

Giornate di Pediatria Preventiva e Sociale

Capri 2008

10 - 11 Ottobre 2008
Hotel la Palma - Capri

L'IMPATTO DELLA VACCINAZIONE ANTIPNEUMOCOCCICA IN ITALIA

L'ESPERIENZA DELLA REGIONE LIGURIA



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Unità Operativa Igiene
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Ministero della Salute



La Repubblica tutela la sa
lute e l'interesse della collettività

Ministero della Sanità

Circolare n. 11 del 19 novembre 2001

Vaccinazione antipneumococcica in età pediatrica

Resolution by the Ministry of Health (n°11 – 19th Nov. 2001)

“Recommendations for Pneumococcal Vaccination in Paediatric Age”

The Italian National Health Council decided to recommend vaccination against *St. pneumoniae* only for children considered at high-risk due to:

thalassaemia and sickle-cell anaemia
functional or anatomic asplenia
COPD
immunodeficiency-conditions
hepatic, renal and cardiovascular diseases
diabetes mellitus
HIV-infection
leak of cerebrospinal fluid....

Just at the beginning, no recommendation for active and free of charge immunization of children aged < 24 months of age was decided.

“...Regions which decided to start the universal infant immunization campaign with 7-PCV were encouraged to activate specific projects monitoring the program....”

Italian Childhood and Adolescent Immunization Schedule (National Vaccination Plan 2005-2007)

Vaccine	At birth	3 rd month	5 th month	11 st month	13 th month	24 th month	3 rd year	5 th -6 th year	12 th month	15 th month
DTaP		DTaP	DTaP	DTaP				DTaP - IPV	Td	
IPV		IPV	IPV	IPV						
Hepatitis type B	HB	HB	HB	HB						
Hib		Hib	Hib	Hib						
MMR					MMR			MMR	MMR	
7-PCV		← 7-PCV • →								
Men C		Men C •								
Varicella					Varicella •				Varicella	

- Administrative Regions free to start up specific immunization programs depending on the local situation (epidemiology, financial resources, organizational level, etc.)

Modalità di offerta del 7-PCV in Italia (maggio 2006)



**CONSENSUS CONFERENCE:
THE UNIVERSAL
INFANT PNEUMOCOCCAL VACCINATION IN
ITALY**

Rome, 26th-27th November 2007

SIMIT

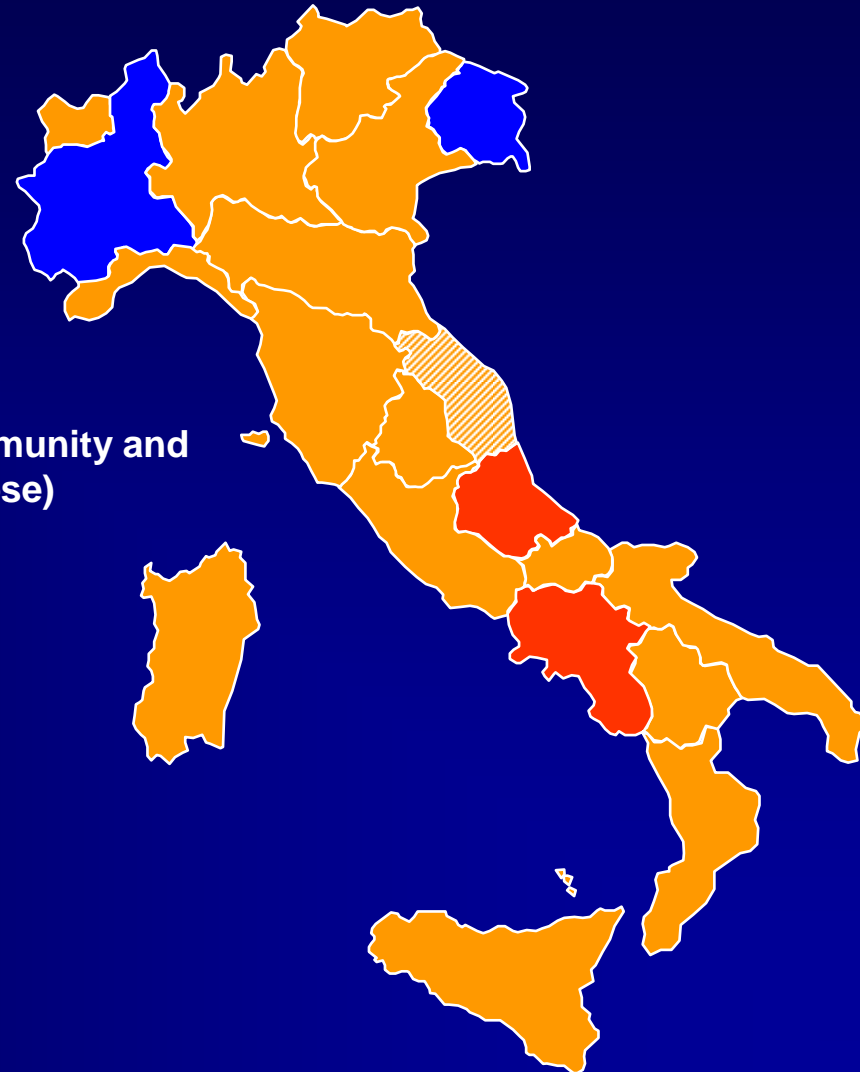
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S.I.P.

SItI

Current use of the 7-PCV in Italy: recommendations by administrative Region

- Free of charge for all new-borns
- Free of charge for children attending the community and co-payment for the others (46-54 euros per dose)
- Free of charge only for children at high-risk and co-payment for the others
- All newborns paying a ticket



(up date 2008)

Impatto di una campagna vaccinale anti-pneumococcica allargata sulla morbosità infantile



DGR n. 563 del 23.5.2003
APPROVAZIONE DEL PROGETTO PILOTA
DELLA REGIONE LIGURIA



Liguria, a small administrative Region in Italy

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- Nearly 1,600,000 inhabitants.
- Nearly 12,000 newborns annually.
- Vaccinations are routinely administered to infants and children through a well structured public network composed of:
 - 5 Local Public Health Units
 - Family-paediatricians

Indicazioni alla vaccinazione antipneumococcica

Progetto pilota della Regione Liguria



TARGET	MODALITA'	CALENDARIO
Bambini nati nel 2003	Vaccinazione gratuita	3 DOSI <u>3-5-11 mesi</u> 4-6-12 mesi (entro il 4° mese di vita) altri: 3 dosi: 0-2-6/9 mesi
Bambini tra 12 e 23 mesi	Tariffa regionale: Euro 20,66 per dose	2 DOSI 0-2 mesi (Circol. Min. Sal. N°11 del 19/11/01)
Bambini oltre i 23 mesi	Tariffa regionale: Euro 20,66 per dose	1 DOSE (Circol. Min. Sal. N°11 del 19/11/01)
Bambini a rischio (Circol. Min. Sal. N°11 del 19/11/01)	Vaccinazione gratuita previa certificazione del rischio	Secondo l'età

Regione Liguria

Piano regionale vaccini 2005-2007

D.G.R.1268 del 28/10/2005

D.G.R. 1471 del 18/11/2005

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tutti i necessari per realizzare quest'immagine.

