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ORIGINAL ARTICLES

Euroroundup

PNEUMOCOCCAL VACCINATION POLICY IN EUROPE

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Infection due to *Streptococcus pneumoniae* (Pneumococcus) (Pnc) is an important cause of invasive clinical manifestations such as meningitis, septicaemia and pneumonia, particularly in young children and the elderly. A 23-valent polysaccharide Pnc vaccine (PPV) has been available for many years and a 7-valent conjugate Pnc vaccine (PCV) has been licensed since 2001 in Europe. As part of a European Union (EU) funded project on pneumococcal disease (Pnc-EURO), a questionnaire was distributed to all 15 EU member states, Switzerland, Norway and the 10 accession countries in 2003 to ascertain current pneumococcal vaccination policy. Twenty three of the 27 target countries, constituting the current European Union (plus Norway and Switzerland), completed the questionnaire.

PPV was licensed in 22 of the 23 responding countries and was in the official recommendations of 21. In all the 20/21 countries for which information was available, risk groups at higher risk of infection were targeted. The number of risk groups targeted ranged from one to 12. At least 17 countries recommend that PPV be administered to all those >65 years of age (in three countries, to those over 60 years of age).

Thirteen countries had developed national recommendations for PCV in 2003. No country recommended mass infant immunisation at that time, but rather targeted specific risk groups (between 1 and 11), particularly children with asplenia (n=13) and HIV infection (n=12). PCV use was restricted to children under two years of age in seven countries, and in four countries to children under five years of age.

Future decisions on use of pneumococcal vaccines in Europe will be decided on the basis of several factors including: local disease burden; the predicted impact of any universal programme, particularly the importance of serotype replacement and herd immunity (indirect protection to the unvaccinated population); the effectiveness of reduced dose schedules, and vaccine cost. Indeed, at least one country, Luxembourg, has since implemented a universal infant PCV immunisation policy.

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Introduction

Pneumococcal (Pnc) disease is caused by the bacterium *Streptococcus pneumoniae* of which more than 90 serotypes are now recognised. Pnc is an important cause of morbidity and mortality in Europe [1] – with the observed burden varying geographically, due in part to differences in healthcare factors such as blood culture practice and antibiotic use [2]. With large reductions in the incidence of *Haemophilus influenzae* type b in many European countries, Pnc is now one of the leading causes of meningitis and invasive bacterial disease in children; Pnc is also one of the main aetiological agents for community-acquired pneumonia in adults and for otitis media in children [1]. Furthermore, in recent years antibiotic resistant strains of Pnc have emerged as an increasing problem, with rates of penicillin resistance ranging up to almost 50% of invasive isolates in some European countries [1].

Two types of pneumococcal vaccine are now licensed in Europe, and include a variable number of capsular serotypes: the older 23-valent Pnc polysaccharide vaccine (PPV) and the newer conjugated 7-valent Pnc vaccine (PCV). PPV provides protection against invasive Pnc disease due to 23 serotypes in subjects older than two years [3]. PCV protects against seven serotypes but also in those younger than two years and provides longer lasting immunity against invasive disease. Conjugate vaccine also protects against non-invasive Pnc disease manifestations such as pneumonia [4]. Post-licensure surveillance following introduction of PCV in the United States in 1999 as a universal infant immunisation programme has shown a large reduction in both invasive and non-invasive disease incidence due to vaccine serotypes in both vaccinated and older unvaccinated populations ('herd immunity'). This reduction in disease has also been accompanied by a fall in the rate of penicillin-resistant Pnc [5]. However, a small increase in invasive disease due to non-vaccine serotypes (termed 'serotype replacement') has also been observed [6].

Historically, individuals at higher risk of Pnc infection such as those with immune system impairment, and more recently, the elderly, have been targeted with PPV in Europe. The licensure of the new 7-valent Pnc conjugate vaccine in Europe by the European Medicine Evaluation Agency (EMEA) in 2001 has re-ignited interest in pneumococcal disease and the most appropriate vaccination strategy in a European setting. A number of factors have contributed to this decision making, including the potentially preventable disease burden and the cost and effectiveness of alternative intervention programmes. For European countries to be able to design the most appropriate

future vaccination strategies, it will be important to understand local pneumococcal disease burden in the context of current and past vaccination strategy. This paper summarises the results of a survey of national Pnc vaccine policy undertaken at the end of 2003 across the European Union (EU) and the accession countries that constitute the current EU. This was undertaken within the framework of the EU funded project Pneumococcal Disease in Europe (Pnc-EURO).

