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LETTER

A Response to: Letter to the Editor Regarding "Cost-Effectiveness of the 13-Valent Pneumococcal Conjugate Vaccine (PCV13) Versus Lower-Valent Alternatives in Filipino Infants"

Johnna Perdrizet · Emily K. Horn · Winniefer Nua · Judith Perez-Peralta · Jennifer Nailes · Jaime Santos · Anna Ong-Lim

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ABSTRACT

This communication seeks to address the questions of Dhere and colleagues in their letter on our study "Cost-effectiveness of the 13-valent pneumococcal conjugate vaccine (PCV13) versus lower-valent alternatives in Filipino infants." We hope to provide clarity on each of the three potential misunderstandings of our cost-effectiveness analysis that were raised by Dhere and colleagues.

J. Perdrizet (✉) · E. K. Horn
Global Health Economics and Outcomes Research, Pfizer Inc., 235 42nd Street, New York, NY 10017, USA
e-mail: johnna.perdrizet@pfizer.com

W. Nua · J. Perez-Peralta
Pfizer Inc., Makati City, Philippines

J. Nailes
Research Institute for the Health Sciences, University of the East Ramon Magsaysay Memorial Medical Center, Quezon City, Philippines

J. Santos
Infectious Diseases Section, Philippine Children's Medical Center, Quezon City, Philippines

A. Ong-Lim
Infectious and Tropical Disease, Department of Pediatrics, College of Medicine-Philippine General Hospital, University of the Philippines, Manila, Philippines

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THE SURVEILLANCE DATA USED IN OUR STUDY IS THE ONLY EXISTING DATA SOURCE FOR SEROTYPE DISTRIBUTIONS, AND IS ALSO USED BY THE PHILIPPINE DEPARTMENT OF HEALTH TO MAKE PUBLIC HEALTH DECISIONS

Dhere and colleagues question the appropriateness of using Research Institute for Tropical Medicine (RITM) data to estimate invasive pneumococcal disease (IPD) serotype distribution and the resulting serotype coverage of PCV13-PFE, PCV10-GSK, and PCV10-SII. In our discussion, we acknowledged that using data from RITM, which is a passive surveillance system with reporting from select sentinel sites, has limitations, and additionally stated that "results need to be interpreted with caution given the lack of contemporary epidemiologic surveillance data for all ages." The Philippine Department of Health (DOH) emphasized that, due to these limitations, "the impact of implementing PCV vaccination over the past years cannot be ascertained." Thus, comparing serotype distributions in past years such as in Dhere and colleagues' letter would not be

appropriate. However, the Philippine DOH specified that, despite these limitations, "surveillance data from the RITM is the only source of evidence on the prevalence of pneumococcal serotypes in the country" [1]. Therefore, the Philippine DOH uses the same RITM data for their own cost-utility analysis of PCVs that they conducted in their 2020 Health Technology Assessment (HTA) to determine whether PCV represents good value for money.

MODELING THE ENTIRE POPULATION ACROSS ALL AGES IS REQUIRED TO CAPTURE THE INDIRECT EFFECTS OF PEDIATRIC PNEUMOCOCCAL VACCINATION PROGRAMS

In Dhere and colleagues' opinion, modeling the impact of pediatric PCV vaccination among older age groups is irrelevant in estimating the cost-effectiveness of PCV national immunization programs (NIPs). PCVs not only have proven direct effects in vaccinated individuals but also have proven indirect vaccine effects in unvaccinated individuals. Herd protection, or protection extended to those who do not receive the vaccine due to a disruption in disease transmission, is a well-documented and established benefit of PCVs [2]. Herd effects are observed through population decreases in PCV-type pneumococcal disease, and thus are relevant in modeling analyses in order to capture the clinical and economic value that these interventions bring to society. Across the hundreds of published economic evaluations of pediatric PCV NIPs, it is the gold standard modeling practice to capture the impact of PCVs across the entire country population, because of the significant indirect protection that vaccines provide among unvaccinated age groups [3]. As such, failing to capture the public health impact of PCV NIPs across the entire population would significantly misrepresent the cost-effectiveness of PCVs.

CLINICAL UNCERTAINTY AROUND PCV10-SII REMAINS DUE TO ITS UNKNOWN IMPACT ON NON-INVASIVE PNEUMOCOCCAL DISEASE, HERD EFFECTS, AND RE-EMERGENCE OF NEWLY UNCOVERED SEROTYPES

Dhere and colleagues suggest that there are no uncertainties surrounding PCV10-SII clinical effects in the real world. As we state in our study, PCV10-SII is licensed based on safety and immunogenicity data from the Serum Institute of India's pivotal phase 3 trial, however "there are no efficacy or effectiveness data for PCV10-SII demonstrating its impact on invasive or non-invasive pneumococcal disease, nasopharyngeal carriage, or herd effects" to date [4]. Moreover, PCV10-SII is the first PCV to not include serotypes 4 and 18C in its formulation, thus the extent of pneumococcal disease re-emergence that may occur in countries that once had vaccine pressure on these serotypes is unknown. To account for the lack of clinical trial and real-world data to inform PCV10-SII model parameters, we conducted the PCV10-SII analysis using a lower and upper bound of all plausible values. Even when we assumed that PCV10-SII will have equal vaccine effectiveness against IPD, pneumonia, and acute otitis media in vaccinated children and equal herd protection among unvaccinated individuals as PCV13-PFE for mutual serotypes, and that serotypes 4 and 18C will remain stable once protection is removed against these serotypes, PCV13-PFE is estimated to remain cost-saving compared with PCV10-SII in the Philippines.

We thank Dhere and colleagues for their questions and hope our responses were satisfactory.

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Compliance with Ethics Guidelines. This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

Data Availability. Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

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