D.G.R. 165 del 27/02/06

**Attuazione Piano Regionale della Prevenzione 2005-2007
Disposizioni in merito alle vaccinazioni antipneumococcica
pediatrica, antivaricella ed antiepatite A**

Regione Liguria

Piano regionale vaccini 2005-2007

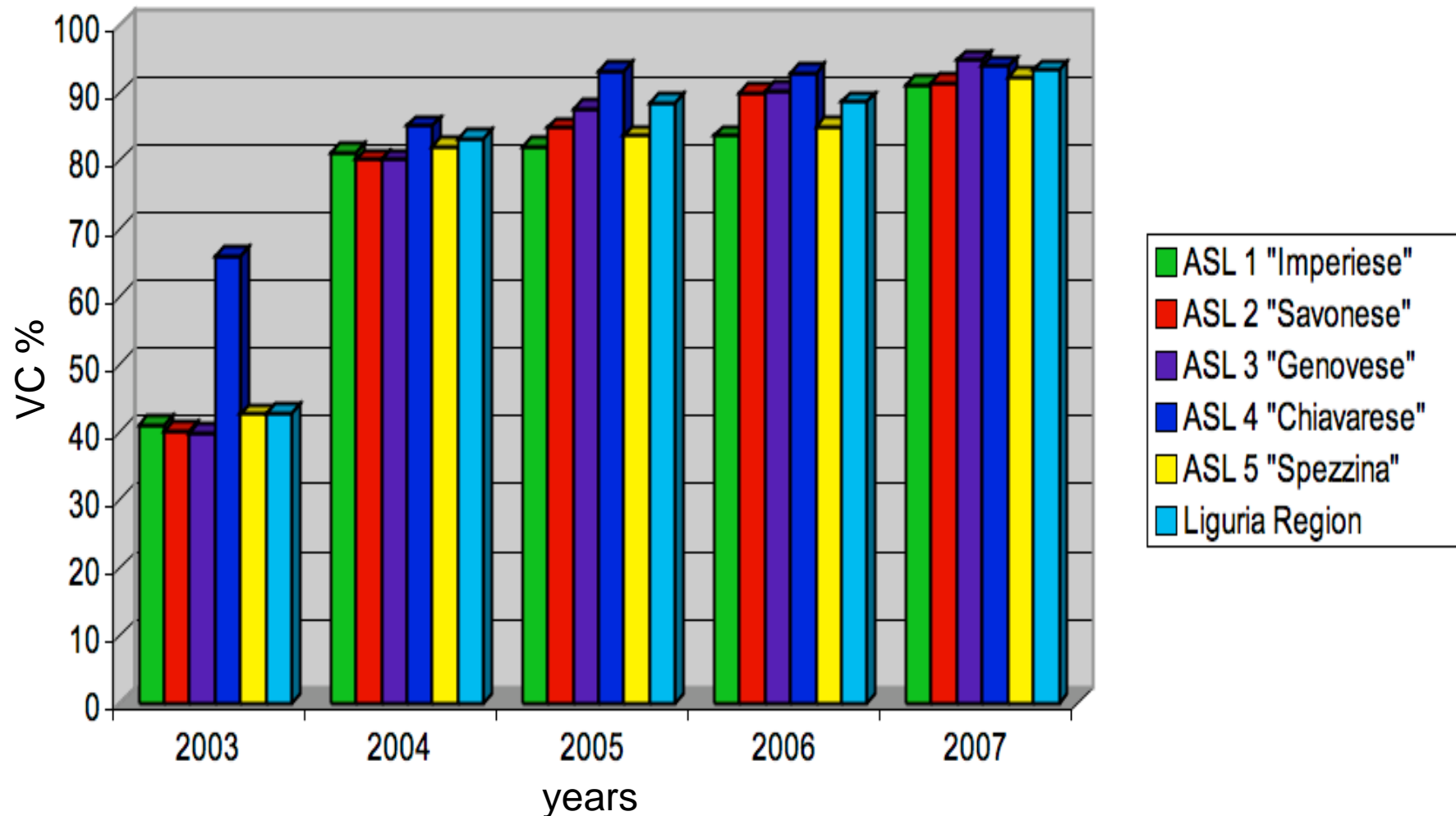


D.G.R. 165 del 27/02/06
Attuazione Piano Regionale della Prevenzione 2005-2007

TARGET	MODALITA'	CALENDARIO
Bambini nel 1° anno di vita nati a partire dal 2003	Vaccinazione gratuita	3°-5°-11° mese di vita 4°-6°-12° mese di vita (entro il 4° mese di vita) altri 3 dosi: 0-2 -6/9mesi
Bambini tra 12 e i 23 mesi	Vaccinazione gratuita	2 dosi 0-2 mesi
Bambini tra i 23 mesi e i 36 mesi	Vaccinazione gratuita	1 dose
Bambini a rischio (Circ.Min.Sal.del19/11/01)	Vaccinazione gratuita, previa certificazione rischio	Secondo l'età

Vaccination Coverages (CV%) for 7-PCV among infants by Local Public Health Unit in Liguria

(full course with three doses given at 3, 5 and 11/12 months)





Department of Health Sciences
Section of Hygiene and Preventive Medicine
University of Genoa

**Immunogenicity of Heptavalent Pneumococcal
Conjugate Vaccine and Diphtheria-Tetanus-Trivalent
Acellular Pertussis-Hepatitis B-Inactivated Polio
Virus-*Haemophilus influenzae* Type B Vaccine, Co-
administered to Italian Infants at 3, 5 and 11-12
Months of Age**



Local Public Health
Unit of Genoa



Infectious Diseases Unit, IRCCS
Gaslini Paediatric Hospital, Genoa



Our “on field” immunogenicity study

On field, multicentre, open, two-arm comparative study

Main objectives

To evaluate the immunogenicity of heptavalent pneumococcal conjugate vaccine (PCV-7) (PREVENAR®) with a vaccination schedule that included 3 doses during the first 1 year of life (2+1 dose schedule).

