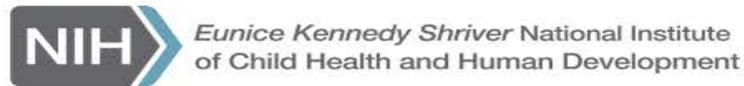


Update: Scientific Research and U.S. Federal Activities on Drugs, Vaccines, Vitamins, and Other Supplements for Pregnant and Lactating Women

Sarah L. Glavin, Ph.D.

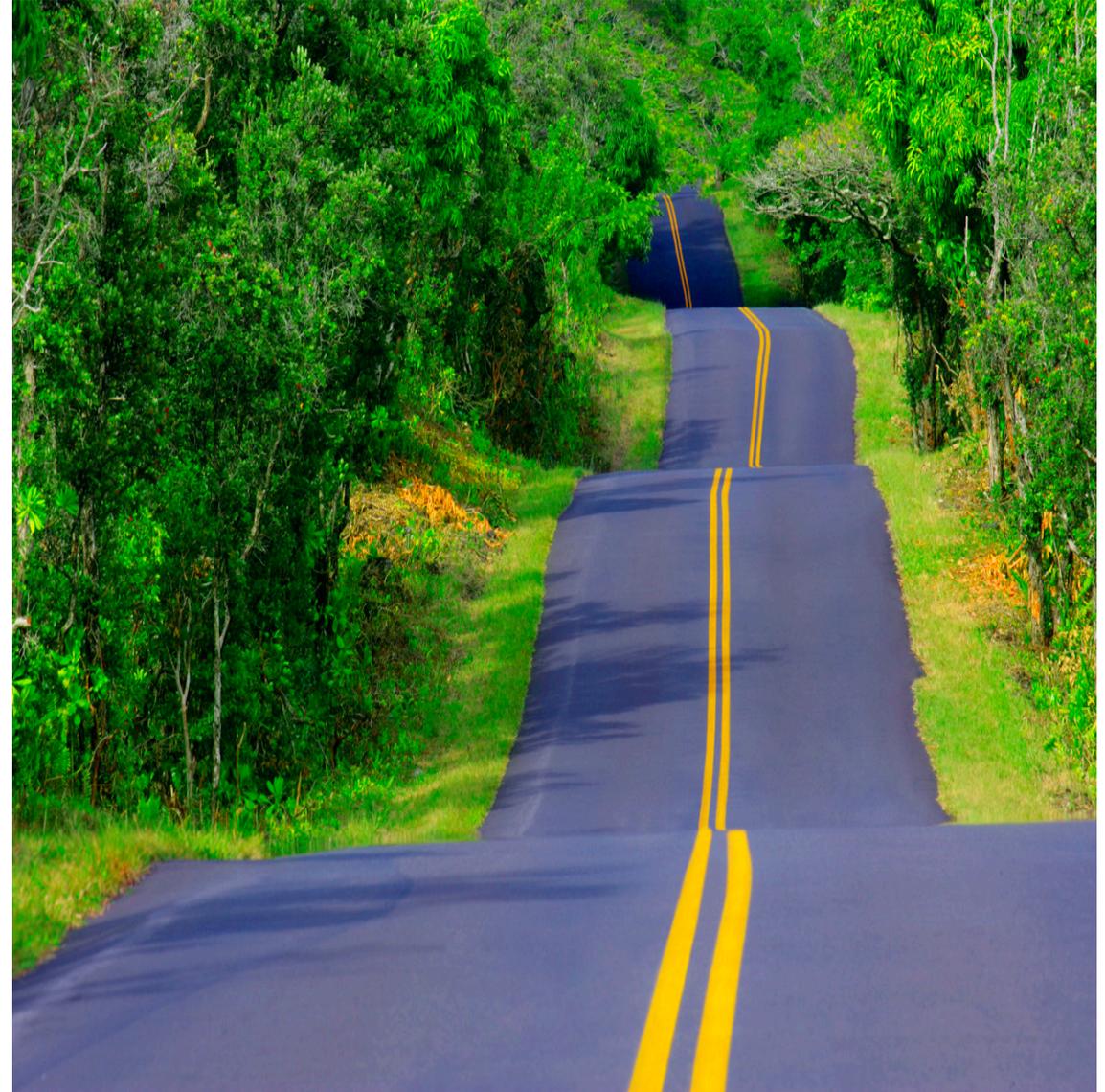
Science Policy, Planning, and Evaluation Branch, NICHD





