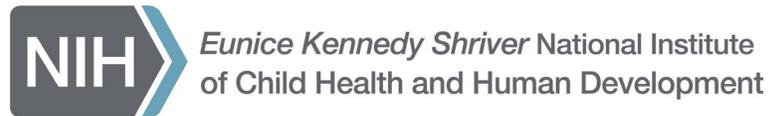


PRGLAC Working Group 3

Implementation Steps for Recommendations 5, 6, and 13



Definitions

- Health Care Providers (HCP)
 - Refers to providers, clinicians, dietitians, lactation consultants, nurses, nurse midwives, nurse practitioners, pharmacists, physicians, physician assistants, community health providers, genetic counselors





Recommendation 5

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

5A. Highlight the importance of research on therapeutic products in pregnant women and lactating women, including the impact of not taking the medication during pregnancy and lactation as well as the impact of not breastfeeding on mother and child

- In order to implement this recommendation the working groups suggests:
 - Conducting a needs assessment and environmental scan to develop a “**Call-to-Action**” to identify the federal agencies, stakeholders and messaging by:
 - Completing an request for proposal (RFP) to identify a public relations/marketing agency to develop the public awareness plan;
 - Identifying and collaborating with public and private organizations that have created successful campaigns (e.g., “Back to Sleep; Got Milk) and to capture the lessons learned;
 - Create and test effective messaging to also include messaging for women who do not take medications during pregnancy and lactation.
 - Collecting real-life patient stories to determine the impact of medications used during pregnancy and lactation.
 - Increasing awareness with the public and clinical investigators that women are not vulnerable by encouraging industry and academic investigators to include pregnant and lactating women in clinical trials.
 - Providing mothers with available safety data for an informed decision to be made by the provider and patient.
- Steps needed to implement this recommendation, and whether any have been started:
 - Continuing with PRGLAC to implement the recommendations;
 - Ongoing outreach to health care providers (HCPs) and consumers through agencies and societies such as CDC, NICHD, FDA OWH, ILCA, Academy of Breastfeeding, MotherToBaby.



5A. Highlight the importance of research on therapeutic products in pregnant women and lactating women, including the impact of not taking the medication during pregnancy and lactation as well as the impact of not breastfeeding on mother and child

- NICHD should lead the implementation of this recommendation.
 - Federal agencies such as NIH, FDA and CDC are needed to pull-through the recommendation to complement and support the on-going work with American College of Gynecology and Obstetrics, Society of Maternal and Fetal Medicine, American College of Clinical Pharmacy, American Pharmacists Association, American Association of Colleges of Pharmacy Organization of Teratology Information Specialists (OTIS-MotherToBaby), Teratology, March of Dimes, National Society of Genetic Counselors, American Medical Association, National Association of Nurse Practitioners in Women's Health, American Academy of Physician Assistants, United States Lactation Consultant Association
- Projected timeline is two years for the development of the public awareness campaign and implementation to follow.
- Budget is dependent on cost components involved with the needs assessment and overall public awareness campaign.



5B. Engage stakeholders such as the Department of Health and Human Services (HHS), professional societies, industry, advocacy groups, and public and global partners

- Create simple and consistent messages to be tailored to the various stakeholders to empower each constituent to have their “call-to-action;”
- Develop trusted content to reach each audience and track response rates;
- Track call-to-action to ensure each stakeholder is engaged.
- Key to success is having all stakeholders engaged with specific plans to ensure the public awareness campaign is reaching its desired outcome.



Take-aways for Recommendation 5

- NICHD* (*recommended) to lead an overall public awareness campaign to reach provider and consumers to discuss the benefits and risks of taking medications during pregnancy and lactation.
- Engagement with public and private stakeholders to complement and support the ongoing efforts and have a specific 'call-to-action' for each stakeholder to ensure the right information is shared between provider and mother.
- Encourage clinicians and women to consider enrolling in clinical trials before, during, and after pregnancy and lactation; and, participate in registries during and after birth.
- Completion of recommended efforts would require additional funding (e.g., appropriations).