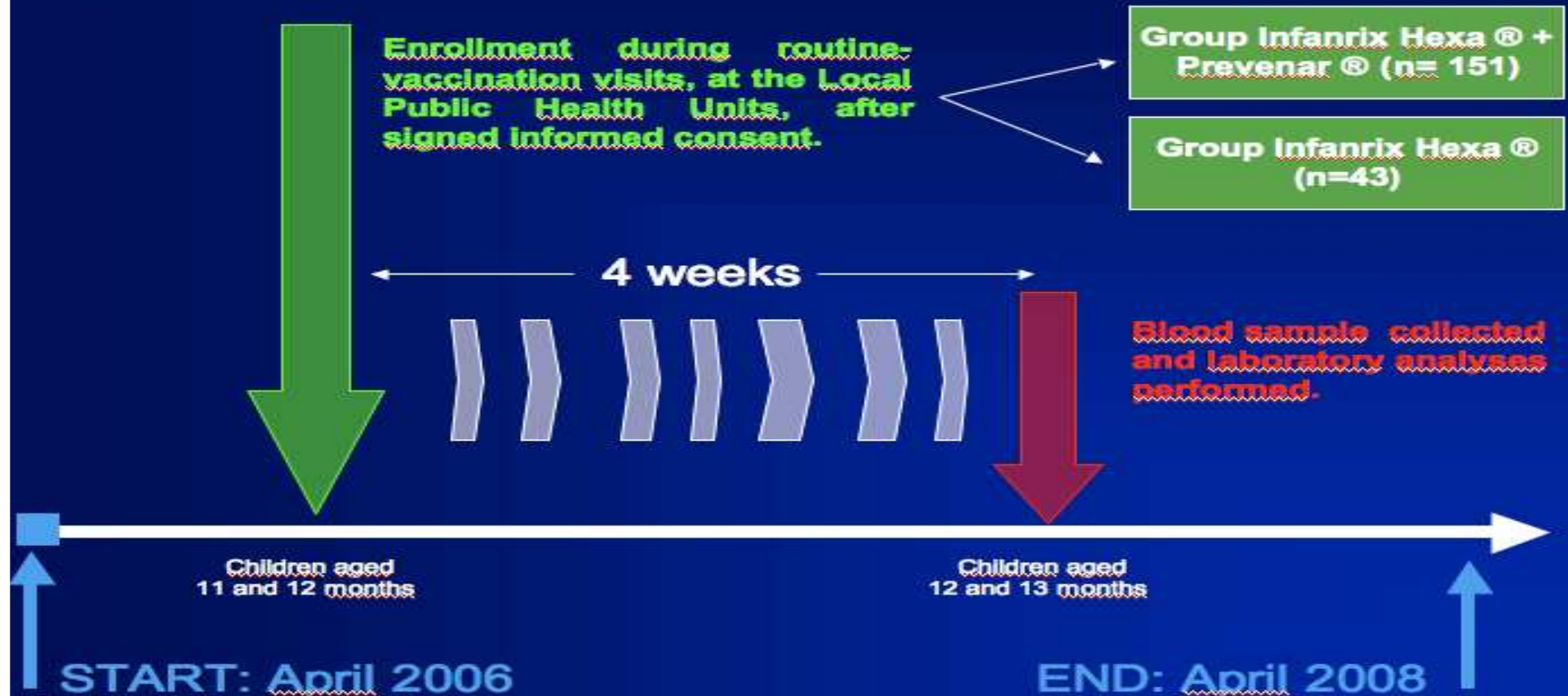
To determine the immune response to heptavalent pneumococcal conjugate vaccine (PCV-7) (PREVENAR®) and hexavalent Diphtheria-Tetanus-Trivalent Acellular Pertussis-Hepatitis B-Inactivated Polio Virus-*Haemophilus influenzae* Type B vaccine (INFANRIX-HEXA®), when co-administered to infants according to a 3-dose course.

Secondary objectives

To demonstrate the non-inferiority of the immune response to hexavalent vaccine when co-administered with the pneumococcal vaccine (PREVENAR® + INFANRIX-HEXA®) in respect with that of the same vaccine when given alone (INFANRIX-HEXA®).



Study design: an “on field” study



Study period (enrollment, blood sampling and lab analyses)
2006-2008 years.

Study population

Healthy infants, regularly immunized at 3, 5 and 11/12 months of age, progressively enrolled in the study at the vaccination-visits within the local Public Health and Paediatric Units in Genoa.





Materials and Methods (I)

- ✓ Sera were separated by centrifugation, aliquoted and stored at -20°C until the assay
- ✓ Samples were tested by standardized and validated enzyme-linked immunosorbant (ELISA) and microneutralization assays for measuring specific antibody response to the vaccinal antigens, as previously described



Materials and Methods (II)

CUT-OFF LEVELS USED:

Anti-Pneumococcal serotypes ($\geq 0.35 \mu\text{g/mL}$)

Antitetanus ($\geq 0.1 \text{ IU/ml}$)

Antidiphtheria ($\geq 0.1 \text{ IU/ml}$)

Anti-PRP ($\geq 0.15 \mu\text{g/ml}$)/($\geq 1 \mu\text{g/ml}$)

Anti-PT/FHA ($\geq 10 \text{ EI. U}$)

Anti-HBs ($\geq 10 \text{ mIU/ml}$)

Anti-Polio 1,2,3 ($\geq 1:8$)



IMMUNOGENICITY PARAMETERS:

Seroprotection rates

GMTs-GMCs

The relevant role of the antibody-response for PCV

For most vaccines, protective activity is mediated either exclusively or primarily by antibodies and the correlate of protection is thus a specified concentration of antibody estimated to confer protection in an immunized population ...

Siber GR et al., Dev Biol Stand 1997

Siber GR et al., Vaccine 2007

It is well known that capsular polysaccharide antibodies are the only known functional and protective antibodies induced by pneumococcal vaccines ...

Jodar L et al., Vaccine 2003

WHO Techn Rep Series n. 927 2005



Available online at www.sciencedirect.com

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Vaccine 21 (2003) 3265–3272

Vaccine

www.elsevier.com/locate/vaccine

Serological criteria for evaluation and licensure of new pneumococcal conjugate vaccine formulations for use in infants[☆]

Luis Jódar^{a,1}, Jay Butler^b, George Carlone^c, Ron Dagan^d, David Goldblatt^e,
Helena Käyhty^f, Keith Klugman^g, Brian Plikaytis^c, George Siber^h,
Robert Kohberger^h, Ih Chang^h, Thomas Cherian^{a,*}

World Health Organization

WHO Technical Report Series n.927 2005.

