
BIOGRAPHICAL SKETCH

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NAME: Morrato, Elaine Hornberger

eRA COMMONS USER NAME (credential, e.g., agency login): MORRATO.E

POSITION TITLE: Associate Professor Health Systems, Management & Policy; Pediatrics; Clinical Pharmacy; and Associate Dean for Public Health Practice

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Purdue University, West Lafayette, IN	BS	05/1988	Biochemistry (Honors)
Johns Hopkins University, Baltimore, MD	MPH	05/2003	Epidemiology
Johns Hopkins University, Baltimore, MD	DrPH	05/2006	Epidemiology
University of Colorado Denver, Denver, CO	Fellowship	08/2006	Pharmaceutical Outcomes Research
Northwestern University, Evanston, IL	Executive Certificate	11/2012	Marketing Management

A. Personal Statement

My role in this training grant application is to be one of the mentors. My role is based upon my experience in dissemination and implementation research, education, and practice. I am Co-Director (with PI=Glasgow) of the Colorado Research in Implementation Science Program within the ACCORDS center. I also direct the Pragmatic Trials and Dissemination and Implementation Research program for the Colorado Clinical & Translational Sciences Institute funded by NIH/NCATS for which I can serve as a navigator of available local resources for the K12 scholars. Previously, I served as the Collaborative Scientific Lead for an AHRQ Center of Excellence for Research in implementation science and prevention and led training workshops on implementation science and published online learning resources that were recognized by AHRQ. Also, relevant to this training grant, I received the President's Excellence in Teaching Award in recognition of my education and training efforts within the Colorado School of Public Health. I am Associate Dean for Public Health Practice and bring a strong practice orientation to my D&I research informed by my tenure working in the pharmaceutical industry and interest in the national dissemination and clinical translation of pharmaceutical innovation. I have been a technical brand manager and led product development commercialization (dissemination and implementation) teams for several national and international OTC and prescription drug initiatives. Today, I advise FDA on issues of drug safety and risk management implementation.

B. Positions and Honors

Positions and Employment

1988 – 2002 Product Development Manager, Procter & Gamble, Cincinnati, OH
Scientist, U.S. Professional Oral Care Product Development (1988-1992)
Senior Scientist, North America National Product Launch Leader, Metamucil (1992-1993) and Global Market Research Leader, Over-the Counter Cholesterol-Lowering Drugs (1993-1994),
Section Head, North American Technical Brand Manager, Prescription Gastrointestinal and Antibiotic Drugs and U.S. Launch Team Leader, Anti-Ulcer Drug (1995 – 1997)
Global Phase IIIb/IV Project Leader and North American Technical Brand Manager, Cardiovascular New Drug Development (1997 – 2000)

Global Phase III and Risk Management Project Leader, Cardiovascular New Drug Development, (2000-2002)

2002-2005 Consultant, Health Care New Business Development, Pharmaceutical and Wellness Market Research Services, Information Resources, Inc., Chicago, IL.

2004 – University of Colorado Anschutz Medical Campus, Aurora, CO

Fellow, Pharmaceutical Outcomes Research, Skaggs School of Pharmacy (2004-2006)

Assistant Professor, Health Systems, Management & Policy; Pediatrics; and Clinical Pharmacy (2006-2012)

Associate Professor (with tenure), Health Systems, Management & Policy; Pediatrics; and Clinical Pharmacy (2012-present)

Associate Dean for Public Health Practice, Colorado School of Public Health (2015 – present)

Honors

1987 Phi Beta Kappa, Purdue University, West Lafayette, IN

2006 Delta Omega Honorary Society in Public Health, Johns Hopkins University, Baltimore, MD

2012 President's Excellence in Teaching Award, Colorado School of Public Health, Aurora, CO

Professional Memberships and Service

2008- Board Certification in Public Health, National Board of Public Health Examiners

2010- Comparative Effectiveness Research (CER) Key Function Committee, NIH and the National Clinical and Translational Science Award (CTSA) Consortium

2009-2013 Member, Drug Safety and Risk Management Advisory Committee, FDA, Rockville, MD.

2012-2013 Scientific reviewer, Patient-Centered Outcomes Research Institute (PCORI)

2014-2018 Member, Pulmonary-Allergy Drugs Advisory Committee, FDA, Rockville, MD.

