, Hernández-Díaz S. Desnutrición infantil y tenencia de la tierra en Cuscatlán seis años después de los acuerdos de paz: un estudio epidemiológico. *Estudios Centroamericanos* 1999;54:367-78
6. Hernández-Díaz S, García-Rodríguez LA. Overview of Epidemiological Studies Published in the Nineties on the Association Between Non-Steroidal Anti-inflammatory Drugs and Upper Gastrointestinal Bleed/Perforation. *Archives of Internal Medicine* 2000;160:2093-2099
7. Hernández-Díaz S, Werler MM, Walker AM, Mitchell AA. Folic Acid Antagonists During Pregnancy and the Risk of Birth Defects. *New England Journal of Medicine* 2000;343:1608-1614.
8. Hernández-Díaz S, Mitchell AA. Folic Acid Antagonists During Pregnancy and the Risk of Birth Defects. [Letter with new findings]. *New England Journal of Medicine* 2001;344:934-935.
9. García-Rodríguez LA, Hernández-Díaz S, De Abajo F. Association between Aspirin and Upper Gastrointestinal Complications. Systematic Review of Epidemiologic Studies. *British Journal of Clinical Pharmacology* 2001; 52: 563-71.
10. Hernández-Díaz S, García-Rodríguez LA. Steroids and Risk of Upper Gastrointestinal Bleed/Perforation. *American Journal of Epidemiology* 2001; 154:1089-1093.
11. Hernández-Díaz S, Werler MM, Walker A, Mitchell AA. Neural Tube Defects in Relation to the Use of Folic Acid Antagonists during Pregnancy. *American Journal of Epidemiology* 2001; 153:961-968.
12. Hernández-Díaz S, García-Rodríguez LA. Epidemiologic Assessment of the Safety of Conventional Nonsteroidal Anti-Inflammatory. *American Journal of Medicine* 2001; 110:20S-27S.
13. García-Rodríguez LA, Hernández-Díaz S. The Risk of Upper Gastrointestinal Complications Associated with Nonsteroidal Anti-Inflammatory Drugs, Glucocorticoids, Acetaminophen, and Combinations of These Agents. *Arthritis Research* 2001; 3:98-101.

14. García-Rodríguez LA, Hernández-Díaz S. Non-Steroidal Anti-Inflammatory Drugs and The Excess Risk Of Upper Gastrointestinal Bleeding and Perforation. *Epidemiology* 2001; 12:570-576. (and reply *Epidemiology*. 2002;13:606)
15. Hernández-Díaz S, García-Rodríguez LA. Incidence of Upper Gastrointestinal Bleeding/Perforation in the General Population. Review of Epidemiologic Studies. *Journal of Clinical Epidemiology* 2002; 55: 157-163.
16. Hernández-Díaz S, Martínez-Losa E, Fernández-Jarne E, Serrano-Martínez M, Martínez-González MA. Dietary Folate and the Risk of Nonfatal Myocardial infarction. *Epidemiology* 2002;13:700-6.
17. Hernández-Díaz S, Werler MM, Louik C, Mitchell AA. Risk of Gestational Hypertension in Relation to Folic Acid Supplementation during Pregnancy. *American Journal of Epidemiology* 2002;156:806-12.
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22. Meyer K, Williams P, Hernández-Díaz S, Cnattingius S. Smoking and the risk of oral clefts: exploring the impact of study designs. *Epidemiology* 2004;15:671-8.
23. Hernán MA, Hernández-Díaz S, Robins JM. A structural approach to selection bias. *Epidemiology* 2004; 15: 615-625.
24. Chan KA, Hernández-Díaz S. Pharmacoepidemiology and Rheumatic Disorders. *Rheumatic Diseases Clinics of North America* 2004;30:835-50.
25. García-Rodríguez LA, Hernández-Díaz S. Risk of Uncomplicated Peptic Ulcer among Users of Aspirin and Nonaspirin Non-Steroidal Anti-Inflammatory Drugs. *American Journal of Epidemiology* 2004; 159:23-31
26. Hernández-Díaz S, Wu XF, Hayes C, Ashok TDS, Badovina R, Werler MM, Kelsey KT, Mitchell AA. Methylentetrahydrofolate Reductase Polymorphisms and the Risk of Gestational Hypertension. *Epidemiology* 2005;16:628-34
27. Werler MM, Mitchell AA, Hernández-Díaz S, Honein MA. Use of nonprescription medications in pregnancy. *American Journal of Obstetrics and Gynecology* 2005; 193:771-7
28. de Jong-van den Berg LTW, Hernández-Díaz S, Werler MM, Louik C, Mitchell AA. Trends and Predictors of Folic Acid Awareness and Periconceptional Use in Pregnancy. *American Journal of Obstetrics and Gynecology* 2005; 192:121-8
29. Meijer WM, Werler MM, Louik C, Hernández-Díaz S, de Jong-van den Berg LTW, Mitchell AA. Can folic acid protect against congenital heart defects in Down syndrome? *Birth Defects Res A Clin Mol Teratol* 2006;76:714-717

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32. Hernán MA, Alonso A, Hernández-Díaz S. Tetanus vaccination and risk of multiple sclerosis: a systematic review. *Neurology* 2006; 67:1-1.
33. Chan JM, Feraco A, Shuman M, Hernández-Díaz S. The Epidemiology of Prostate Cancer – with a focus on non-steroidal anti-inflammatory drugs (NSAIDS). *Hematology and Oncology Clinics of North America* 2006;20:797-809.
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35. Hernández-Díaz S, Schisterman EF, Hernán MA. The birth weight "paradox" uncovered? *American Journal of Epidemiology* 2006;164:1115-20.
36. Louik C, Hernández-Díaz S, Werler MM, Mitchell AA. Nausea and Vomiting of Pregnancy: Maternal Characteristics and Risk Factors. *Paediatric and Perinatal Epidemiology* 2006;20:270-8.
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41. Hernández-Díaz S, Werler MM, Mitchell AA. Gestational hypertension in pregnancies supported by infertility treatments: role of infertility, treatments, and multiple gestations. *Fertility and Sterility* 2007; 88:438-45.
42. Hernández-Díaz S, García-Rodríguez LA. Non-Steroidal Anti-inflammatory Drugs and the Risk of Lung Cancer. *International Journal of Cancer* 2007;120:1565-72.
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44. Hernández-Díaz S, Van Marter L, Werler MM, Louik C, Mitchell AA. Risk factors for Persistent Pulmonary Hypertension of the Newborn. *Pediatrics* 2007;120:e272-82.
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46. *Toh S, Hernández-Díaz S. Statins and fracture risk. A systematic review. *Pharmacoepidemiology and Drug Safety* 2007;16:627-640.
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53. Cooper W, Hernández-Díaz S, Arbogast PG, Ray WA. Antibiotics potentially used in response to bioterrorism and major congenital malformations. *Paediatric and Perinatal Epidemiology* 2009; 23: 18–28).
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INVITED COMMENTARIES, INVITED EDITORIALS, AND LETTERS

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BOOK CHAPTERS

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