Epidemiology of invasive pneumococcal disease in Catalonia Report 2012-2016

Catalan Microbiological Reporting System

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Subdirectorate-General for Epidemiological Surveillance and Public Health Emergency Response

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Coordination:

Pilar Ciruela and Mireia Jané

Subdirectorate-General for Epidemiological Surveillance and Public Health Emergency Response. Public Health Agency of Catalonia

Authors:

Pilar Ciruela,[1] Conchita Izquierdo,[1] Sonia Broner,[1] Sergi Hernández,[1] Carme Muñoz-Almagro,[2] Román Pallarés,[3] Mireia Jané,[1] Catalan Working Group on Invasive Pneumococcal Disease.[4]

[1] Sub-directorate General for Epidemiological Surveillance and Public Health Emergency Response. Public Health Agency of Catalonia.

[2] Sant Joan de Déu University Hospital. Public Health Support Laboratory.

[3] Bellvitge University Hospital.

[4] Catalan Working Group on Invasive Pneumococcal Disease: P Ciruela, C Izquierdo, S Broner, S Hernández, M Jané (Public Health Agency of Catalonia, Barcelona); C Muñoz-Almagro, C Esteva, MF de Sevilla, D Henares (Sant Joan de Déu University Hospital, Esplugues, Public Health Support Laboratory); R Pallarés, C Ardanuy, I Grau (Bellvitge University Hospital, Bellvitge); F Marco (Clínic Hospital, Barcelona); J Llaberia (Santa Creu i Sant Pau Hospital, Barcelona); A González-Cuevas (Sant Joan de Déu Health Complex General Hospital, Sant Boi de Llobregat); A Díaz (Nens Hospital, Barcelona); MT Martin, N Larrosa (Vall d'Hebron University Hospital, Barcelona); M Sierra (Barcelona Hospital, Barcelona); M Curriu (Sant Bernabé Hospital, Berga); C Gallés, P Hernández (Sant Jaume Hospital, Calella); P Gassiot (Figueres Hospital, Figueres); M Martínez-Zurita (Josep Trueta Hospital, Girona); C Martí (Granollers General Hospital, Granollers); M Morta (Sant Joan de Déu Hospital, Manresa); G Sauca (Mataró Hospital, Mataró); A Gassós (Sant Joan de Déu de Martorell Hospital, Martorell); E Sanfeliu (Olot i Comarcal de la Garrotxa Hospital, Olot); F Ballester, I Pujol (Sant Joan Hospital, Reus); M Olsina (Catalunya General Hospital, Sant Cugat del Vallès); X Raga (Sant Pau i Santa Tecla Hospital, Tarragona); F Gómez-Bertomeu (Joan XXIII Hospital, Tarragona); MO Pérez-Moreno (Verge de la Cinta Hospital, Tortosa); A Vilamala, M Navarro (Vic Hospital Consortium, Vic); M Ribelles (Arnau de Vilanova de Lleida University Hospital, Lleida); E Padilla, N Prim (Catalonia Reference Laboratory); D Fontanals (Parc Taulí University Hospital. Institute for Research and Innovation Parc Taulí I3PT. UAB, Sabadell); MA Benitez, E Jou, C Sanjosé (CLILAB Diagnòstics); M Giménez, MD Quesada (Germans Trias i Pujol University Hospital, Badalona); JC de la Fuente (Móra d'Ebre Municipal Hospital); A Calderon (Badalona Municipal Hospital, Badalona); PJ Ayala (Terres de l'Ebre Clinic); L Vega (Quirón-Dexeus University Hospital, Barcelona); J Pérez-Jové (Catlab-Terrassa Analytical Centre, AIE); C Balado, I Valle (Dr. F Echevarne Analysis Laboratory).

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Table of contents

1 Introduction

Invasive pneumococcal disease (IPD) is a major public health problem worldwide and the cause of a broad spectrum of diseases of varying severity, ranging from otitis media to meningitis. IPD is defined by the isolation or detection of *Streptococcus pneumoniae* DNA or antigen from a normally sterile site (blood, cerebrospinal fluid, pleural fluid, peritoneal fluid and synovial fluid, among others).

