Impact of childhood pneumococcal vaccination programmes and activities for pneumococcal vaccines in the EU and EEA \EFTA countries

Collaboration between VENICE II project and ECDC

VENICE II

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Content

Abbreviations

ECDC European Centre for Disease Prevention and Control
EEA European Economic Area
EFTA European Free Trade Association
EU European Union
IP Immunization Programme
IPD Invasive Pneumococcal Disease
VENICE Vaccine European New Integrated Collaboration Effort

ISO 3166-1 Country Codes

AT	Austria
BE	Belgium
BG	Bulgaria
CY	Cyprus
CZ	Czech Republic
DK	Denmark
EE	Estonia
FI	Finland
FR	France
DE	Germany
GR	Greece
HU	Hungary
IS	Iceland
IE	Ireland
IT	Italy
LV	Latvia
LT	Lithuania
LU	Luxembourg
MT	Malta
NL	The Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SK	Slovakia
SI	Slovenia
ES	Spain
SE	Sweden
GB	United Kingdom

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Background

Epidemiological surveillance is paramount to provide decision makers with solid data on burden of disease and impact of vaccination. Based on an ECDC call for tender, a group of experts led by Germaine Hanquet, prepared in 2008 an inventory of surveillance systems for invasive pneumococcal disease and vaccination policy in EU. The information on the use of PCV7 vaccine was also collected by EUVAC-NET in 2008. The surveys of pneumococcal 7-valent vaccine (PCV7) use policies revealed that 15/27 countries in European Union introduced PCV7 vaccine in the universal schedule. Of the 15 countries, 12 were monitoring the impact of the vaccine – mostly by monitoring trends of incidence, 11 reported monitoring vaccination uptake, 11 were collecting information on the vaccination status of cases, 10 were registering vaccine failures on a regular basis, 11 reported having a surveillance of serotype replacement and two countries already calculated vaccine effectiveness (Norway and the United Kingdom). The inventory of surveillance systems also revealed important differences in the method of invasive pneumococcal disease (IPD) data collection, and in the purpose of epidemiological as well as microbiological surveillance.

In the field of vaccination, also the Health Technology Assessment (HTA) could represent an innovative and effective tool to address the decision makers in the introduction of a new vaccine and in the way of introducing it (target population, age, modalities of offer and so on). Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. A wide range of methods is employed in order to evaluate whether and to what extent the new technology contributes to health improvement: epidemiological impact, economical costs or benefits, social and ethical acceptability, juridical and organizational aspects. HTA represents a useful tool to orientate decision makers toward better allocation of economic resources, according both to safety, efficacy and effectiveness, appropriateness and costs of the new technology and population health needs.

Objectives of the study

The aim of this survey was to gain an overview of the impact of childhood pneumococcal vaccination programmes and health technology assessment activities for this vaccine in the EU and EEA\EFTA countries.

Objectives of the survey were to assess the capacity of countries to monitor vaccine effectiveness using different methods, to assess the availability of information on surveillance data useful for the VE evaluation and also to collect information on performered assessments of the impact of vaccination programmes. Basic information on epidemiologic and microbiological surveillance in the countries has been collected in order to monitor the changes in surveillance systems, compared to previous EU surveys.

Specific objectives:

- to collect information on vaccination programmes, including information on practice at sub-national level;
- to collect information on Health Technology Assessment (HTA) activities on pneumococcal vaccination carried out at national level;
- to identify the entity and quality of data which would be available in each member state to perform a new HTA;
- to explore data availability for evaluation of the impact of pneumococcal vaccination programmes in European countries.

Methods

A cross-sectional electronic survey was undertaken in June-August 2010.

This survey was a collaborative study between the European Centre of Disease Control and Prevention (ECDC) and the VENICE II Project within the European Union (EU) and European Economic Area (EEA) Member States (MS). Each MS previously identified and enrolled gatekeepers, who are responsible for conducting all VENICE surveys inside their countries (http://venice.cineca.org/participating_countries.html).

Currently, 27 EU and two EEA (NO and IS) countries are participating in the VENICE II project.

A standardized questionnaire was predominantly developed using close-ended questions, with optional space for input of free text. The electronic questionnaire was filled directly online by gatekeepers in each country, or by an expert nominated by the gatekeeper.

The survey consisted of three sections:

- PNC Surveillance System, Section 1: describing surveillance systems for pneumococcal disease;
- PNC Vaccination Strategies, Section 2: investigating pneumococcal vaccination policies (products, schedules and recommendations);
- PNC Health Technology Assessment, Section 3: including questions on availability of economic data for cost-benefit and cost-effectiveness evaluations, in order to explore the availability of data for HTA on pneumococcal vaccination in European countries.

MSs were asked to complete the electronic questionnaire between 10 of June and 31 of July 2010. The accompanying letter to MSs explained the objectives and rationale of the study. Non-responders were reminded twice by email, and the deadline extended until 20th August 2010.

A validation of the survey results was planned, by asking the gatekeepers to revise this report.

Results

Section 1. Surveillance of pneumococcal disease

Response

The response for the first section was 86.2% (25/29 countries); the response for data validation was 84% (21/25countries). The countries that validated data are (BE, CY, CZ, DK, EE, FR, DE, HU, IS, IE, IT, LV, LT, NL, NO, PL, PT, SK, ES, SE, GB).

Organization of the surveillance system

At the time of the survey, twenty-three (79.3%) countries had at least one surveillance system for pneumococcal disease, on the basis of which the national incidence of the disease is estimated (BE, BG, CY, CZ, DK, EE, FI, FR, DE, HU, IS, IE, IT, LV, LT, NL, NO, PL, SK, SI, ES, SE, GB). Five of these had two systems in their countries (BE, DE, IS, IE, GB). AT did not have a national surveillance system for pneumococcal disease, but reporting of IPD was mandatory according to national law on infectious diseases; different sources of data exist and a future system will take into account of those. In PT pneumococcal disease will be included in the reformed communicable disease notification system. Information of a total of 27 surveillance systems has been collected. Name and institution in charge of the surveillance system are listed in table 1.

For 24 systems the surveillance is organized at national level and covers all regions; for the remaining three (IT, LT, UK-Scotland) systems the surveillance is organized at regional level but the data flow together at national level. Most of all surveillance systems are comprehensive, only two systems are sentinel.