Presentation Overview

- Scientific Literature
- U.S. and International Funding Sources in Research Literature
- U.S. Federal Activities





Updates since August Task Force Meeting



- + Added 3 new conditions to literature analysis –
 - Asthma
 - Nausea and vomiting/ hyperemesis
 - Low milk supply
- + Added vitamins, herbals, supplements to literature, federal activities
- + Quantified research gaps identified in August meeting of the Task Force
- + Completed funding data



Literature: Introduction, Objectives, and Methods



Objectives

- 1) Quantify the literature by condition, type of research, and subtopic;
- 2) Identify gaps by condition, type of research, and subtopic;
- 3) Determine funding sources for original research.

Note: Did not address rigor or quality of research studies





Scope and Methods

- ✓ PubMed searches, January 2006 to August 2017
 - Population: pregnant and/or lactating women
 - 15 Conditions/categories
 - Therapies:
 - Drugs/pharmaceuticals
 - Vitamins and other supplements
- ✓ Titles, abstracts, and articles reviewed
 - Screen out false positives
 - Classify by research type
 - Identify funding source (for original research only)
- ✓ MeSH and text analysis, then review, to identify articles by subtopics
- ✓ 24,969 articles reviewed; 13,628 unique articles in final database



Research Types

- Basic/pre-clinical (Original Research)
- Pharmacokinetic and pharmacodynamic -- PK/PD (Original Research)
- Population and database -- large scale or population-representative data (Original Research);
- Randomized controlled clinical trials – RCT (Original Research)
- Case series or cohort study (Original Research)
- Case report
- Review
- Editorial/commentary
- Other – original research not otherwise classified (Original Research)



