

Society for Maternal-Fetal Medicine Presentation to the NICHD PRGLAC Implementation Working Group of Council

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March 22, 2024



Society for
Maternal•Fetal
Medicine

High-risk pregnancy experts

MISSION

SMFM supports the clinical practice of maternal-fetal medicine by providing education, promoting research, and engaging in advocacy to optimize equitable perinatal outcomes for all people who desire or experience pregnancy.



Society for
Maternal•Fetal
Medicine



Chronic Conditions

- Cardiovascular disease
- Hypertension
- Obesity
- Renal disease
- Asthma
- Sickle cell disease
- Lupus
- Epilepsy
- Thyroid disease
- Thrombophilia
- Mental health disorders

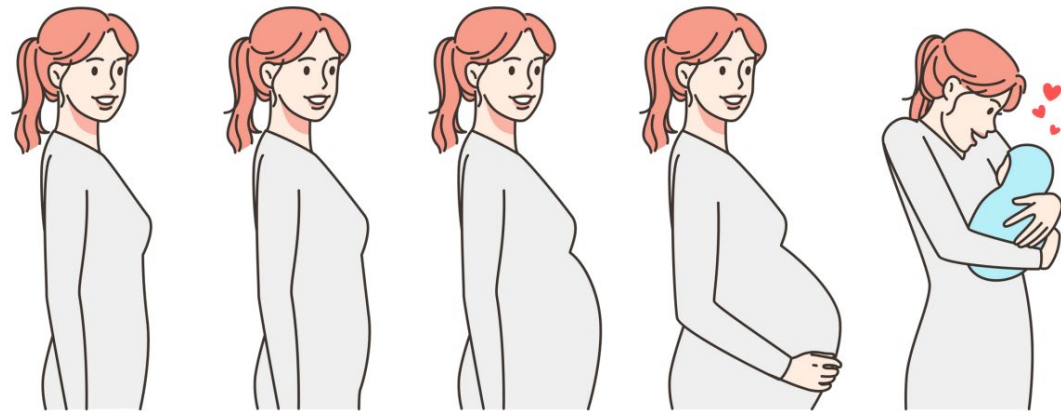
Infectious disease

- HIV
- Hepatitis
- Tuberculosis

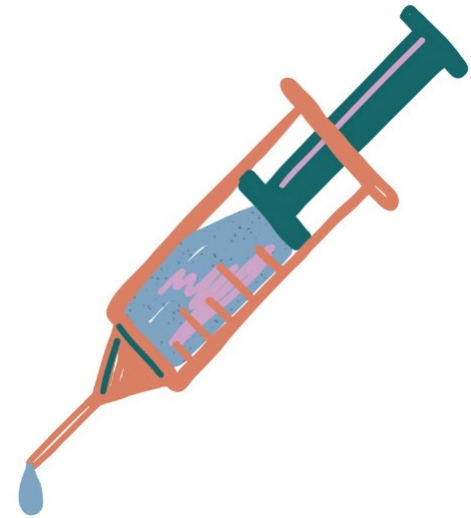
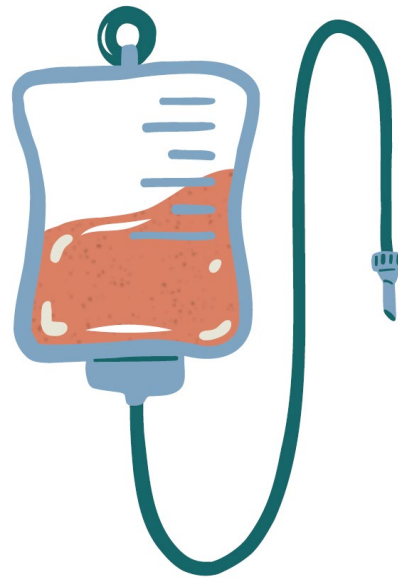


Preeclampsia or eclampsia
Gestational diabetes
Placental complications
Mental health disorders
Hyperemesis gravidarum

Our goal is to improve the health of women, so we see fewer high-risk pregnancies...



...no matter how successful our work, some women will need access to therapeutics and information about their safety and efficacy



PRIORITIES



- Require the Food and Drug Administration to update regulations to remove pregnant people as a vulnerable research population (Recommendation 1)
- Establish an online hub of information on clinical trials and registries enrolling pregnant and lactating people (Recommendation 6/Recommendation 13)
- Create an education campaign targeted toward consumers and clinicians on enrolling pregnant and lactating people in clinical trials and registries (Recommendation 5/ Recommendation 6)
- Initiate new clinical research at the National Institutes of Health on existing and new medications prescribed for pregnant and lactating people (Recommendation 9)
- **Reconstitute PRGLAC to monitor progress on its original 15 recommendations and subsequent implementation plan (Recommendation 15)**

Recommendation 10

Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research



10D

Develop guidance for IRBs and investigators about the inclusion of pregnant women and lactating women in research