Methods

A standardised questionnaire was designed and sent to the national public health institutes of each of the current 25 European Union member states and Switzerland and Norway in late 2003, 10 of them in the accession phase. Data from returned questionnaires were entered and analysed in Excel.

Results

Twenty three of the 27 countries completed and returned the questionnaire. Non-responders were Greece, Hungary, Poland and Spain.

Use of pneumococcal polysaccharide vaccine

A 23-valent PPV vaccine has been licensed in 22 of the 23 responding countries (not in Malta) from the 1980s onwards [TABLE 1], with vaccine from two manufacturers: Sanofi-Pasteur MSD and Wyeth-Lederle. With the exception of Portugal, the remaining countries have developed national recommendations for PPV.

All countries with national recommendations for PPV have implemented strategies to target groups at higher risk of invasive pneumococcal disease [TABLE 1].

The recommended vaccination schedule is generally a single dose, although at least four countries recommend a booster dose after three to six years, at least for certain groups, such as those whose antibody levels decline rapidly.

Country specific risk-group recommendations are outlined in Table 2. The number of risk groups (those individuals at higher risk of invasive disease due to their underlying condition) ranged from one to 12 (median nine groups, n=20) [TABLE 1]. Almost all countries recommended vaccination of individuals with splenic dysfunction (n=19), immunosuppression (n=17), chronic pulmonary disease (CPD)(n=18), chronic cardiac disease (CCF)(n=16) and chronic liver disease (n=15). Seventeen countries recommended that the polysaccharide vaccine be administered to all those >65 years of age: three of these countries made this recommendation for all those over 60 years of age.

TABLE 1

Reported use of 23-valent pneumococcal polysaccharide vaccine in 23 European countries, 2003

	Vaccine licensed	National recommendation for risk groups	Year of introduction	Booster dose recommended	>65 year olds	Number of risk groups [1]	Cost free or refunded
Austria (AUS)	Yes	Yes	2003	na	Yes	9	Yes[5]
Belgium (BEL)	Yes	Yes	1993	na	Yes[6]	11	No[2]
Czech Republic (CZE)	Yes	Yes	-	na	Yes	6	Yes
Cyprus (CYR)	Yes	Yes	na	na	Yes	11	Yes[5]
Denmark (DEN)	Yes	Yes	1980	na	Yes	9	Yes[5]
England (ENG)	Yes	Yes	1992	No[4]	Yes	8	Yes
Estonia (EST)	Yes	Yes	na	na	Yes	9	No
Finland (FIN)	Yes	Yes	na	After 3-5 yrs[7]	Yes	12	No
France (FRA)	Yes	Yes	na	na	No	5	Yes
Germany (GER)	Yes	Yes	1985	After 6 yrs	Yes[6]	7	Yes
Ireland (IRE)	Yes	Yes	1999	na	Yes	11	Yes
Italy (ITA)	Yes	Yes	1999	na	Yes	-	No
Latvia (LAT)	Yes	Yes	2001	na	Yes	2	Yes[5]
Lithuania (LIT)	Yes	Yes	na	na	Yes	9	No
Luxembourg (LUX)	Yes	Yes	1992	na	Yes[6]	12	No
Malta (MAT)	No	No	-	-	-	-	-
Netherlands (NET)	Yes	Yes	na	na	No	5	Yes
Norway (NOR)	Yes	Yes	na	na	Yes	9	Yes[5]
Portugal (POR)	Yes	No	-	-	-	-	-
Slovak Republic (SLK)	Yes	Yes	1999	After 3-5 yrs	na	na	na
Slovenia (SLO)	Yes	Yes	2003	na	Yes	10	Yes[5]
Sweden (SWE)	Yes	Yes	1994	na	No	10	Yes[3]
Switzerland (SWI)	Yes	Yes	2000	After 5 yrs	Yes	9	Yes[5]

1 Of the following 12 risk groups: splenectomised, cardiovascular disease, chronic pulmonary disease, diabetes mellitus, alcoholism, chronic liver disease, cerebrospinal fluid leaks, immunosuppressed, HIV infected, over 65 years of age, nursing home resident and other

