załącznik nr 1 do Zarządzenia
Prezesa AOTM nr 18/2012

Formularz zgłaszania uwag do analizy weryfikacyjnej Agencji Oceny Technologii Medycznych i analiz wnioskodawcy[1]

	Formularz zgłaszania uwag do analizy weryfikacyjnej AOTM:
Numer:	BIP – 059, analiza AOTM-OT-4350-9/2014
Tytuł:	Wniosek o objęcie refundacją leku: Prevenar 13 (szczepionka przeciw pneumokokom polisacharydowa skoniugowana 13-walentna, adsorbowana), kod EAN 5909990737420 we wskazaniu: profilaktyka zakażeń pneumokokowych u nowonarodzonych dzieci z populacji ogólnej do ukończenia drugiego roku życia

Uwagi (pkt. 2) wraz z wypełnioną i własnoręcznie podpisaną Deklaracją Konfliktu Interesów (pkt. 1) należy złożyć w siedzibie Agencji Oceny Technologii Medycznych, ul. I. Krasickiego 26, 02-611 Warszawa, bądź przesłać przesyłką kurierską lub pocztową na adres siedziby Agencji.

Uwagi można zgłaszać w terminie 7 dni od dnia opublikowania analiz w Biuletynie Informacji Publicznej (BIP). Uwagi dostarczone do siedziby AOTM po upływie tego terminu nie będą rozpatrywane.

UWAGA! Zgłoszone uwagi i deklaracja konfliktu interesów będą publikowane w BIP AOTM[2].

1. **Deklaracja konfliktu interesów (DKI)**[3] – do wypełnienia w przypadku uwag do analizy weryfikacyjnej

Imię i nazwisko osoby składającej DKI dotyczącej złożenia uwag do upublicznionej analizy weryfikacyjnej: dr hab. n med. Piotr Albrecht.....

Dotyczy wniosku/ów będącego/ych przedmiotem obrad Rady Przejrzystości:

Wniosek o objęcie refundacją leku: Prevenar 13 (szczepionka przeciw pneumokokom)

Czego dotyczy DKI:

- ☐ ~~Udział w posiedzeniu Rady Przejrzystości- członka Rady Przejrzystości w dniu,~~
- ☐ ~~Przygotowanie ekspertyzy/opracowania w formie pisemnej lub ustnej dla Rady Przejrzystości dotyczącego: ..~~
- ☐ ~~Udział w posiedzeniu Rady Przejrzystości eksperta z dziedziny medycyny, której dotyczą omawiane na posiedzeniu wnioski lub informacje w dniu,~~
- ☐ ~~Udział w posiedzeniu Rady Przejrzystości innej osoby zaproszonej przez przewodniczącego Rady, w dniu,~~
- ☐ ~~Udział w posiedzeniu Rady Przejrzystości osoby przygotowującej opinie w trakcie procesu analitycznego, dotyczące prowadzonych przez Agencję ocen technologii medycznych lub świadczeń opieki zdrowotnej, w dniu,~~
- ■ **Złożenie uwag do upublicznionej analizy weryfikacyjnej,**

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[1] *zgodnie z art. 35 ust. 4 ustawy z dnia 12 maja 2011 r. o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych (Dz. U. z 2011 r. Nr 122, poz. 696 z późn. zm.)*

☐ ~~Złożenie uwag w związku z upublicznionym porządkiem obrad Rady Przejrzystości w dniu.~~

UWAGA!

Część A należy wypełnić w przypadku występowania konfliktu interesów.

Część B należy wypełnić w przypadku braku konfliktu interesów.

<u>Część A</u>

Oświadczam, że ja, mój małżonek/moja małżonka, mój zstępny lub wstępny w linii prostej, osoba, z którą/ osoby, z którymi pozostaję we wspólnym pożyciu[4], wykonuję/ją zajęcia zarobkowe na podstawie

Stosunku pracy ☐

Umowy o świadczenie usług zarządczych ☐

Umowy zlecenia ☐

Umowy o dzieło ☐

Innej umowy o podobnym charakterze ☐

na rzecz podmiotów określonych w art. 31s ust. 8 pkt 1-3 (cytowany poniżej)