- 10D.a. Revise federal regulations to include a definition of what constitutes “acceptable risk” for pregnant women’s or lactating women’s participation in research, including their offspring
- 10D.b. Standardize the informed consent procedures for enrolling pregnant women and lactating women in clinical research
- **10D.c. Provide IRBs with recommended practices to facilitate inclusion of pregnant women and lactating women in study designs**

Recommendation 3

Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics



3A

Develop and support training and career development opportunities in obstetric and lactation pharmacology and therapeutics for both clinical and basic science

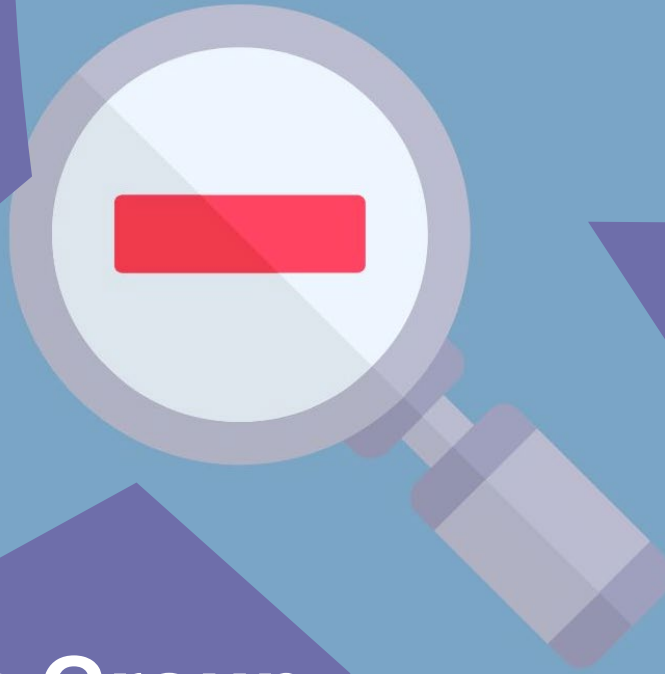
3B

Develop mentors in obstetric and lactation pharmacology and therapeutics for both clinical and basic science

3C

Increase the knowledge and engagement of healthcare providers regarding obstetric and lactation pharmacology and therapeutics

**Women First
Research
Coalition**



**Friends of
NICHD**

**Ad Hoc Group
for Medical
Research**

Recommendation 3

Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics



3A

Develop and support training and career development opportunities in obstetric and lactation pharmacology and therapeutics for both clinical and basic science

- 3A.a. Outlines existing types of training programs
- 3A.b. Recommends the establishment new training opportunities
- 3A.c Outlines challenges to expanding the workforce and opportunities to overcome those challenges
- **3A.d Recommends increasing awareness of career opportunities through recruitment and awareness as professional society (SMFM) meetings**

Recommendation 6

Develop and implement evidence-based communication strategies with healthcare providers on information relevant to research on pregnant women and lactating women



6A

Increase the knowledge of healthcare providers regarding obstetric and lactation therapeutics and research needs

6B

Increase the engagement of healthcare providers to disseminate information from research findings to their patients

6C

Increase the engagement of healthcare providers to discuss participation in clinical trials, research, and registries

6D

Develop appropriate strategies for sharing and interpreting research findings and risk

Recommendation 6

Develop and implement evidence-based communication strategies with healthcare providers on information relevant to research on pregnant women and lactating women



6A

Increase the knowledge of healthcare providers regarding obstetric and lactation therapeutics and research needs

- 6A.a. Foster two-way communication between research community and healthcare providers about obstetric and lactation therapeutic research needs
- **6A.b. Increase healthcare providers' awareness of obstetric and lactation therapeutic research needs**
- 6A.c. Encourage healthcare providers' engagement by increasing continuing education opportunities

Recommendation 6

Develop and implement evidence-based communication strategies with healthcare providers on information relevant to research on pregnant women and lactating women



6B

Increase the engagement of healthcare providers to disseminate information from research findings to their patients

- 6B.a. Maximize existing resources, adapting for use by healthcare providers and their patients
- 6B.b. Partner with professional societies to facilitate healthcare provider's knowledge of and access to information about research findings relevant to pregnant and lactating women
- 6B.c. Encourage healthcare providers' engagement by increasing continuing education opportunities

Recommendation 6

Develop and implement evidence-based communication strategies with healthcare providers on information relevant to research on pregnant women and lactating women



6C

Increase the engagement of healthcare providers to discuss participation in clinical trials, research, and registries

- **6C.a. Establish and maintain a readily accessible website to increase awareness of clinical research opportunities**
- 6C.b. Assist healthcare providers in finding time for discussions with patients about participating in research
- 6C.c. Explore incentives for healthcare providers to discuss clinical trials with their patients
- 6C.d. Include healthcare providers in planning for clinical trials