Recommendation 6

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

6A. Increase the knowledge of health care providers regarding obstetric and lactation therapeutics and research needs

- Optimize communication with federal and advocacy partners
- Develop and disseminate lists
 - List of research needs identified by healthcare providers (HCP) and disseminated to funding agencies
 - List of available clinical trials identified by funding agencies and disseminated to HCP
- Develop Campaigns focused on HCP and researchers
 - Campaign providing education
 - Campaign providing awareness
- Involve stakeholders/federal agencies: NIH* (*recommend to lead), FDA, ACOG, SMFM, ACCP, APhA, OTIS-MotherToBaby, March of Dimes, JCAHO, Indian Health Service, industry and including specific national organizations for HCP and researchers
- Potential costs: Unknown at this time
- Potential timeframe: 3 years



6B. Increase the engagement of health care providers to disseminate information from research findings to their patients

- Establish trusted, up-to-date, far-reaching resource for healthcare providers (HCP) to access information regarding clinical trials (example, clinicaltrials.gov specifically for pregnancy and lactation) but
 - Needs to be user-friendly (examples, Medscape and Up-to-date)
 - Consider an App (example, USPSTF EPS)
- Educate HCP
 - How to access this clinical research resource
 - How to communicate with their patients regarding this resource
- Involve stakeholders/federal agencies: NIH, CDC, consider multi-agency approach
- Potential costs: unknown
- Potential timeframe: 2-3 years



6C. Increase the engagement of health care providers to discuss participation in clinical trials, research, and registries

- Determine barriers to HCP discussion of patient participation in clinical trials
- Improve HCP awareness and access with a central location for clinical trial information
- Provide scripts to aid HCP in how to inform patients of clinical trials/registries
- Improve efficiency in the clinical trial/registry enrollment system
- Incentivize HCP to enroll patients into studies with mechanisms such as continuing education credits
- The Common Rule, FDA guidance to industry, and PRGLAC are initial steps to be shared with HCP
- Stakeholders/federal agencies: NIH to lead but not to house the registries. Need registries to be in an easily accessible system; explore potential of third party to house the registry.
- Potential cost and timeframe: unknown



6D. Develop appropriate strategies for sharing and interpreting research findings and risk

- Determine mechanism through which to share data
- Determine the rules of data sharing (including appropriate disclaimers when data is insufficient to analysis or form conclusions including rights to publish the data)
- Develop a NIH campaign such as the NICHD Safe Sleep Campaign to disseminate information to HCP
- Incentivize HCP to review PRGLAC results by subsidized CE or subsidized access to information such as medical journal subscriptions
- Steps have been started but barriers persist
 - Several pregnancy/lactation specific resources are available for this, but nearly all of them require a purchase for access to the information
 - Studies are published in medical journals that are not available to all HCP
- Stakeholders/federal agencies: CDC to lead, ACOG, ACNM, AWOHNN
- Potential costs and timeframe: USAID's Knowledge SUCCESS grant as a model



Take-aways for Recommendation 6

- NICHD develop list of available research opportunities and a campaign to inform healthcare providers (HCP) of the available list and best methods including scripts by which to share this information with their patients
- Involve stakeholders/federal agencies: NIH* (*recommend to lead), FDA, ACOG, SMFM, ACCP, APhA, OTIS-MotherToBaby, March of Dimes, JCAHO, Indian Health Service, industry and including specific national organizations for HCP and researchers
- Establish trusted, up-to-date, far-reaching single resource for HCP to access information regarding clinical trials
- Determine barriers to HCP discussion of patient participation in clinical trials
- Incentivize HCP to enroll patients into studies with mechanisms such as continuing education credits





Recommendation 13

Optimize registries for pregnancy and lactation

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

- Steps:
 - Determine content, acceptable registry studies to post (i.e., is there a level of scientific rigor required); define goal, policies, procedures, governance, etc.
 - Develop public-private partnership to host a trusted website for comprehensive registry listings
 - Determine cost, identify web design company, make a plan for maintaining website and frequency of updates
 - Learn from other's experience: AHRQ's Registry of Patient Registries (RoPR), clinicaltrials.gov, FDA's OWH pregnancy exposure registry site, and NIH's NLM regarding LactMed
- Stakeholders to involve:
 - Various pharmaceutical companies, academic medical centers/universities or other organizations already engaged in registry studies (e.g., North American Antiepileptic Registry, OTIS), professional medical societies, health systems, payers, researchers, patients, NIH*/NLM, FDA*, AHRQ*, CDC
- Estimated cost for running website ~\$100,000+/year, based on RoPR
- Missing information:
 - Determine whether registration on this website is voluntary, or if regulation is required for registration so as to ensure a comprehensive listing.
 - Input based on other's experience for creating and maintaining a user-friendly website that is a trusted source