2014- Scientific reviewer, numerous NIMH mental health services study sections

2004- Member, International Society for Pharmacoepidemiology. Founding member of the Benefit-Risk Assessment, Communication and Evaluation Special Interest Group (2012-)

C. Contribution to Science

1. *Antipsychotic Metabolic Risk Management*. My early publications focused on understanding the effects of FDA drug safety warnings on physician behaviors using administrative claims data and mixed methods. Over the past decade, I have had a particular focus in understanding the uptake of metabolic screening in patients with serious mental illness receiving second-generation antipsychotics. Both the medical condition and the medications prescribed increase a patient's risk of cardiovascular disease and early mortality. I have been PI on several federal and private industry-funded studies in collaboration with Missouri Medicaid and the Department of Mental Health investigating the adoption of diabetes and lipid screening resulting in 11 publications, including proceedings from a national conference on *Adipogenic and Metabolic Effects of Antipsychotic Drugs* (NIMH/NIDDK R13MH086166) for which I served on the organizing committee. These studies demonstrated little effect of drug warnings on screening behaviors and highlighted a gap in adherence to regulatory and medical guidelines. Findings have contributed to CME efforts and HEDIS measures to promote screening. This research has also informed my recent investigation, *Metabolic Screening: Prioritizing Implementation Strategies for Mental Health* (R21 MH 097045), to identify how best to improve screening among Medicaid beneficiaries.

a. **Morrato EH**, Druss, B, Hartung DM, Valuck RJ, Allen RR, Campagna E, Newcomer JW.

Metabolic testing rates in three state Medicaid programs after FDA Warnings and ADA/APA Recommendations for Second-Generation Antipsychotic Drugs. *Arch Gen Psych* 2010; 67(1): 17-24. PMID: 20048219

b. **Morrato EH**, Nicol G, Maahs D, Druss B, Hartung DM, Valuck RJ, Allen RR, Campagna E, Newcomer JW. Metabolic risk monitoring in children receiving second-generation antipsychotic drugs *Arch Ped and Adolesc Med*, 2010 Apr;164(4):344-51. PMID: 20368487

c. **Morrato EH**, Brewer, S, Campagna EJ, Dickinson, LM, Thomas, DSK, Druss BG, Miller B, Newcomer JW, Lindrooth RC. Glucose Testing for Adults Receiving Antipsychotics: A Population-Based Prescriber Survey on Behaviors, Attitudes and Barriers in Medicaid *Psych Serv* 2015. Apr 1:appips201500181. PMID: 27032657

d. **Morrato EH**, Campagna EJ, Brewer SE, Dickinson LM, Thomas DSK, Miller BF, Dearing J, Druss BG, Lindrooth RC. Metabolic Testing for Adults in a State Medicaid Program taking