In more than two thirds of the surveillance systems the reporting is mandatory (Table 2). General population is under surveillance in almost all systems (BE, BG, CY, CZ, DK, EE, FI, FR, HU, IS, IE, IT, LV, LT, NL, NO, PL, SK, SI, ES, SE, GB); specific risk groups are under surveillance in BE (0-15 years) and DE (hospitalized children up to 16 years).

The reporting process to the surveillance system can be initiating at different level and by more than one professional figure in each system (Graph 1); case reporting is performed by the hospital laboratory in 24 (89%) surveillance systems, by hospital doctor in 21 (77.8%) and by both in 18 (66.7%) of the 27 surveillance systems. Also GP can initiate the reporting process in 15 (55.6%) systems.

Both cases and microbiological isolates are reported through almost all surveillance systems (n=21 BE(2), BG, CZ, DK, EE, FR, HU, IS(1)(2), IE(1)(2), IT, LV, LT, NO, PL, SK, SI, ES, SE, GB(1); Table 3). Apart from the Bulgarian surveillance system that collects aggregated data, 88.9% (n=24) of surveillance systems collect individual data; LT collects both aggregated and individual data (Table 4).
Some countries provided a detailed description of their national surveillance system, shown in table 5.

Table 1. Details of the surveillance system

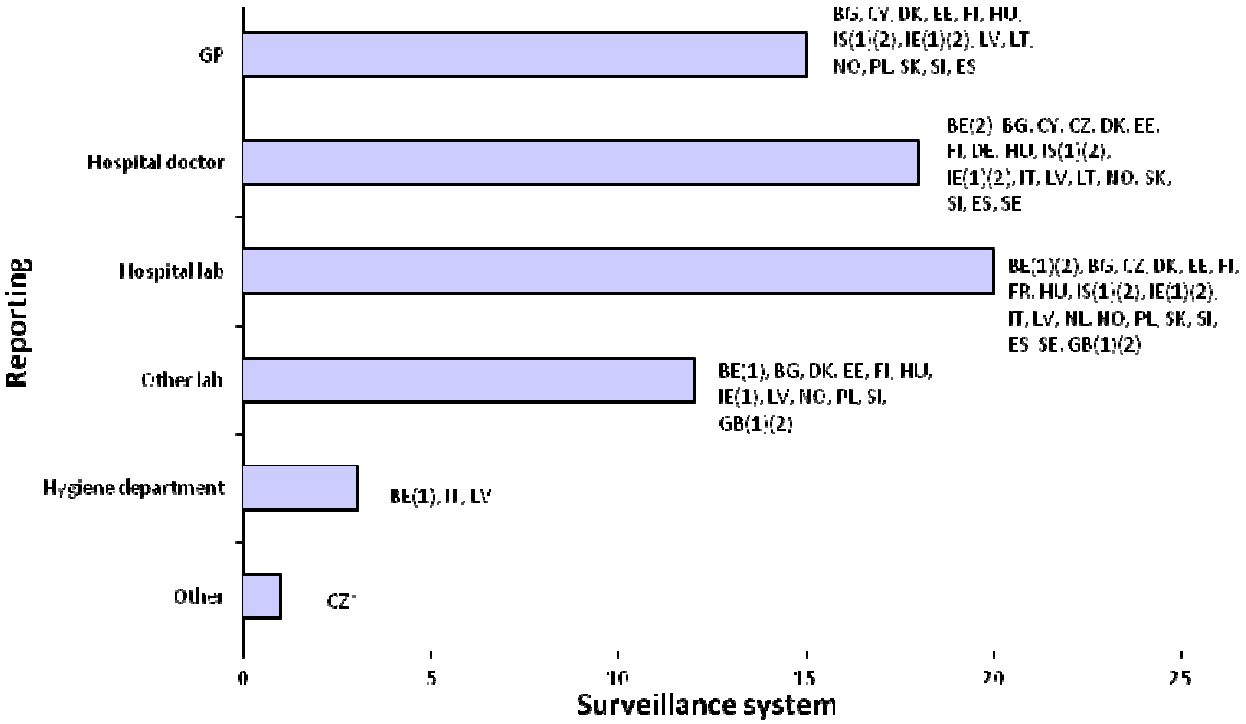
Country	Name	Institution	Level	Type
Belgium	(1) Sentinel laboratory network	Scientific Institute of Public Health	National level	Sentinel
	(2) PediSurv - Network of paediatricians	Scientific Institute of Public Health	National level	Comprehensive
Bulgaria	National surveillance system	Ministry of Health, National Center of Infectious and Parasitic Diseases	National level	Comprehensive
Cyprus	Surveillance of Mandatory Notified CD	Ministry of Health	National level	Comprehensive
Czech Republic	Enhanced surveillance of IPD	National Institute of Public Health	National level	Comprehensive
Denmark	National notification system for CD	Statens Serum Institut	National level	Comprehensive
Estonia	National surveillance	Health Board	National level	Comprehensive
Finland	National Infectious Disease Register	National institute for health and welfare	National level	Comprehensive
France	Network of laboratories (Epibac)	Institut de Veille Sanitaire	National level	Sentinel
Germany*	ESPED (Paediatric Surveillance Unit)	University of Munich	National level	Comprehensive
Hungary	Pneumococcal meningitis	National Centre for Epidemiology	National level	Comprehensive
Iceland	(1) Invasive pneumococcal surveillance system	Directorate of Health	National level	Comprehensive
	(2) National surveillance	Directorate of Health	National level	Comprehensive
Ireland	(1) Computerized infectious disease reporting system (CIDR)	Health Protection Surveillance Centre	National level	Comprehensive
	(2) CIDR and EARS-Net	HSE HPSC	National level	Comprehensive
Italy	National Surveillance of Invasive Bacterial Diseases	Istituto Superiore di Sanità	Regional level	Comprehensive
Latvia	"State monitoring and surveillance system for infectious diseases (VISUMS)"	State Agency "Infectology Centre of Latvia"	National level	Comprehensive
Lithuania	IPD passive surveillance system	Communicable Diseases and AIDS Centre	Regional level	Comprehensive
The Netherlands	NRC for bacterial meningitis	RIVM, NRBM	National level	Comprehensive
Norway	The Norwegian Surveillance System for Communicable Diseases (MSIS)	Norwegian Institute of Public Health	National level	Comprehensive
Poland	Mandatory IPD surveillance system	National Institute of Public Health - National Institute of Hygiene	National level	Comprehensive
Slovakia	Epidemiological Information System - EPIS	Regional Public Health Authority of SR, Banska Bystrica	National level	Comprehensive
Slovenia	National CD surveillance system (SURVIAL)	NIPH	National level	Comprehensive
Spain	Spanish surveillance network	National Centre Of Epidemiology - ISC III	National level	Comprehensive
Sweden	The National Surveillance System for Communicable Diseases	The Swedish Institute for Infectious Disease Control	National level	Comprehensive
United Kingdom	(1) Enhanced pneumococcal surveillance England and Wales	Health Protection Agency	National level	Comprehensive
	(2) Scotland: S. pneumoniae Invasive Disease Enhanced Reporting (SPIDER)	Health Protection Scotland	Regional level	Comprehensive