„8.Członkowie Rady Przejrzystości, ich małżonkowie, zstępni i wstępni w linii prostej oraz osoby, z którymi członkowie Rady Przejrzystości pozostają we wspólnym pożyciu, nie mogą:
1) być członkami organów spółek handlowych lub przedstawicielami przedsiębiorców prowadzących działalność gospodarczą w zakresie wytwarzania lub obrotu lekiem, środkiem spożywczym specjalnego przeznaczenia żywieniowego, wyrobem medycznym;
2) być członkami organów spółek handlowych lub przedstawicielami przedsiębiorców prowadzących działalność gospodarczą w zakresie doradztwa związanego z refundacją leków, środków spożywczych specjalnego przeznaczenia żywieniowego, wyrobów medycznych;
3) być członkami organów spółdzielni, stowarzyszeń lub fundacji prowadzących działalność, o której mowa w pkt 1 i 2;"
Proszę podać szczegóły, które Pani/Pan uzna za niezbędne, oraz nazwy podmiotów, z którymi wiążą Panią/Pana (małżonka/małżonkę, zstępnych lub wstępnych w linii prostej lub osoby z którymi pozostaje Pan/Pani we wspólnym pożyciu) relacje powodujące konflikt interesów. Opis powinien być możliwie zwięzły.

.....Wykłady, sponsorowane wyjazdy na Kongresy na których prezentowane były prace naukowe dla firm Wyeth, Pfizer, GSK, Novartis.....

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[4] *niepotrzebne skreślić*

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.....

Oświadczam, pod rygorem odpowiedzialności karnej za składanie fałszywych oświadczeń z art. 233 § 1 i 6 ustawy z dnia 6.06.1997r. Kodeks karny (Dz. U. 1997 Nr 88, poz. 553 z późn. zm.), że według mojej najlepszej wiedzy powyższe dane są zgodne ze stanem faktycznym i kompletne. Wyrażam zgodę na gromadzenie, przetwarzanie i udostępnianie moich danych osobowych w celu identyfikacji konfliktu interesów zgodnie z ustawą o ochronie danych osobowych z dnia 29.08.1997 r. (Dz. U. Nr 133, poz. 883 z późn. zm.).

Data składania i podpis osoby składającej DKI .....

Część B

Oświadczam, iż z uwagi na niewystępowanie okoliczności określonych w art. 31s ust. 9 *ustawy z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych* (Dz. U. z 2008 r. Nr 164, poz. 1027 z późn. zm.), dotyczących mojej osoby, mojego małżonka/mojej małżonki, moich zstępnych lub wstępnych w linii prostej, osoby, z którą/ osób, z którymi pozostaję we wspólnym pożyciu, nie jestem w konflikcie interesów.

Oświadczam, pod rygorem odpowiedzialności karnej za składanie fałszywych oświadczeń z art. 233 § 1 i 6 ustawy z dnia 6.06.1997r. Kodeks karny (Dz. U. 1997 Nr 88, poz. 553 z późn. zm.), że według mojej najlepszej wiedzy powyższe dane są zgodne ze stanem faktycznym i kompletne. Wyrażam zgodę na gromadzenie, przetwarzanie i udostępnianie moich danych osobowych w celu identyfikacji konfliktu interesów zgodnie z ustawą o ochronie danych osobowych z dnia 29.08.1997 r. (Dz. U. Nr 133, poz. 883 z późn. zm.).

Data składania i podpis osoby składającej DKI ..... 22 05 2014 .....

2. Uwagi do analizy weryfikacyjnej AOTM

Numer* (rozdziału, tabeli, wykresu, strony)	Uwagi

* Umożliwiający identyfikację fragmentu analizy, do którego odnoszą się wniesione uwagi; nie dotyczy w przypadku uwag ogólnych.

3. Uwagi do analiz wnioskodawcy[5]

a. Uwagi do analizy klinicznej

Numer* (rozdziału, tabeli, wykresu, strony)	Uwagi
	W załączeniu wyniki oceniające efektywność bezpośrednią i pośrednią szczepień masowych PCV7/PCV13 prowadzonych w Radomiu. Wskazują one na znaczna efektywność rzeczywistą szczepionki PCV13 w Polsce. Widać to także w porównaniu populacji szczepionej i nieszczepionej (Kielce i Ostrowiec Świętokrzyski).

* Umożliwiający identyfikację fragmentu analizy, do którego odnosi się uwaga; nie dotyczy w przypadku uwag ogólnych.

b. Uwagi do analizy ekonomicznej

Numer* (rozdziału, tabeli, wykresu, strony)	Uwagi

* Umożliwiający identyfikację fragmentu analizy, do którego odnosi się uwaga; nie dotyczy w przypadku uwag ogólnych.

c. Uwagi do analizy wpływu na budżet podmiotu zobowiązanego do finansowania świadczeń ze środków publicznych

Numer* (rozdziału, tabeli, wykresu, strony)	Uwagi

* Umożliwiający identyfikację fragmentu analizy, do którego odnosi się uwaga; nie dotyczy w przypadku uwag ogólnych.

d. Uwagi do analizy racjonalizacyjnej

Numer* (rozdziału, tabeli, wykresu, strony)	Uwagi

[5] analizy, o których mowa w art. 25 pkt 14) lit. c oraz art. 26 pkt 2) lit. h oraz i Ustawy z dnia 12 maja 2011 r. o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych (Dz. U. z 2011 r. Nr 122, poz. 696 z późn. zm.)

