

The Heptavalent Pneumococcal Conjugate Vaccine Immunization Project by Bangkok Metropolitan in Thai Infants

Wongwat Liulak MD*,
Usa Thisyakorn MD**

*Communicable Disease Control Division, Health Department, Bangkok Metropolitan, Bangkok, Thailand.

**Department of Pediatrics, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand

Background: *Streptococcus pneumoniae* is the most common cause of bacteremia, sepsis, meningitis, pneumonia, sinusitis and otitis media in children worldwide. Several studies have shown that the heptavalent pneumococcal conjugate vaccine (PCV7) is highly immunogenic, safe and effective against disease caused by serotypes contained in the vaccine.

Objective: To determine the safety and efficacy of PCV7 administered to Thai infants.

Material and Method: Ninety-seven infants received four doses of PCV7. Three primary doses were given 2 months apart starting at the age of 2-6 months and the booster dose at the age of 12-15 months. Reactogenicity and safety were evaluated from parent reports. The impact of PCV7 on the occurrence of invasive pneumococcal disease (IPD) among vaccinees was examined.

Results: PCV7 was well tolerated. Two infants reported low-grade fever. None of the vaccinees developed IPD during the 1-year period following the first PCV7 dose.

Conclusion: Primary immunization followed by a booster dose of PCV7 appeared safe and efficacious in preventing IPD in Thai children.

Keywords: Invasive pneumococcal disease, Pneumococcal conjugate vaccine, Thailand, Infants

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Streptococcus pneumoniae (pneumococcus) is responsible for a wide spectrum of infections ranging from asymptomatic carriage to overwhelming sepsis⁽¹⁾. Recognizing the high burden of pneumococcal disease in young children and the safety and efficacy of PCV7 in this age group, the World Health Organization (WHO) recommends that it should be a priority to include this vaccine in national immunization programs, particularly in countries where mortality among children aged < 5 years is > 50/1000 live births or where > 50,000 children die annually⁽²⁾. In Thailand PCV7 has been licensed and for sale since 2007 but is not currently included in the universal immunization schedule. The vaccine is used mainly in the private sector among families who can afford the cost.

In honor of the auspicious occasion of His

Majesty King Bhumibol Adulyadej's 80th Birthday Anniversary on the 5th of December 2007, the Bangkok Metropolitan Administration organized a project titled, "Prevention of invasive pneumococcal disease in children". All children born on the 5th of December 2007 were invited to join the project and receive PCV7 free of charge. We assessed the safety and efficacy of PCV7 among vaccinated children.

Material and Method

Children who were born in the Bangkok Metropolitan area on December 5, 2007 were eligible to receive four doses of PCV7 starting at age 2 months, with a primary series of three doses 2 months apart and one booster dose at 12-15 months of age. Safety and reactogenicity were assessed after each vaccine dose as recommended by the Thailand Ministry of Public Health⁽³⁾. Before each vaccination, the parents were interviewed for the adverse events of previous vaccination. The telephone interviews for adverse events were conducted at 2 weeks and 1 month after the

Correspondence to:

Thisyakorn U, Department of Pediatrics, Faculty of Medicine, Chulalongkorn University, Bangkok 10330, Thailand
Phone: 0-2256-4912
E-mail: fmeduty@mail.md.chula.ac.th

thirds and fourth dose of PCV7. To identify possible IPD cases after vaccination, vaccinees were followed-up every 2 months for the first 6 months and every 3 months thereafter for 1 year after the first PCV7 vaccination. Home visit by the health officer were do to the families as needed.

Results

There were 149 children born in Bangkok on the 5th of December 2007. Ninety-seven children joined the project while 52 eligible children were unable to join due to migration to other provinces after birth. The age at first PCV7 vaccination was between 3-6 months (Table 1). Of 97 children who joined the project, 90 (93%) completed a three-dose primary PCV7 series with a booster dose. Seven children (7.2%) did not receive all four doses of PCV7; three received a three-dose primary series without the booster dose and four children received only the first dose of PCV7. The reason for not completing all doses was migration to another province in each case.