Over 90 *S. pneumoniae* serotypes have been identified based on the composition of its polysaccharide capsule. Circulation of these serotypes and, therefore, the epidemiology of IPD have changed in recent years concomitantly to the introduction of the 7-valent pneumococcal conjugate vaccine (PCV7) in 2000 in the USA and in 2001 in Europe. PCV7 includes the serotypes: 4, 6B, 9V, 14, 18C, 19F and 23F. Catalonia started marketing the 10-valent pneumococcal conjugate vaccine (PCV10) in 2009 and the 13-valent pneumococcal conjugate vaccine (PCV13) in 2010, replacing PCV7. PCV10 includes the PCV7 serotypes and serotypes 1, 5 and 7F; and PCV13 includes the PCV10 serotypes and serotypes 3, 6A and 19A.

Up until July 2016 in Catalonia, none of the conjugate vaccines were included in the systematic vaccination schedule and only infants with risk factors were indicated for vaccination. However, pneumococcal conjugate vaccines have been recommended by paediatricians and are administered according to SPC indications. Since 2016, the pneumococcal vaccine has been administered at 2, 4 and 11 months of age, based on the guidelines of the National Health System Interregional Council.[1,2]

Since 1999, vaccination with the 23-valent pneumococcal polysaccharide vaccine (PPSV23) has been recommended for over-65s.

Since 1995, surveillance of confirmed cases of IPD has been conducted through the Catalan Microbiological Reporting System (SNMC). The SNMC is a basic health information system, part of the Epidemiological Surveillance Network, and consists of a group of microbiology laboratories in public and private hospitals and medical centres in Catalonia (list of centres).

These centres (45 public hospitals, 1 private hospital and 4 primary care centres) represent 83% of acute patient hospital beds in the public hospital network.

Decree 203/2015,[3] of 15 September, which created the Epidemiological Surveillance Network of Catalonia and which regulates reporting systems for notifiable diseases and epidemic outbreaks, establishes SNMC as one of the systems for reporting notifiable diseases. The decree also creates a list of new notifiable diseases, which includes IPD as a notifiable disease exclusively by microbiological reporting.

Since 2012, the Subdirectorate-General for Epidemiological Surveillance and Public Health Emergency Response (SGVRESP) of the Public Health Agency of Catalonia (ASPCAT) has participated in a European IPD active surveillance project (PROC/2012/031) 'Assessing the impact of vaccination with conjugate vaccines on the epidemiology of the invasive pneumococcal disease in Europe',[4] together with another nine European regions. The aim of the project is to carry out active surveillance of IPD in Europe to increase knowledge of IPD epidemiology and study the overall impact and effectiveness of vaccination for the disease using conjugate vaccines in infants under 5 years of age.

In 2015 the IPD surveillance project (PROC/2015/020) was broadened to study the overall impact, mortality and effectiveness of pneumococcal conjugate vaccines in infants aged under 5 and adults aged 65 and over. Since then, more European countries have joined the project, to create a network of 15 regions from 11 countries.

The report for 2012-2014[5] showed a significant drop in the incidence of IPD among all age groups, except the over-65s, from 2012. Furthermore, the incidence of the serotypes included in PCV13 dropped significantly in all age groups, headed by the 65 and over group.

2 Objectives

The aim of this report is to describe the epidemiology of IPD and changes in circulating serotypes among the different age groups and their clinical presentation in the years 2012-2016 in cases reported to the SNMC of the SGVRESP.

3 Methods

The information in this report is based on confirmed cases of acute IPD reported by laboratories in the SNMC in the period 2012-2016, based on the criteria of the European Centre for Disease Prevention and Control (ECDC), whose case definition of IPD is: 'Isolation of *Streptococcus pneumoniae* DNA or antigen from a normally sterile site'.

During this period, in the context of the European IPD surveillance project, enhanced and proactive surveillance of the disease was carried out and microbiological variables were included through the following sources of information:

1) The Public Health Surveillance Support Laboratory for IPD at Sant Joan de Déu University Hospital, which is responsible for identifying the *S. pneumoniae* serotype using the PCR technique and *multilocus sequence typing* (MLST) with samples received from certain laboratories. In addition, the strains are sent to the Spanish Pneumococcal Reference Laboratory at the National Centre for Microbiology in Majadahonda.