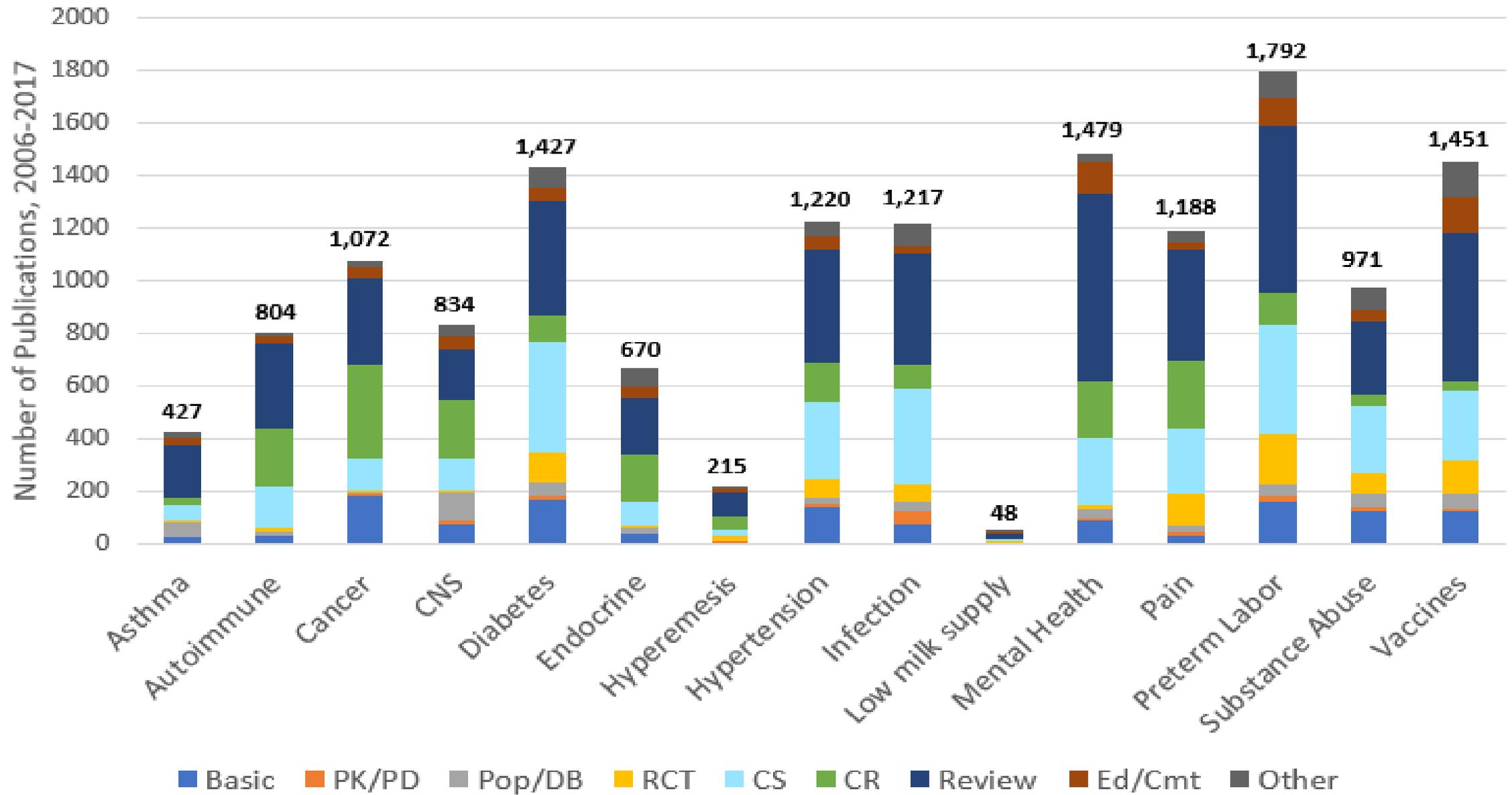
Conditions

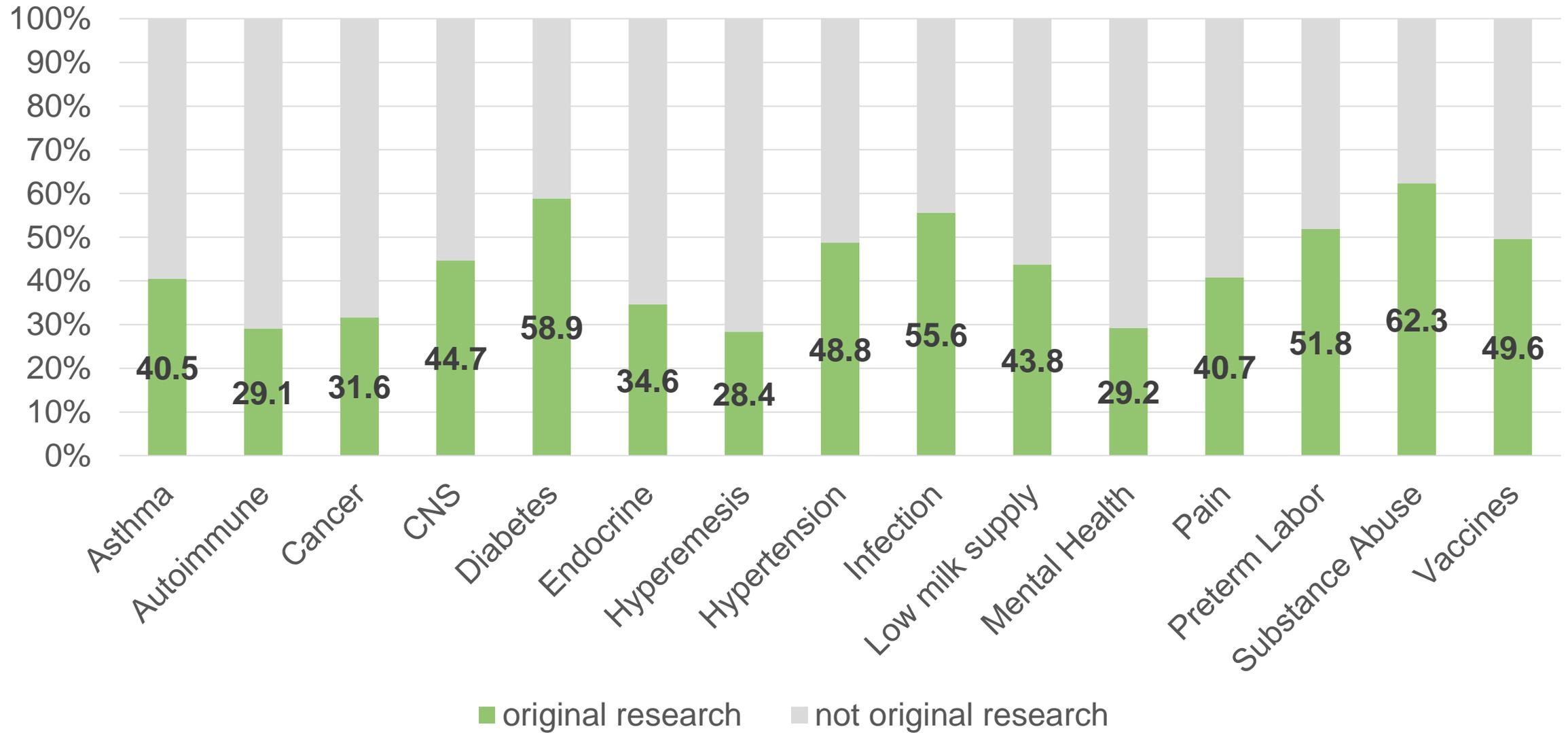
1. Asthma (Added since August TF meeting)
2. Autoimmune diseases*
3. Cancer
4. Central nervous system disorders
5. Diabetes (all types)
6. Endocrine disorders*
7. Hypertensive disorders
8. Infectious diseases
9. Low milk supply (Added since August TF meeting)
10. Mental health
11. Nausea and vomiting/
hyperemesis gravidarum
(Added since August TF meeting)
12. Pain
13. Preterm birth
14. Substance abuse
15. Vaccines