Following the guidelines for surveillance and investigation of adverse events following immunization, it was found that 2 children developed low-grade fevers within 24 hours after the first PCV7 dose. There was no other local or systemic reactions reported. In the one-year follow-up, there was no report of hospitalization, pneumonia or IPD.

Discussion

PCV7 has been licensed and for sale in Thailand since 2007 but is not currently included in the universal immunization schedule, despite recommendations for routine immunization in children by WHO⁽²⁾. The vaccine is used mainly in the private sector by children whose families can afford it. The project entitled, "Prevention of IPD in children" organized by the Bangkok Metropolitan Administration in honour of the auspicious occasion of His Majesty King Bhumibol Adulyadej's 80th Birthday Anniversary has successfully confirmed the safety and efficacy of

PCV7, as previously found in studies in the other countries⁽⁴⁾.

Of the 97 children who joined the project, 7 (7.2%) did not complete the three-dose primary PCV7 series and booster dose, because they moved to other provinces. Despite the high migration rate of persons in the Bangkok Metropolitan area⁽⁵⁾, 92.8% of the children in this project received all four PCV7 doses. This demonstrates the successful efforts by all health centers under the Bangkok Metropolitan Administration to ensure high immunization coverage.

The incidence of IPD requiring hospitalization in rural Thailand was found to range from 10.6 to 28.9 per 100,000 population. These estimates are in a similar range to those in the USA before pneumococcal conjugate vaccine introduction, providing important data to guide public health policy and inform the vaccine decision-making process in Thailand^(1,6). Research studies evaluating the cost-effectiveness of PCV7 in Thailand are also needed to further inform vaccine policy discussions. The need for these discussions is made more pressing by the rapid emergence of drug-resistant pneumococci causing IPD in Thailand^(1,7,8). Increasing pneumococcal infections and antimicrobial resistance highlight the need for developing an effective vaccination program to reduce the risk of pneumococcal disease in Thai children.

Conclusion

In honor of the auspicious occasion of His Majesty King Bhumibol Adulyadej's 80th Birthday Anniversary on the 5th of December 2007, the Bangkok Metropolitan Administration has successfully organized a project titled, "Prevention of IPD in children". Ninety-seven children joined the project and received at least one dose of pneumococcal conjugate vaccine. The only adverse events identified were two children with low-grade fevers after the first vaccine dose. No children had IPD during the 1-year follow-up period.

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Table 1. Age distribution of children at receipt of first PCV7 dose.

Age	Number of children
3 months	55
4 months	31
5 months	10
6 months	1

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โครงการฉีดวัคซีนป้องกันโรคไอพีดี (*Invasive Pneumococcal Disease IPD*) ในเด็กไทย โดยกรุงเทพมหานคร

วงวัฒน์ ลิ่วลักษณ์, อุษา ทิสยากร

เนื่องในมหาวโรกาสที่พระบาทสมเด็จพระเจ้าอยู่หัวภูมิพลอดุลยเดชฯ ทรงเจริญพระชนมายุครบ 80 พรรษา เมื่อวันที่ 5 ธันวาคม พ.ศ. 2550 กรุงเทพมหานครได้จัดทำโครงการเฉลิมพระเกียรติ "การสร้างเสริมภูมิคุ้มกันโรคไอพีดีในเด็ก" โดยการฉีดวัคซีนป้องกันโรคไอพีดีชนิด conjugate แก่เด็กในกรุงเทพมหานคร ที่เกิดในวันที่ 5 ธันวาคม พ.ศ. 2550 มีเด็กเข้าร่วมโครงการดังกล่าวทั้งสิ้น 97 ราย จากการติดตามเฝ้าระวังอาการภายหลังการได้รับวัคซีนพบว่า มีเด็ก 2 ราย ที่มีไข้ต่ำๆ หลังจากได้รับวัคซีนเข็มแรก และการติดตาม สุขภาวะของเด็กในโครงการดังกล่าวเป็นเวลา 1 ปี ตั้งแต่ได้รับวัคซีนเข็มแรก จนถึงเข็มสุดท้าย ไม่พบว่ามีเด็กรายใดในโครงการเจ็บป่วยด้วยโรคไอพีดีเลย