2. *Dissemination and Implementation Science*. My interest in implementation science stems from my experience leading North American and European Phase IIIb/IV development teams to promote the adoption and commercialization of new drugs and indications when I was an R&D manager in the pharmaceutical industry. My experience informs my research examining the adoption of drug warnings and other medical evidence in the U.S. healthcare system. In my academic setting, I contribute my scientific knowledge through the training and development programs I lead as Director of Pragmatic Trials and Dissemination and Implementation Science (NIH CTSA Consortium) and as former Collaborative Scientific Lead and Education Director for an AHRQ Center of Excellence in the implementation of clinical preventive services), and as PI for an AHRQ-funded conference to develop an implementation science research agenda for the appropriate use of clinical preventive services. My training curriculum and workshops were featured by AHRQ in *Training the Next Generation of Leaders in Clinical Preventive Services: Profiles from the AHRQ Research Centers for Excellence*. We have converted our workshop programs into an innovative on-line interactive web platform in order to extend the reach and usability of the learning content.
 - a. **Morrato EH**, Rabin B, Proctor J, Cicutto LC, Battaglia CT, Lambert-Kerzner A, Leeman-Castillo B, Prah-Wretling M, Nuechterlein BM, Glasgow RE, Kempe A. Bringing it Home: Expanding the Local Reach of Dissemination and Implementation Training via a University-Based Training Workshop 2015 *Implement Sci* 2015 Jul 4;10:94. PMID: 4490605
 - b. **Morrato EH**, Rabin B, Cameron C, Glasgow RE. "Users' Guide to Dissemination and Implementation in Health for Researchers and Practitioners". Colorado Research in Implementation Science Program (CRISP), University of Colorado Denver, Anschutz Medical Campus. Released October 2014. www.CRISPebooks.org
 - c. **Morrato EH**, Rabin B, Cameron C, Glasgow RE. "Users' Guide to Pragmatic Clinical Trials". Colorado Research in Implementation Science Program (CRISP), University of Colorado Denver, Anschutz Medical Campus. Released July 2015. www.CRISPebooks.org
3. *Regulatory Science of Pharmaceutical Risk Management*. This contribution is a synthesis of my research focus on the uptake of FDA drug warnings and my knowledge of implementation science. In 2007 the FDA was given expanded authority involving drug safety; the field of pharmaceutical risk management is an emerging science. I have contributed my knowledge on how to promote and evaluate the adoption of physician and patient behaviors in 40+ FDA advisory committee meetings and expert workshops on drug safety and risk management. I was also the lead author for the Benefit Risk Assessment, Communication, and Evaluation (BRACE) Special Interest Group's "International Society for Pharmacoepidemiology (ISPE) Response to FDA Questions: Standardization and Evaluation of Risk Evaluation and Mitigation Strategies (REMS)". I strive to merge the science of dissemination and implementation with the practice of pharmaceutical risk management.
 - a. Radawski C, **Morrato EH**, Hornbuckle K, et al. on behalf of the BRACE Special Interest Group. Benefit-Risk Assessment, Communication and Evaluation (BRACE) throughout the Life Cycle of Therapeutic Products: Overall Perspective and Role of the Pharmacoepidemiologist *Pharmacoepidem* 2015 Oct 12. doi: 10.1002/pds.3859. PMID: 26456379
 - b. Smith MY, **Morrato EH**. Advancing the field of pharmaceutical risk minimisation through application of implementation science best practices. *Drug Safety* 2014 Jul 9. PMID: 25005707
 - c. **Morrato EH**, Ling S. The FDA Drug Safety and Risk Management Advisory Committee: A Case Study Evaluation of Meeting Frequency, Content and Outcomes Before and After FDAAA. *Medical Care* 2012; 50 (11): 970–986. PMID: 23047787
 - d. **Morrato EH**, Allison DB, FDA Approval of Obesity Drugs-- A Difference in Risk-Benefit Perceptions. *JAMA* 2012; online Sep 19; 308(11): 1097-1098. PMID: 22990266
4. *Comparative Effectiveness Research*. As an implementation scientist and epidemiologist, my contribution to the CER field has been two-fold: integration of implementation science into CER research and conduct

of observational CER studies. The first two publications (a and b) stemmed from my involvement on the CER Key Function Committee for the NIH/NCATS Clinical & Translational Science Award Consortium. This work provided a framework for incorporating patient engagement throughout the research process and informed strategies developed by the Patient-Centered Outcomes Research Institute (PCORI). The work also identified national training and development needs regarding implementation of CER evidence. Due to this work, I was invited to participate in a national *Conference for Developing Curricula for Teaching Patient Centered Comparative Effectiveness Research* sponsored by the Agency for Healthcare Research and Quality, PCORI, and the PhRMA Foundation in 2014; and have been re-invited to participate in their follow-up conference on CER evidence dissemination.

I have also served as PI on observational CER studies using administrative claims data. One paper (c) compared outcomes for long-acting vs. orally-delivered antipsychotics and found long-acting products may lead to reduced emergency department utilization. The second paper (d) demonstrated methods for examining geospatial data embedded in patient-level claims data as a possible source of confounding.