2 Except those with insurance

3 Varies between regions

4 Unless a rapid decline in antibody levels

5 Some risk groups

6 >60 year olds targeted

7 For immunocompromised only

na= not available

TABLE 2

Country-specific recommendations for use of pneumococcal polysaccharide vaccine by risk group in 19 European countries

	AUS	BEL	CZE	CYP	DEN	ENG	EST	FIN	FRA	GER	IRE	LAT	LIT	LUX	NET	NOR	SLO	SWE	SWI
Splenic dysfunction	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes[1]	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Chronic cardiovascular disease	Yes	Yes[2]	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Chronic pulmonary disease	Yes	Yes[2]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Diabetes mellitus	Yes	Yes[2]	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	No	No	Yes	Yes	Yes
Alcoholism	Yes	Yes[2]	No	Yes	No	No	No	Yes	Yes	No	Yes	No	na	Yes	No	No	No	Yes	No
Chronic liver disease	Yes	Yes[2]	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes
CSF fluid leak	Yes	No	No	Yes	Yes	No	No	Yes	No	Yes	Yes	No	na	Yes	No	Yes	Yes	Yes	Yes
Immunodeficiency	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
HIV infected	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes
> 65 years of age	Yes[4]	Yes[4]	Yes[3]	Yes	Yes	Yes[5]	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes[4]	No	Yes	Yes	Yes[3]	Yes
In nursing home	No	Yes	Yes	Yes	No	No	Yes	Yes	No	No	No	No	na	Yes	No	Yes	Yes	No	No

1 Children only
2 >45 years old
3 In some regions
4 >60 years old
5 Phased introduction from 2003 onwards
6 Under consideration
na= not available
Information not available for Slovak Republic

A variety of other risk groups were also targeted including individuals with cochlear implants (England), chronic renal disease (Finland, Germany, Luxembourg and Ireland), travellers with certain chronic conditions (Lithuania), those with repeated pneumococcal infections (Norway) and those with Down's syndrome (Sweden).

For those countries where the vaccine was recommended, in most instances (n=14) the vaccine was either free or the cost refunded, at least for some risk groups [TABLE 1]

Use of Pneumococcal conjugate vaccine

Twenty of the 23 responding countries had a pneumococcal conjugate vaccine officially licensed, but not Estonia, Malta, or Slovenia [TABLE 3]. In all cases, this was the 7-valent vaccine manufactured by Wyeth-Lederle (*Prevenar*). No other PCV was commercially available at that time. By 2003, 13 of these 20 countries had developed and implemented national recommendations for use of this vaccine since 2001. For seven countries, mainly in central Europe and Scandinavia, the vaccine is licensed but national recommendations are not yet in place or are being developed (Czech Republic, Denmark, Latvia, Lithuania, Netherlands, Portugal and Sweden). The recommended schedule is enerally three doses one to two months apart from the second or third month of life. At least nine countries recommend a booster dose after the age of one year.

TABLE 3

Reported use of pneumococcal conjugate vaccine in 23 European countries, 2003

	Vaccine licensed	National recom-mendation	Universal strategy	Risk group policy	Year of intro-duction	Primary schedule (age in months)	Booster dose (age in months)	Target groups*	Child <2 years	Cost refunded or free of charge
Austria	Yes	Yes	No	Yes	2003	3, 4, 5	24	9	Yes	Yes[2]
Belgium	Yes	Yes	No	Yes	na	na	na	6	Yes[1]	##
Czech Republic	Yes	No	-	-	-	-	-	-	-	-
Cyprus	Yes	Yes	No	Yes	2003	2, 4, 6	12-15, 24	11		Yes
Denmark	Yes	No	No	Yes	-	3, 5, 7	15	7	Yes	Yes[2]
England	Yes	Yes	No	Yes	2003	2 to 24, 2-3 doses		9	Yes[1]	Yes
Estonia	No	No	-	-	-	-	-	-	-	-
Finland	Yes	Yes	No	Yes	2002	2, 4, 6	24		Yes[1]	No
France	Yes	Yes	No	Yes	2003	2, 3, 4	24	8	Yes	Yes
Germany	Yes	Yes	No	Yes	2002	2, 3, 4	>12	9	Yes	Yes
Ireland	Yes	Yes	No	Yes	2002	12	24	10	Yes	Yes
Italy	Yes	Yes	No	Yes	2002	2 to 24, 2-3 doses		9	Yes	Yes[2]
Latvia	Yes	No	No	Yes	-	na	na	1	na	Yes[2]
Lithuania	Yes	No	No	-	-	-	-	-	-	-
Luxembourg	Yes	Yes	Yes	No	2004	2, 3, 4	12-15	-	-	Yes
Malta	No	No	-	-	-	-	-	-	-	-
Netherlands	Yes	No	-	-	-	-	-	-	-	-

