BIOGRAPHICAL SKETCH

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NAME: Cooper, William O.

eRA COMMONS USER NAME: cooperwo

POSITION TITLE: Cornelius Vanderbilt Professor of Pediatrics and Health Policy

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Transylvania University, Lexington, KY	B.A.	1987	Chemistry
Vanderbilt University School of Medicine, Nashville, TN	M.D.	1991	Medicine
University of Cincinnati College of Medicine, Cincinnati	-	1994	Pediatrics resident
University of Cincinnati College of Medicine, Cincinnati	-	1995	Chief resident
Vanderbilt University School of Medicine, Nashville, TN	-	1997	Gen. Peds fellow
Vanderbilt Peabody Graduate School, Nashville, TN	Non-Degree	1996	Statistical methods
Vanderbilt University School of Medicine, Nashville, TN	M.P.H.	1997	Public Health

A. Personal Statement

I have the expertise, leadership, and motivation necessary to successfully serve as a coinvestigator on this proposal to focus on critical questions related to the maternal-infant dyad affected by the opioid crisis. I am a practicing pediatrician with a background in health services research and pharmacoepidemiology, where I have published over 120 manuscripts describing population-based studies of medication use in children and pregnant women. My research has focused on assessing the safety of medications for a variety of vulnerable populations, including studies of adverse fetal outcomes following psychotropic drugs in children and exposures to medications during pregnancy for populations of women in the Tennessee Medicaid program, with studies of ACE inhibitor exposures and cardiac malformations, effects of antibiotics taken during pregnancy, the fetal effects of immunosuppressive medications taken for autoimmune conditions, and current work exploring the fetal effects of opioid medications taken during pregnancy. I have successfully competed for funding to support my research program and have been the principal investigator for 10 federally funded research projects. I have also collaborated with many of the other co-investigators participating in the proposed work.

B. Positions and Honors

Positions and Employment

1997-2003 Assistant Professor of Pediatrics (tenure track), Vanderbilt University Medical Center
2003-2008 Associate Professor of Pediatrics (tenured), Vanderbilt University Medical Center, Nashville, TN
2008-present Professor of Pediatrics and Health Policy, Vanderbilt University Medical Center, Nashville, TN
2000-2012 Vanderbilt Center for Education and Research in Therapeutics (Associate Director, 2004-2012)
2001-2010 Director for Students, Vanderbilt Master of Public Health Program, Nashville, TN
2001-present Investigator, Vanderbilt Center for Health Services Research, Nashville, TN
2006-present Director of Research, Division of General Pediatrics, Vanderbilt University Medical Center
2010-2013 Director, Vanderbilt Master of Public Health Program, Nashville, TN
2010-present Vice Chair for Faculty Affairs, Department of Pediatrics, Nashville, TN
2014-present Associate Dean for Faculty Affairs & Director, Vanderbilt University School of Medicine
2018-present Vice President for Patient and Professional Advocacy, Vanderbilt University Medical Center

Other Experience and Professional Memberships

2005-2010 Editorial Board, Academic Pediatrics
2009-2010 NIMH, Mental Health Services in Non-Specialty Settings Study Section, member
2008-2013 Drug Safety and Risk Management Advisory Committee, US Food and Drug Administration
2013 Centers for Disease Control and Prevention, Safe Medications in Pregnancy Expert Panel
2014 Testimony, United States Senate Committee on Health, Education, Labors, and Pensions, Medication Safety in Children

Honors

2010 Vanderbilt Academy for Excellence in Teaching
2011 Dean's Distinguished Lecture, University of Kentucky
2012 Chancellor's Award for Research, Vanderbilt University
2012 Cornelius Vanderbilt Professor of Pediatrics & Health Policy
2013 Research Award, Academic Pediatric Association
2016 Edward D. Harris Professionalism Award, Alpha Omega Alpha
2017 Miller-Sarkin Lecturer, Cincinnati Children's Hospital
2017 Dr. Martin Luther King, Jr. Award, Vanderbilt University