- a. Concannon TW, Meissner P, Grunbaum JA, McElwee N, Guise J-M, Santa J, Conway PH, Daudelin D, **Morrato EH**, Leslie, LK. A New Taxonomy for Stakeholder Engagement in Patient-Centered Outcomes Research. *Journal of General Internal Medicine*. Epub 2012 Apr 13. DOI: 10.1007/s11606-012-2037-1. PMID: 22528615
- b. **Morrato EH**, Concannon TW, Meissner P, Shah ND, Turner BJ. Dissemination and Implementation of Comparative Effectiveness Evidence: Key Informant Interviews with Clinical and Translational Science Award Institutions. *J Comparative Effectiveness Research* 2013; 2(2): 185-194. PMID: 24236560
- c. **Morrato EH**, Parks J, Campagna EJ, Muser E, Thomas DS, Fang H, Doshi D. Comparative effectiveness of injectable paliperidone palmitate versus oral atypical antipsychotics: early postmarketing evidence. *J Comparative Effectiveness Research* 2014. Sep 24:1-11. PMID: 25251693
- d. Root ED, Thomas DSK, Campagna EJ, **Morrato EH**. Adjusting for Geographic Variation in Observational Comparative Effectiveness Studies: A Case Study of Antipsychotics Using State Medicaid Data *BMC Health Services Research*.2014, 14:355. PMID: 25164423

Complete List of Published Work in MyBibliography:

<http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/47915743/?sort=date&direction=descending>

D. Research Support

Ongoing

UL1TR001082, TL1TR001081, KL2TR001080 (Sokol) 10/01/2013 – 09/30/2018
NIH / NCATS

Colorado Clinical & Translational Sciences Institute (CCTSI)

The Clinical and Translational Science Award (3 grants) to the University of Colorado Denver will support the institutional academic home for research and training in clinical and translational sciences. This award is for continuation of the CCTSI during 2013-2018

Role: Director, Pragmatic Trials and Dissemination/Implementation Research Unit

Director, Innovation-Corps (I-Corps@CCTSI) (1 of 10 CTSA programs nationally selected to launch the NSF-developed I-Corps curriculum to help translate research innovation into the market place)

R13 HS23723-01 (Morrato) 11/15/2014–11/14/2016

AHRQ

Implementation Research Agenda: Appropriate Use of Clinical Preventive Services

This conference and year-long engagement process will develop a national implementation science research agenda to address issues of under-, over- and inequitable use of clinical preventive services in primary care.

Role: PI

R25 CA183725, (Co-PIs: Sahler, Noll) 04/15/2015-03/31/2020

NCI/NIH

Providing Psychosocial Care in Pediatric Oncology Problem-Solving Skills Training for Clinicians

This research aims to train and nationally disseminate specific coping strategies that would facilitate the adjustment of caregivers learning their child had been diagnosed with cancer.

Role: Co-Investigator (Dissemination Lead)

R18 HS022690-01 (Holtrop)

AHRQ

08/01/14-01/31/17

Maximizing Care Management Effectiveness in Primary Care

Research has shown that care management services can improve chronic disease patient outcomes, however, in real-world implementation, results are mixed. This study will provide practical and translatable information about what makes care management work and how quality improvement activities may be related to care management improvement over time as to maximize the benefit in community-based primary care.

Role: Co-Investigator (Social Network Analysis)

R25 HS 023214 (Suarez-Almazor)

6/1/1014 – 5/31/2019

AHRQ

Methods Training in Patient-Centered Cancer Outcomes Research

Role: Consultant, External Scientific Advisory Committee

Contract 1300-UCD (PI: O'Leary)

4/1/2015-3/31/2017

PCORI

Building Networks of Engaged Parents for Patient-Centered Pediatric Research

Role: Consultant, Leadership Team

Completed

R21 MH 097045 (Morrato)

12/1/2012-11/30/2015

NIMH

Metabolic Screening: Prioritizing Implementation Strategies for Mental Health

Role: PI

R01 HS022956 (Schilling)

09/30/2013 – 03/31/2015

AHRQ

SAFTINet: Optimizing Value and Achieving Sustainability

Role: Co-Investigator (Business Model Lead)

P01 HS 021138-01 (Kempe)

10/01/2011 – 09/30/2015

AHRQ

Center for Research in Implementation Science and Prevention (CRISP)

Role: Collaborative Scientific Lead (co-PI) and Training-Education Lead

R44 AG038316 (Tien)

9/1/2010-8/31/2013

NIA, NIH

SocioWorks: Integrated Web Platform for Applications of Social Network Analysis

Role: Co-Investigator (Site PI, Policy Level Demonstration Project)

Janssen Pharmaceuticals, Inc. (Morrato)

7/1/2012 – 7/31/2013

Comparative effectiveness of paliperidone palmitate when used in a real-world clinical setting

Role: PI