* Umożliwiający identyfikację fragmentu analizy, do którego odnosi się uwaga; nie dotyczy w przypadku uwag ogólnych.

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ARTICLE

Significant decline in pneumonia admission rate after the introduction of routine 2+1 dose schedule heptavalent pneumococcal conjugate vaccine (PCV7) in children under 5 years of age in Kielce, Poland

M. Patrzalek · P. Albrecht · M. Sobczynski

Received: 27 October 2009 / Accepted: 3 April 2010

Abstract This study was performed to estimate the effect of heptavalent pneumococcal conjugate vaccine (PCV7) on the pneumonia admission rate in children younger than 5 years of age, after the introduction of routine 2+1 dose schedule immunization. We compared the pneumonia admission rate (number of cases per 1,000 population) 2 years before and 2 years after the introduction of PCV7 in 2006. Only children with radiologically confirmed pneumonia were analyzed. The vaccination rate in the analyzed periods was around 99%. In the period preceding the implementation of PCV7, the average pneumonia admission rate was 41.48/1,000 and 6.15/1,000 for 1-year-old and 2–4-year-old children, respectively. Statistical analysis showed a significant fall in this rate in two consecutive years after PCV7 implementation ($p<0.0000001$ for 1-year-old and $p=0.011$ for 2–4-year-old children, respectively). In the first year of vaccination, the admission number decreased in these two groups by about 65 and 23%, respectively. In the second year, only a few percent fall in the admission rate was noted. In children younger than 2 years of age, the age group targeted for vaccination, pneumonia-related healthcare utilization declined substantially following PCV7 introduction. These results suggest that PCV7 may play an important role in reducing the burden of pneumonia in Poland.

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Introduction

Acute respiratory infections (ARIs) are among the leading causes of childhood morbidity and mortality, especially in developing countries [1]. The World Health Organization (WHO) data clearly indicate that *Streptococcus pneumoniae* is the most frequent cause of deaths worldwide and is responsible for >1.6 million deaths annually of children under 5 years of age, with pneumonia being the major cause [2]. Before the introduction of heptavalent pneumococcal conjugate vaccine (PCV7), the incidence of pneumonia in children below 5 years of age in Europe and USA was, similar to in Poland, around 34–40/1,000 [3–5]. *S. pneumoniae* was considered to be responsible for 17–44% of pneumonia-related hospitalizations in children in this age group [6–8]. PCV7 was included in the vaccination calendar initially in the USA (2000), and then, gradually, in about 45 other countries. Clinical trials showed that PCV7 had originally led to a completely unexpected reduction in the frequency of pneumonia, dating back to children below 5 years of age, depending on the applied analysis protocol, of 23.4% (Northern California Kaiser Permanente; NCKP) [9] or 30.3% (NCKP; reanalysis) [10] and intent-to-treat appropriately of 17.7% [9] and 25.5% [10]. In the postlicensure

Table 1 Size of the child population in selected age groups and the number of pneumonia cases before (2004 and 2005) and after (2007 and 2008) implementation of the vaccination program

Age (years)	Year							
	2004		2005		2007		2008	
	N	*n*	*N*	*n*	*N*	*n*	*N*	*n*
0–1	3,279	154	3,279	117	3,534	53	3,774	51
2–4	4,937	34	4,882	26	4,858	23	4,939	19

N—number of living children: *n*—number of pneumonia cases

(blood count, C-reactive protein [CRP], and erythrocyte sedimentation rate [ESR]). To ensure maximum reliability of the analysis, only pneumonia cases confirmed radiologically by two independent radiologists were taken into consideration and all cases of pneumonia were reassessed. Nearly all cases were coded in ICD10 as J18 and only a very small number as J15. None were encrypted as J13.

Data concerning the general number of pneumonia cases in Kielce for all age groups were derived from the Świętokrzyski Provincial Branch of the National Health Fund in Kielce.

The incidence rates were presented as the number of cases per 1,000 population and were calculated on the basis of the data available at the National Centre for Statistics in Poland (GUS). Analysis of covariance (ANCOVA) as a case of the general linear model (GLM) with binomial and negative binomial error structure was used for modeling pneumonia incidence. *p*-values <0.05 were considered as statistically significant. All data were analyzed using R version 2.2.1 and its "base" and "MASS" packages [17].

