Real World Data and Real World Evidence Regarding Research Specific to Lactating Persons: Challenges and Opportunities

Christina Chambers, PhD, MPH

Department of Pediatrics

Division of Environmental Science & Health
UC San Diego School of Medicine
Herbert Wertheim School of Public Health and Longevity Science

NASEM Meeting, June 15, 2023

Center for Better Beginnings

UC San Diego School of Medicine

Electronic Medical Records as a Source of Data

- Electronic medical records are not routinely structured to properly identify breastfeeding habits of infants/children and link these to maternal exposures from the medical record and ultimately to infant health outcomes

- However, this would likely be feasible within many health systems

Electronic Medical Records as a Source of Data

Received: 3 January 2023 | Revised: 17 April 2023 | Accepted: 17 May 2023

DOI: 10.1002/pds.5643

ORIGINAL ARTICLE

WILEY

The most common medications dispensed to lactating persons: An electronic health record-based approach

Kristin Palmsten[1] | Gabriela Vazquez-Benitez[1] | Meghan M. JaKa[2] | Gretchen Bandoli[3,4] | Katherine A. Ahrens[5] | Elyse O. Kharbanda[1]

Abstract

Purpose: Using a novel, electronic health record (EHR)-based approach, to estimate the prevalence of prescription medication use at 2, 4, and 6 months postpartum among lactating individuals.

Methods: We utilized automated EHR data from a US health system that records infant feeding information at well-child visits. We linked mothers who received prenatal care to their infants born May 2018–June 2019, and we required infants to have ≥1 well-child visit between 31 and 90 days of life (i.e., 2-month well-child visit with a ±1 month window). Mothers were classified as lactating at the 2-month well-child visit if their infant received breast milk at the 2-month well-child visit. For subsequent well-child visits at 4 and 6 months, mothers were considered lactating if their infant was still receiving breast milk.

Results: We identified 6013 mothers meeting inclusion criteria, and 4158 (69.2%) were classified as lactating at the 2-month well-child visit. Among those classified as lactating, the most common medication classes dispensed around the 2-month well-child visit were oral progestin contraceptives (19.1%), selective serotonin reuptake inhibitors (8.8%), first generation cephalosporins (4.3%), thyroid hormones (3.5%), nonsteroidal anti-inflammatory agents (3.4%), penicillinase-resistant penicillins (3.1%), topical corticosteroids (2.9%), and oral imidazole-related antifungals (2.0%). The most common medication classes were similar around the 4 and 6-month well-child visits although prevalence estimates were often lower.

UC San Diego
SCHOOL OF MEDICINE

Challenges & Opportunities with Electronic Health Records

Challenges

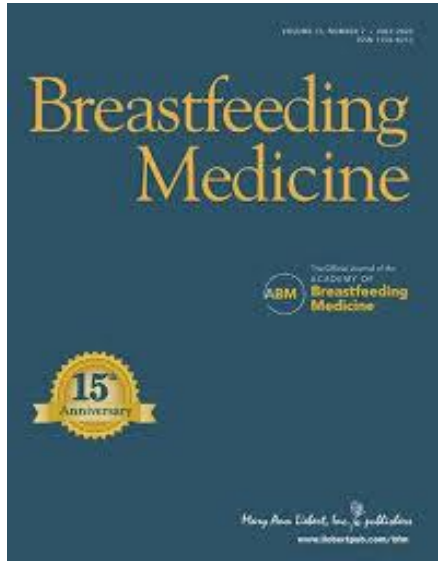
- not knowing if a medication documented as dispensed in the maternal record was actually taken and when
- many medications/vaccines would not be documented in medical record, e.g., OTC
- details about breastfeeding exposure may not be available

Opportunities

- electronic health care systems could be expanded to capture additional information as well as samples if desired

Real World Data from Stand-Alone Biorepositories for Research

Nationwide Mommy's Milk Human Milk Research Biorepository (HMB) established at UC San Diego in 2014



Breastfeeding Medicine, Vol. 15, No. 3 | Clinical Research

The Design and Mechanics of an Accessible Human Milk Research Biorepository

Gretchen Bandoli, Kerri Bertrand, Maryana Saoor, and Christina D. Chambers

Published Online: 9 Mar 2020 | https://doi.org/10.1089/bfm.2019.0277

UC San Diego
SCHOOL OF MEDICINE

Objectives of HMB

- To provide a nationwide platform to study the safety of medications in lactation
  - Rx medications
  - OTC medications
  - Vaccines, herbal products
- To examine prevalence and potential consequences of environmental contaminants
- To serve as a resource for other research teams and networks to address key questions about human milk
- To advance human research and best practices regarding breastfeeding through community partnerships

UC San Diego
SCHOOL OF MEDICINE

HMB Study Design

Samples

- 50 mL milk sample up to full expression, can be repeated samples – local collection or shipped overnight on ice packs
- Samples aliquoted and stored at -80° C at UC San Diego biobank
- Addition of paired blood samples self-collected from mothers/infants using a Tasso device