(continued Table 3)

	Vaccine licensed	National recom-mendation	Universal strategy	Risk group policy	Year of intro-duction	Primary schedule (age in months)	Booster dose (age in months)	Target groups*	Child <2 years	Cost refunded or free of charge
Norway	Yes	Yes	No	Yes	2001	na	na	2	na	Yes[2]
Portugal	Yes	No	-	-	-	-	-	-	-	-
Slovak Republic	Yes	Yes	No	Yes	2003	2 to 24, 2-3 doses		0	Yes	No
Slovenia	No	No	-	-	-	-	-	-	-	-
Sweden	Yes	No	-	-	-	-	-	-	-	-
Switzerland	Yes	Yes	No	Yes	2001	2, 3, 4	12	8	Yes#	Yes

* Of the following 12 risk groups: splenectomised, chronic cardiovascular disease, chronic pulmonary disease, diabetes mellitus, alcoholism, chronic liver disease, cerebrospinal fluid leaks, immunosuppressed, HIV infected, over 65 years of age, nursing home residents and others

1 Under 5 years of age
2 Applies to some risk groups
Not yet determined
na= not available
Information not available for Slovak Republic

At the time of the original questionnaire in 2003, no European country recommended mass infant immunisation. In 2004, at least one country (Luxembourg) recommended PCV for all children under 24 months of age (universal infant immunisation). In all countries with national recommendations, conjugate vaccine was targeted at specific risk groups. In many countries (at least seven), use in target groups is restricted to children less than two years of age, and in four countries to those under five years of age (Belgium, England, Finland and Switzerland). The number of risk groups range from one to 11 (median 8, n=13) [TABLE 3]: the most common are individuals with asplenia (n=13), CCF (n=11), CPD (n=11), diabetes (n=11), immune deficiency (n=11) and HIV infection (n=12). Use in all persons over 65 years of age is recommended in one country, Cyprus.

Other risk groups targeted include those with chronic renal disease (Finland, Ireland, England and Germany) and children with ventilatory tubes inserted (France). In France, young children in families with more than three pre-school children or children attending daycare are also targeted.

In the majority of countries where PCV is recommended (n=12), the vaccine is reported to be free or the cost refunded, at least for some risk groups [TABLE 4].

Discussion

This article provides a summary of pneumococcal vaccine policy in Europe at the end of 2003 and illustrates differences in national pneumococcal policy across Europe ranging from no licensure of any pneumococcal vaccine to the more recent introduction of a universal Pnc conjugate vaccine programme in infancy in 2004 in at least one country. These variations in national vaccination policy have been previously well documented for other vaccine programmes [7].

The Pnc polysaccharide vaccine, PPV, has been widely recommended in some European countries for over two decades for groups perceived to be at higher risk of invasive disease. The evidence base for the true risk of Pnc in these groups may vary from country to country, but has not been systematically collated. We demonstrate that by 2003, the number of risk groups actually targeted ranges dramatically across the countries of the EU. Furthermore, we found that a large number of countries recently implemented programmes for all individuals older than 65 years. There is limited published evidence of the effectiveness of PPV targeted at populations at higher risk of invasive infection [3,8], whereas a 'universal' elderly PPV programme has been shown to be both effective [9] and cost-effective [10] against

TABLE 4

Country-specific recommendations for use of pneumococcal conjugate vaccine by risk-group in 14 European countries