DE: Another surveillance system is in place in Germany at national level. Sentinel laboratory network (Pneumoweb) - Robert Koch-Institute. NL: Comprehensive for meningitis for all patients, and for bacteraemia for children up to 5 years

Table 2. Kind of reporting

Voluntary	Mandatory
BE (1)(2), FR, DE, IT, NL, GB (1)(2) (n=8)	BG, CY, CZ, DK, EE, FI, HU, IS (1)(2), IE(1)(2), LV, LT, NO, PL, SK, SI, ES, SE (n=19)

Graph 1. Reporting process - notifier



*Regional epidemiologist

DE: other labs are reporting within the Pneumoweb-Sentinel laboratory network

Table 3. Reported information

Only Cases	Only Microbiological Isolates	Cases and Isolates
CY (n=1)	BE(1), FI, DE, NL, GB(2) (n=5)	BE(2), BG, CZ, DK, EE, FR, HU, IS(1)(2), IE(1)(2), IT, LV, LT, NO, PL, SK, SI, ES, SE, GB(1) (n=21)

Table 4. Kind of data collected

Aggregated data	Individual data
BG, LT (n=2)	BE(1)(2), CY, CZ, DK, EE, FI, FR, DE, HU, IS(1)(2), IE(1)(2), IT, LV, LT, NL, NO, PL, SK, SI, ES, SE, GB(1)(2) (n=26)

Note: (1) and (2) refers to different surveillance systems in the same country (See Table 1)

Table 5. System description

Country	System description
Belgium (1) *Sentinel laboratory network*	Sentinel network with voluntary unpaid participation by 100 sentinel microbiology laboratories, representing 58% of all in 2009 recognized private or hospital microbiology laboratories situated in 33 of 43 Belgian districts. Samples are sent to the reference laboratory responsible for laboratory diagnostic testing, for confirmatory testing of samples from other laboratories or for serotyping of isolates and antibiotic resistance testing.
Belgium (2) PediSurv - *Network of paediatricians*	As of October 2002 an active epidemiological surveillance is carried out by 40% of the Belgian pediatricians and 37% of the general practitioners in Brussels. 80% of the hospitals with a pediatric department participated. Participation is voluntary with monthly reporting of cases of Acute Flaccid Paralysis (AFP), measles and mumps. Invasive pneumococcal disease (IPD) was added in October 2005 following introduction of the 7-valent pneumococcal conjugate vaccine and congenital rubella syndrome (CRS) in 2007. A standardized form is used to obtain case-specific clinical, laboratory and epidemiological information. Notification is done by mail or Internet and zero-reporting is requested. This surveillance is supplemented by data from other sources like laboratory surveillance and notifications by the health agencies of the different communities.
Bulgaria	The legal framework for communicable diseases surveillance (CDS) in Bulgaria is the Law on Health with the respective regulations relating to CDS. Sixty infectious and parasitic diseases are subject of compulsory registration, notification and reporting by Ordinance â„– 21 of the MoH of 18 July 2005. HIV/AIDS, Tuberculosis and STDs are subject of specific surveillance. The CDs surveillance system in Bulgaria is structured vertical on three levels: central, intermediate and peripheral. This structure is assisted by the laboratory facilities network. The general flow of information is simple and direct.
Cyprus	As soon as a case of a mandatory notified communicable disease is being diagnosed, the general practitioner or hospital doctor is responsible to report it to the Surveillance Unit by sending the notification form. The Unit collect, analyze and evaluate all relevant data and co-ordinate all Health Services involved. The electronic data-base is being updated and a feedback mechanism operates for all sites.
Czech Republic	Mandatory country-wide reporting of clinical and epidemiological data on IPD (consistent to EC case definition) to National Institute of Public Health (=EPIDAT database) and forwarding of isolates with laboratory and clinical data to National Reference Laboratory at NIPH for typing (= NRL database). Compilation of EPIDAT + NRL database into one SURVEILLANCE database, with the exclusion of duplicity of reporting.
Denmark	Mandatory reporting of clinical data on IPD to Statens Serum Institut and to the local public health office together with mandatory reporting of laboratory results on IPD and forwarding of isolates to Statens Serum Institut for subtyping.
Estonia	Surveillance system is based on double-notification, mandatory and country-wide.
Finland	All pneumococcal isolated from blood or CNS fluid are reported to the register and also the cultured isolate collected.
France	The surveillance system relies on a national network of acute medical care hospitals laboratories which provide data on meningitis and bacteriemiae cases caused by streptococcus pneumoniae.
Germany	ESPED is an active surveillance system for invasive pneumococcal disease including all German children hospitals. We have another laboratory based sentinel surveillance system (Pneumoweb), this is not population based and therefore estimation of incidence is not possible. Penumoweb allows to assess trend in serotype distribution in all age groups. Data on children are merged with ESPED data and used for capture-recapture-assessment.
Hungary	In Hungary there has been a syndrome-based surveillance system for purulent meningitis since 1998. The reported syndrome-based diagnosis is modified to an aetiology-based diagnosis in the electronic database of NPHMOS (National Public Health and Medical Officers Service) when the aetiology is confirmed by laboratory investigations. Therefore only Pneumococcal meningitis is notifiable from the IPD manifestations.
Ireland (1) *Computerized infectious disease reporting system (CIDR)*	Since 2003 mandatory surveillance of invasive pneumococcal disease is required under infectious disease legislation. Both clinicians and laboratories are required to notify to public health. Information on the individual patient is merged into the one event on CIDR, bringing together both the clinical information as well as the microbiology information. In addition, IPD isolates are sent to the reference laboratory for typing and anti-microbial resistance testing. Information in relation to the isolate is then linked to the patient information already received - so that one source of information can be analysed in relation to notifications