2) The Spanish Pneumococcal Reference Laboratory at the National Centre for Microbiology in Majadahonda. This centre studies the *S. pneumoniae* serotype (by Quellung reaction) and the antibiotic sensitivity of the samples received.

The serotype is identified using the Quellung reaction or, when not possible, by PCR.

The variables studied are sex, age (age groups: <2 years, 2-4 years, 5-19 years, 20-64 years and 65 years or more), diagnostic data, clinical presentation, clinical sample, microbiological technique and serotype. The serotype is also analysed in terms of its inclusion in the pneumococcal conjugate vaccines (PCV7, PCV10 and PCV13).

With regard to **statistical analyses**, incidence rates were calculated based on demographic data from the Statistical Institute of Catalonia (IDESCAT) for the age groups studied.

The impact assessment was carried out by incidence rate ratio (IRR) with 95% confidence intervals, assuming the Poisson distribution, comparing 2016 with 2012. Impact was analysed using the formula (1-IRR)*100.

The analysis was performed using the Statistical Package for Social Sciences (SPSS 19.0) and R 3.2.0 (R Development Core Team 2015).

4 Results

Incidence by age group

In the period 2012-2016, a total of 4,656 cases of IPD were reported, representing an incidence rate of 12.4 cases per 100,000 persons-year. The highest incidence rates were among infants under 2 years of age (41.0 cases per 100,000 persons-year), in adults aged 65 or over (32.2 cases per 100,000 persons-year) and in infants aged 2 to 4 years (22.1 cases per 100,000 persons-year) (Figure 1). The incidence in men was higher than in women for all age groups (2,729 cases; 58,6%).

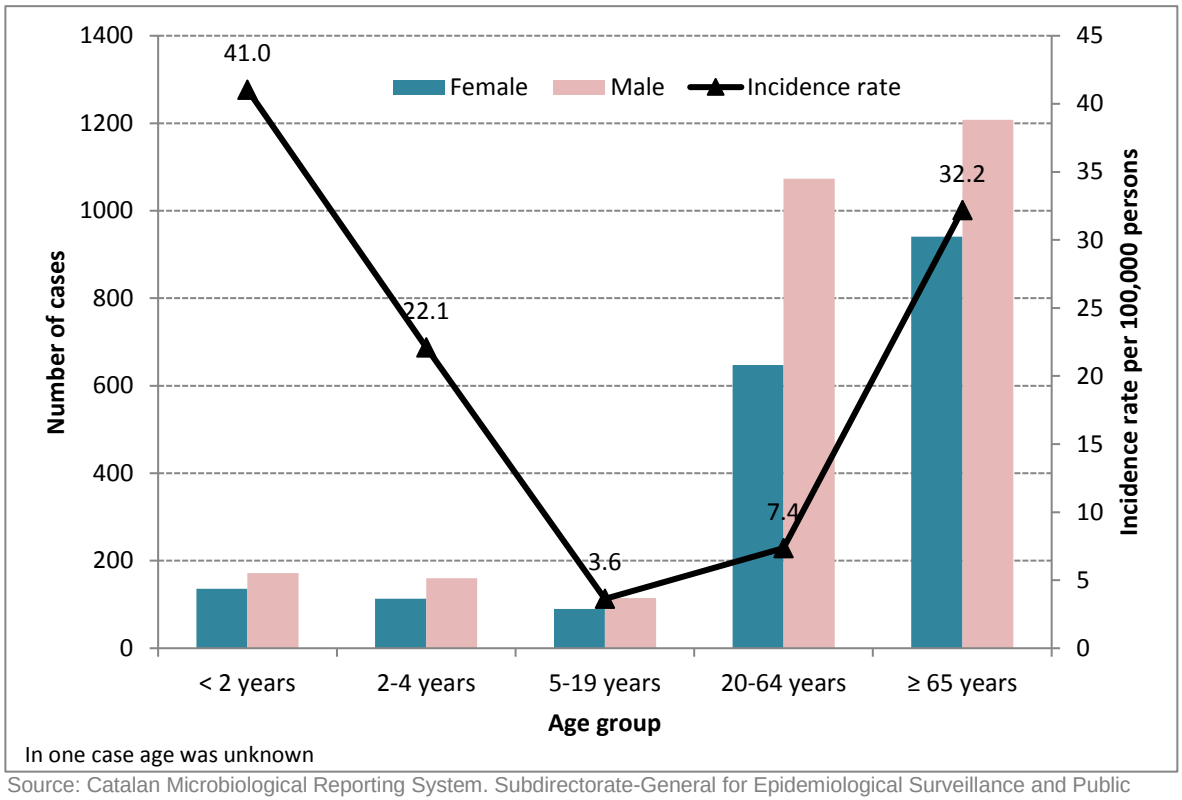
Diagnosis was by culture in 4,464 cases (95.9%); PCR in 156 cases (3.3%) and antigen detection in 36 (0.7%) cases.

