

# Working Group #3: Communication Report

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## Working Group 3: Communication

- Co-chairs: Camille Fabiyi (AHRQ) and Kaveeta Vasisht (FDA)
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## Communication Recommendations

- 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 women and lactating women.
- 13. Optimize registries for pregnancy and lactation



5. Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women.

Has any part of the recommendation been implemented to date?

- Input available:
  - Paradigm shift - change to Common Rule published: Pregnant women are not regarded as a vulnerable population so that more research can be conducted;
    - however, extent of awareness among practitioners unknown, likely low;
    - need to disseminate widely



## 5. Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women.

What are the key factors needed to implement the recommendation?

- **Develop written national communications strategy**
  - Disperses mistrust of participating in research among women, their families, communities, HCPs
  - Look at pregnant and lactating persons (includes age and gender), separately
  - Create a matrix of stakeholders and actions
    - Target a variety of stakeholders
    - Develop framework for enhancing the approach for shared decision-making between patient and provider
      - Educate about benefits of breastfeeding as standard using available evidence
      - Articulate the benefits vs. risks
  - Identify knowledge gaps, trusted sources of information, costs, metrics
- Leverage lessons learned from stakeholders (OTIS, etc.)
- Optimize access to and use of government and other available, high-quality, evidence-based resources (facts sheets, FDA-OWH registry webpage)



5. Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women.

Are there any major obstacles that could prevent implementation?

- Costs
- Lack of clinical trials in pregnant and lactating persons
- Misunderstandings/misinformation about harms
- Mistrust with the healthcare system
- Lack of education and training on communication among HCPs
- Limited teaching among HCPs on how to use the available information



5. Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women.

What additional information or expertise do you need to complete your work?

- High quality messaging, including infographics, literacy considerations
- Stakeholders (OTIS, AACP, etc.)
- Lessons learned from other campaigns on lactation and pregnancy
- Marshall all available literature/resources (e.g., meta-analyses, social and behavioral change, WHO prioritization exercise)



6. Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant women and lactating women.

Has any part of the recommendation been implemented to date?

- Inputs available:
- FDA Guidance documents
- FDA OWH pregnancy registry webpage





6. Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant women and lactating women.

What are the key factors needed to implement the recommendation?

- Continuing education credits to educate HCPs
- Connect licensure/re-licensure to training for HCPs
- Knowledge management (e.g., learning communities)
- Leverage information from existing resources
- Increase engagement across all specialties, societies, membership orgs to disseminate information to HCPs



6. Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant women and lactating women.

Are there any major obstacles that could prevent implementation?

- Not addressing diversity of health literacy among patients
- Limited time for HCPs to engage patients
- Fears of medical liability
- Lack of one central location for information/resources
- Information from different HCPs (incl. doulas/midwives/CHWs)



6. Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant women and lactating women.

What additional information or expertise do you need to complete your work?

- Inventory of available resources and toolkits
- Understand resources (e.g., human, financial) for campaign



## 13. Optimize registries for pregnancy and lactation

Has any part of the recommendation been implemented to date?

- Inputs available:
  - FDA guidance-
    - Postapproval pregnancy safety studies, Clinical lactation studies guidance
  - FDA-OWH pregnancy registry webpage for FDA approved drugs
  - NICHD – PregSource research registry
  - AHRQ patient registry
  - PIANO registry
  - Taskforce report - Appendix



## 13. Optimize registries for pregnancy and lactation

What are the key factors needed to implement the recommendation?

- Awareness of and access to registries
- Patient recruitment and retention in registries
- Need clinical lactation studies
- Registries with lactation information
  - LacSource – (similar to PregSource) to capture short and long-term outcomes on maternal and infant health
- Potential to align registries and align studies with registries
- Making the business case for pregnancy and lactation with registries



## 13. Optimize registries for pregnancy and lactation

Are there any major obstacles that could prevent implementation?

- Patient recruitment (especially patients from underrepresented groups)
- Consent from both parents is currently needed to participate (varies by state)
- Quality of data (e.g., patient adherence to the treatment regimen)
- Lengthy registration process, age of mother & parental consent issues (may exclude pregnant minors)
- Lack of linked maternal-infant data through registries
- Registries are expensive to develop and maintain



## 13. Optimize registries for pregnancy and lactation

What additional information or expertise do you need to complete your work?

- Centralization of registry information
- Understand costs associated with recruitment and management of registries
- Multi-stakeholder engagement
- Understand existing IT infrastructure, cross-cutting across federal agencies & stakeholders (include informaticians)



Questions?