	AUS	BEL	CYP	DEN	ENG	FIN	FRA	GER	IRE	ITA	LAT	NOR	SLK	SWI
Splenic dysfunction	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Chronic cardiovascular disease	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes
Chronic pulmonary disease	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes
Diabetes mellitus	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes
Alcoholism	No	No	Yes	No	No	No	na	No	No	No	No	No	No	No
Chronic liver disease	Yes	No	Yes	No	Yes	No	na	No	Yes	Yes	No	No	No	Yes
CSF fluid leaks	No	No	Yes	Yes	na	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes
Immunodeficiency	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes
HIV infected	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes
>65 Years of age	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No
Nursing home	No	No	Yes	No	No	No	No	No	No	Yes[1]	No	No	No	No
Other groups	Yes	-	-	-	Yes	Yes	Yes[2]	Yes	Yes	-	-	-	-	-
Free of charge	Yes[5]	$	Yes	No	Yes[3]	No	No	Yes	Yes	Yes[3]	Yes[3]	Yes[3]	No	Yes[3]
Refunded	Yes[5]	$	No	Yes[4]	-	Yes[5]	Yes[3]	Yes[5]	Yes	-	No	No	No	Yes[3]

1 Some regions
2 Additional target groups in France are children <2 Years old & breastfed < 2mts, belonging to families with 3 or more pre-school children, being taken care of with others (>2) more than 4 hrs per week
3 All recommended groups
4 Splenectomised persons only
5 In some circumstance e.g. privately insured
$ Decision not yet taken
na= not available

invasive Pnc disease (at least in the United Kingdom). We did not collate information on the uptake of these various programmes, but ad hoc studies have suggested that targeted high-risk programmes often have difficulty achieving high levels of coverage [11], whereas 'universal' programmes such as those targeting all those over 65 years of age may be easier to implement. It will be important to ensure surveillance systems are in place to monitor the coverage, impact and effectiveness of these various PPV programmes in Europe.

Following the recent licensure of the 7-valent PCV in Europe, we found that the majority of countries have now included the new vaccine in their national recommendations. In 2003, PCV was targeted at certain groups of children under two years of age who are at higher risk of invasive infection (under five years in some countries), with the number of recommended risk groups varying dramatically from country to country from very limited to very extensive indications including children attending daycare, such as in France. In this article, we have gathered information only on national recommendations: the coverage and impact of these programmes has not been collated and remain largely unreported. The factors that influence the coverage achieved (and thus the eventual impact) in any one country are manifold. However, it is important to note that in a number of countries, a large proportion of all vaccination may be administered through the private sector, where insurance schemes may (or may not) reimburse cost of vaccination. Clearly, this raises issues of equity and access to healthcare. It will be important to ensure that national surveillance schemes fully capture the programmatic impact of PCV administered through both the public and private sectors.

No country in the European Union had implemented a universal PCV programme at the time of the original questionnaire in 2003. Future decisions on the use of pneumococcal vaccines in Europe, in particular PCV, will be decided on the basis of a number of factors: disease burden and the effectiveness and cost effectiveness of alternative interventions. The Pnc disease burden in European settings is recognised to vary across the continent [2] due both to differences in healthcare factors affecting observed rates of disease (such as use of antibiotics and blood culture [12,13]), and also to real differences in pneumococcal epidemiology (such as Pnc serotype distribution and the prevalence of antibiotic resistance [2,14]). High quality pre-vaccination surveillance data will be critical for informed national decision making for local vaccination policy. Secondly, the impact of the universal PCV programme in North America is increasingly evident, particularly the size of the herd immunity effect with evidence of significant protection for older, unvaccinated populations (together with evidence of serotype replacement – the emergence of non-vaccine serotypes, for instance, as observed in acute otitis media [15]). Finally, the cost-effectiveness of any PCV programme (compared to PPV programme) will be influenced by recent clinical trial evidence of the effectiveness of alternative primary immunisation schedules involving fewer doses of vaccine [16]. Indeed, at least one European country, Luxembourg, introduced a universal infant immunisation programme in 2004, with a three dose primary course and a booster dose in the first year of life.

We have demonstrated a diversity of Pnc vaccination programmes in Europe, and these are rapidly evolving. It will be critical for countries to ensure that high quality surveillance systems are in place to monitor the impact and effectiveness of these programmes and to ensure future interventions, particularly in relation to possible introductions of PCV, are undertaken in an informed fashion based on local Pnc disease epidemiology.

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