Impact analysis

In 2016, 916 cases were reported and the overall incidence rate was 12.2 cases per 100,000 persons-year. A 9% drop in the overall incidence rate compared to 2012 was observed (IRR: 0.91; 95% CI: 0.83-0.99; p = 0.035) (Table 1).

In 2016, the highest incidence rates were among infants under 2 (38.2 cases per 100,000 persons-year), followed by adults aged 65 or over (32.5 cases per 100,000 persons-year) and 2- to 4-year-olds (20.9 cases per 100,000 persons-year). The drop in incidence in 2016 was significant in the 2-4 age group (31%) and in the 5-19 age group (36%).

Figure 1. IPD incidence by age group and sex. Catalonia, 2012-2016



In one case age was unknown

Source: Catalan Microbiological Reporting System. Subdirectorate-General for Epidemiological Surveillance and Public Health Emergency Response. Public Health Agency of Catalonia.

Table 1. IPD incidence by age group and years. Catalonia, 2012-2016

Age group	2012		2013		2014		2015		2016		2012-2016		IRR 2016 vs. 2012 (95% CI)	p value
	No.	IR	No.	IR	No.	IR	No.	IR	No.	IR	No.	IR		
<5 years	161	38.0	104	25.2	97	24.5	117	30.6	102	27.5	581	29.3	0.72 (0.56-0.93)	0.011
<2 years	82	50.1	58	37.2	51	34.6	63	44.3	54	38.2	308	41.0	0.76 (0.53-1.09)	0.141
2-4 years	79	30.4	46	17.9	46	18.5	54	22.5	48	20.9	273	22.1	0.69 (0.47-0.99)	0.047
5-19 years	55	5	50	4.5	26	2.3	37	3.2	37	3.2	205	3.6	0.64 (0.41-0.99)	0.042
20-64 years	386	8.1	339	7.2	318	6.8	348	7.5	329	7.1	1,720	7.4	0.88 (0.76-1.02)	0.094
≥65 years	413	32.1	451	34.5	388	29	449	33.0	448	32.5	2,149	32.2	1.01 (0.88-1.16)	0.882
Total*	**1,016**	**13.4**	**944**	**12.5**	**829**	**11**	**951**	**12.7**	**916**	**12.2**	**4,656**	**12.4**	**0.91 (0.83-0.99)**	**0.035**

Source: Catalan Microbiological Reporting System. Subdirectorate-General for Epidemiological Surveillance and Public Health Emergency Response. Public Health Agency of Catalonia.
IR: Incidence rate per 100,000 persons-years, IRR: Incidence rate ratio.
*In one case age was unknown.

Clinical signs

Most cases presented with pneumonia (74.9%; 3,489/4,656). Rates for non-focal bacteraemia, meningitis and other clinical presentations were 13.6%, 8.1% and 3.4%, respectively (Table 2).

Pneumonia was the most frequent clinical presentation in all age groups. The incidence rate was higher in adults aged 65 or over (24.9 per 100,000 persons-year), followed by under-2s (21.2 per 100,000 persons-year). Meningitis had a higher incidence rate among under-2s (4.9 per 100,000 persons-year).

