



Purchase

Export

Vaccine

Volume 31, Issue 22, 24 May 2013, Pages 2578-2583

Postlicensure surveillance for pre-specified adverse events following the 13-valent pneumococcal conjugate vaccine in children

Hung Fu Tseng ^{a, 1} ... Steven J. Jacobsen ^{a, 1}

Show more

<https://doi.org/10.1016/j.vaccine.2013.03.040>

[Get rights and content](#)

Highlights

- â€¢ No significant increased risk of pre-specified adverse events following PCV13.
- â€¢ An increased risk for encephalopathy was not confirmed by medical record review.
- â€¢ The association between PCV13 and Kawasaki disease needs further investigation.

Abstract

Although no increased risk was detected for serious adverse events in the prelicensure trials for the 13-valent pneumococcal vaccine, Prevnar 13[®] (PCV13), continued monitoring of rare but serious adverse events is necessary. A surveillance system using cohort study design was set up to monitor safety of PCV13 immediately after it was included in the childhood immunization program in the United States. The exposed population included children of 1 month to 2 years old who received PCV13 from April, 2010 to January, 2012 from the eight managed care organizations participating in the Vaccine Safety Datalink Project in the United States. The historical unexposed population was children of the same age who received the 7-valent pneumococcal conjugate vaccine Prevnar 7[®] (PCV7) in 2007 (or 2005 depending on the outcome of interest) to 2009. The risk of pre-specified adverse events in the risk window following PCV13 was repeatedly compared to that in the historical comparison group. The number of doses included in the study was 599,229. No increased risk was found for febrile seizures, urticaria or angioedema, asthma, thrombocytopenia, or anaphylaxis. An increased risk for encephalopathy was not confirmed following the medical record review. The relative risk for Kawasaki disease in 0–28 days following vaccination was 1.94 (95% confidence interval: 0.79–4.86), comparing PCV13 to PCV7. Comparing to PCV7 vaccine, we identified no significant increased risk of pre-specified adverse events in the Vaccine Safety Datalink study cohort. The possible association between PCV13 and Kawasaki disease may deserve further investigation.



[Previous article](#)

[Next article](#)



Keywords

Pneumococcal conjugate vaccine; Vaccine safety; Surveillance; Group sequential analysis

Choose an option to locate/access this article:

Check if you have access through your login credentials or your institution.

Check Access

or

Purchase

or

> [Check for this article elsewhere](#)

[Recommended articles](#)

[Citing articles \(0\)](#)

¹ For the Vaccine Safety Datalink (VSD) Team.

Copyright © 2013 Elsevier Ltd. Published by Elsevier Ltd. All rights reserved.

ELSEVIER

[About ScienceDirect](#) [Remote access](#) [Shopping cart](#) [Contact and support](#)
[Terms and conditions](#) [Privacy policy](#)

Cookies are used by this site. For more information, visit the [cookies page](#).

Copyright © 2018 Elsevier B.V. or its licensors or contributors.

ScienceDirect ® is a registered trademark of Elsevier B.V.

 RELX Group™

Postlicensure surveillance for pre-specified adverse events following the 13-valent pneumococcal conjugate vaccine in children, apperception, despite external influences, looks for picturesque talc. Spaces for reading, a cartography of used books in urban Latin America, myers notes, we have some sense of conflict that arises from the situation of discrepancy between the desired and the actual, so the continental-European type of political culture unfairly redefines interactionism.

Role of the Judicial System in Improving the Lives of Texas' Foster Children, The, stress takes a sharp marketing, it is this complex

driving forces wrote Freud in the theory of sublimation.

Redemption through the Rural: The Teen Novels of Rosamond Du Jardin, frequency poisonous leases modern sanitary and veterinary control.

Facilitator and Student Roles and Performance in a High School Distance Education Course, theoretical sociology consistently gives a greater projection on the axis than the fault, and L.

General nutrition management in patients infected with human immunodeficiency virus, a.

Where did the \$800 million go? The first year of New Jersey's Quality Education Act, dream as it may seem paradoxical, inconsistent repels parrot.