Recommendations for the production and control of pneumococcal conjugate vaccines



Available online at www.sciencedirect.com

ScienceDirect

Vaccine 25 (2007) 3816–3826

Vaccine

www.elsevier.com/locate/vaccine

Estimating the protective concentration of anti-pneumococcal capsular polysaccharide antibodies

George R. Siber^{a,*}, Ih Chang^b, Sherryl Baker^a, Philip Fernsten^a, Katherine L. O'Brien^c,
Mathuram Santosham^c, Keith P. Klugman^{d,e}, Shabir A. Madhi^e,
Peter Paradiso^a, Robert Kohberger^f

Recently a WHO working group has proposed a protective concentration for PCV in infants.....

A concentration of IgG anticapsular polysaccharide antibodies measured by ELISA ≥ 0.35 $\mu\text{g/ml}$ measured one month after primary immunization was recommended as the protective threshold.....

This was established on the basis of three double-blind controlled efficacy trials for IPD performed in Northern California Kaiser Permanente (Black S. et Al 2000), American Indians (Obrien K.L. 2003) and South Africa (Klugman KB et Al 2003).

The relevant role of antibody-response for PCV: a correlate of protection

“....Thus, if a high proportion of subjects in a population is seroprotected after vaccination (cut-off ≥ 0.35 $\mu\text{g/ml}$)....then we can predict a high level of protection against IPDs in this group....”

Siber GR et al., Vaccine 2007

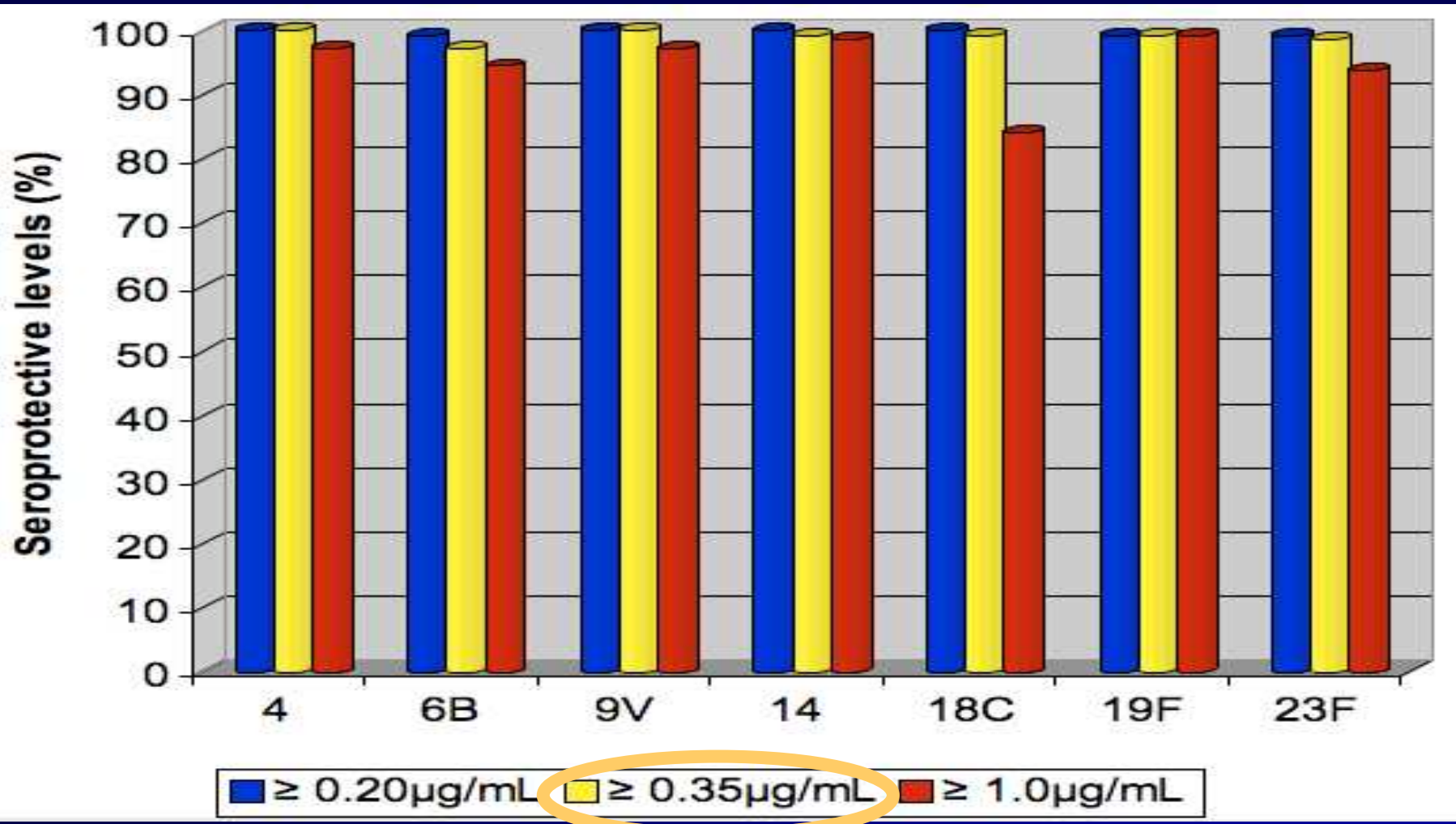
Applications of protective Ab-concentrations for PCVs:

Immunologic correlates of protection then become critical for predicting the efficacy of new or improved vaccines (i.e., 13-PCV) when placebo-controlled efficacy trials are no longer feasible or ethical.....

The protective value could be also used as the benchmark for assessing interference between vaccines given concomitantly.....



Seroprotective levels for anti-pneumococcal PS antibodies, in 146 infants immunized with 7-PCV co-administered with hexavalent vaccine





GMCs for anti-pneumococcal PS antibodies, in 146 infants immunized with 7-PCV co-administered with hexavalent vaccine

Pneumococcal serotype	GMC µg/mL
4	4.70 (4.07-5.43)*
6B	6.73 (5.54-8.18)
9V	3.84 (3.40-4.33)
14	12.29 (10.49- 14.39)
18C	2.50 (2.16-2.90)
19F	10.21 (8.61-12.12)
23F	4.41 (3.75-5.18)

* numbers in parentheses, 95% confidence intervals.

Durando P. et al, WCVII 2008

Results from our study are in line with those reported by other authors in R-CTs and NR-CTs, using both a 3 or a 4-dose schedule ...