Table 2. IPD incidence by clinical presentation and age group. Catalonia, 2012-2016

Clinical presentation	<2 years		2-4 years		5-19 years		20-64 years		≥65 years		IPD global	
	No.	IR	No.	IR	No.	IR	No.	IR	No.	IR	No.	IR
Pneumonia	159	21.2	218	17.6	167	3.0	1,281	5.5	1,664	24.9	3,489	9.3
Non-focal bacteraemia	95	12.7	32	2.6	20	0.4	226	1.0	260	3.9	633	1.7
Meningitis	37	4.9	16	1.3	8	0.1	156	0.7	161	2.4	379[a]	1.0
Other forms*	17	2.3	7	0.6	10	0.2	57	0.2	64	1.0	155	0.4
Total	308	41.0	273	22.1	205	3.6	1,720	7.4	2,149	32.2	4,656[a]	12.4

Source: Microbiological Reporting System of Catalonia. Subdirectorate-General for Epidemiological Surveillance and Public Health Emergency Response. Public Health Agency of Catalonia.
IR: Incidence rate per 100,000 persons-year.
*Peritonitis: 79; arthritis: 42; cellulitis: 11; cholescystitis: 7; endofthalmitis: 4; endocarditis: 2; mastoiditis: 3; chorioamnionitis: 1; pericarditis: 1; pancreatitis: 1; epiglottitis: 1; cerebral empyema: 1; lumbar spondylodiscitis: 1; biopsy of the aneurysmal sac: 1.
[a] In one case age was unknown.

Serotype study

The distribution of serotypes identified during the period 2012-2016 is shown in Figure 2.

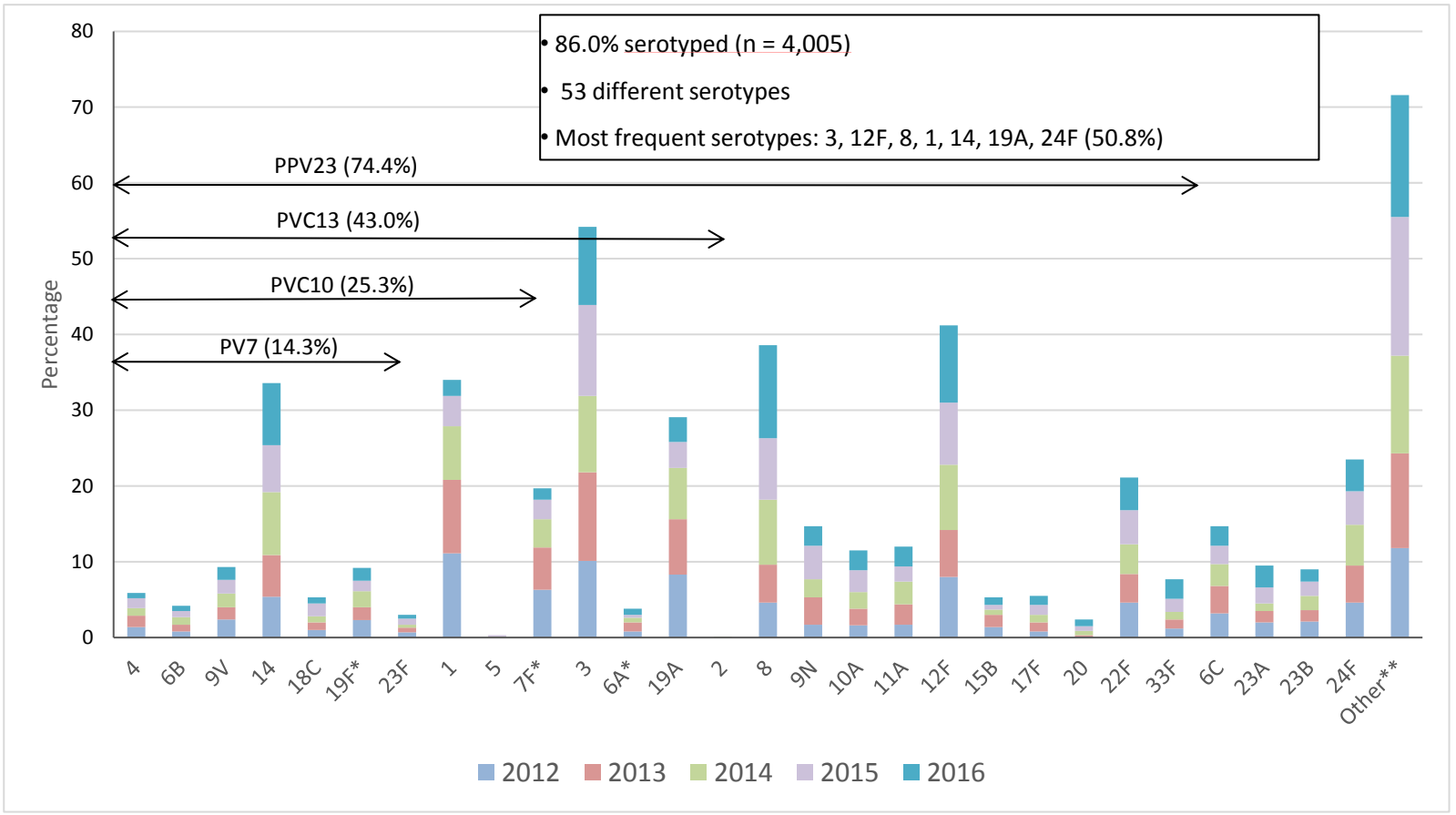
In the period 2012-2015, the serotype was identified in 86.6% of diagnosed cases (3,239/3,740) and 52 different serotypes were detected. The most frequent serotypes were: 3, 1, 12F, 19A, 8, 14, and 24F, representing 50.8% of cases. The serotypes included in PCV7 represented 14.3% of cases, those included in PCV10 represented 27.1%, those in PCV13 were 45.5% and those in PPSV23 were 75.0%.

