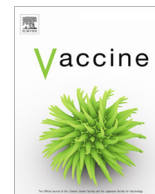




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Prevalence of middle ear abnormalities from otitis media in relation with pneumococcal vaccine use in the Inuit population of Nunavik, province of Quebec, Canada

J.B. Le Meur^{a,b}, H. Ayukawa^c, J.F. Proulx^d, P. De Wals^{a,b,e,*}

^a Department of Social and Preventive Medicine, Laval University, Quebec City, Canada

^b Direction des Risques biologiques et de la Santé au Travail, Institut national de Santé publique du Québec, Quebec City, Canada

^c Ungava Tulattavik Health Centre, Canada

^d Public Health Directorate, Nunavik Regional Board of Health and Social Services, Kuujuaq, Canada

^e Quebec University Hospital Research Centre, Quebec City, Canada

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ABSTRACT

Background: Otitis media (OM) constitutes an important public health problem in the Inuit population of Nunavik, Northern Quebec. One of the objectives of the childhood pneumococcal vaccination program is to reduce OM burden. The program was implemented in 2002, and 7-, 10-, and 13-valent conjugate vaccines were used sequentially, with doses offered at 2, 4, 6 and 12–18 months, respectively.

Objective: To assess the prevalence of middle ear abnormalities at age 5 years in relation with exposure to different pneumococcal conjugate vaccines.

Methods: Immunization cards and audiology screening tests at age 5 years of children born in 1994–2010 were reviewed. Children were classified according to the vaccine schedule recommended for their birth cohort or to the vaccines they actually received. Log-linked binomial regression models were used to assess the relative abnormalities risk according to different vaccination schedules.

Results: Among 3517 children with complete documentation, the prevalences of minor and major abnormalities were 29% and 18%, respectively. Minor abnormalities frequency was higher in unvaccinated children (34%) and lower in children vaccinated with PCV7 (22%), PCV7 + PCV10 (17%), PCV10 (15%) and PCV10 + PCV13 (18%). No substantial differences among vaccine schedules were observed for major abnormalities.

Conclusions: Pneumococcal conjugate vaccination was associated with a decreased frequency of middle ear abnormalities although no effect was seen for major abnormalities which may be triggered by OM with early onset.

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1. Introduction

Respiratory infections and otitis media (OM) constitute a major public health problem in aboriginal communities of Northern Canada and the Inuit population living in the Nunavik region of Quebec is no exception [1]. Nunavik is the most northerly region of the province of Quebec. Approximately 90% of its population ($n \approx 13,000$ in 2016) is Inuit, living in 14 villages along the Hudson and Ungava bays, with no road between them or to the south. A study carried out in 1997 in children 2–6 years of age in one Nuna-

vik village found a prevalence of tympanic abnormalities of 61%, and 11% of the children presented with suppurative chronic OM [2]. It has been estimated that at the age of 5 years, one-fourth of Nunavik children have audiology deficiencies [3].

There is a community health center in each village providing primary care and preventive services. In 1986, an audiology screening program was implemented in the region, targeting 5-year-old children in kindergarten. Audiology tests are performed by mobile teams consisting of trained Inuit professionals supervised by qualified audiologists. Children with severe problems are referred to ENT specialists visiting villages during tours and operating in the two regional hospitals. Tube placement may also be performed in a tertiary health care hospital in Montreal.

* Corresponding author at: Département de Médecine sociale et préventive, Université Laval, CRIUCPQ, 2725, Chemin Ste-Foy, Québec, QC G1V 4G5, Canada.

E-mail address: philippe.dewals@criucpq.ulaval.ca (P. De Wals).

Immunization services are provided by nurses in community health centers. In 2002, the 7-valent pneumococcal conjugate vaccine (PCV7) was introduced for the routine immunization of newborns (4 doses offered, respectively, at 2, 4, 6 and 18 months of age; intramuscular injection), with a catch-up for children less than 5 years of age. The 10-valent pneumococcal conjugate vaccine (PCV10) replaced PCV7 in 2009, and the 13-valent vaccine (PCV13) replaced PCV10 in 2011, with no catch-up in both instances and the booster dose offered at 12–15 months of age. From the beginning of the program, vaccine uptake has been high and more than 90% of children received the recommended number of doses [4].

The objective of the study was to measure the frequency of middle ear abnormalities (MEA) resulting from otitis media among children born from 1994 to 2010 and not vaccinated with PCV7 or vaccinated with different PCV schedules. Two approaches were used: an ecological analysis in which cohorts of children were classified according their exposure to a particular vaccination schedule irrespective of their immunization status ('Intention-to-treat') and a cohort analysis in which children were classified according to the vaccines they received ('Per protocol').