* Excludes diabetes



Literature: Updated Results







Basic/Pre-clinical



Cancer; Diabetes;
Hypertension; Substance
Abuse



Autoimmune; Low Milk
Supply; Pain

RCT



Low milk supply; Pain;
Preterm labor; Vaccines



Asthma; Autoimmune;
Cancer; CNS; Endocrine;
Mental Health

PK/PD

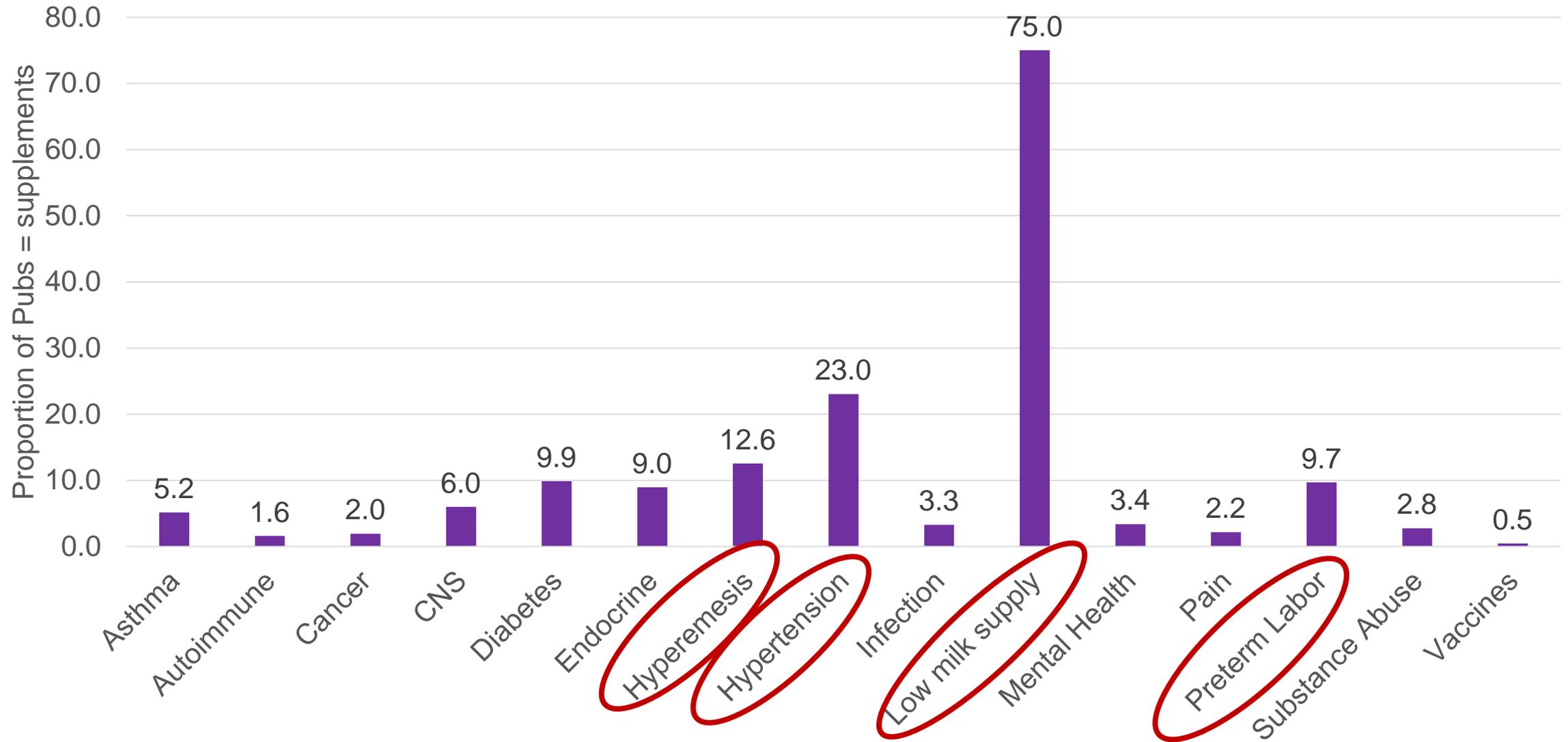


Infection



All other conditions



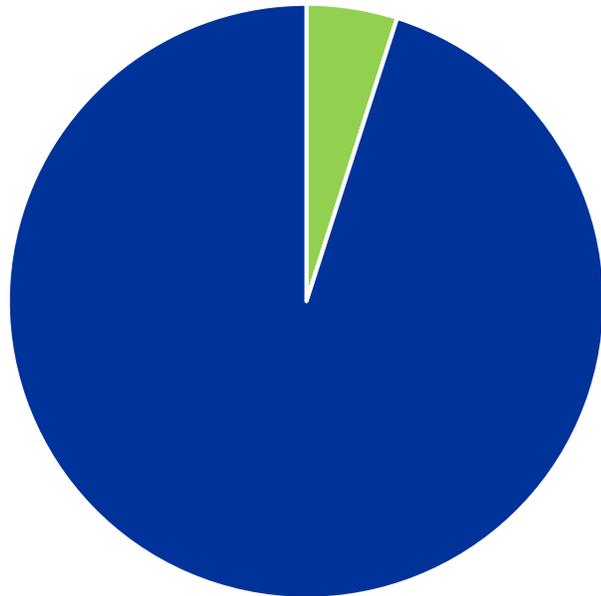




Publications that Address Lactation

All Publications

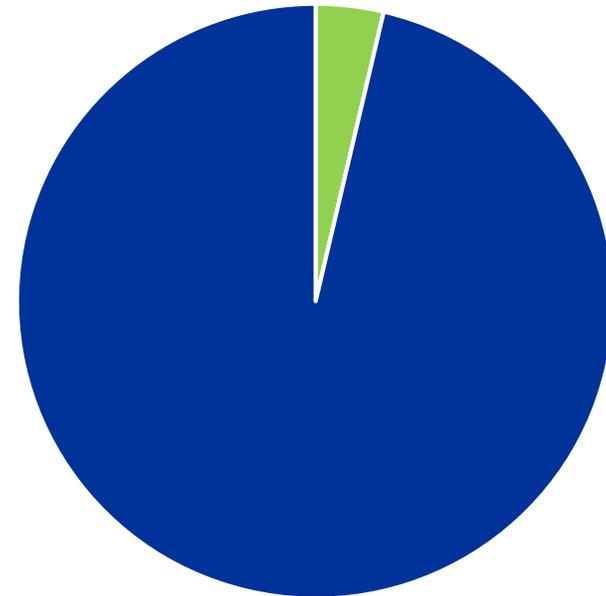
4.9 lactation



95.1 pregnancy only
■ lactation ■ pregnancy only

Original Research

3.7 lactation



96.3 pregnancy only
■ lactation ■ pregnancy only



Specific Disorders Common in Pregnant and Lactating Women, Yet Under-represented in Research Literature

Chronic pain
Bipolar
Cocaine
Tuberculosis
Hepatitis B
Hepatitis A
stroke
CMV infection
MS
Rheumatoid arthritis
Anxiety
Low milk supply
Hepatitis C
Marijuana
Group B strep
Asthma
Urinary tract infections
Malaria
Type 1 diabetes
Amph/ meth
Migraine headache
Lupus
Spinal cord injury
Nausea/vomiting
Schizophrenia