Ireland (2) *CIDR and EARS-Net*	CIDR - computerised infectious disease reporting system is a web-based system used by all areas and most hospitals. IPD isolates are notifiable to CIDR, and are then linked to clinical notifications. we also have isolates submitted as part of EARS-net and have used this system to compare the notifications- in recent times we have found that there is 99% completeness in reporting on CIDR as part of a national serotyping project - we also compare the isolates sent to typing and make sure that all individuals for whom samples are submitted for typing have also been notified on CIDR.
Italy	The system require the notification of all invasive bacterial diseases due to Meningococcus, Pneumococcus, Haemophilus influenzae plus all the bacterial meningitis cases. Due to different system at regional level, the notification are sent in most of the cases from the hospital to Local health Unit. From here to the region and to the Istituto Superiore di Sanità where they are aggregated and analyzed. A web system working for two years permits to collect the notification directly from the source (hospital) changing progressively from a Regional system to a national one. Meningitis by pneumococcus are collected from 1994, sepsis and other invasive disease from 2007.
Latvia	Cabinet Regulation No. 7 Adopted 5 January 1999 "Procedures for Registration of Infectious Diseases" If a health care practitioner has established that a patient has an infectious disease referred to in Annex 2 of these Regulations or if he or she has professionally substantiated suspicion that a patient has become infected with the disease referred to in Annex 2 of these Regulations, the health care practitioner, in accordance with Paragraph 7 of these Regulations, shall notify regarding:6.1. diagnosis of the infectious disease;6.2. change or cancelling of the diagnosis of the infectious disease;6.3. the final diagnosis of the infectious disease, laboratory confirmation thereof and the outcome of the disease;Head of microbiological examination laboratory or authorised person thereof shall notify detection of the infectious disease-causing agents referred to in Annex 3Link: http://www.likumi.lv/doc.php?id=20667
Lithuania	From health care practitioner (Primary diagnosis) notification by phone/ fax or paper form goes to the Regional Public Health Centers (regional level), which registers data, performs epidemiological investigation and reports to the national level " Centre for Communicable diseases and AIDS (CCDA)". GP sends specimens to the national laboratory, which gives feedback information to GP. CCDA gives information to the Ministry of Health, collaborates with other interested institutions.Confirmed diagnosis within the agreed procedures goes to the ECDC, WHO and other international institutions.
The Netherlands	The pneumococcal surveillance system is a laboratory-based surveillance system that collects nationwide bacterial isolates from blood and cerebrospinal fluid (CSF) of almost exclusively patients requiring hospitalization. Isolates from other normally sterile bodily fluids comprise less than 3% of all isolates. All medical laboratory sent in voluntary isolates from CSF or blood of patients with IPD. For isolates from CSF the coverage is >90%. Nine sentinel microbiology laboratories spread across the Netherlands covering approximately 4.1 million inhabitants, a representative proportion of 25% of the Dutch population, have sent all pneumococcal isolates from normally sterile sites to the NRBM from 2004 onwards (so not only CSF but also blood isolates).To determine the impact of vaccination we have now (for 2004-2010) enhanced our surveillance to include also clinical data such as outcome, duration of hospitalisation, clinical picture etc.
Poland	Surveillance was implemented and covers the whole spectrum of invasive pneumococcal disease since 2005. It has low sensitivity, especially in relation to less severe outcomes and adult cases. The National Pneumococcal Lab maintains a system which is not entirely integrated with the main universal system. It serves for serotype distribution evaluation, but not for national incidence estimation.
Slovakia	Mandatory reporting is only for IPD – meningitis. Voluntary reporting is for all other diseases caused by *S. pneumoniae* (e.g. pneumoniae, otitis, sepsis)
Slovenia	Slovenia has laboratory based surveillance. NIPH laboratory collects all invasive isolates isolated in all regional microbiological and hospital labs. They confirm the strain identification, do the serotyping and determine the antimicrobial susceptibility. They also perform molecular typing.
Spain	Until now only meningitis caused by *Streptococcus pneumoniae* is under surveillance.
Sweden	Cases are reported with full identity both by clinicians and laboratories via the electronical reporting system-Sminet.
United Kingdom (1) *England and Wales*	System is based on reconciliation of electronically reported cases and cases identified by referral of a culture for serotyping to get a national total of all IPD case in England and Wales.

Case definitions and laboratory methods

All cases of IPD are reported in 23 (85%) surveillance systems. In four countries (FR, HU, LV, ES), specific clinical presentations are reported (Table 6).

Case definition for IPD surveillance differs among the systems. The 2008 EC definition is adopted by 15 (55.6%) surveillance systems while the 2002 EC definition by 4 (14.8%) systems. Eight (29.6%) surveillance systems adopted their own IPD case definition (Table 7).