Results

Table 1 encompasses the number of hospitalizations due to radiologically confirmed pneumonia in children aged 0–1 year and 2–4 years, as well as the size of the population of Kielce in the years 2004, 2005, 2007, and 2008. In 2004 and 2005, i.e., in the period without mass vaccination, the incidence rate in the first year of life was 46.96/1,000 and 35.68/1,000, respectively (mean: 41.32/1,000), and in children aged 2–4 years, it was 6.88/1,000 and 5.32/1,000, respectively (mean: 6.11/1,000). Figure 1 presents the number of hospitalized pneumonia cases per 1,000 children residing in Kielce in the form of an average of two years preceding vaccination (2004 and 2005) and two subsequent years (2007 and 2008) after implementation of the vaccination program.

The risk of pneumonia hospitalization in children in their first year of life and between their second and fourth years was modeled by a binomial distribution. Analysis based on the model revealed that the reduction of incidence rate in subsequent years in both age groups, as observed in Fig. 1, varied but was statistically significant (for children in their first year of life $p<0.0000001$, for children aged 2–4 years $p=0.01$). As early as in the first year after the implementation of vaccination, the number of hospitalized pneumonia cases in children aged 0–1 year decreased by almost 65%, and in children aged 2–4 years, it decreased by 23%. In 2008, a subsequent, but lower, decrease in hospitalization rate in both groups was observed, as presented in Fig. 1. The decrease was 10% in the group aged 0–1 year and 18% in the group aged 2–4 years. During the same period (2006–2008), the frequency of the admission rate for acute diarrhea as the internal control group showed a growing tendency. The log-linear model with quasi-Poisson errors revealed the observed trends to be significant ($p=0.0173$) for all ICDs and there were no differences between A04, A08, and A09 in the rates of growth because the interaction between year and kind of ICDs was not significant.

Analysis of pneumonia incidence in individuals over 4 years of life revealed a significant diversity. Table 2 presents

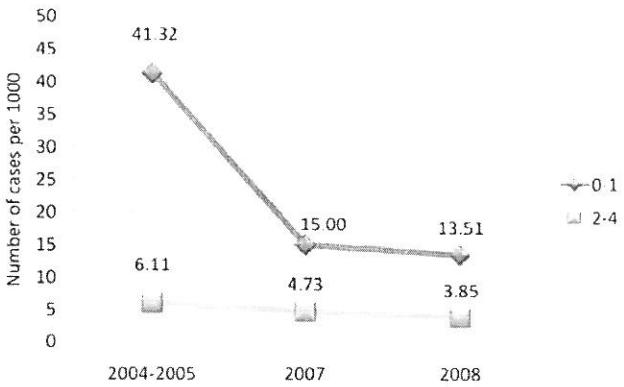

Fig. 1 Pneumonia hospitalization rates in age groups 0–1 and 2–4 years in Kielce before and after the introduction of pneumococcal vaccinations

unvaccinated people, through decreases in the nasopharyngeal carriage of vaccine serotypes [20, 21].

Decline in the rates of all-cause pneumonia admissions in Kielce, Poland, suggests that *S. pneumoniae* was a major contributor to the burden of pneumonia admissions in young children in this town [22, 23], similar to in the USA, and provides an estimate of the burden of pneumococcal pneumonia admissions in young children due to PCV7 vaccine serotypes.

Unfortunately, in most cases in Poland, including in the city of Kielce, establishing the etiology of pneumonia is very difficult due to economic, logistic, and technical reasons. The research groups experienced these difficulties while conducting a sponsored epidemiological study [24] concerning the IPD frequency in Poland. In a 2-year period, only 134 samples fit for determining the etiological factor reached the central reference laboratory, of which as many as 108 were culture-negative.

Further, our study suggests a substantial effect on one of the most common reasons for hospital admissions not only in Kielce but throughout Poland and in other countries [21, 25, 26].

Observations similar to those for *S. pneumoniae* were made for *Haemophilus influenzae* type B pneumonia in Gambia, where substantial reductions in overall pneumonia were attributable to immunization with conjugate vaccines against this bacterium [27].

As evidenced in this study, surprisingly favorable results of PCV7 immunization may also be related to the relatively high serotype coverage of PCV7 vaccine in the Polish population, which, according to our findings, amounted to 73–77% in children under 5 years of age [24].

The 3+1 scheme of PCV7 vaccination is generally recognized and applied in many countries. However, the Municipal Council in Kielce decided to apply the 2+1 scheme, as it was not only cheaper, which was a particularly important factor in this case, but also, as evidenced in numerous studies [13, 15, 16, 28], was as efficient in a mass vaccination pattern as the original 3+1 scheme. The scheme was, thus, approved for population vaccination also in the registration dossier. Also in Poland, the 2+1 scheme proved to be efficient in population vaccination.