In 2016, the serotype was identified in 83.6% of diagnosed cases (766/916) and 45 different serotypes were detected. The most frequent serotypes were: 8, 3, 12F, 14, 22F, 24F and 19A; representing 52.8% of cases. The serotypes included in PCV7 represented 14.3% of cases, those included in PCV10 represented 17.8%, those in PCV13 were 32.2% and those in PPSV23

were 71.9%. In infants under 2, the serotypes included in PCV10 and PCV13 were represented in 23.8% and 28.6% of cases, respectively. In the 2-4 age group, they represented 25.0% and 45.0% of cases, respectively.

Bearing in mind the percentages of serotypes included in the vaccines, in 2016 a decrease in those included in PCV10 (34%), PCV13 (29%) and PPSV23 (4%) were observed compared to the 2012-2015 period.

Figure 2. IPD serotypes distribution by year. Catalonia, 2012-2016



Source: Catalan Microbiological Reporting System. Subdirectorate-General for Epidemiological Surveillance and Public Health Emergency Response. Public Health Agency of Catalonia.
* In eight cases only serogroup was known: two 19F/B/C, one 9V/A, two 6A/C and three 7F/A.
** 11B, 11C, 11F, 13, 15,15A, 15C, 16F, 18A, 18F, 21, 22A, 24B, 25F, 27, 29, 31, 34, 35A, 35B, 35C, 35F, 37, 38, 39, 7B, 7C, 9L and other non-vaccine serotypes.
PCV7: serotypes included in the 7-valent pneumococcal conjugate vaccine; PCV10: serotypes included in the 10-valent pneumococcal conjugate vaccine; PCV13: serotypes included in the 7-valent pneumococcal conjugate vaccine 13-valent; PPV23: serotypes included in the 23-valent pneumococcal vaccine (serotype 6A is not included in the PPV23).

An overall analysis of IPD-causing serotypes by age group shows that, in infants under 2, the serotypes included in PCV7, PCV10 and PCV13 represented 21.1%, 25.7% and 40.6% of cases, respectively. In infants aged 2-4, the serotypes included in PCV7, PCV10 and PCV13 represented 18.0%, 39.1% and 63.5% of cases, respectively.