Table 6. Cases of IPD reported

All cases of Invasive Pneumococcal Disease	Specific clinical pictures	
BE(1)(2), BG, CY, CZ, DK, EE, FI, DE, IS(1)(2), IE(1)(2), IT,LT, NL, NO, PL, SK, SI, SE, GB(1)(2) (n=23)	*Meningitis* *Sepsis* *Bacteraemia*	FR, HU, LV, ES (n=4) LV (n=1) FR, LV (n=2)

LV: All confirmed or not confirmed cases of meningitis; all confirmed cases of IPD

Table 7. Current case definition

Decision	Case definition for *Streptococcus pneumoniae* infection (invasive)	Country
2002 (2002/253/EC)	Clinical description: *S. pneumoniae* causes many clinical syndromes, depending on the site of infection (e.g. acute otitis media, pneumonia, bacteraemia, or meningitis). Laboratory criteria for diagnosis. One of the following: - Isolation of *S. pneumoniae* from a normally sterile site (e.g. blood, cerebrospinal fluid, or, less commonly, joint, pleural or pericardial fluid) - Detection of *S. pneumoniae* nucleic acid from a normally sterile site - For probable case: Detection of *S. pneumoniae* antigen from a normally sterile site Case classification: - Possible: A clinically compatible case without any laboratory confirmation or with identification from a non-sterile site - Probable: A clinically compatible case that is antigen positive - Confirmed: A clinically compatible case that is laboratory confirmed.	BG, IE(1)(2), SI (n=4)
2008 (28/IV/2008)	Clinical Criteria: Not relevant for surveillance purposes Laboratory Criteria. At least one of the following three: - Isolation of *S. pneumoniae* from a normally sterile site - Detection of *S. pneumoniae* nucleic acid from a normally sterile site - Detection of *S. pneumoniae* antigen from a normally sterile site Case classification: A. Possible case not annotated B. Probable case not annotated C. Confirmed case: Any person meeting the laboratory criteria.	CY, CZ, DE, EE, HU, IS(1)(2), LV, LT, NL, PL, SK, ES, SE, GB(2) (n=15)
	Other*	BE(1)(2), DK, FI, FR, IT, NO, GB(1) (n=8)

Note: (1) and (2) refers to different surveillance systems in the same country (See Table 1)

* Other:

BE(1)(2): Isolation from normally sterile fluid

DK: All laboratory confirmed IPD. Laboratory confirmation: isolation of *S.pneumoniae* from a sterile site (e.g CSF, blood, peritoneum, pleural, ect...) in patients of all age groups + PCR confirmed cases.

FI: NIDR receives notifications on laboratory findings. These are converted as cases using the following algorithm: Repeat culture findings in the same individual (have unique identifier) within a 3-month period from the first positive culture are merged into one case a finding in blood or CSF = IPD finding in blood = bacteremia finding in CSF with or without blood = meningitis.

FR: Isolation of S. *pneumoniae* and/or detection of *S. pneumoniae* nucleic acid from/in blood or CSF

IT: A patient with compatible symptomatology with laboratory confirmed IPD by one of the following laboratory methods: Isolation from blood, spinal fluid or any other normally sterile site; Positive detection of pneumococcal antigen in a spinal fluid sample; PCR positive in a sample from any normally sterile site; positive direct gram stain in a sample from any normally sterile site. There is not definition for possible and probable cases.

NO: Case with identification of *S. pneumoniae* in blood, CSF or other normally sterile body fluid or tissue

GB(1): PCR positive cases of pleural fluid or CSF as carriage in young children can result in PCR positivity in blood

Only confirmed cases are reported to 22 surveillance systems while the remaining countries collect all variety of cases with different case classifications (possible, probable and confirmed; Table 8).

Laboratory methods for case confirmation also differ. Isolation of *S. pneumoniae* is used for case confirmation in all 27 systems, detection of *S. pneumoniae* nucleic acid with PCR is used in 25 (92.6%) systems and antigen detection in 18 (66.7%) systems (Table 9).

Table 8. Data collected by the surveillance system

Only confirmed cases	Possible, probable and confirmed cases
BE(1)(2), CY, CZ, DK, EE, FI, FR, DE, HU, IS(1)(2), IT, NL, NO, PL, SK*, SI, ES, SE, GB(1)(2) (n=22)	BU, IE(1)(2), LV, LT (n=5)

*Confirmed cases are collected only in meningitis and sepsis.

Note: (1) and (2) refers to different surveillance systems in the same country (See Table 1)

Table 9. Laboratory methods to confirm a case

Country	Culture	PCR	Ag detection (Latex)	Antibody testing	Direct Gram coloration	Other
Belgium (1)(2)	√	√				
Bulgaria	√	√				
Cyprus	√		√	√	√	
Czech Republic	√	√	√			
Denmark	√	√				
Estonia	√	√	√			
Finland	√	√	√			
France	√	√				
Germany	√	√				
Hungary	√	√				√[1]
Iceland (1)(2)	√	√	√		√[2]	
Ireland (1)(2)	√	√	√			
Italy	√	√	√[3]			
Latvia	√	√	√			
Lithuania	√	√	√			
The Netherlands	√	√				
Norway	√	√	√			
Poland	√	√	√			
Slovakia	√		√		√	
Slovenia	√	√				
Spain	√	√	√			
Sweden	√	√	√			
United Kingdom (1)(2)	√	√	√			

[1] HU: Capsular reaction test using type-specific sera, MLST
[2] IS: Only in one surveillance system (1- Invasive pneumococcal surveillance system)
[3] IT: Antigen is accepted only if test is performed on spinal fluid

Note: (1) and (2) refers to different surveillance systems in the same country (See Table 1)

National Typing capacity

With the exception of EE, IE and SK, all other countries have a National Reference Laboratory. IE has access to reference facilities as part of research project. Among them, 19 (70.4%) serotype pneumococcal strains and 14 (51.8%) perform molecular typing (Table 10).

Table 10. Characteristics of National Reference Laboratory (NRL) and National Typing capacity

Country	NRL	Kind of Typing at NRL	Samples typed at NRL	N of typing laboratories	Collection of results at national level
Belgium (1)(2)	Yes	Serotyping	All samples	1	Yes
Bulgaria	Yes	Serotyping and Molecular typing	Part of samples	2-5	No
Cyprus	Yes	Serotyping	All samples	1	No
Czech Republic	Yes	Serotyping	All samples	1	Yes
Denmark	Yes	Molecular typing	All samples	1	Yes
Estonia	No	None	Other	>5	Yes
Finland	Yes	-	-	-	-
France	Yes	Serotyping and Molecular typing	Part of samples	1	Yes
Germany	Yes	Serotyping and Molecular typing	Part of samples	2-5	Yes
Hungary	Yes	Serotyping and Molecular typing	All samples	1	Yes
Iceland	Yes	Serotyping and Molecular typing	All samples	1	Yes
Ireland (1)	Yes	Serotyping and Molecular typing	All samples	1	Yes
Italy	Yes	Serotyping and Molecular typing	Part of samples	2-5	No
Latvia	Yes	None	Other	-	No
Lithuania	Yes	Serotyping	Other	1	Yes
The Netherlands	Yes	Serotyping and Molecular typing	All samples	1	Yes
Norway	Yes	Serotyping and Molecular typing	Part of samples	1	Yes
Poland	Yes	Serotyping and Molecular typing	Part of samples	2-5	Partially
Slovakia	No	None	Other	>5	Yes
Slovenia	Yes	Serotyping and Molecular typing	All samples	1	Yes
Spain	Yes	Serotyping and Molecular typing	Part of samples	2-5	Yes
Sweden	Yes	Serotyping	Part of samples	2-5	Yes
United Kingdom (1)	Yes	Serotyping	All samples	2-5	Yes
United Kingdom (2)	Yes	Serotyping and Molecular typing	All samples	1	Yes