Previous findings showed that the group aged between 18 and 39 years had the second highest percentage decline in invasive pneumococcal disease after children younger than 5 years of age, suggesting a vaccine herd effect [20]. This age group includes parents of young children, so they could have benefited from reduced exposure to pneumococci when their children were immunized with PCV7.

The lack of an apparent decrease in pneumonia incidence in individuals after the fourth year of life, i.e., the so-called population effect, may be related to too a short period of vaccination and our observation, as well as to imperfect coding and classification of pneumonia in adults, in particular, in outpatient settings.

The increase in birth rate, observed despite a systematic decrease in the city population size, may be explained by the willingness of young mothers to take advantage of free vaccination of their children, and, thus, their registration for permanent residence in Kielce.

This exceptionally high vaccination rate (99% vs., for instance, 93.4% reached in the best year in the Liguria Region program [14]) resulted not only from the good performance and efficacy of vaccination points, but most likely also from free-of-charge access to the vaccine. The cost of complete PCV7 vaccination, even in the 2+1 scheme, under the conditions of a private healthcare system, amounts to at least 25% of the average monthly salary in Poland.

Our study provides a comprehensive assessment of the changes in pneumonia admission rates after implementation of the PCV7 immunization program in Kielce, Poland. We used a strong quasi-experimental design to assess the effect of PCV7 vaccination. The observed reductions in radiologically confirmed pneumonia admissions suggest that, before the introduction of PCV7, *S. pneumoniae* was a major contributor to childhood pneumonia in Kielce, Poland, and provide an estimate of the burden of pneumococcal pneumonia admissions in young children due to PCV7 vaccine serotypes. Our results support the constantly growing evidence of the beneficial effects of the pneumococcal conjugate vaccines in children. Further, this substantial effect obtained in this study targeted one of the most common reasons for hospital admissions in Poland.

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The impact of PCV7/PCV13 children's vaccination on the incidence of pneumonia morbidity in Kielce, Poland in a 7-year observation period.

Authors: Patrzałek M.[1], Goryński P.[2], Kotowska M.[3], Albrecht P.[3]

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[3] Department of Pediatric Gastroenterology and Nutrition, Medical University of Warsaw, Poland

Background and aims

In 2006, the city of Kielce, Poland introduced PCV7 (since 2011, PCV13) mandatory vaccination programme for children <2 years of age. The aim of this study was to analyse the direct and indirect effects of PCV7/ PCV13 vaccination on pneumonia incidence rate in the 7-year follow-up period in comparison to the city of Ostrowiec Świętokrzyski, where there was no mandatory vaccination scheme present.

Methods

PCV7/PCV13 vaccines were given in a 2 + 1 scheme. The compliance rate for vaccinations reached approx. 99%. The following age groups were analysed: 0-1, 30-49, 50-65 and 65+ years in a period of 2006-2012. Cochran–Armitage test investigated the significance of the trend in pneumonia morbidity. The significance of deviations was tested. The importance of the trend (in case of deviations from linearity) was confirmed by Mantel test.

Results

The greatest decrease in pneumonia morbidity in analysed period was observed for children <2 years of age: 96.5% (2005, 25/1000; 2012, 0.88/1000). In the 65+ age group, there was a 66.5% decline for all diagnosed pneumonia, followed by lower, also statistically significant, decline in other age groups: 30.8% (30-49 yrs) and 56.8% (50-64 yrs). The decreasing trend continued for seven consecutive years of observation. We demonstrated also a statistically significantly higher rate of pneumonia incidence among all age groups in the city, Ostrowiec Świętokrzyski, not conducting mass pneumococcal vaccination programme.

Conclusions

The results clearly proved, with a statistical significance, direct and indirect effectiveness on pneumonia prevention due to PCV7/PCV13 mass vaccination programme.

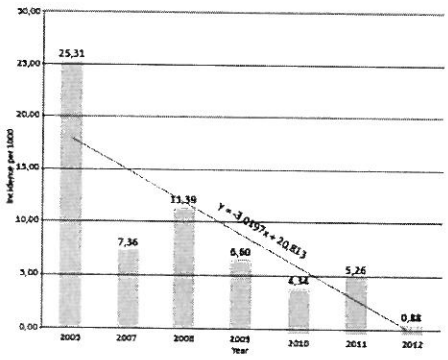

Fig. 1. Pneumonia incidence rate among children <2 years in the period 2005-2012 with regression line.

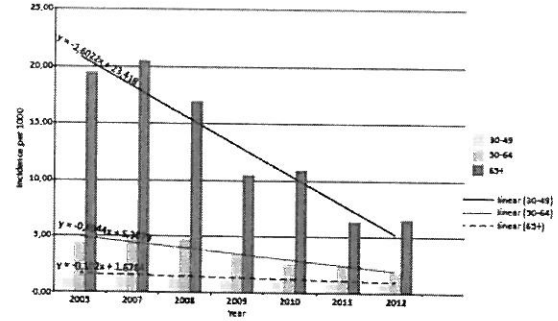

Fig.2. Pneumonia incidence rate among analyzed age groups (30-49, 50-64, 65+) in the years 2005-2012 with regression lines.