Impact of serotype distribution

A drop in the incidence rate in under-2s was observed, specifically in the 6 additional serotypes: PCV10 and non-PCV7 (100%) and PCV13 and non-PCV10 (88%), while the serotypes included in PCV7 remained stable (Table 3).

In the other age groups analysed (2 to 4, 5 to 19, 20 to 64 and ≥ 65), a drop in the incidence rate of the three additional serotypes in PCV10 and non-PCV7 was observed. This drop led to a decrease in the overall incidence of serotypes in PCV13 in all age groups except 5-19.

In addition, a 33% increase in the incidence rate of serotypes not included in PCV13 (non-PCV13) was observed in the 65 and over age group.

Table 3. IPD serotypes distribution by age group and year. Catalonia, 2012-2016

Age group	2012		2013		2014		2015		2016		IRR 2016 vs. 2012 (95% CI)	p value
	No.	IR	No.	IR	No.	IR	No.	IR*	No.	IR		
<2 years												
PCV7	13	7.9	12	7.7	10	6.8	10	7.0	10	7.1	0.89 (0.35-2.2)	0.951
PCV10 non PCV7	8	4.9	2	1.3	1	0.7	1	0.7	0	0.0	0.00 (0.00-0.68)	0.014
PCV10	21	12.8	14	9.0	11	7.5	11	7.7	10	7,1	0,55 (0,23-1,22)	0,161
PCV13 non PCV10	20	12.2	7	4.5	7	4.7	3	2.1	2	1,4	0,12 (0,01-0,48)	< 0,001
PCV13	41	25.1	21	13.5	18	12.2	14	9.9	12	8,5	0,34 (0,16-0,66)	0,001
Non-Pn13	30	18.3	26	16.7	28	19.0	41	28.9	30	21,2	1,16 (0,67-1,99)	0,661
Total	71	43.4	47	30.2	46	31.2	55	38.7	42	29.7	0.68 (0.46-1.02)	0.061
2-4 years												
PCV7	10	3.9	5	1.9	9	3.6	9	3.7	9	3.9	1.02 (0.37-2.78)	1
PCV10 non PCV7	23	8.9	12	4.7	8	3.2	5	2.1	1	0.4	0.05 (0.00-0.30)	< 0.001
PCV10	33	12.7	17	6.6	17	6.8	14	5.8	10	4.4	0.34 (0.15-0.71)	0.002
PCV13 non PCV10	14	5.4	13	5.1	9	3.6	13	5.4	8	3.5	0.65 (0.23-1.65)	0.436
PCV13	47	18.1	30	11.7	26	10.5	27	11.2	18	7.8	0.43 (0.24-0.76)	0.002
Non-Pn13	20	7.7	13	5.1	11	4.4	19	7.9	22	9.6	1.24 (0.65-2.4)	0.581
Total	67	25.8	43	16.7	37	14.9	46	19.1	40	17.4	0.67 (0.44-1.01)	0.058

Age group	2012		2013		2014		2015		2016		IRR 2016 vs. 2012 (95% CI)	p valor
	No.	IR	No.	IR	No.	IR	No.	IR	No.	IR		
5-19 years												
PCV7	3	0.3	3	0.3	2	0.2	6	0.5	9	0.8	2.85 (0.71-16.34)	0.173
PCV10 non PCV7	28	2.5	25	2.2	13	1.2	9	0.8	9	0.8	0.30 (0.13-0.66)	0.002
PCV10	31	2.8	28	2.5	15	1.3	15	1.3	18	1.5	0.55 (0.29-1.02)	0.057
PCV13 non PCV10	3	0.3	4	0.4	1	0.1	4	0.3	3	0.3	0.95 (0.13-7.08)	1
PCV13	34	3.1	32	2.9	16	1.4	19	1.7	21	1.8	0.59 (0.32-1.04)	0.069
Non-Pn13	12	1.1	6	0.5	5	0.4	13	1.1	10	0.9	0.79 (0.31-2.00)	0.735
Total	46	4.2	38	3.4	21	1.9	32	2.8	31	2.7	0.64 (0.39-1.03)	0.067
20-64 years												
PCV7	45	0.9	37	0.8	39	0.8	43	0.9	25	0.5	0.57 (0.34-0.96)	0.031
PCV10 non PCV7	63	1.3	55	1.2	36	0.8	29	0.6	13	0.3	0.21 (0.11-0.39)	< 0.001
PCV10	108	2.3	92	2.0	75	1.6	72	1.6	38	0.8	0.36 (0.24-0.53)	< 0.001
PCV13 non PCV10	56	1.2	48	1.0	45	1.0	44	1.0	41	0.9	0.76 (0.49-1.15)	0.205
PCV13	164	3.4	140	3.0	120	2.6	116	2.5	79	1.7	0.50 (0.38-0.65)	< 0.001
Non-Pn13	171	3.6	152	3.2	157	3.4	181	3.9	199	4.3	1.20 (0.97-1.48)	0.088
Total	335	7.0	292	6.2	277	5.9	297	6.4	278	6.0	0.86 (0.73-1.01)	0.061