FR: 1. All samples are serotyped for meningitis cases (children i.e. 0-15 years and adults) and for bacteareamia and sepsis cases (children) 2. A sample of bacteareamia cases (1/6) isolated in adults are serotyped every 2 years.
IE (CIDR): Serotyping is performed using a combination of molecular methods (multiplex PCR) and is done as part of a research funded project. However the laboratory has not formally been identified by the National authorities as the national reference laboratory.
IT: Serotyping is performed on all the samples that arrives at NRL (around 10% of all reported cases)
LV : Serotyping or molecular typing is not performed yet
PL: The NRL receives the majority of samples through public health departments. Serotyping is performed on all samples. Molecular typing is performed on all samples in selected time periods.

Note: (1) and (2) refers to different surveillance systems in the same country (See Table 1)

Data Management

Table 11. Variables collected through the surveillance system

Country	Date of notification	Source of notification	Demographic variables	Date of onset of symptoms	Type of sample	Date of sampling	Laboratory test details	Type of IPD	Hospitalization	Date of hospitalization	Date of discharge	Underlying conditions	Vaccination status	Type of vaccine	Date of vaccine administration	Antibiotic resistance	Clinical outcome	Date of death	Serotyping	Molecular typing
Belgium (1)	√	√	√		√	√										√			√	
Belgium (2)	√	√	√	√	√	√	√	√	√	√		√	√	√	√		√		√	
Bulgaria									√											
Cyprus	√	√	√	√	√		√	√	√	√		√	√				√		√	
Czech Republic	√	√	√	√	√	√	√	√	√	√			√	√	√	√	√	√	√	√
Denmark	√	√	√	√	√	√		√	√	√		√	√			√	√	√	√	√
Estonia	√	√	√	√	√	√	√	√	√	√			√		√	√	√	√		
France	√	√	√		√	√	√	√	√							√			√	
Germany		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Hungary	√	√	√	√	√	√	√	√	√	√	√		√				√	√		
Iceland (1)	√	√	√		√	√	√	√								√	√		√	√
Iceland (2)	√	√	√	√	√	√	√	√	√							√	√	√	√	√
Ireland (2)	√*	√*	√*	√*	√*	√*	√	√	√	√	√	√	√*	√	√	√	√	√	√*	√
Italy	√	√	√	√	√	√	√	√	√	√		√	√	√	√		√		√	
Latvia	√	√	√	√	√	√	√	√	√	√			√				√	√		
Lithuania	√	√	√	√				√	√	√		√	√		√		√	√		
The Netherlands	√	√	√		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Norway	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Poland			√	√	√	√	√	√	√	√	√	√	√		√	√	√	√	√	√
Slovakia	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Slovenia	√	√	√	√	√	√		√	√	√	√		√	√	√	√	√		√	√
Spain	√	√	√	√	√		√	√	√								√		√	
Sweden	√	√	√	√	√	√	√						√			√			√	
United Kingdom (1)	√	√	√		√	√	√	√								√			√	
United Kingdom (2)	√	√	√	√	√	√	√	√								√			√	√

IE: For all children born since 2000 additional data is routinely collected since 2008. For children and adults born before 2008 additional data is sometimes collected since 2008. (*) Core notification data on all cases.

Note: (1) and (2) refers to different surveillance systems in the same country (See Table 1)

Information collected through each surveillance system and available at national level are listed in Table 11. Approximately 80% of the surveillance systems have data available in an electronic database (BE, CY, CZ, DK, EE, DE, HU, IE, IT, LV, LT, NL, NO, PL, SK, SI, ES, SE, GB); surveillance data in the French system are available on an electronic database with the exception for the results of serotyping; four systems have no data available in an electronic database (BG, IS, LT). FI didn't answer this part of the section. Frequencies of the electronic database update and data analisys are showed in Table 12.

Table 12. Availability of an electronic database for surveillance data, frequency of update and analysis

Country	Availability	Frequency of update	Frequency of data analysis
Belgium (1)	Yes	Monthly	Monthly to quarterly
Belgium (2)	Yes	Monthly	Yearly
Bulgaria	No		Weekly or more frequent than monthly
Cyprus	Yes	Weekly	Monthly to quarterly
Czech Republic	Yes	Weekly	Yearly or more frequently
Denmark	Yes	Daily	Monthly to quarterly
Estonia	Yes	Daily	Monthly to quarterly
France	Partially	Monthly	Yearly
Germany	Yes	Daily	Monthly to quarterly
Hungary	Yes	Daily	Monthly to yearly
Iceland (1)	No	-	Yearly
Iceland (2)	No	-	Monthly to quarterly
Ireland	Yes	Daily	Monthly to quarterly
Italy	Yes	Weekly	Yearly
Latvia	Yes	Daily	Weekly or more frequent than monthly
Lithuania	Yes	Daily	Yearly
The Netherlands	Yes	Quarterly	Yearly
Norway	Yes	Daily	Monthly to quarterly
Poland	Yes	Monthly	Twice a year
Slovakia	Yes	Daily	Monthly to quarterly
Slovenia	Yes	Weekly	Yearly
Spain	Yes	Yearly	Yearly
Sweden	Yes	Daily	Yearly
United Kingdom (1)	Yes	Weekly	Monthly to quarterly
United Kingdom (2)	Yes	Weekly	Twice a year

CZ: Surveillance data are analyzed yearly or more frequently on request (for Ministry of Health or for scientific presentations)

FR: Serotyping process (NRCP) and surveillance analysis (EPIBAC) are carried out on two distinct databases and are meregd in an aggregated format by age-group and site of isolation (blood or CSF)

Note: (1) and (2) refers to different surveillance systems in the same country (See Table 1)

Sensitivity of the surveillance

The sensitivity of seven (26%) surveillance systems has been assessed, at least once in the last ten years; five of them using the "capture-recapture" method and two comparing different sources. Other 13 systems provide a "guesstimate" of their systems' sensitivity. Changes in the next three years have been planned in eight systems (Table 13).

