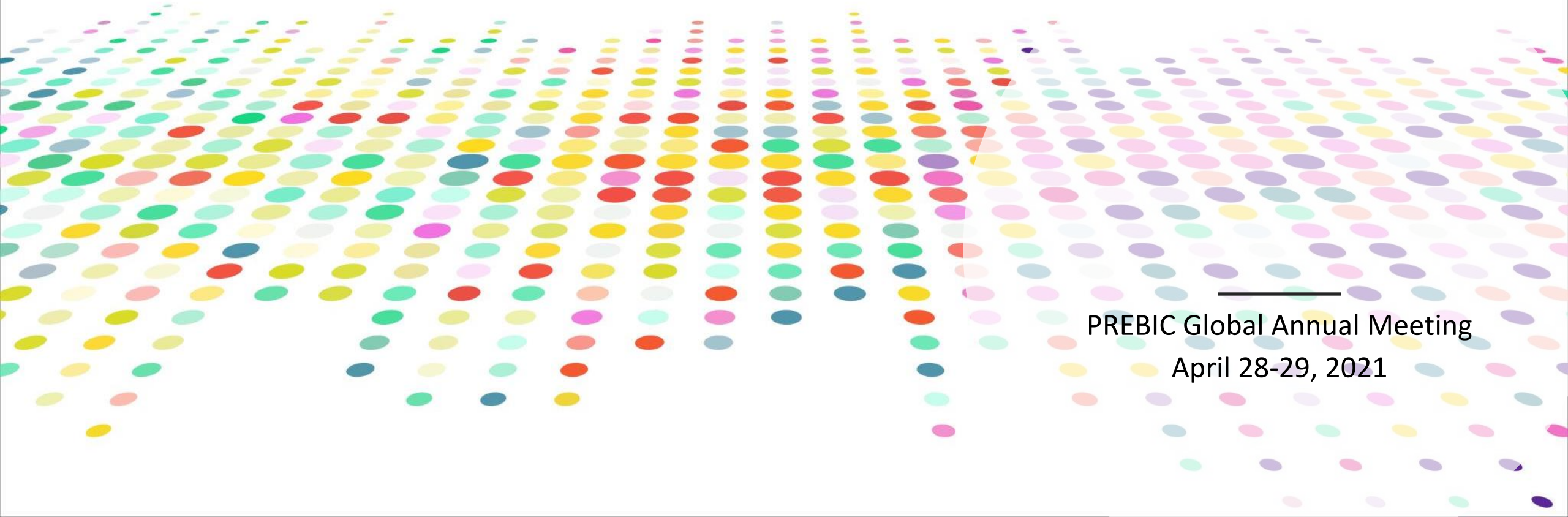
Epidemiology and Health Disparities Working Group



PREBIC Global Annual Meeting

April 28-29, 2021

Working Group Members

- *Members*

- Cynthia Gyamfi-Bannerman, Columbia University Medical Center
- Sandie Ha, University of California, Merced
- Ashley Hill, University of Pittsburgh
- Ben Mol, Monash University
- Annette Regan, University of San Francisco
- Neil Sarkar, Brown University

- *PREBIC Board Liaison*

-Kwame Adu-Bonsaffoh, University of Ghana

- *Facilitator*

- Brandie DePaoli Taylor, Temple University

Why have we not made meaningful progress in preventing PTB?

- Standardization of epidemiologic study design and reporting remains an issue
  - We cannot compare results across studies because of lack of standardization in approach and variable measurement

- Importance of social and physical environment
  - Largely ignored unless the primary focus of an investigation
    - Social context
    - Violence
    - The paternal role
  - Attempts and approaches to measure meaningful interaction are rare

Why have we not made meaningful progress in preventing PTB?

- Methods for measuring and addressing disparities
  - Beyond standard measures of SES and race/ethnicity, there is a lack of harmonization of health disparities data
    - Best practices in the measurement of health disparities
    - Understanding measures appropriate for different populations
    - Applying Public Health Critical Race praxis to capture the nuanced, intersectional experiences and impacts of social systems and structures on marginalized groups

- Acknowledgement of PTB subtypes
  - Problem with using composite measure of PTB
  - There is guidance for phenotyping of PTB, why is it not followed?

