

## Session 2

# Real World Opportunities and Challenges in Using GLP1 Receptor Agonists for CNS Disorders

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# Session Speakers

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**Karen Glanz, PhD**, George A. Weiss University Professor,  
School of Nursing, University of Pennsylvania

A Lived Experience Perspective on Accessibility and Equity

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**Jiang Bian, PhD**, Chief Data Scientist of UF Health, Professor  
of Biomedical Informatics, UF College of Medicine

RWE for Repurposing GLP-1 Agonists in CNS Disorders

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**Robert Kosko, PharmD, MPH**, Commissioned officer in the  
United States Public Health Service, Senior Program  
Management Officer for the Drug Shortage Staff, FDA

GLP-1 Agonists Supply and Shortage

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**Fatima Stanford, MD, MPH**, Associate Professor of Medicine  
and Pediatrics, Massachusetts General Hospital and Harvard  
Medical School

Equity and GLP1 Agonist Access

## FDA definitions on RWD and RWE

## Real world data (RWD)

“Data relating to patient health status and/or delivery of health care routinely collected from a variety of sources

## Real-world data

|                                                                                    |                           |                                                                                    |                              |                                                                                    |                 |
|------------------------------------------------------------------------------------|---------------------------|------------------------------------------------------------------------------------|------------------------------|------------------------------------------------------------------------------------|-----------------|
|   | Electronic medical record |   | Patient reported outcome     |   | Social media    |
|   | Claims                    |   | Health monitoring device     |   | Mobile health   |
|   | Registries                |   | Lab results                  |   | Pharmacy data   |
|  | Surveys                   |  | Genetic tests and biomarkers |  | Medical imaging |



## Real world evidence (RWE)

“ Clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD

Evidence supporting:

- Effectiveness & Safety
- Heterogeneity in treatment effect

***E.g., Ibrance (palbociclib) – FDA expanded the indication of Ibrance for male breast cancer using RWE from EHRs***



## Experiment Settings: 'Ideal World'



## Real World



### GLP1 agonists in CNS disorders

- **Long term** effect of GLP1 agonists on CNS disorders?
- Safety profile of GLP1 agonists in special populations (**pregnancy, children, aging populations**)?
- **Individualized** treatment effect and precision dosing of GLP1 agonists (e.g., clinically high/low benefit users, balance of intended vs. off-target effect)?
- **Head-to-head** comparisons of the benefit-risk profile among individual drugs (e.g., semaglutide vs. tirzepatide)?

# Real World GLP1 Agonist Use: **Accessibility & Disparities**

GLP1 agonist uptake

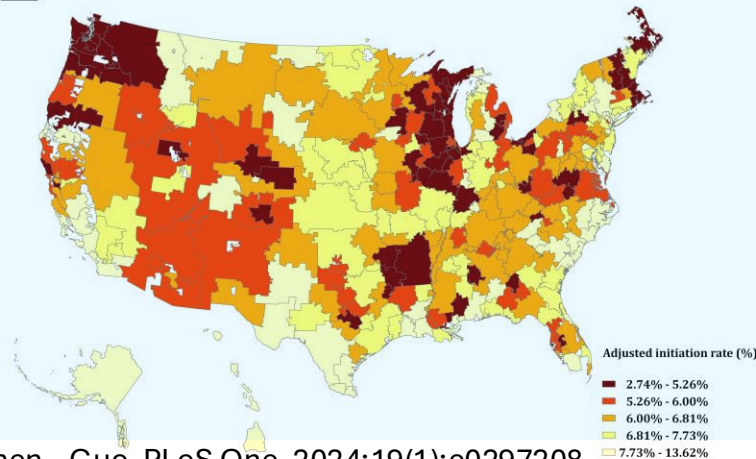


**Racial Disparities**

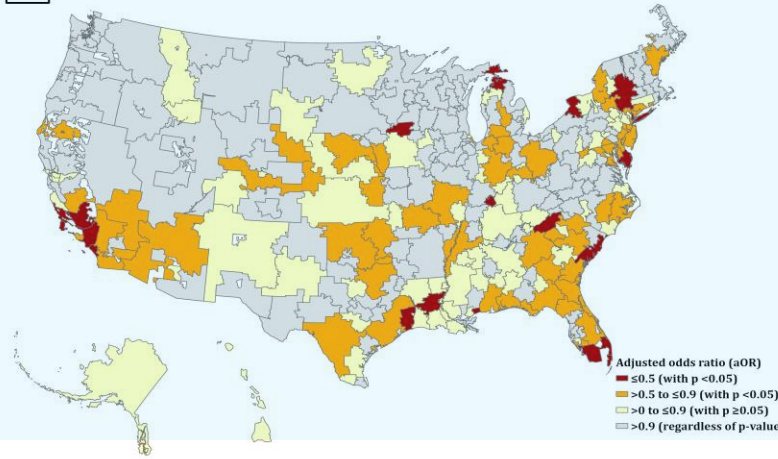


**SDoH (median household income)**

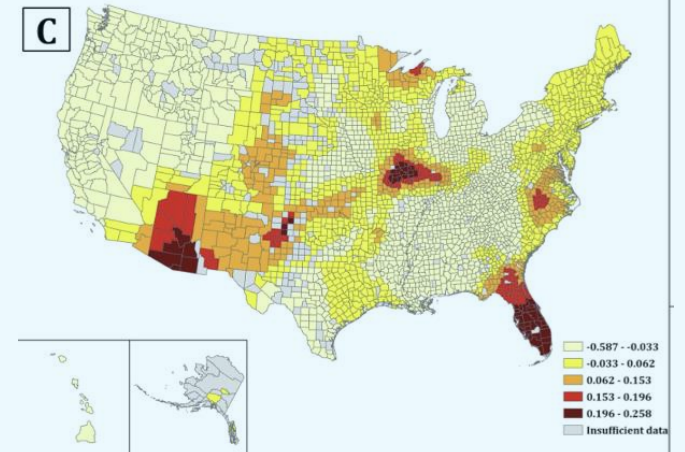
A



B



C



Chen...Guo. PLoS One. 2024;19(1):e0297208.

- Will GLP-1 agonists **exacerbate existing health disparities**?
- Causes underlying GLP1 agonist shortage and how such shortage impacts health outcomes and disparities?
- A **multistakeholder** prescription for improving equity in GLP1 agonist access: Pharmaceutical Manufacturers, Health Care Payers, Prescribers, Health Care Researchers...

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