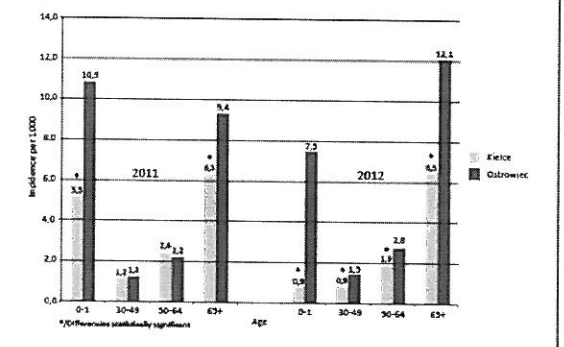

Fig. 3. Comparison of pneumonia incidence rate among analyzed age groups (0-1, 30-49, 50-64, 65+) in Kielce and Ostrowiec Świętokrzyski in the years 2011 and 2012.

Reference: Patrzałek M, Goryński P, Albrecht P. Indirect, population impact of universal PCV7 vaccination of children in 2+1 schedule on the incidence of pneumonia morbidity in Kielce, Poland. EJCMID 2012;31(11):3023-8.

Patrzałek M.[1], Goryński P.[2], Kotowska M.[3] Albrecht P.[3]

THE IMPACT OF PCV7/PCV13 CHILDREN'S VACCINATION ON THE INCIDENCE OF PNEUMONIA MORBIDITY IN KIELCE, POLAND IN A 7-YEAR OBSERVATION PERIOD.

[1] NZOZ "Promed" Kielce, Poland

[2] National Institute of Public Health, National Institute of Hygiene, Warsaw, Poland

[3] Department of Paediatric Gastroenterology and Nutrition, Medical University of Warsaw

Abstract

Background and aims

In 2006, the city of Kielce, Poland introduced PCV7 (since 2011, PCV13) mandatory vaccination programme for children <2 years of age. The aim of this study was to analyse the direct and indirect effects of PCV7/ PCV13 vaccination on pneumonia incidence rate in the 7-year follow-up period in comparison to the city of Ostrowiec Świętokrzyski, where there was no mandatory vaccination scheme present.

Methods

PCV7/PCV13 vaccines were given in a 2 + 1 scheme. The compliance rate for vaccinations reached approx. 99%. The following age groups were analysed: 0-1, 30-49, 50-65 and 65+ years in a period of 2006-2012. Cochran–Armitage test investigated the significance of the trend in pneumonia morbidity. The significance of deviations was tested. The importance of the trend (in case of deviations from linearity) was confirmed by Mantel test.

Results

The greatest decrease in pneumonia morbidity in analysed period was observed for children <2 years of age: 96.5% (2005, 25/1000; 2012, 0.88/1000). In the 65+ age group, there was a 66.5% decline for all diagnosed pneumonia, followed by lower, also statistically significant, decline in other age groups: 30.8% (30-49 yrs) and 56.8% (50-64 yrs). The decreasing trend continued for seven consecutive years of observation. We demonstrated also a statistically significantly higher rate of pneumonia incidence among all age groups in the city, Ostrowiec Świętokrzyski, not conducting mass pneumococcal vaccination program.

Conclusions

The results clearly proved, with a statistical significance, direct and indirect effectiveness on pneumonia prevention due to PCV7/PCV13 mass vaccination programme.