According to the country experts, pneumonia and sepsis are the most under-represented clinical conditions (Table 14).

Table 13. Sensitivity of the surveillance system

Country	Sensitivity calculation	Estimated sensibility	Guesstimate	Method for estimation	Year of estimation	Change planned
Belgium (1)	Yes	84	-	Capture-recapture	2006	No
Belgium (2)	Yes	84	-	Capture-recapture	2008	No
Bulgaria	No	-	80	-	-	No
Cyprus	No	-	-	-	-	No
Czech Republic	No	-	99	-	-	No
Denmark	No	-	75	-	-	Yes
Estonia	No	-	70 - 100	-	-	No
France	Yes	64	-	Capture-recapture	2006	Yes
Germany	Yes	58	-	Capture-recapture	2009	No
Hungary	No	-	40	-	-	Yes
Ireland (1)	Yes	98	-	Comparing sources	2008	Yes
Ireland (2)	Yes	99	-	Comparing sources	2010	Yes
Italy	No	-	-	-	-	Yes
Latvia	No	-	-	-	-	No
Lithuania	No	-	60	-	-	Possible
The Netherlands	Yes	30	95	Capture-recapture	2001	-
Norway	No	-	90	-	-	No
Poland	No	-	40	-	-	No
Slovakia	No	-	80	-	-	Yes
Slovenia	No	-	-	-	-	No
Spain	No	-	50	-	-	Yes
Sweden	No	-	95	-	-	No
United Kingdom (1)	No	-	90	-	-	No
United Kingdom (2)	No	-	70	-	-	No

Note: (1) and (2) refers to different surveillance systems in the same country (See Table 1)

BE: This is the sensitivity of the combined surveillance systems with record linking of laboratory surveillance and surveillance by the pediatricians (PediSurv).
CY: Planned to be calculated within 2 years.
FR: Sensitivity is measured on a two step process 1) % population coverage 2) % completeness of reporting. Population coverage is estimated by the proportion of French acute care hospitalizations covered by the participating hospitals (#300); this is realized every year. The population coverage is over 78% since 2003. In addition the under notification of cases by the participating hospitals (missed cases) is estimated from three sources capture-recapture analysis. It is estimated to be 80%. Last capture-recapture analysis was done in 2006.
DE: sensitivity groups - children up to 16 years.
NL: With the sentinel system (including 9 laboratories) the sensitivity will be > 90%.

Table 14. Particular condition under-represented in the surveillance

Meningitis	Sepsis	Other condition	
HU, LT, SK (n=3)	BG, DE, IT, LV, LT, SK, ES (n=7)	*Pneumonia* *Otitis Media* *Bacteraemia* *Pericarditis* *Arthritis*	BG, EE, LV, LT, NO, PL, SK, SI, ES (n= 9) BG, SK (n=2) BG, PL, SK (n=3) ES (n=1) ES (n=1)

FR: non bacteremic pneumococcal infections are not included in the surveillance
IT: Number of IPD other than meningitis is under represented

Dissemination

Pneumococcal disease surveillance results of 23 systems are publicly available. Almost all of them are disseminated at intervals of 6 months - one year. Data and references of the most recent available reports are listed below (Table 15).

Table 15. Dissemination of pneumococcal disease surveillance results

Country	Dissemination	Intervals	Public information on serotypes	Last national report	Last peer-reviewed journal	Last Internal report
Belgium (1)	Yes	<=6 months	Yes	2008	-	-
Belgium (2)	Yes	Yearly	Yes	2008	-	-
Bulgaria	Yes	<=6 months	No	May 2010	-	July 2010
Cyprus	Yes	<=6 months	No	December 2009	-	-
Czech Republic	Yes	Yearly	Yes	April 2010	2009	-
Denmark	Yes	<=6 months	Yes	February 2010	-	-
Estonia	Yes	<=6 months	No	June 2010	-	December 2009
France	Yes	Yearly	Yes	July 2010	August 2008	-
Germany	Yes	<=6 months	Yes	-	June 2009	-
Hungary	Yes	<=6 months	Yes	June 2010		
Iceland (1)	Yes	Yearly	Yes	January 2009	-	-
Iceland (2)	Yes	Yearly	Yes	January 2010	-	-
Ireland (1)	Yes	<=6 months	Yes	June 2010	July 2005	May 2006
Ireland (2)	Yes	Other	Yes	August 2010	June 2010	
Italy	Yes	Other	Yes	-	2005	2010
Latvia	No	-	-	-	-	-
Lithuania	Yes	Yearly	No	-	-	-
The Netherlands	Yes	Yearly	Yes	March 2009	May 2010	-
Norway	Yes	Yearly	No	June 2008	January 2010	-
Poland	Yes	<=6 months	Other	September 2009	-	June 2010
Slovakia	Yes	Yearly	No	2010	-	-
Slovenia	Yes	Yearly	Yes	February 2010	May 2008	-
Spain	Yes	Yearly	No	-	-	2008
Sweden	Yes	Yearly	Yes	May 2010	-	-
United Kingdom (1)	No	-	-	-	-	-
United Kingdom (2)	No	-	-	-	-	-

IE: CIDR and EARS-Net - Dissemination of results is planned to be done every quarter
IT: Synthetic data are available every 3 months on the web site. A comprehensive report every 3-5 years
PL: Results are only provided for scientific meetings
SE: Information on serotype distribution is published once a year

Note: (1) and (2) refers to different surveillance systems in the same country (See Table 1)

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Spain

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List of most recent pneumococcal disease surveillance data uploaded on a public website, date and link to website

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Bulgaria (July 2010) http://www.ncipd.org
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Section 2. Vaccination Strategies

Response

The response for the second section was 100% (29 countries); the response for data validation was 86.2% (25/29 countries). The countries that validated data are (BE, CY, CZ, DK, EE, FR, DE, GR, HU, IS, IE, IT, LV, LT, LU, MT, NL, NO, PL, PT, RO, SK, ES, SE, UK).