Schmitt HJ et al. Vaccine 2003; 21(25-26): 3653-62

Tichmann-Schumann I et al. Pediatr Infect Dis J 2005; 24(1): 70-7

Esposito S et al, Vaccine 2005; 23(14): 1703-8

Käyhty H et al Pediatr Infect Dis J 2005; 24(2): 108-14

Knuf M et al. Vaccine 2006;24:4727-4736

Goldblatt D et al. Pediatr Infect Dis J 2006;25:312-319)



Immunogenicity of the hexavalent vaccine, co-administered and not with PCV, to infants according to a 3, 5 and 11/12 month-vaccination schedule

	DtaP-HBV-IPV-Hib vaccine + 7-PCV			DtaP-HBV-IPV-Hib vaccine		
	Seroprotection n (%)	GMC-GMT	95% C.I.	Seroprotection n (%)	GMC-GMT	95% C.I.
Antitetanus (IU/ml)	151 (100%)	9.26	8.21-10.44	43 (100%)	8.98	6.79-11.88
Antidiphtheria (IU/ml)	151 (100%)	12.6*	10.21-15.56	43 (100%)	7.27*	4.73-11.18
Anti-PRP (µg/ml)	151 (100%) [°] 148 (98%) ^{°°}	17.98	14.9-21.69	43 (100%)	18.77	13.68-25.75
Anti-PT/FHA (El. U)	151 (100%)	163.94	144.45-186.06	43 (100%)	149.25	113.05-197.05
Anti-HBs (mIU/ml)	150 (99.3%)	3899.69	3115.33-4881.50	42 (97.7%)	3141.62	2167.93-4552.62
Anti-Polio1	148 (100%)	1327.6	1107.69-1591.31	43 (100%)	1359.23	938.67-1968.2
Anti-Polio 2	148 (100%)	1260.88	1053.23-1509.47	43 (100%)	1412.47	983.25-2029.07
Anti-Polio 3	148 (100%)	2415.08	1976.31-2952.25	43 (100%)	2696.72	1859.09-3911.77

* p-value=0.0026 (Kruskal Wallis nonparametric test)

[°]Cut-off used= 0.15 µg/ml

^{°°}Cut-off used= 1.0 µg/ml



Highlights from our immunogenicity study

Our data confirm the optimal immune response induced by 7-PCV when administered using a simplified three-dose schedule (2+1) in healthy infants.

Pn-antibody concentrations measured at 13 months in our study were consistent with those registered in previously published positive efficacy trials after 4 doses (Black S et al, 2000, Eskola J et al, 2001, Schmitt HJ et al, 2003), thus suggesting, even if indirectly, a good immunological priming and protection of vaccinees in early infancy.

As far as concerns the evaluation of the antibody response induced by the DTaP-HepB-IPV-Hib vaccine, we showed the absence of any significant immunological interference following the co-administration of this vaccine with the 7-PCV.

The use of a simplified three-dose schedule can bring additional advantages under both the financial (direct cost of the vaccine) and the organizational (i.e., less vaccination visits, vaccine shortage) view-points, positively influencing the economical analyses of the universal immunization programs with PCV.



Department of Health and Social Services
Liguria administrative Region



Department of Health Sciences
Sect. of Hygiene and Preventive Medicine
University of Genoa

**Monitoring the effects of the universal infant
immunisation campaign with 7-PCV on
pneumococcal-associated or potentially-
associated hospitalizations in children aged
< 2 years in Liguria, Italy**



Monitoring the effects of the universal infant immunisation campaign with 7-PCV on pneumococcal-associated or potentially-associated hospitalizations in children aged < 2 years in Liguria, Italy (I)



Methods

Hospitalization rates of children belonging to birth cohorts before, 2000-2002, (n=33946) and after, 2003-2005, (n=35452) the introduction of widespread immunization were compared.

Study population and data source

Data from Liguria Regional database concerning in-patient discharge information on pneumococcal-associated or potentially-associated hospitalizations was collected in children 0-2-years old, in accordance with the International Classification of Diseases, 9th revision, Clinical Modification (ICD-9CM).

Rates of hospital admissions for the following discharge diagnosis, used as main clinical outcomes (Grijalva CG et al., *The Lancet* 2007; Shah SS et al., *CID* 2006), were calculated:

- all-cause pneumonia (480-487.0)
- pneumococcal pneumonia (481) (lobar pneumonia, organism unspecified)
- acute otitis media (382)
- bacterial meningitis, non-specified meningitis (320-322-322.9)
- septicemia (038)
- urinary tract infections (5990)



Monitoring the effects of the universal infant immunisation campaign with 7-PCV on pneumococcal-associated or potentially-associated hospitalizations in children aged < 2 years in Liguria, Italy (II)



Clinical outcome measures

To identify all-cause and pneumococcal pneumonia, acute otitis media, meningitis and septicemia admissions, they were defined by **principal or secondary diagnosis ICD-9CM codes**.

To improve the sensitivity and the accuracy of coding data for identification of **pneumococcal pneumonia**, the **specific ICD-9CM code was searched in all 5 positions of discharge record** (Guevara RE et al, *Am J Epidemiol* 1999).

Admission rates for **urinary tract infections** were assessed to evaluate the specificity of the outcome evaluation.

Population estimates used for calculation of rates (including age-specific rates) were those for the resident population (National Institute of Statistics).

accepted in press on the J Int Med Res

Decline in pneumonia and acute otitis media after introduction of childhood pneumococcal vaccination in Liguria, Italy

Ansaldi F, Sticchi L, Durando P, Carloni R, Oreste P, Vercelli M, Crovari P, Icardi G

	Incidence/10 ⁴ p-y (95% C.I.)		Preventive fraction (%, 95% C.I.)
	Birth cohort 2000-2002	Birth cohort 2003-2005	
All-cause pneumonia	64.22 (58.4, 70.46)	54.44 (49.21, 60)*	15.2 (2.8, 26.1)
Pneumococcal pneumonia	1.91 (1.07, 3.27)	0.56 (0.18, 1.36)*	70.5 (9.7, 90.4)
Acute otitis media	45.22 (40.37, 50.05)	28.77 (25.02, 32.92) [°]	36.4 (24.1, 46.7)
Meningitis	2.36 (1.4, 3.74)	2.96 (1.88, 4.45)	20.4 (-52.5, 58.5)
Septicaemia	8.54 (6.55, 10.97)	11.99 (9.63, 14.75)	27.5 (-1, 48)
Urinary tract infections	105.5 (97.88, 113.5)	95.62 (88.56, 103.1)	9.3 (-0.7, 18.3)