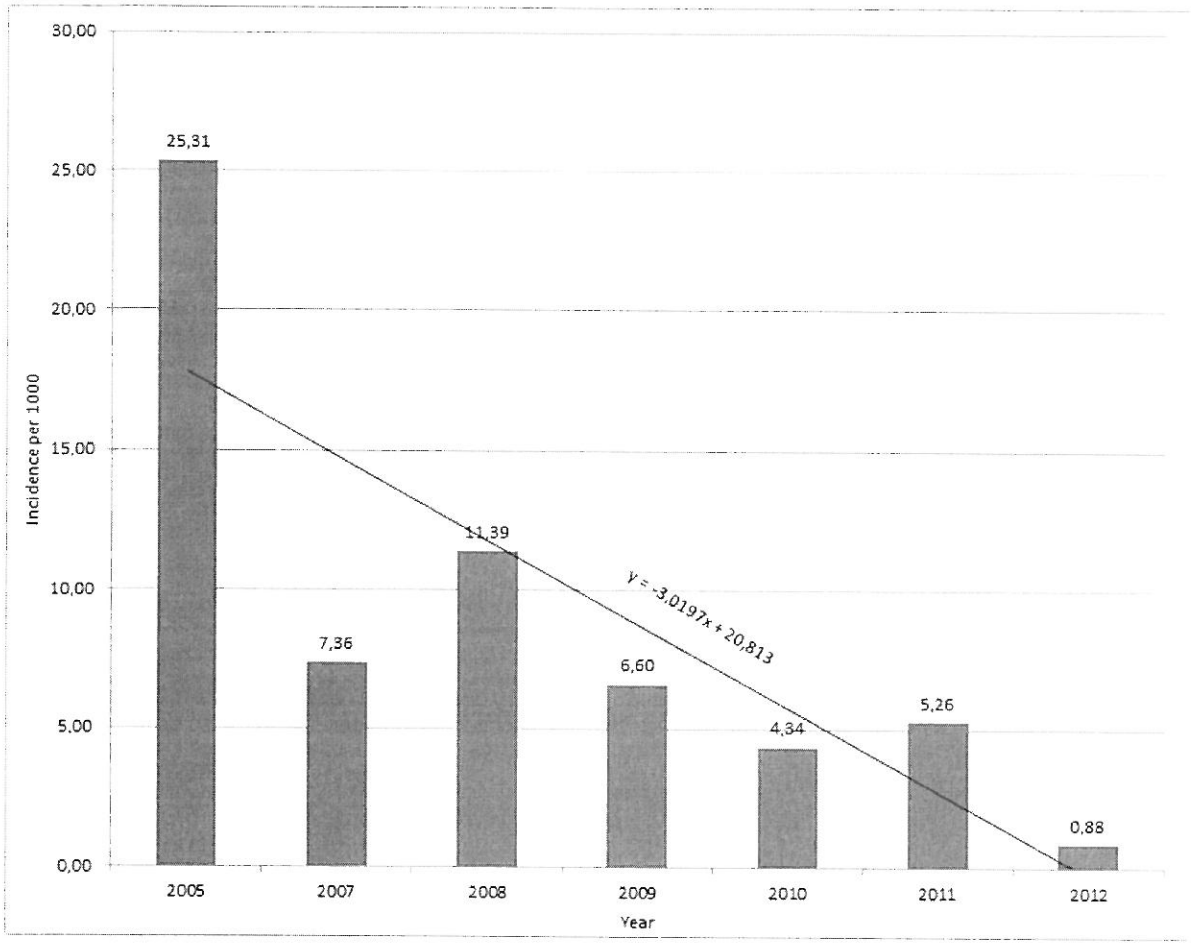

Fig. 1. Pneumonia incidence rate among children <2 years in the period 2005-2012 with regression line.