Number of Publications in Other Gap Areas Identified in August TF Meeting

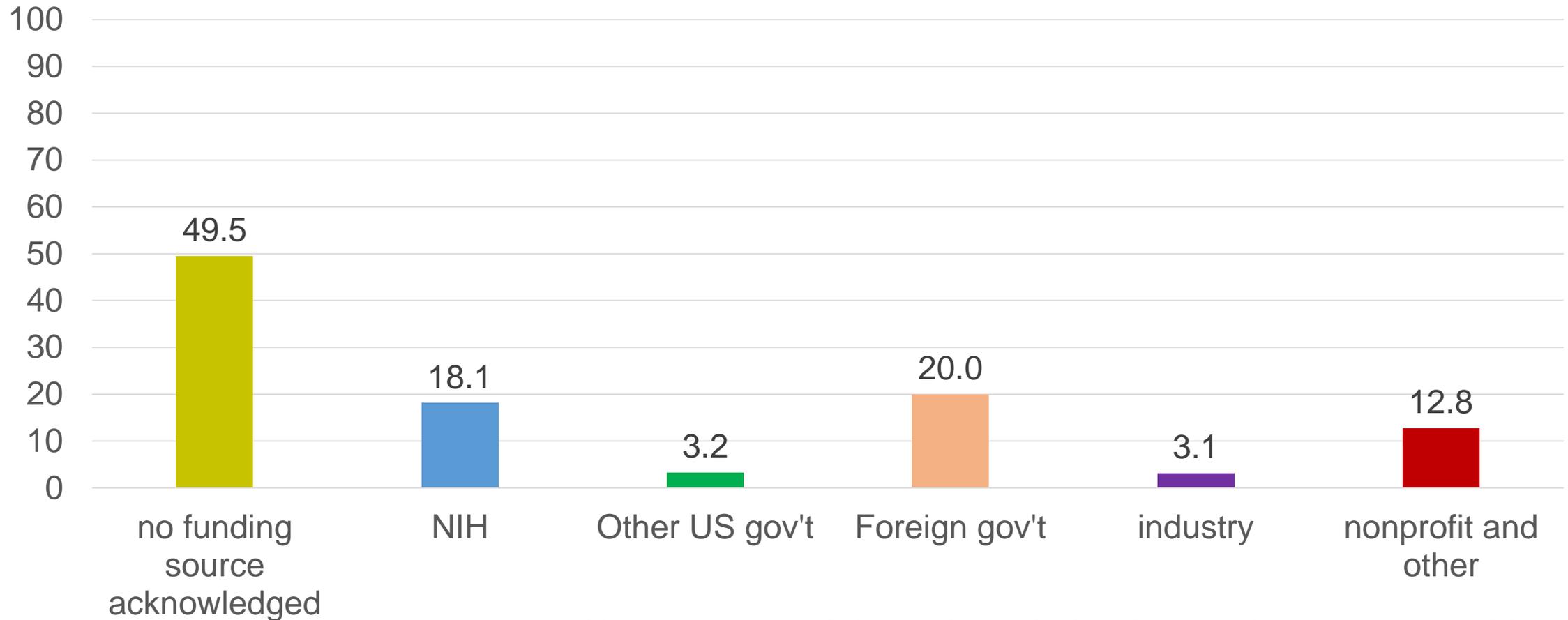
	PK/PD	n=169; 1.2 %
	Placental transport	n=28, 0.2%
	Late-emerging effects of prenatal exposure	n=31, 0.2%
	Impact of untreated disease	
	New drugs for pregnancy-specific conditions	n ~ 0



Funding Sources



Types of Funding Sources for Original Research on Therapies for Pregnant and Lactating Women



Note: some articles acknowledged more than one type of funding.