Do we need to re-address standardizing epidemiologic studies of PTB?

Guidance for design and analysis of observational studies of fetal and newborn outcomes following COVID-19 vaccination during pregnancy

Deshayne B. Fell [a,b,*,1], Michelle C. Dimitris [b,2], Jennifer A. Hutcheon [c,3], Justin R. Ortiz [d,4], Robert W. Platt [e,f,g,5], Annette K. Regan [h,i,6], David A. Savitz [j,7]

Vaccine 39 (2021) 1882–1886

Designing Drug Trials: Considerations for Pregnant Women

Jeanne S. Sheffield,[1] David Siegel,[2] Mark Mirochnick,[3] R. Phillips Heine,[4] Christine Nguyen,[5] Kimberly L. Bergman,[6] Rada M. Savic,[7] Jill Long,[8] Kelly E. Dooley,[9] and Mirjana Nesin[8]

Clinical Infectious Diseases® 2014;58(S7):S437–44

A Standardized Template for Clinical Studies in Preterm Birth

Leslie Myatt, PhD[1], David A. Eschenbach, MD[2], Stephen J. Lye, PhD[3], Sam Mesiano, PhD[4], Amy P. Murtha, MD[5], Scott M. Williams, PhD[6], and Craig E. Pennell, MB. BS, PhD[7]; International Preterm Birth Collaborative (PREBIC) Pathways and Systems Biology Working Groups

Reproductive Sciences
19(5) 474-482

DOI: 10.1177/1933719111426602
http://rs.sagepub.com
SAGE

Methodologic issues in the design and analysis of epidemiologic studies of pregnancy outcome

David A Savitz Department of Community and Preventive Medicine, Mount Sinai School of Medicine, New York, USA, **Nancy Dole** Carolina Population Center, University of North Carolina, Chapel Hill, North Carolina, USA and **Amy H Herring** Department of Biostatistics, University of North Carolina School of Public Health, Chapel Hill, North Carolina, USA

Statistical Methods in Medical Research 2006; **15**: 93–102

Scand J Work Environ Health 1999;25 suppl 1:5—7

Design options and sources of bias in time-to-pregnancy studies

by Jørn Olsen, MD[1]

Olsen J. Design options and sources of bias in time-to-pregnancy studies. *Scand J Work Environ Health* 1999;25 suppl 1:5—7.

Do we need to re-address standardizing epidemiologic studies of PTB?

- We believe that prior work can be updated by including the following:
  - 1) Provide a minimal dataset that incorporates valid measures of social determinants of health and measures of physical environment
  - 2) Address epidemiologic concerns including measurement error, confounding, and bias
    - Include forms of truncation bias due to gestational timing
    - Appropriate selection of covariates to avoid bias
    - Addressing bias in design and analysis
  - 3) New/hybrid study designs
  - 4) Discuss inference to target populations
    - Lack of understanding of generalizability vs. transportability and limited understanding of methods to address external validity

Do we need to re-address standardizing epidemiologic studies of PTB?

- Application issues to address
  - Observation studies vs. clinical trials
  - Global perspectives
    - How to adapt guidance according to available resources for data collection
    - Addressing differences in social determinants across populations
      - Discrimination measures vary across populations
  - Addressing different study objectives
    - Intervention
    - Etiologic
    - Prediction
  - Teasing out sophisticated methods that might not work in real-world settings
  - Guidance on interaction, mediation and effect modification
    - Need to consider social X environment interactions
    - RERI is useful to identify high-risk groups for intervention

Other considerations/continuing discussion

- Narrow our focus?
  - E.g., design of preconception studies to understand factors increase risk PTB
  - E.g., design of studies to address social determinants of PTB
  - E.g., provide guidance based on PTB subtype

- Are there other gaps in the epidemiologic literature consider?

Next steps

- Continue discussions to identify future research needs in epidemiology

- Meet in May to solidify the epidemiology/health disparities working group focus and goals

Suggestions/Comments?