Recruitment Sources

- MotherToBaby Services and MotherToBaby Pregnancy Studies (US and Canada)
- Social media
- Lactation consultants, Donor Milk Banks, pediatric/pharmacy referrals

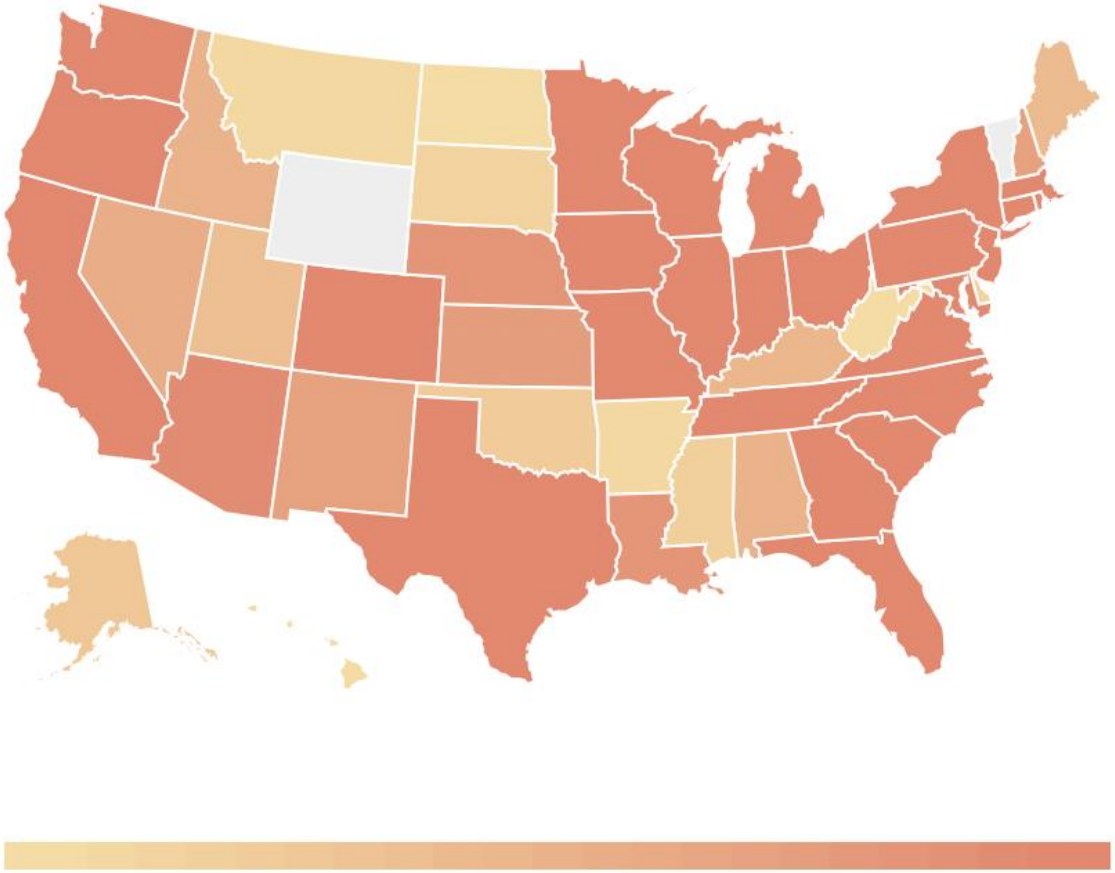
Meta-Data

- Demographics, maternal and child health, and detailed breastfeeding habits
- Exposure to recreational drugs, alcohol, tobacco, caffeine, and all Rx & OTC medications, supplements, herbal products, vaccines day-by-day over past 14 days
- Infant adverse reaction checklist
- Stress, anxiety, depression screening, food frequency questionnaires
- Neurobehavioral questionnaires 12-36 months; face-to-face testing for subset
- Medical records abstraction for mother and infant annually