Variation in Funding Sources Across Categories

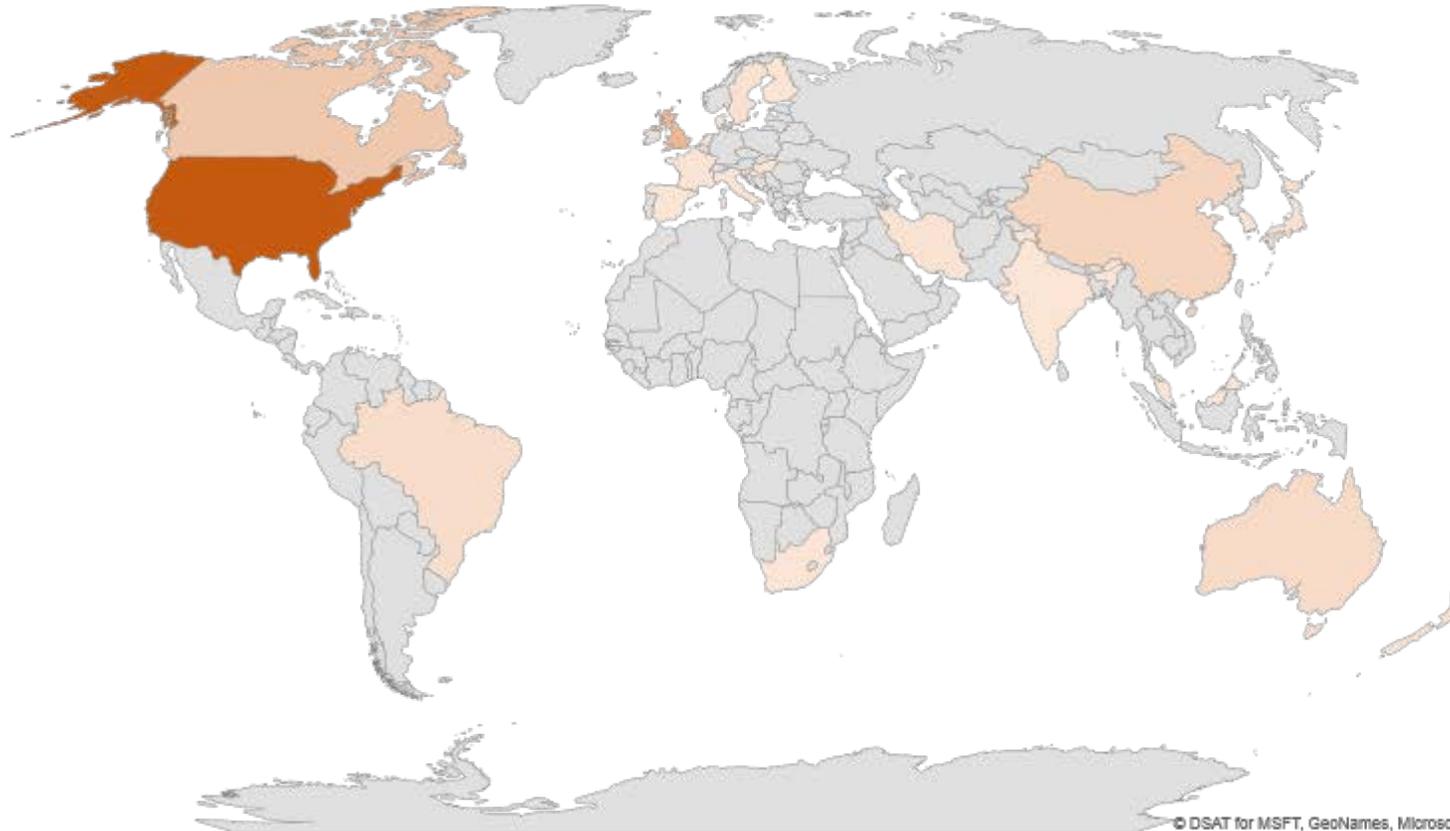
- Vaccines:
 - Lowest proportion of articles without acknowledged funders
- Infectious diseases:
 - Higher proportion with gov't and foreign gov't funding
- Substance abuse and Preterm birth:
 - Higher proportion with NIH funding
- Cancer, CNS, Autoimmune, Asthma:
 - Higher proportions from disease-specific nonprofits not related to pregnancy



Country of Origin for Government and Nonprofit Funding Sources

Key gov't funders:

- NIH (USA)
- MRC (UK)
- CIHR (Canada)
- NSF (China)
- CNPq (Brazil)
- NHMRC (Australia)





Update: U.S. Federal Government Activities



U.S. Federal Activities: Research

- Prenatal exposure
 - Potential toxicology of drugs and devices
 - Environmental exposure
 - Occupational exposures
 - Military exposure
- Effects of prenatal exposure on both woman and fetus
- Wide range of efforts, although congenital anomalies are an area of focus



U.S. Federal Activities: Research

- Safety and efficacy of therapies
 - Preclinical research
 - PK/PD
 - Cohort/observational
 - Clinical trials
 - Vaccine safety
 - Global health



U.S. Federal Activities: Research

- Utilization and Quality of Care:
 - Effects of federal programs
 - Coordination of care for individuals in federal programs
 - Dissemination of evidence-based practices
 - Medication use
 - Maternal Immunization
 - Large databases



U.S. Federal Activities: Health Care and Clinical Practice



- Federal programs: Medicaid, VA, TRICARE, FQHCs, MCH block grants, others
- USPSTF





U.S. Federal Activities: Communications



Focus areas include:

- Breastfeeding
- Maternal immunization
- Postpartum depression
- Substance abuse/ opioids



LactMed
A TOXNET DATABASE

Depression and Anxiety Happen. **Getting Help Matters.**