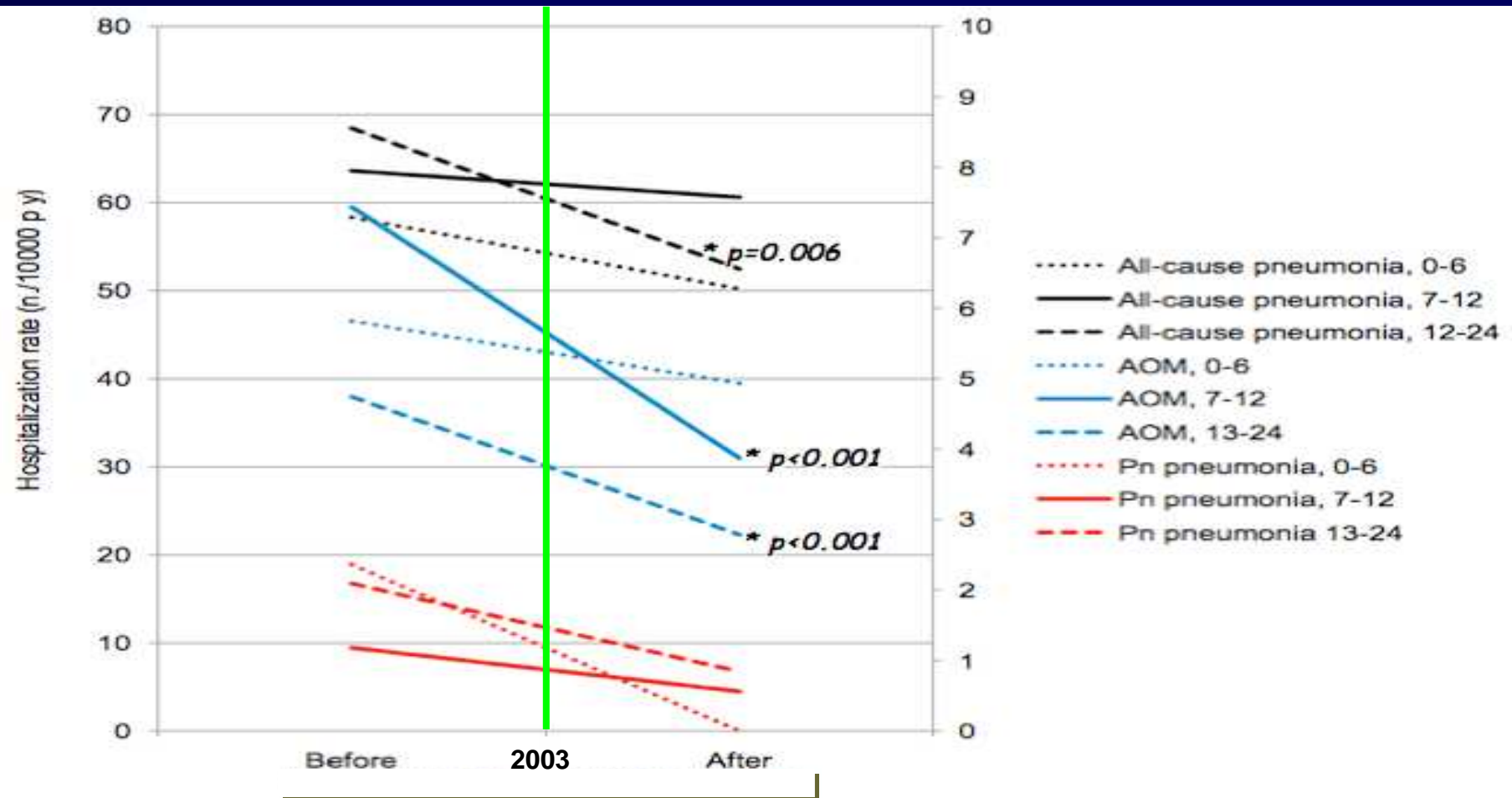
* p<0.05

[°] p<0.01

accepted in press on the J Int Med Res

Decline in pneumonia and acute otitis media after introduction of childhood pneumococcal vaccination in Liguria, Italy

Ansaldi F, Sticchi L, Durando P, Carloni R, Oreste P, Vercelli M, Crovari P, Icardi G



Decline in pneumonia admissions after routine childhood immunisation with pneumococcal conjugate vaccine in the USA: a time-series analysis

Carlos G Grijalva, J Pekka Nuorti, Patrick G Arbogast, Stacey W Martin, Kathryn M Edwards, Marie R Griffin

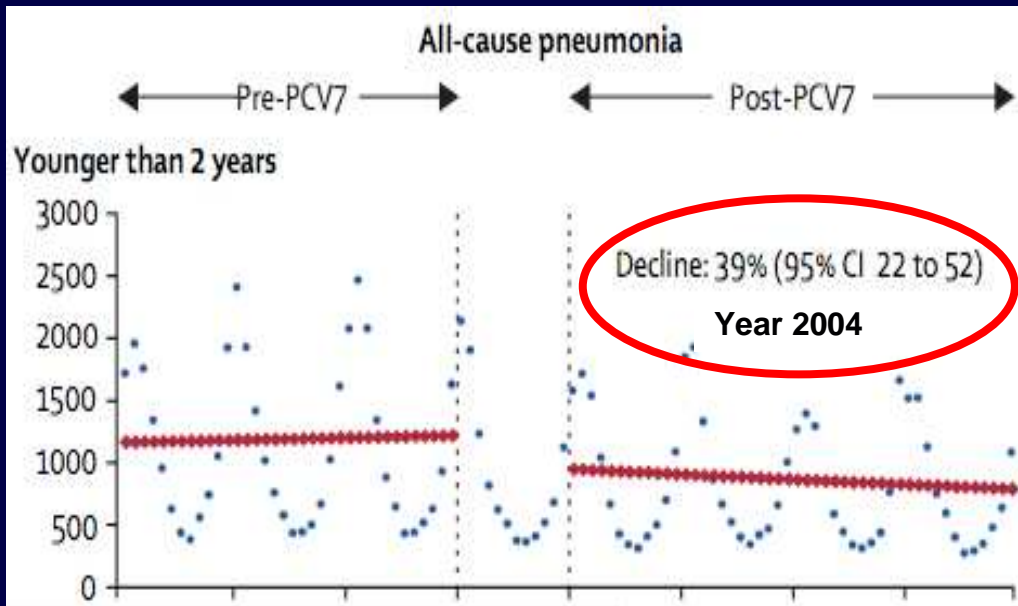
Data from Nationwide Inpatient Sample (Agency for Health Care), representing 20% of all US admissions (nearly 35.000.000 per year), were analysed with an interrupted time-series analysis that used PNEUMONIA (ALL-CAUSE and PNEUMOCOCCAL) admission rates as the main outcomes.

Monthly admission rates estimated for years after vaccination with PCV (2001-2004) were compared with expected rates calculated from pre-PCV years (1997-1999).

The year of vaccine introduction (2000) was excluded.

Rates of admission for dehydration were assessed for comparison.