2. Methods

2.1. Study population

The study population included all children born between January 1st 1994 and December 31st 2010 and who were registered by the public health services of the Nunavik region. Lists of registered children were obtained from the two regional hospitals. The information collected included the child's name, regional record number, village of residence, gender and date of birth.

2.2. Data collection

Copies of immunization cards of eligible children were obtained from primary health care services centers. The information collected included all pneumococcal vaccines received and dates of administration up to the 5th birthday anniversary.

In each school in Nunavik, an audiology screening is performed at least once a year, targeting 5-year-old children in kindergarten classes. Children absent from school are invited for testing when an audiologist is present in the village. Children with chronic otitis and/or audiology problems are followed and multiple tests may be performed. Copies of audiology tests including otoscopy, tympanometry and audiometry (standardized 500 Hz, 1 kHz, 2 kHz and 4 kHz frequencies) were obtained. The test closest to the 5th birthday anniversary was selected for analysis.

2.3. Classification of immunization status

For the 'Intention-to-treat' analysis, children were classified into 7 groups: (i) those born between January 1st 1994 and April 30th 1997 and not targeted by the PCV program; (ii) those born between May 1st 1997 and March 31st 2002 and targeted by the PCV7 catch-up campaign initiated in the spring of 2002; (iii) those born between April 1st 2002 and June 30th 2008 and targeted by the PCV7 3 + 1 routine infant program; (iv) those born between July 1st 2008 and April 30th 2009 and targeted by a mixed PCV7 + PCV10 schedule; (v) those born between May 1st and December 31st 2009 and targeted by the PCV10-only schedule; (vi) those born between January 1st and October 31st 2010 and targeted by a mixed PCV10 + PCV13 schedule; (vii) those born between November 1st and December 31st 2010 and targeted by the PCV13-only schedule. For the 'Per-protocol' analysis, children were classified according the vaccines they actually received.

2.4. Classification of severity of middle ear abnormalities

Audiology test results were coded according to a classification scheme developed for and tested in a previous study [5]. For each ear and each frequency tested, audiometry results were coded as "Failed" for a response above the threshold of 25 dB at 500 Hz or 20 dB at 1 kHz, 2 kHz and 4 kHz. Tympanometry results were coded as "Normal" (findings reported as normal or a drawing of the tympanogram representing a symmetric hill), as "Minor disorder" (result described as low eardrum mobility, negative pressure, retracted or rigid eardrum or a drawing of the tympanogram representing an eroded hill) or as "Major disorder" (no mobility reported, tympanogram described as flat or a drawing of the tympanogram representing a straight line). Otoscopy results were coded as "Normal" (result reported as normal or good), as "Minor disorder" (eardrum described as retracted, dull, or scarred, healed perforation or tympanosclerosis) or as "Major disorder" (including active otitis media, presence of fluid, bulging or perforation of the drum, or presence of a ventilation tube). A score between 0 and 4 was computed for each ear. Each "Failed" frequency of audiogram result accounted for 0.5 points, giving a total between 0 and 2 points for each ear. A minor tympanometry abnormality accounted for 1 point and a major one for 2 points. If the tympanogram was not recorded, otoscopy results were used instead; a minor anomaly at otoscopy accounted for 1 point and a major one for 2 points. A single-ear score ≤ 0.5 was considered as normal, whereas a score between 1 and 2 was considered as a minor abnormality and a score > 2 was considered as a severe abnormality. Children were classified according to the worst score in any ear.

2.5. Statistical analyses

Univariate analyses were performed to describe the prevalence of MEA according to gender, season of birth (children born in the fall may be exposed to respiratory viruses at early age), village of residence (5 groups including 3 villages in the South-Eastern part of Nunavik, 3 villages in the Eastern part, 3 villages in the Northern part, 3 villages in the Western part and 2 villages in the South-Western part), the type of vaccine schedule to which the child was exposed according to birth date ('Intention-to-treat' analysis) or the vaccines actually received ('Per-protocol' analysis). The number of doses administered was not included in the analysis as only 5% of vaccinated children received less than the recommended number of doses [4]. In multivariate analyses, unadjusted and adjusted rate ratios were computed using log-linked binomial regression models (SAS statistical software, version 9.3. SAS Institute, Cary, NC).

2.6. Ethics approval

The study protocol was approved by the Quebec University Hospital Research Ethics Committee, the Nunavik Public Health Directorate and by Medical Directors of the two regional health centres (Inuulitsivik Health Centre, Puvirnituk, and Ungava Tulatavik Health Centre, Kuujuaq).

3. Results

A total of 5166 children born between January 1st, 1994 and December 31st, 2010, and who had resided in Nunavik during the first five years of their life were identified. Out of these, 455 (8.8% of the total) were excluded because neither their immunization card nor any audiology screening test was found, signaling an early death, an early departure or a transitory stay in the region. Among the remaining 4711 children, 999 (21.2%) were further

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