Introduction

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This supplement was created to provide transparent documentation and access to the planning phase of the largest, multi-site etiological study for childhood pneumonia being undertaken since the Board of Science and Technology for International Development (BOSTID) studies were done in the 1980s [1]. The Pneumonia Etiology Research for Child Health (PERCH) study will use a case-control design to characterize the etiologic distribution of pathogens that are causing severe pneumonia among children under 5 years of age who have been hospitalized for their illness in seven countries in Africa and Asia (Africa: Basse, Gambia; Kilifi, Kenya; Bamako, Mali; Soweto, South Africa; Lusaka, Zambia. Asia: Kamlapur and Matlab, Bangladesh, Sao Kaeo and Nakhon Phanom, Thailand). A large number of individuals and institutions have provided input, guidance, advice, literature reviews, and materials that have contributed to the study design and procedures. A specific goal of the study was to assure that the processes, information and decisions are made fully available to other researchers in order to leverage the lessons garnered from the development of the PERCH protocol for the greatest possible impact.

The PERCH project is coordinated by a core team of individuals who have expertise in epidemiology, clinical medicine, statistics, laboratory diagnostics and study conduct; the PERCH Core team is comprised of individuals from the Johns Hopkins Bloomberg School of Public Health, the University of Otago and the Oxford University/KEMRI Wellcome Trust.

The PERCH Core team commissioned a Pneumonia Methods Working Group (PMWG), which consists of 16 external experts in these domains. The PMWG provided critical, consensus-driven advice on 90 clinical, laboratory and epidemiologic design issues that were difficult to resolve. Issues have been referred to the PMWG for which alternate approaches would meaningfully impact the study results and for which controversy or lack of consensus existed on the optimal approach. The process and content of the PMWG work is described further by Levine et al [2].

The site selection was carried out by a request for proposals, with 52 applicants responding to the request. A Site Selection Committee, external and independent of the PERCH Core team, was charged with reviewing the applications and providing a score for each applicant. These were reviewed during an in-person meeting of the Site Selection Committee, and the short list was reviewed for strategic areas of focus by the PERCH Core team and the study sponsor, The Bill & Melinda Gates Foundation.

The papers in this supplement aim to address the rationale behind the epidemiologic, clinical, laboratory and statistical design components of the PERCH study. The papers describe the output of this process, with some presenting the key decision points and justifications for certain elements of the study design, and others describing the background documentation

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and literature review that formed the basis of these decisions. In addition, this supplement offers several papers that address ancillary issues to the main study, such as the bioethics of conducting pneumonia research in developing countries and an approach to post-mortem specimen collection. Lastly, the supplement contains two papers describing pilot etiological childhood pneumonia studies that were undertaken in Kenya and New Caledonia, which provided data to design the larger PERCH study. In addition to this supplement, additional documentation can be found in the full set of PMWG documents and the PERCH protocol, which are freely available for consultation and consideration (http://www.jhsph.edu/ivac/perch.html).

The decisions reached and incorporated into the PERCH study design are not the only ones that could have been reached, as in some cases, the decisions were based on expert opinion rather than firm data. We offer these papers as a means to share with those who were not present during the process and deliberations, and for those who were involved, a set of written documents that reflects the process and deliberations undertaken. Designing epidemiologic studies inherently requires some degree of subjective decision making, and we do not necessarily believe all future pneumonia etiology studies should strictly follow the PERCH methodology. However, the process of decision making for PERCH was rigorous, deliberative and inclusive and took 18 months to complete. We hope that these efforts can benefit other researchers and result in a greater degree of-standardization in the field of childhood pneumonia research.

Notes

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