13B. Develop registry standards and common data elements 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

- Steps:
 - Input from stakeholders, healthcare providers; Discuss standards with experts who are actively conducting and/or evaluating results of such studies (CDC, MotherToBaby, conCEPTION, FDA, etc.)
 - Encourage electronic medical record companies to create standardized templates for information collection; meet with professional medical societies to encourage use of this standard form
 - Partner with NICHD ECHO to include long-term pediatric outcomes that also detail maternal medication exposure during pregnancy and lactation
 - Learn from other's experience: AHRQ's registry outcome measure harmonization project, AHRQ checklist of best practices/registry standards, NIH's Common Data Element Task Force, ACOG's Prenatal Record and reVITALize obstetric data definitions, ICHOM, and the Strategically Coordinated Women's Health Registry Network
- Stakeholders to involve:
 - Electronic medical record systems, pregnancy app developers, professional organizations, investigators conducting and/or evaluating outcomes of registry studies, HHS agencies (lead TBD*)
- Missing information:
 - A governance structure for who would "own" the common data element set, how it would be updated, and a funding stream for maintenance would need to be determined. Will use of the common data element set be voluntary or might there be a mechanism to make it mandatory?



13C. Facilitate access to data and transparency of information in registries; use ART registry as a model

- Steps:
 - Understand confidentiality/data ownership issues; understand the costs to facilitate data access and transparency
 - Understand the historical mistrust of populations with respect to research participation, how this intersects with registry data
 - Define a plan for when, what, and how data is shared (e.g., validation by experts, disclaimers/publication rights)
 - Clearly and widely communicate the existence of such data/registries, where and how to access these data
 - Learn from other's experience: AHRQ handbook includes extensive discussion about governance procedures, access to data, transparency; Alliance for Innovation on Maternal Health (AIM), CDC, NIH, MotherToBaby, AntiRetroviral Pregnancy Registry (ART)
- Stakeholders to involve:
 - CDC*, NIH, FDA
- Estimated timeline for steps:
 - 6 months to understand existing program experiences, costs, and other issues; Additional 1 year to determine data sharing plan
- Missing information: Governance, data use agreement policies, etc. (including costs for accessing the data by researchers). The group should consider HIPAA, IRB issues, patient protection and privacy issues.



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

- Steps:
 - Understand obstacles to achieve disease/condition-focused registries; make plan to overcome obstacles
 - Develop public-private partnerships, with respected stakeholders in the space, that can elicit collaboration from drug manufacturers and incentivize prescribers and participants
 - Make disease/condition-focused postmarketing studies in pregnant women a regulatory requirement when more than one prescription drug product (in adjunct or switchover) may be used by the target population
 - Learn from other's experience: FDA Guidance for Industry – Postapproval Pregnancy Studies
- Stakeholders to involve:
 - FDA, CDC*, NIH*, MotherToBaby, AntiRetroviral Pregnancy Registry, North American Anti-epileptic Drug Registry, Teratology Society; consultants who have advised drug manufacturers on disease-based registries
- Estimated timeline for steps:
 - Regulatory requirement established within 2 years
- Missing information:
 - Governance, data ownership and publication policies, etc. Funding stream for maintenance. Voluntary or mandatory participation.
 - Consider a distributed data model (e.g., PCORI, OHDSI, Sentinel)



Take-aways for Recommendation 13

- Explore developing a public private partnership with Industry, Foundation for NIH (FNIH), Academia and other private sector partners that would examine a knowledge gap related to a current, commonly used medication or therapeutic in pregnant and lactating women, as a use case
- Determine appropriate incentives for drug companies, prescribers and patients
 - It is very important to consider patients as partners, provide as much information in a timely manner.
- Determine voluntary vs. mandated components
- Establish policies for governance/data ownership
- Establish funding stream for maintenance
- Learn from others' experiences to further inform obstacles, cost estimates and timeline estimates
- Lead HHS Agency dependent on capabilities and alignment with mission; likely requires collaboration across multiple Agencies; consider if an outside organization is appropriate to lead





Discussion