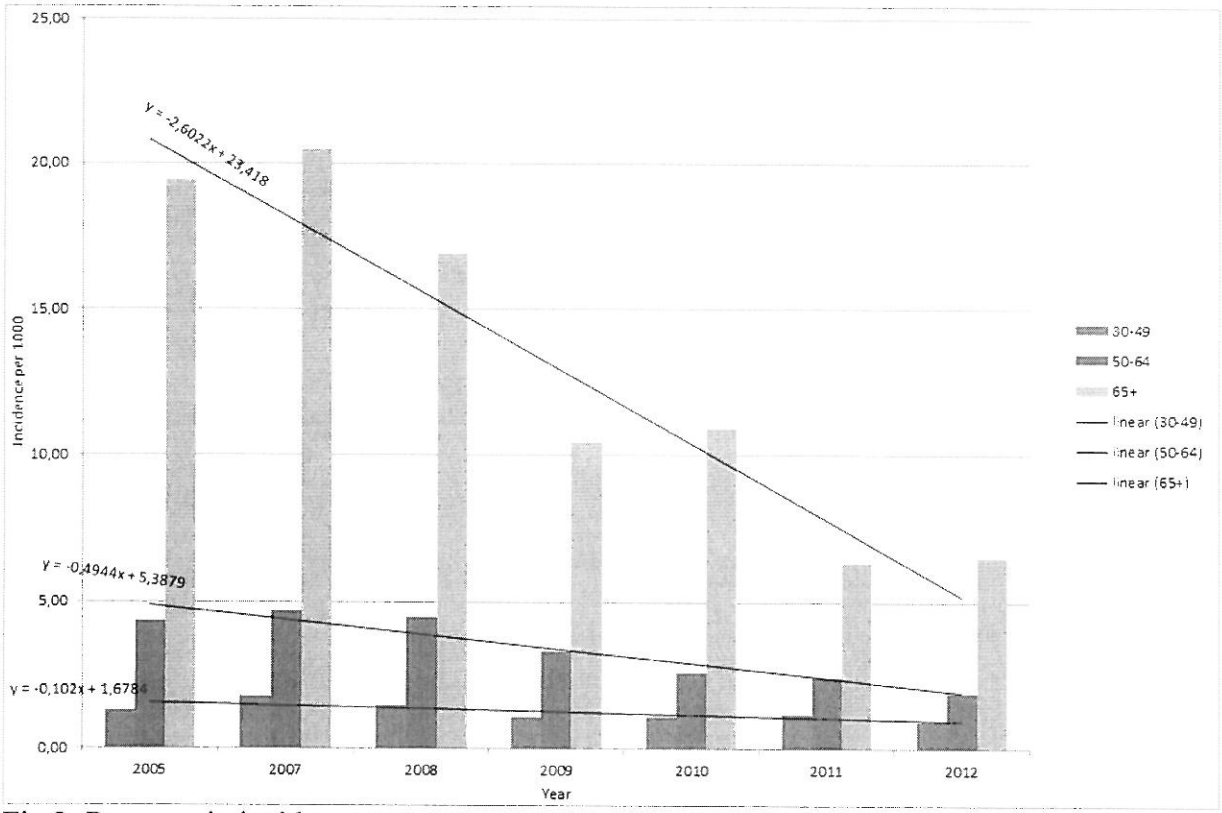

Fig.2. Pneumonia incidence rate among analyzed age groups (30-49, 50-64, 65+) in the years 2005-2012 with regression lines.

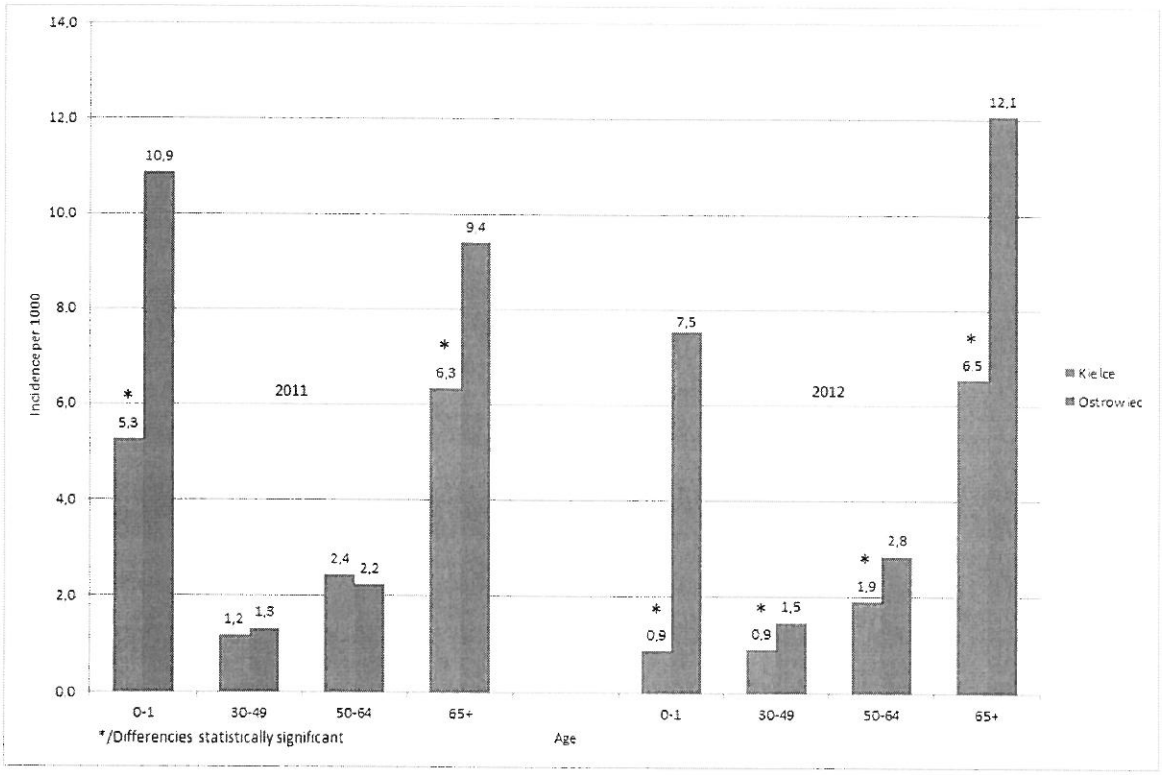

Fig. 3. Comparison of pneumonia incidence rate among analyzed age groups (0-1, 30-49, 50-64, 65+) in Kielce and Ostrowiec Świętokrzyski in the years 2011 and 2012.

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