PRGLAC Implementation Working Group of NACCHD

Meeting One

November 17, 2023

Historical Context

- **2016: Congress established PRGLAC** via the 21st Century Cures Act to identify and address gaps in knowledge regarding safe and effective therapies and vaccines for pregnant and lactating women.
- **Representation from all sectors**: multiple NIH institutes, CDC, FDA, AHRQ, HRSA, HHS, VA, professional societies, industry, academia, non-profit organizations. NICHD as lead.
- 2018: PRGLAC Report to Congress included **15 recommendations** to promote the inclusion of pregnant and lactating women in clinical trials.
- HHS Secretary extended PRGLAC charter, requesting guidance on implementation.
- 2020: PRGLAC issued an **Implementation Plan.**
- 2021: PRGLAC's charter expired

PRGLAC Recommendations

1. Integrate pregnant women and lactating women in the clinical research agenda
2. Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women
3. Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics
4. Remove regulatory barriers to research in pregnant women
5. Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women
6. Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant and lactating women
7. Reduce liability to facilitate an evidence base for new therapeutic products that may be used by women who are, or may become, pregnant and by lactating women

8. Develop separate programs to study therapeutic products used off-patent in pregnant women and lactating women using the NIH BPCA as a model
9. Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women
10. Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research
11. Leverage established and support new infrastructures/collaborations to perform research in pregnant women and lactating women
12. Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant women and lactating women
13. Optimize registries for pregnancy and lactation
14. The HHS Secretary should consider exercising the authority provided in law to extend the PRGLAC Task Force when its charter expires in March 2019 (extended to March 13, 2021)
15. Establish an Advisory Committee to monitor and report on implementation of recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research

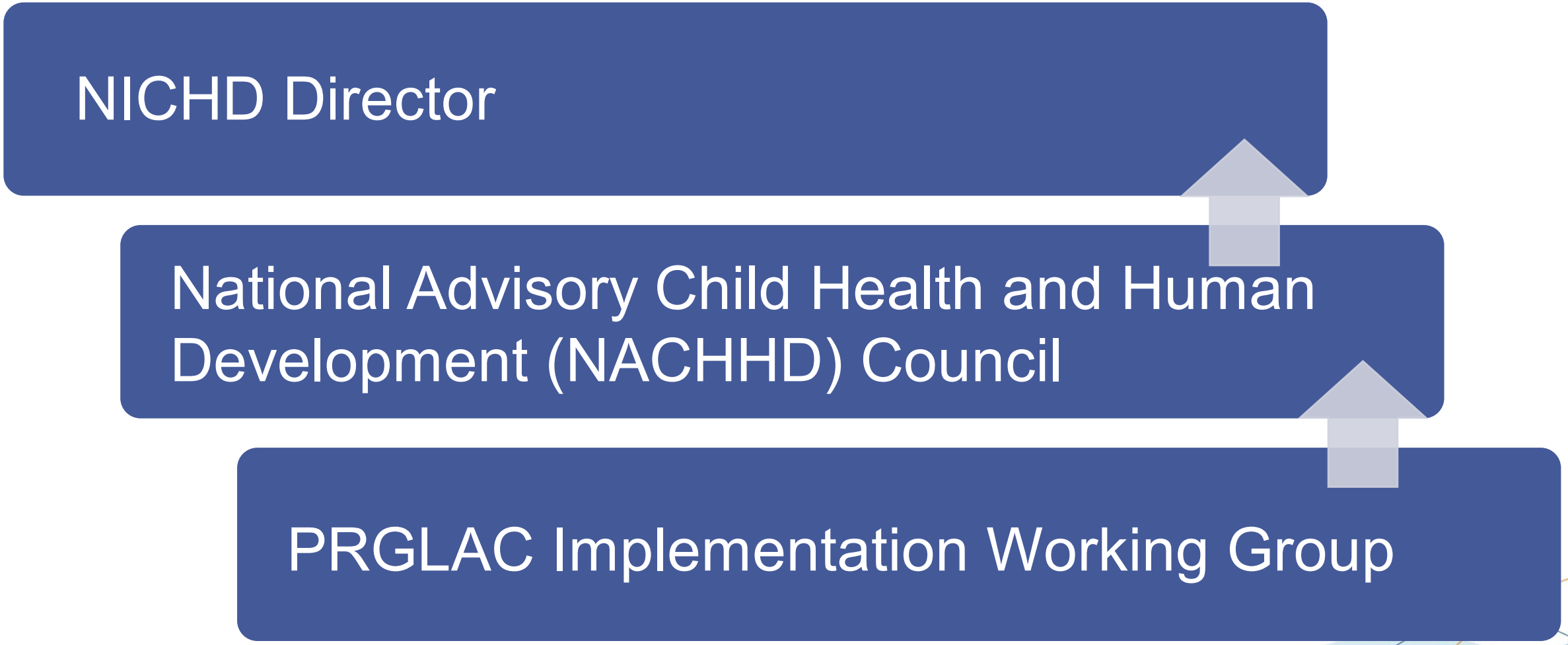
The Working Group of NACCHD

Congressional Language

Report Language from Consolidated Appropriations Act of 2023 (P.L. 117-328).