C. Contribution to Science

1. As a pediatric pharmacoepidemiologist, my studies have focused on the quality of prescription medicine care and effects of policy, particularly focusing on policies that effect prescribing of medications. These studies provided opportunities to understand and inform health policy by quantifying the effects of policies and pointing out potential unintended consequences of health policy decisions.
    a. Sox C, Cooper WO, DiGuisseppe D, Christakis DA. Provision of pneumococcal prophylaxis for children with sickle cell disease. *Journal of the American Medical Association* 2003; 290: 1057-1061 PMID: 12941678.
    b. Eckrich MJ, Wang WC, Yang E, Arbogast PG, Morrow A, Dudley JA, Ray WA, Cooper WO. Adherence to transcranial Doppler screening guidelines among children with sickle cell disease. *Pediatr Blood Cancer* 2013;60:270-4. PMID: 22744996
    c. Patrick SW, Cooper WO, Davis MM. Prescribing opioids and psychotropic drugs in pregnancy. *BMJ* 2017;358:j3616. PMIE: 28768614.
    d. Lopata SM, McNeer E, Dudley JA, Wester C, **Cooper WO**, Carlucci JG, Espinosa CM, Dupont W, Patrick SW. . Hepatitis C Testing Among Perinatally Exposed Infants. Pediatrics. 2020 Mar;145(3):e20192482. doi: 10.1542/peds.2019-2482. Epub 2020 Feb 14.PMID: 32060140
2. Because most studies of psychotropic medications have limited data on the unintended consequences of these medications in children prior to regulatory approval and marketing, much of our knowledge of pediatric drug safety comes from post-marketing, population-based studies. I have served as the principal investigator or coinvestigator on a series of studies designed to increase our understanding of a variety of adverse effects among children treated with psychotropic medications. Most of these studies were designed to address important safety signals (e.g. FDA Adverse Event Reports) that led to widespread public health concern, including potential cardiac effects of medications used to treat ADHD, metabolic effects of antipsychotics in children, and risk for suicidal behavior among children taking antidepressants. Thus, the findings of these studies were met with great interest and have influenced drug policy by the Food and Drug Administration, HealthCanada, and the European Medicines Agency.
    a. Cooper WO, Habel LA, Sox CM, Chan KA, Arbogast PG, Cheetham TC, Murray KT, Quinn VP, Stein CM, Callahan ST, Fireman BH, Fish FA, Kirshner HS, O'Duffy A, Connell FA, Ray WA. ADHD drugs and serious cardiovascular events in children and young adults. *N Engl J Med.* 2011 Nov 17; 365(20): 1896–1904. PMCID: PMC4943074
    b. Bobo WV, Cooper WO, Stein CM, Olfson M, Graham DJ, Daugherty J, Fuchs DC, Ray WA. Antipsychotics and the risk of Type 2 diabetes in children and youth. *JAMA Psychiatry* 2013; 70:1067-1075. PMID: 23965896
    c. Cooper WO, Callahan ST, Shintani AS, Fuchs DC, Shelton RC, Dudley JA, Graves AJ, Ray WA. Antidepressants and suicide attempts in children. *Pediatrics*. 2014 Feb; 133(2): 204–210. doi: 10.1542/peds.2013-0923 PMCID: PMC3904271

d. Ray WA, Stein CM, Murray KT, Fuchs DC, Patrick SW, Daugherty J, Hall K, Cooper WO. Association of Antipsychotics with Increased Risk of Unexpected Death in Children and Youth. *JAMA Psychiatry* 2019;76:162-171. PMID 30540347.

3. I have conducted studies focused on the effects of prescription opioids on vulnerable populations including children, pregnant women, and the developing fetus. In recent years, there has been a substantial increase in the prescribing of opioid medications across the United States. Much of this increased prescribing has been associated with an increased number of reports of adverse effects for various populations. This series of studies, in which I served as principal investigator or coinvestigator have explored the trends in prescribing o opioids in various populations and the adverse effects.
    a. Ray WA, Chung CP, Murray KT, Cooper WO, Hall K, Stein CM. Out-of-hospital mortality among patients receiving methadone for non-cancer pain. JAMA Intern Med. Author manuscript; PMC 2016 Mar 1.Published in final edited form as: *JAMA Intern Med*. 2015 Mar 1; 175(3): 420 427. doi: 10.1001/jamainternmed.2014.6294 PMCID: PMC4346542
    b. Patrick SW, Dudley JA, Martin P, Harrell F, Warren MD, Hartmann K, Ely EW, Grijalva C, Cooper WO. Prescription opioid epidemic and infant outcomes. *Pediatrics*. 2015 May; 135(5): 842–850. doi: 10.1542/peds.2014-3299 PMCID: PMC4411781
    c. Ray WA, Chung CP, Murray KT, Cooper WO, Hall K, Stein CM. Out-of-hospital mortality among patients receiving methadone for noncancer pain. *JAMA Intern Med*. 2015 Mar; 175(3): 420-7. PMID: 25599329, PMCID: PMC4346542, PII: 2091400, DOI: 10.1001/jamainternmed.2014.6294, ISSN: 2168-6114.
    d. Maalouf FI, Cooper WO, Slaughter JC, Dudley J, Patrick SW. Outpatient pharmacotherapy for neonatal abstinence syndrome. *J Pediatr* 2018;199:151-157. PMID: 29754866.

