

## 7-country study examining the causes of childhood pneumonia outlined

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The scientific journal *Clinical Infectious Diseases* has released its March Special Supplement focusing entirely on the research design of and pilot data from the Pneumonia Etiology Research for Child Health (PERCH) Project, which seeks to identify the causes of pneumonia among the world's most vulnerable populations. PERCH, led by the International Vaccine Access Center (IVAC) at the Johns Hopkins Bloomberg School of Public Health in collaboration with 7 research centers worldwide, is the largest and most comprehensive study of the etiology of childhood pneumonia conducted in more than 20 years. Pneumonia is the leading cause of death among children under age five, but while the disease is easy to recognize, the causes of pneumonia, which claims the lives of approximately 1.6 million children each year, are not.

"This supplement provides a unique opportunity to share our rigorous, deliberative and inclusive process in designing the PERCH study. We hope that our work can benefit other researchers and result in a greater degree of <u>standardization</u> in child <u>pneumonia</u> research," said Orin Levine, lead investigator on the study and professor of International Health at Johns Hopkins Bloomberg School of Public Health. "In learning more about the causes of pneumonia, we can design better treatments, diagnostics and vaccines to save children's lives."

PERCH, which is made possible by a grant from the Bill & Melinda Gates Foundation, will enroll up to 6,000 children 1-59 months old with severe or very severe pneumonia and a similar number of healthy children from seven selected study sites in order to understand the



interplay between risk factors and infection by deadly viruses and bacteria. The seven study sites represent diverse geographic areas and disease ecologies that are expected to face the highest pneumonia disease burden in the coming decades and include Thailand, Bangladesh, The Gambia, Kenya, Mali, South Africa and Zambia.

PERCH was designed with the consultation of 16 external pneumonia experts over the course of 18 months. These experts informed the epidemiologic, clinical, laboratory and statistical design components of the study. Investigators from the seven study sites also contributed to the study design, and in addition ensured local relevance and feasibility.

The timing of PERCH is crucial as the pneumonia landscape has changed significantly since the last major multi-site research studies were conducted by the Board of Science and Technology for International Development (BOSTID) in the 1980s. Bacterial pathogens, especially *Haemophilus influenzae* and *Streptococcus pneumoniae*, were recognized to be the major etiologies of pneumonia mortality. Consequently, treatment and prevention strategies have focused primarily on targeting these agents. Since the BOSTID studies, the world has experienced the HIV pandemic, increased malaria control and a scaled up effort to introduce pneumococcal and Hib conjugate vaccines, as well as advancements in scientific technologies. The results of the PERCH study, strategically designed to reflect the expected epidemiological situation in 2015 and beyond, will provide important evidence to guide the next generation of pneumonia prevention and treatment approaches.

"As the world's epidemiologic settings change, we must stay ahead of the next challenge so we do not lose ground in the fight to reduce child mortality," said Dr. Katherine O'Brien, co-principal investigator of PERCH, and professor of International Health at Johns Hopkins. "PERCH will study and evaluate pneumonia and its causes using



previously unavailable innovative and more sensitive diagnostic tools."

The <u>Clinical Infectious Diseases</u> supplement will include 15 articles providing the project's scope and methodology, while addressing the rationale behind the approaches to and design components of PERCH. In addition, the supplement provides results from two PERCH pilot projects in Kilifi, Kenya and Noumea, New Caledonia, which helped to inform the design of the larger study. Also included in the supplement is a review of previous and other ongoing pneumonia etiology studies (88 studies published from 2000 to June 2010 plus 65 unpublished studies), which reinforced the need for standardization of methods and analyses for present and future etiology studies in order to optimize their cumulative potential.

Results of the PERCH project are expected to become available in 2014. The study protocol, case report forms and standard operating procedures are available online at <u>http://www.jhsph.edu/ivac/perch.html</u>.

Provided by International Vaccine Access Center

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