The Committee includes $200,000 for the creation of an Advisory Committee to monitor and report on the implementation of the recommendations from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). PRGLAC's 2020 Implementation Plan called for the creation of an Advisory Committee to monitor and report on implementing recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical trials. Additionally, the Committee directs the Secretary to submit a report to Congress within 180 days of the date of enactment of this Act outlining the Department's progress on implementing each of PRGLAC's 15 recommendations from the Implementation Plan it submitted to the Secretary in August 2020 (H. Report: 117-403).

Organizational Structure



The Working Group of Council and Objectives

- Recommended in the Implementation Plan (Recommendation #15)
- **The Working Group will:**
  - Review publicly available materials pertaining to implementation progress
  - Invite speakers from relevant Federal agencies or non-federal entities to discuss progress to-date on PRGLAC implementation plan, including possible barriers
  - Report their findings to NICHD Council and submit the report to Congress
    - Implementation progress
    - Provide recommendations to facilitate implementation, where necessary
    - Advise reconsideration, as relevant

Timeline

Information Gathering & Meetings:
September 2023–March 2024

- November 2023 (virtual)
- January 2024 (virtual)
- March 2024 (in-person)

Writing:
March–April 2024

- Draft WG report

Finalize Report:
June–July 2024

- June: Present findings to Council
- July: Finalize report and share with Congress

Review of Implementation Progress by Cluster

Cluster A: Conduct clinical research and trials

Cluster B: Education, outreach, training, and career development

Cluster C: Policy, regulatory, and liability

Cluster D: Registries and real-world data

Cluster E: Novel drug discovery and development

Working Group Work Plan

- **Meeting One (November 17, 2023)**:
  - Overview of PRGLAC 1.0, Cluster D (Registries and real-world data)
- **Meeting Two (January 19, 2024):**
  - Clusters A + E (Conduct clinical research and trials, Novel drug discovery and development)
  - Cluster C (Policy, regulatory, and liability)
- **Meeting Three (March 22, 2024, in person):**
  - Cluster B (Education, outreach, training, and career development)

Today's Agenda
Cluster D (Registries and Real-World Data)

Cluster A: Conduct clinical research and trials

Cluster B: Education, outreach, training, and career development

Cluster C: Policy, regulatory, and liability

Cluster D: Registries and real-world data

Cluster E: Novel drug discovery and development

Today's Focus
PRGLAC Recommendations 12 & 13

1. Integrate pregnant women and lactating women in the clinical research agenda
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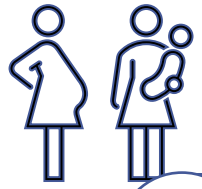

8. Develop separate programs to study therapeutic products used off -patent in pregnant women and lactating women using the NIH BPCA as a model
9. Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women
10. Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research
11. Leverage established and support new infrastructures/collaborations to perform research in pregnant women and lactating women
12. **Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant women and lactating women**
13. **Optimize registries for pregnancy and lactation**
14. The HHS Secretary should consider exercising the authority provided in law to extend the PRGLAC Task Force when its charter expires in March 2019 (extended to Mar 13, 2021)
15. Establish an Advisory Cmte to monitor and report on implementation of recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research

- Fulfilled
- Ongoing, planned
- Requires attention/reconsideration

Recommendation 12: Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant and lactating women

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12A. Design health record systems to link mother and infant records

12B. Leverage large studies and databases including health systems, health plans, surveillance systems, EMRs, registries

12C. Use novel data resources

12D. Use innovative methods of data analytics

12E. Require common data elements (CDEs) to facilitate collaboration and use

Recommendation 13: Optimize registries for pregnancy and lactation

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13A. Create a user-friendly website for registry listing

13B. Develop registry standards and CDEs that facilitate input of pertinent data with easy, transparent access to obtain information in real time: Include maternal, obstetric, and child outcomes, along with birth defects

13C. Facilitate access to data and transparency of information in registries: Use the ART registry as a model

13D. Develop disease-/condition-focused registries: Move toward a single registry for all therapeutic products with input from stakeholders

Questions?