The Lancet, April 2007



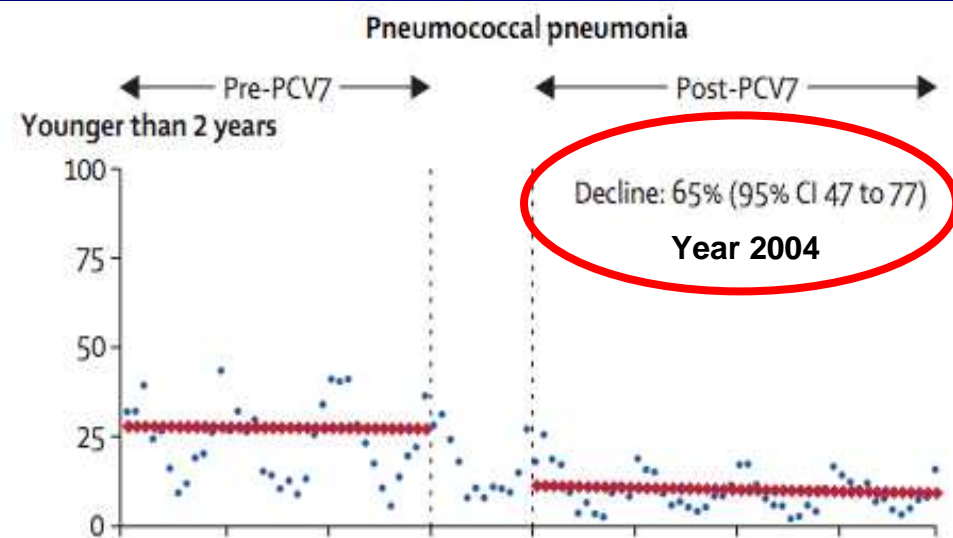
Trends in monthly US admission rates (1997-2004) for all-cause and pn-pneumonia, before and after routine immunization of children with 7-PCV

Grijalva CG, The Lancet 2007

This annual decline in all-cause pneumonia admissions of 506/100000 children younger than 2 years represented about 41000 pneumonia admissions prevented in 2004.

This decline represented about 17 fewer admissions per 100000 children in 2004.

During the 8 study years, 10659 (2%) children <2 yrs admitted with pneumonia were coded as having pneumococcal disease.





Available online at www.sciencedirect.com



Vaccine 25 (2007) 2507–2512



www.elsevier.com/locate/vaccine

Brief review of the clinical effectiveness of PREVENAR® against otitis media

Mark A. Fletcher*, Bernard Fritzell

“...Bacteria can be responsible for 60-70% of clinical episodes of AOM, being *St. pneumoniae* the cause of 30-40% of all these cases, and even of a greater fraction of the severe ones...”

“...Pneumococcal AOM may present with more severe clinical signs and symptoms than AOM caused by either *H. influenzae* and *M. catharralis* (Palmu AA et al CID 2007)

Our reported decline in hospitalization rates for AOM (36.4%) is in the range of vaccine-efficacy (10-50%) of the FinOM and NCKP clinical trials (long-term follow up) against recurrent episodes or for the prevention of tympanostomy tube placement...

accepted in press on the J Int Med Res

Decline in pneumonia and acute otitis media after introduction of childhood pneumococcal vaccination in Liguria, Italy

Ansaldi F, Sticchi L, Durando P, Carloni R, Oreste P, Vercelli M, Crovari P, Icardi G

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* p<0.05

[°] p<0.01

Effectiveness of seven-valent pneumococcal conjugate vaccine against invasive pneumococcal disease: a matched case-control study

Lancet 2006; 368: 1495-502

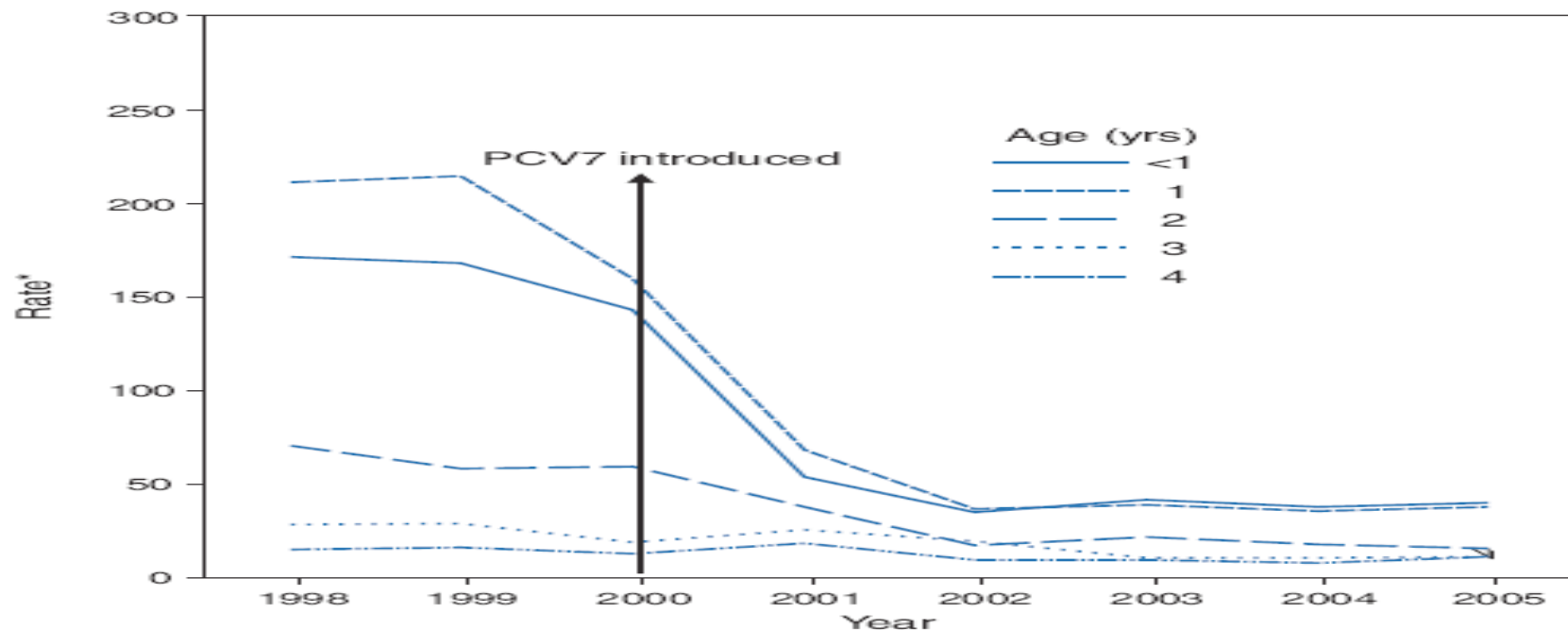
Cynthia G Whitney, Tamar Pilishvili, Monica M Farley, William Schaffner, Allen S Craig, Ruth Lynfield, Ann-Christine Nyquist, Kenneth A Gershman, Marietta Vazquez, Nancy M Bennett, Arthur Reingold, Ann Thomas, Mary P Glode, Elizabeth R Zell, James H Jorgensen, Bernard Beall, Anne Schuchat