Age group	2012		2013		2014		2015		2016		IRR 2016 vs. 2012 (95% CI)	p value
	No.	IR	No.	IR*	No.	IR	No.	IR	No.	IR		
≥65 years												
PCV7	51	4.0	48	3.7	51	3.8	50	3.7	56	4.1	1.02 (0.69-1.53)	0.976
PCV10 non PCV7	28	2.2	31	2.4	21	1.6	14	1.0	4	0.3	0.13 (0.03-0.38)	< 0.001
PCV10	79	6.1	79	6.0	72	5.4	64	4.7	60	4.4	0.71 (0.50-1.00)	0.053
PCV13 non PCV10	73	5.7	92	7.0	64	4.8	69	5.1	56	4.1	0.72 (0.50-1.03)	0.072
PCV13	152	11.8	171	13.1	136	10.2	133	9.8	116	8.4	0.71 (0.55-0.91)	0.007
Non-Pn13	181	14.1	214	16.3	197	14.7	266	19.5	257	18.6	1.33 (1.09-1.61)	0.004
Total	333	25.9	385	29.4	333	24.9	399	29.3	373	27.0	1.05 (0.09-1.22)	0.580

Source: Catalan Microbiological Reporting System. Subdirectorate-General for Epidemiological Surveillance and Public Health Emergency Response. Public Health Agency of Catalonia.
IR: Incidence rate per 100,000 persons-years, IRR: Incidence rate ratio.
PCV7: serotypes included in the 7-valent pneumococcal conjugate vaccine; PCV10: serotypes included in the 10-valent pneumococcal conjugate vaccine; PCV13: serotypes included in the 13-valent pneumococcal conjugate vaccine; PCV10 non PCV7: serotypes included in the PCV10 and not included in the PCV7 (1, 5, 7F); PCV13 non PCV10: serotypes included in the PCV13 and not included in the PCV10 (3, 6A, 19A).

5 Conclusions

In 2016:

- The overall incidence rate was 12.2 cases per 100,000 persons-year.
- The age group with the highest IPD incidence rate was infants under 2, followed by the 65 and over and the 2-4 age groups.
- The most frequent serotypes were 8, 12F, 3, 14, 22F, 24F and 19A; representing 53.0% of cases.
- The serotypes included in PCV7 represented 14.3% of cases, those in PCV10 represented 17.8% and those in PCV13 represented 32.2%.
- In children under 2, the serotypes included in PCV10 and PCV13 represented 23.8% and 28.6% of cases, respectively. In the 2-4 age group, they represented 25.0% and 45.0% of cases, respectively.

From 2012 to 2016:

- The overall incidence rate of IPD in 2016 was 9% lower than in 2012.
- A significant decrease in the incidence of IPD was observed in the 2-4 age group (31%) and 5-19 age group (36%).
- The incidence of serotypes included in PCV10 dropped significantly in the 2-4 and 20-64 age groups, while the incidence of serotypes in PCV13 dropped significantly in all age groups, headed by 5-19 year olds.
- The incidence of serotypes not included in conjugate vaccines (non-PCV13) increased significantly in the 65 and over age group.
- Precise, continuous epidemiological surveillance of IPD is required to detect changes in the incidence of the disease and circulating serotypes.

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