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Federal Coordinating Council on Comparative Effectiveness Research  
The U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

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Dear Sir/Madam:

The American Academy of Pediatrics (AAP) is pleased to have the opportunity to provide input on the Federal Coordinating Council's deliberations on comparative effectiveness research. The Academy and its 60,000 members applaud the FCC's efforts to assess the utility of comparative effectiveness research in mitigating increases in overall healthcare spending and to permit the public, providers, and health care purchasers to make more evidence-based decisions about available treatment options. Increasing rates of chronic conditions among children and adolescents and the opportunities for preventing adult health concerns in childhood make for a compelling need to focus comparative effectiveness research on several child health topics.

The AAP urges the FCC to base comparative effectiveness research on the pediatric priorities articulated by the Institute of Medicine (IOM) Priorities Areas for National Action. Relevant child health topics on this list include:

- Care coordination (cross-cutting across many conditions)
- Self-management/health literacy (cross-cutting)
- Asthma—appropriate treatment for persons with mild/moderate persistent asthma
- Children with special health care needs
- Type I and Type II Diabetes—focus on appropriate management of early disease
- Childhood and adolescent immunizations
- Major depression—screening and treatment, particularly in the adolescent population.
- Medication management—preventing medication errors and overuse of antibiotics
- Nosocomial infections—prevention and surveillance
- Pregnancy and childbirth—appropriate prenatal and intrapartum care
- Obesity – appropriate prevention, management, and treatment options.

More specific areas for research of comparative effectiveness in pediatrics follow:

*Asthma:* Compare relevant asthma outcomes across groups of patients with good or poor adherence to asthma controller therapy, and to determine the value of using inhaled steroid treatment alone or in fixed combinations with long-acting bronchodilators. Also, compare use of pulmonary function tests in the office versus home peak flows in management of asthma in children to reduce emergency visits and hospitalization. There also is a growing interest in measuring the ability of children to self-manage their asthma condition. This is of critical importance due to the amount of time children spend in settings other than the home (eg, school, athletic events).

- *Behavioral*: Identify the most effective approach for addressing behavior/conduct problems (including oppositional/defiant disorder, parent/child interaction problems, conduct disorder) in young children through comparison of structured and unstructured behavioral interventions, family and individual therapy (including school-based interventions), and/or medications. Assess alternative approaches for preventive care visits to stimulate language development during the first three years of life and promote school readiness. Assess the effectiveness of interventions to manage children with autism. Additional research in the effectiveness of various approaches to treating adolescent depression, particularly for those suffering from chronic depression.
- *Children and Youth with Special Health Care Needs (CYSHCN)*: Compare the outcome, cost, family satisfaction, and functional participation for those CYSHCN with complex chronic disorders with and without formal medical care coordination models, such as Medical Home, to integrate primary-tertiary care. Assess the effectiveness of physical therapy, occupational therapy, and speech therapy in improving functioning for CYSHCN. Assess the effectiveness of common surgical procedures for CYSHCN including g-tube placement, Nissen fundoplication, and spinal rods/fusion for scoliosis. Assess the transitions of CYSHCN from pediatric to adult health care.
- *Immunizations*: Assess the effectiveness of systems such as clinician-based reminders and recalls, immunization registries, and financial incentives to raise immunization up-to-date rates. Assess adverse events associated with immunizations.
- *Integrative Medicine*: Compare the effectiveness versus risks of an integrative medicine model of care (for primary, secondary or tertiary prevention) for one of a number of conditions in the pediatric population, particularly chronic conditions such as pain.
- *Nutrition/Obesity*: Assess strategies to promote successful breastfeeding during the first 6 months of life. Assess feeding practices and obesity prevention strategies in all age groups, especially in infants. Assess the effectiveness of special formulas and nutritional supplements used to promote growth in CYSHCN. Assess alternative interventions to manage GERD in children to prevent failure to thrive.
- *Overuse of Antibiotics*: Assess care processes and system changes to reduce excessive use of antibiotics, especially related to upper respiratory infections and otitis media.
- *Nosocomial Infections*: Assess methods to reduce the hospital acquisition of resistant pathogens in the nursery and inpatient units
- *Preventive Care*: Assess the efficiency and effectiveness of new and innovative models for the delivery of preventive care in the medical home setting.

The FCC should include emerging delivery systems and programs as part of its comparative effectiveness research efforts. There also should be a focus on health disparities so that the goal of the health care system is health equity for all children. In addition, the FCC should include a serious examination of the effectiveness of current and emerging quality improvement methodologies as they relate to changing culture and driving change at the national, state, community, and practice levels. The science of quality improvement implementation, particularly in the pediatric population, deserves special attention as the FCC embarks on this landmark opportunity.

The AAP embraces the goal of establishing improved quality of care through the promotion of evidence-based decision-making, improved efficiency, and ultimately cost savings throughout the health system. Nevertheless, the Academy has several concerns regarding how a federal

comparative effectiveness research body can best measure, and subsequently, evaluate pediatric services. In particular, as the depth and breadth of pediatric research lags behind that of adult research, we believe it is critical to target new research funding to study clinical interventions in children and to develop the necessary information for comparative effectiveness decisions.

The AAP offers the following suggestions to the FCC:

- Data gathered and processed by the FCC must not be derived only from Medicare data, but should include data from Medicaid and the Children's Health Insurance Program as well as from commercial health plans, where available. The Immunization Safety Office of the Centers for Disease Control utilizes the Vaccine Datalink System to monitor vaccine safety in a large population of privately insured children. This same population of children could be utilized to answer comparative effectiveness questions.
- Due to the lack of available data in pediatrics, we urge the FCC to analyze differences in clinical outcomes among patient subgroups, such as children and racial and ethnic minorities. As a unique and diverse group of individuals, children have health care needs that are distinct from those of adults. As a result, the FCC should include representatives from the pediatric community and address pediatric-appropriate research.
- The FCC needs to consider how to improve enrollment of children, particularly children from minority populations, in randomized controlled trials, especially drug trials, based in part on the IOM report, *Ethical Conduct of Clinical Research Involving Children*.
- The FCC should expand the evaluation of medications, devices, and interventions to include alternative models of service delivery and the implementation of structured quality improvement methodologies. It also should actively seek the meaningful input of families in designing its vision and strategic framework, operate under a transparent process in the production of objective information, and explore its impact on the promotion of innovation in the health care sector, particularly in advancements in health care for children with chronic conditions.

The American Academy of Pediatrics appreciates the opportunity to provide comments on the Federal Coordinating Council's initiatives for comparative effectiveness research. We welcome the opportunity to provide assistance as the FCC continues its efforts to provide thoughtful research and recommendations to improve the delivery of our nation's health care. If you have any questions or concerns regarding these comments, please contact Junelle Speller at 847/434-7650.

Sincerely,



David T. Tayloe, Jr, MD, FAAP  
President

DTT/js