March 14, 2012

Eugene Washington, MD, MSc
Chair, PCORI Board of Governors
Patient-Centered Outcomes Research Institute
Public Comments
1701 Pennsylvania Ave. NW,
Suite 300
Washington, DC 20006


Dear Dr. Washington:

On behalf of the members of the American College of Nurse-Midwives (ACNM), I am pleased to submit these comments on the recently issued Draft National Priorities for Research and Research Agenda Version 1, Presented for Public Comment January 23, 2012.

This research agenda seeks to elicit the best evidence for prevention, treatment and health care options that are aligned with patient needs. ACNM believes that women’s health care and maternity care must receive top priority in this research agenda. Childbirth accounts for nearly one in four hospital discharges and represents the most common and costly hospital condition paid for by either Medicaid or private insurers. Cesarean section is now the most common operating room procedure in the US, and the US maternal mortality rate doubled from 1987 to 2006; US women have a higher risk of dying from pregnancy-related complications than women in 40 other technologically-advanced countries. A research agenda that helps to determine best practices for optimal maternity care and outcomes would save women’s lives, decrease unnecessary procedures and save health care dollars.

In this context, we have provided the specific suggestions below.

About ACNM and our Membership
ACNM is the national professional organization representing Certified Nurse-Midwives (CNM®) and Certified Midwives (CM®). CNMs and CMs provide a full range of primary
health care services for women from adolescence beyond menopause. These services include primary care, gynecologic and family planning services, preconception care, care during pregnancy, childbirth and the postpartum period, care of the normal newborn during the first 28 days of life, and treatment of male partners for sexually transmitted infections. Midwives provide initial and ongoing comprehensive assessment, diagnosis and treatment. They conduct physical examinations; prescribe medications including controlled substances and contraceptive methods; admit, manage and discharge patients; order and interpret laboratory and diagnostic tests and order the use of medical devices. Midwifery care also includes health promotion, disease prevention, and individualized wellness education and counseling. These services are provided in partnership with women and families in diverse settings such as ambulatory clinics, private offices, community and public health systems, homes, hospitals and birth centers.

1. **Assessment of Prevention, Diagnosis, and Treatment Options.** Research should focus on 1) clinical options with emphasis on patient preferences and decision-making, 2) biological, clinical, social, economic, and geographic factors that may affect patient outcomes.

ACNM Recommendations:
- Use of informed consent documents for various places of birth and VBAC decision-making and study the impact of these on outcomes
- Collection of relevant data about patients’ decisions on place of birth and relationship with perinatal outcomes
- Increased research on the outcomes of midwifery care, particularly in hospital-based settings where most certified nurse-midwives/certified midwives (CNM/CMs) practice
- Increased support research on complimentary and alternative approaches to manage health and wellness for women.

2. **Improving Healthcare Systems.** Research should focus on 1) ways to improve access to care, receipt of care, coordination of care, self-care, and decision-making, 2) use of non-physician healthcare providers, such as nurses, and physician assistants, and the impact on patient outcomes, 3) system-level changes affecting all populations, diseases, and health conditions.

ACNM Recommendations:
- Support and study of community-based prenatal care services that include access to social and support services with CNM/CM as primary providers
- Research on outcomes (patient and cost) of CNM/CM-led care models compared to medical model care
• Examine provider opportunities and incentives to implement evidence based maternity care practices within hospital settings
• Study the cost effectiveness of CenteringPregnancy© prenatal care compared to traditional prenatal care

3. Communication and Dissemination. Research should focus on 1) strategies to improve patient and clinician knowledge about prevention, diagnosis and treatment options, 2) methods to increase patient participation in care and decision-making and the impact on health outcomes, 3) communication tools that enhance decision-making and achieve desired outcomes, 4) ways to use electronic data (“e-health records”) to support decision-making, 5) best practices for sharing research results.

ACNM Recommendations:
• Explore provider patterns of communicating risk of pregnancy conditions
• Research on the use of Paling Palettes ©and other risk communication tools to aid client understanding/decision making is needed.

PCORI encourages bold thinking about research projects. This means that PCORI is looking to you—patients, caregivers, professionals, and the general public—for help in shaping its national priorities and research agenda.

4. Addressing Disparities. Research should focus on 1) ways to reduce disparities in health outcomes, 2) benefits and risks of healthcare options across populations, 3) strategies to address healthcare barriers that can affect patient preferences and outcomes.

ACNM Recommendations:
• Research that studies the links between environmental stress, allopathic load, weathering, ecosocial theory, genetics, race, ethnicity, and gender with poor perinatal outcomes for vulnerable populations of women are critically needed
• CNM/CM could develop and test interventions to reduce stressors experienced by pregnant women and measure the short and long-term effects.
• Study of interventions to reduce inequities in health care and care access.

5. Accelerating Patient-Centered and Methodological Research. Research should focus on 1) ways to improve the quality and usefulness of clinical data in follow-up studies, 2) methods to combine and analyze clinical data that follow patients over time, 3) use of registries and clinical data networks to support research about patient-centered outcomes, including rare diseases, 4) strategies to train researchers and enable patients and caregivers to participate in patient-centered outcomes research.
ACNM Recommendations:

- Research to examine strategies to decrease unnecessary interventions in childbirth and to decrease cesarean birth.
- More perinatal research using the Optimality Index (a 54-item tool developed as a means to assess the process and outcomes of perinatal care in healthy women). This tool shows promise for clinical research, especially in evaluating subtle differences between study groups. The tool may also have utility as a quality benchmark to evaluate advanced practice nursing care nationally by using common definitions and metrics. The index could also provide a framework for studies to develop and test interventions that support normal birth by providing consistency in ways researchers evaluate quality care measures.
- Improved access to and quality of birth certificate data and other national perinatal data sources would help monitor patient outcomes nationally through outcomes research on large data sets.
- More incentives and opportunities for collaborative clinically relevant research are needed.
- Support for qualitative research methods would allow for the voices of childbearing women to shape the direction of future research.

In Conclusion
Midwifery-led models of care, both for prenatal and childbirth care, provide safe and satisfying care to women and have been shown to decrease costs, increase the incidence of normal, physiological birth and provide excellent outcomes for women and their newborns. Now is the time to address women’s health and maternity care options in our national research priorities.

Please contact ACNM Executive Director Lorrie Kline Kaplan, CAE, at (240) 485-1810 or lkaplan@acnm.org to discuss these comments further or if ACNM can be of additional assistance. Thank you for your attention to these important issues, and for consideration of these comments.

Sincerely,

Holly Powell Kennedy, CNM, PhD, FACNM, FAAN
President