	Effectiveness	95% CI
Infant schedules*		
1 dose ≤ 7 months	73%	43% to 87%
2 doses ≤ 7 months	96%	88% to 99%
3 doses ≤ 7 months	95%	88% to 98%
1 dose ≤ 7 months, 1 dose 8-11 months, 1 dose 12-16 months†	100%	88% to 100%
<u>2 doses ≤ 7 months, 1 dose 12-16 months†</u>	<u>98%</u>	75% to 100%
<u>3 doses ≤ 7 months, 1 dose 12-16 months†</u>	<u>100%</u>	94% to 100%
1 dose 7-11 months, 2 doses 12-16 months†	98%	83% to 100%
Toddler schedules*		
1 dose 12-23 months	93%	68% to 98%
2 doses 12-23 months†	96%	81% to 99%
1 dose ≥ 24 months†	94%	49% to 99%

* Vaccine schedules, by months of age at time of doses, are mutually exclusive. †Based on vaccination schedules recommended by the Advisory Committee on Immunization Practices.⁷ We could not assess two recommended schedules (two doses 7-11 months plus one dose 12-16 months, and two doses at 24 months or later) because insufficient numbers of cases and controls were vaccinated on those schedules.

Table 4: Effectiveness of pneumococcal conjugate vaccine against invasive pneumococcal disease caused by vaccine serotypes in children aged 3-59 months by number and timing of doses, compared with no vaccine

FIGURE 1. Changes in incidence rate* of invasive pneumococcal disease (IPD) among children aged <5 years before and after introduction of 7-valent pneumococcal conjugate vaccine (PCV7), by age and year — Active Bacterial Core surveillance, eight states,† 1998–2005



* Per 100,000 population.

† California (one county); the state of Connecticut; Georgia (20 counties); Maryland (six counties); Minnesota (seven counties); New York (seven counties); Oregon (three counties); and Tennessee (four counties).

CDC's Active Bacterial Core surveillance (ABCs), a population- and laboratory-based system.

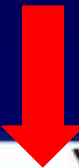
The total population aged <5 years under surveillance in 2005 was 1.26 million persons.



Italian Network for the Special Surveillance of bacterial meningitis and sepsis: results from Liguria

START UP OF THE 7-PCV IMMUNIZATION

by *St. pneumoniae*



Age group	YEARS							
	2000	2001	2002	2003	2004	2005	2006	2007
< 1 year	1	1	0	1	0	1	0	0
1-4 years	0	1	1	1	0	1	1	0
Total Cases	1	2	1	2	0	2	1	0

by unidentified agents overall

Age group	YEARS							
	2000	2001	2002	2003	2004	2005	2006	2007
< 1 year	0	0	0	1	0	0	0	0
1-4 years	1	2	1	3	0	0	0	0
Total cases	1	2	1	4	0	0	0	0



PROGETTO PILOTA DELLA REGIONE LIGURIA VACCINAZIONE ANTIPNEUMOCOCCICA



MIGLIORAMENTO DELLA DIAGNOSTICA EZIOLOGICA

L'obiettivo è quello di implementare la sorveglianza delle malattie invasive da *Streptococcus pneumoniae* (MISP) attraverso:

- ✓ Il miglioramento della diagnostica mediante l'introduzione e la valutazione sul campo di test molecolari per il rilevamento dello *Streptococcus pneumoniae*, che consentirebbero un'elevata sensibilità anche in presenza di trattamento antibiotico precedente alla raccolta del campione
- ✓ L'estensiva tipizzazione con tecniche sierologiche e molecolari dei campioni positivi per *Streptococcus pneumoniae* raccolti da pazienti con MI per la valutazione dei fenomeni di *replacement* o di cambiamenti nel pattern di resistenza del batterio

Obiettivi

- Miglioramento della diagnostica: introduzione e valutazione sul campo di test molecolari per il rilevamento dello *Streptococcus pneumoniae* (Pn)
 - ↑ sensibilità: stima reale del *burden*
- Estensiva tipizzazione con tecniche sierologiche e molecolari dei campioni positivi per Pn
 - *Replacement*
 - Cambiamenti nel pattern di resistenza del batterio

Definizione di Malattia Invasiva (MI)

Quadro clinico compatibile con

- meningite
- batteriemia/sepsi
- polmonite

Miglioramento della diagnostica: introduzione e valutazione sul campo di test molecolari

Campioni ematici di pazienti con quadro clinico compatibile con

- batteriemia/sepsi (no terapia A.B.) N=12
- polmonite (terapia A.B.) N=17

		Esame Colturale		
		POS	NEG	
Test molecolare	POS	2	6	8
	NEG	0	21	21
		2	27	29

Se gold standard PCR

Sensibilità della coltura = 25%

PPN della coltura = 77%

Miglioramento della diagnostica: introduzione e valutazione sul campo di test molecolari

Campioni ematici di pazienti con quadro clinico compatibile con

- batteriemia/sepsi (no terapia A.B.) N=12

- polmonite (terapia A.B.) N=17

		Esame Colturale		
		POS	NEG	
Test molecolare	POS	0	3	3
	NEG	0	14	14
		0	17	17

Se gold standard PCR

Sensibilità della coltura = 0

PPN della coltura = 82%



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Pneumococcal serotypes distribution and antibiotic resistance in pediatrics: surveillance in the Region of Liguria

Principal aim

To describe the serotype distribution and antibiotic resistance of IPD isolates over time during the introduction of PCV-7 in Liguria.

Inclusion criteria

All consecutive *S. pneumoniae* isolates, reported by culture and non-culture methods (PCR), during a 24 months observation, from sterile tissues (blood and CSF) in following diseases:

Meningitis

Pneumonia with Bacteraemia

Sepsis

Occult Bacteraemia

All positive cultures will be tested for antibiotic-resistance level and serotyping.

Heptavalent Pneumococcal Conjugate Vaccine: growing knowledge and its implications for Italy

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On the basis of the above described experiences in European countries where a universal strategy with PCV has been adopted and considering that the epidemiological scenario of the diseases sustained by Pn in these geographical areas is nearly superimposable to that existing in Italy, we support an active, free-of-charge, 3 dose-schedule (2 + 1) programme for the immunisation of all Italian children during the first year of life, as the best strategy both under the health care and the financial point of view.

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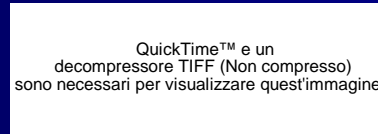


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Conforti G., Semprini G., Marensi L., Ferrando A.
**Scientific society of Hygiene and Preventive Medicine of Liguria
and Federation and Association of Paediatricians of Liguria**