4. The adverse fetal effects of medications taken by women during pregnancy are virtually unknown at the time of initial marketing. Given the fact that up to 50% of pregnancies in women are unplanned, many women may become pregnant while taking a medication and face important questions about the safety of the medication for her developing fetus. However, many conditions, if left untreated during pregnancy, can worsen the mother's health and threaten the health and development of her fetus. I have participated in a series of studies designed to assess the effects of prescription medications taken during pregnancy on pregnancy and fetal outcomes. These studies have led to policy changes by drug regulatory agencies in the United States and abroad and have changed medical practice by informing prescribing recommendations for professionals who provide care for women who are pregnant or likely to become pregnant.
    a. Cooper WO, Hernandez-Diaz S, Arbogast JG, Dudley J, Dyer SM, Gideon P, Hall K, Ray WA. Major congenital malformation after first trimester exposure to ACE inhibitors. *New England Journal of Medicine* 2006; 354:2443-2451. PMID: 16760444
    b. Cooper WO, Cheetham TC, Li, D-K, Stein CM, Callahan ST, Moragn TM, Shintani AK, Chen N, Griffin MR, Ray WA. Adverse fetal outcomes associated with immunosuppressive medications for chronic immune mediated diseases in pregnancy. *Arthritis Rheumatol*. 2014 Feb; 66(2): 444–450. doi: 10.1002/art.38262 PMCID: PMC4077326
    c. Veeranki SP, Gebretsadik T, Mitchel EF, Tylavsky FA, Hartert TV, Cooper WO, Dupont WD, Dorris SL, Hartman TJ, Carroll KN. Maternal folic acid supplementation during pregnancy and early childhood asthma. *Epidemiology*. 2015 Nov; 26(6): 934–941. doi: 10.1097/EDE.0000000000000380 PMCID: PMC4900760
    d. Maalouf F, Cooper WO, Stratton SM, Dudley J, Ko J, Banerji A, Patrick SW. Positive predictive value of administrative data for neonatal abstinence syndrome. *Pediatrics*. 2019 Jan;143(1). pii: e20174183. doi: 10.1542/peds.2017-4183. Epub 2018 Dec 4 .PMID: 30514781

Complete List of Published Work in MyBibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/william.cooper.2/bibliography/41142426/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

5R01DA045729-03 Patrick(PI) 04/15/20180-1/31/2022
NIH/NIDA
Improving Access to Treatment for Women with Opioid Use Disorder
The major aims is to determine whether:1a) pregnant women with opioid use disorder are more likely to experience difficulty accessing OAT when compared with non-pregnant women, 1b) insurance type modifies ability to access OAT,and2) state policies promote or hinder access to treatment.
Role: Co-Investigator

5R01HD097344-03 Ray (PI) 01/01/2019-12/31/2020
NIH/NICHD
Antipsychotics and the Risk of Unexpected Death in Children and Youth
We aim to test the hypothesis that the risk of unexpected deaths and total mortality in children and youth who are antipsychotic new users with a) ADHD or disorders of behavior/conduct, b) unipolar depressive or anxiety disorders, or c) bipolar disorders is greater than that for comparable patients starting alternative medications and to define how risk of unexpected deaths and total mortality in children and youth who are antipsychotic new users varies with a) individual drug, b) dose, and c) concurrent CNS depressant
Role: Co-Investigator

Completed Research Support

U01 HL133996 Hankins (PI) 08/08/2016-06/30/2020
NIH/NHLBI
Re-aiming at Hydroxyurea Adherence for Sickle Cell with MHEALTH (RE-HASH)
Role: Co-Investigator, project lead for drug utilization core project

1L1CMS331461-01-00 Rothman (PI) 05/01/2015 – 04/30/2019
Centers for Medicare and Medicaid Services
Mid-South Practice Transformation Network
The Mid-South PTN will bring together a diverse range of clinical practices including practices with and without prior experience in quality improvement (QI). The PTN will utilize the burgeoning VHAN, which is currently building infrastructure to support the largest practice network in the Southeast.
Role: Co-investigator

R01HD074584 Ray (PI) 01/01/2013 - 12/31/2018
NIH/NHLBI
Prescribed Opioid Safety in Children
We will study the toxicity of prescribed opioids in children. Study findings could increase the safety of these potentially hazardous medications for vulnerable children.
Role: Co-investigator

VUMC78169(NU58DD00010) Cooper (PI) 09/30/2019-09/29/2020
Centers for Disease Control and Prevention
Tennessee Sickle Cell Disease Surveillance Program
Goals are to identify persons with sickle cell through Medicaid data and to link the data with analysis design.

VUMC69267 Cooper (PI) 11/01/2018-10/31/2020
University of Tennessee Health Science Center
ECOSYSTENN: Education and Clinical Outcomes in Youth with Sickle Cell in Tennessee
Role: Site PI

VUMC60846 (U01HL133996) Hankins (PI) 08/08/2016-06/30/2020
NIH/NHLBI
Re-aiming at Hydroxyurea Adherence for Sickle Cell with MHEALTH (RE-HASH)

Role: Co-Investigator, project lead for drug utilization core project

T32HD060554 Williams/Barkin (multi-PI) 05/01/2009-04/30/2020
NIH/NICHD
Conducting Child Health Care Research in Vulnerable Populations
The major goal of the project is to support the career development of pediatric physician-scientists who will become the future leaders in child health research in vulnerable populations.
Role: Mentor