UC San Diego
SCHOOL OF MEDICINE

Growth Trajectory

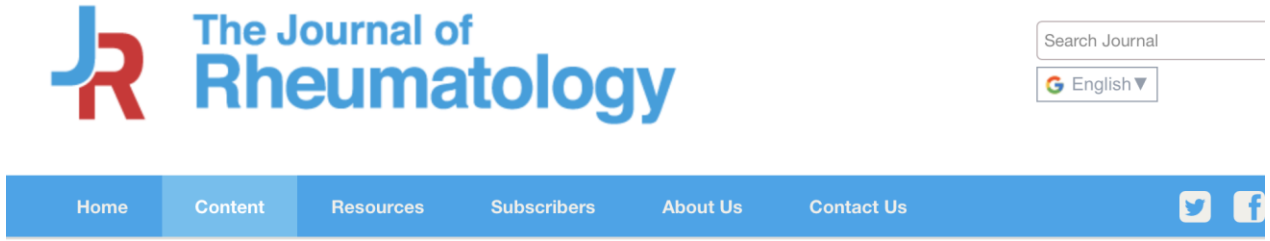
MOTHERS DISTRIBUTION BY STATES

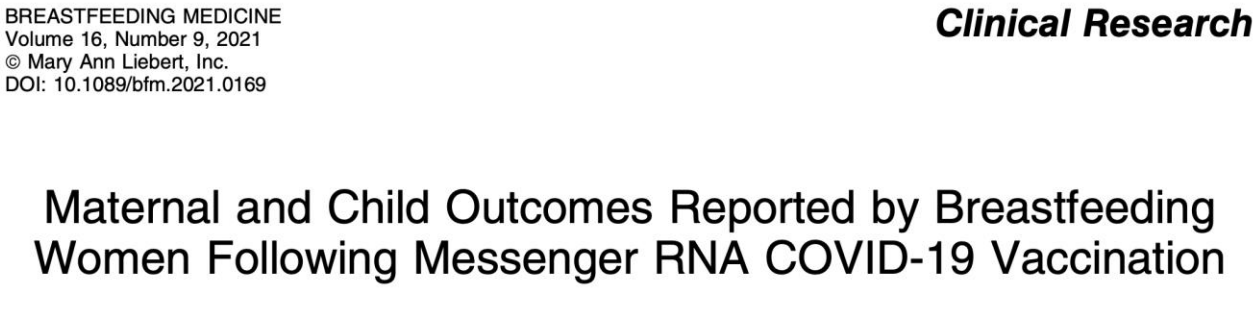


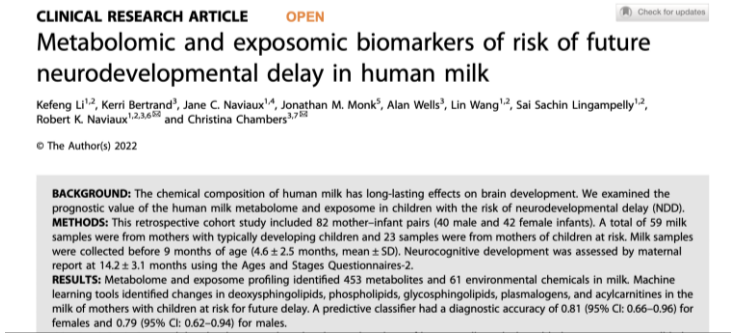
UC San Diego
SCHOOL OF MEDICINE

Psychother	N	Immune	N	Pain/Antibiotic	N	Other	N
sertraline	296	infliximab	14	oxycodone	123	atorvastatin	1
citalopram	32	etanercept	10	hydrocodone	127	rosuvastatin	2
duloxetine	6	abatacept	3	acyclovir	23	enalapril	3
clonazepam	10	tocilizumab	7	oseltamivir	15	labetalol	73
fluoxetine	46	adalimumab	34	cephalexin	62	levothyroxine	232
gabapentin	13	methotrexate	3	amoxicillin	44	metformin	25
lamotrigine	23	prednisone	102	azithromycin	39	mesalamine	16
desvenlafaxine	3	dupilimab	6	clindamycin	22	metoprolol	13
pregabalin	2	tofacitinib	2	doxycycline	3	nifedipine	54
trazodone	9	ustekinumab	19	levofloxacin	7	riveroxban	1
buproprion	42	certolizumab	39	metronidazole	13	domperidone	19
lorazepam	23	mepolizumab	1	methylphenidate	5	zolpidem	11
respiridone	1	apremilast	2	amphetamine salts	15	ondansetron	23
aripripazole	5	vedolizumab	19	sumatriptan	23	prucalopride	3
escitalopram	50	hydroxychloroquine	46	naltrexone	4	Covid Vaccine	742

Examples of HMB Primary Work

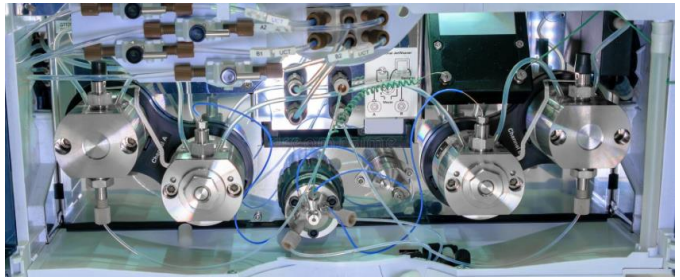






UC San Diego
SCHOOL OF MEDICINE

EU ConcePTION Project with a Similar Model: Multiple EU Countries, Samples Analyzed and Banked in Upsalla Sweden



https://www.imi.europa.eu/projects-results/project-factsheets/conception
https://www.imi-conception.eu/general/

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking ConcePTION grant n° 821520

Challenges & Opportunities with Human Milk Biobanks

Challenges

- potential variability in sample integrity for various medications with home collection (being tested)
- Sustainability of the biobank as a resource

Opportunities

- could potentially be used to address efficacy if desired
- can fulfill post-marketing commitments/requirements for new medications