Type of vaccine, schedule and target groups

As of August 2010, childhood pneumococcal vaccination has been implemented in all 29 European countries. The vaccination is recommended in 21 countries (72.4%), voluntary in 5 countries (17.2%) and mandatory in 3 countries (10.4%). For 26 countries the decision on vaccination policy and PCV implementation procedures was taken at national level, for remaining 3 countries (IT, MT, ES) decision was taken at sub-national level.

Of the three pneumococcal conjugate vaccines available on the market, PCV7 was in use in 24 countries, PCV10 in 16 countries and PCV13 in 21 countries. Six countries (BE, HU, IE, NO, SK, ES) had already planned or were considering, the introduction of PCV13 in their national immunization programme by 2011.

In 12 of 22 countries, where different pneumococcal conjugate vaccines are available, there is no possibility to choose the vaccine, because the decision is taken at national/regional level. For remaining 13 countries the decision is left to children parents' discretion (n=3) or to pediatrician/vaccination service discretion (n=7; table 17). In three countries (DK, IT, SE) different PCV are used only in some sub national units.

Pneumococcal conjugate vaccines is included in the routine immunization programme in 23 (79.3%) of 29 countries (AT, BE, BG, CY, CZ, DK, FI, FR, DE, GR, HU, IS, IE, IT, LV, LU, NL, NO, PL, SK, ES, SE, UK); of the five remaining countries, two (RO, SI) have planned to introduce this vaccine during the next three years. In Malta the policy for universal vaccination programme in infants has been approved (the programme will start in 2012).

In countries (n=24) with PCV already included in routine immunization programme, vaccination is recommended universally in 13 (54.2%), risk-based in 5 (20.8%) and both in 6 (25%). The year of PCV introduction in the routine immunization programme of each country is presented in Table 18. After introduction, 10 (41.7%) countries performed at least one catch-up campaign.

Table 16. PCV strategy at August 2010

Country	PCV introduction strategy	Level of decision	PCV in use	Year of PCV13 implementation
Austria	Recommended	At national level	pcv10/pcv13	
Belgium	Recommended	At national level	pcv7	2011
Bulgaria	Mandatory	At national level	pcv7/pcv10	
Cyprus	Recommended	At national level	pcv10/pcv13	
Czech Republic	Recommended	At national level	pcv7/pcv10/pcv13	
Denmark	Recommended	At national level	pcv7/pcv13	
Estonia	Recommended	At national level	pcv7/pcv13	
Finland	Voluntary	At national level	pcv7/pcv10/pcv13	
France	Recommended	At national level	pcv7/pcv13	
Germany	Recommended	At national level	pcv10/pcv13	
Greece	Recommended	At national level	pcv7/pcv10/pcv13	
Hungary	Recommended	At national level	pcv7/pcv13	2010
Iceland	Voluntary	At national level	pcv7/pcv10/pcv13	
Ireland	Recommended	At national level	pcv7	2010
Italy	Recommended	At sub national level	pcv7/pcv10/pcv13	
Latvia	Mandatory	At national level	pcv7	
Lithuania	Voluntary	At national level	pcv7/pcv10	
Luxemburg	Recommended	At national level	pcv13	
Malta	Recommended	At sub national level	pcv7/pcv10/pcv13	
Netherlands	Recommended	At national level	pcv7	
Norway	Recommended	At national level	pcv7	2011
Poland	Recommended	At national level	pcv7/ pcv13	
Portugal	Recommended	At national level	pcv10/pcv13	
Romania	Voluntary	At national level	pcv7/pcv10/pcv13	2011
Slovakia	Mandatory	At national level	pcv7/pcv13	
Slovenia	Recommended	At national level	pcv7/pcv10	2010
Spain	Voluntary	At sub national level	pcv7/pcv10/pcv13	2010
Sweden	Recommended	At national level	pcv7/pcv10/pcv13	
United Kingdom	Recommended	At national level	pcv7/pcv13	

BE: Recommendation is at national level. Implementation and timing is different and decided at sub national level.
DK: Since April 2010, PCV13 gradually replaced PCV7
EE: Estonian Ministry of Social Affairs recommends PCV vaccination to children and adults with underlying conditions; immuncompromized children and adults; children and adults, who have aspirin or immunosuppressive therapy; children and adults with organ transplantation; social care facilities residents; HIV positive; alcoholics; people aged > 65 years.
IT: There are 21 regions that decide autonomously the vaccine strategies. There is a national document from MoH that recommend a schedule. However the Regions cannot follow. This document (National Plan for Vaccination) should be produced every 3 years but at the present the last available version is 2005-2007. In this document Vaccination for PNC was recommended only considering the local epidemiological situation and the resources availability. The difference among the Regions in implementation of the new vaccines could be very evident. However up today almost all 20 Regions offer this vaccination to the general population. The new national plan is planned to be approved by the end of 2010 and will recommend PNC vaccination for general population at 3,5,11 months of age.
MT: ACIP recommends universal vaccination for children under 5 years of age. Decision presently is at Financial Authority level. Currently the vaccine is only offered free of charge to high-risk cases only.
NL: Plan of PCV10 implementation in 2011 in the Dutch National Immunization Program.
PT: PCV vaccine is not included in the NIP; it is just recommended, free of charge, for risk groups until 59 m of age

ES: Only the Autonomous Region of Madrid included the 7v pneumococcal vaccination in its childhood vaccination schedule.

Table 17. Vaccine choice

The decision is taken at national/regional level	The decision is left to children parents' discretion	The decision is left to paediatrician/vaccination service discretion
AT, BE, DK, FI, FR, HU, IE, IT, LV, LU, NL, NO, PL, PT, SK, ES, SE, GB (n=18)	BG, IS, LT, RO (n=4)	CY, CZ, EE, DE, GR, MT, SI (n=7)

Table 18. PCV introduction and catch up campaign

Country	PCV Introduction	Date of introduction	Catch-up campaign	Age groups of catch-up campaign
Austria	risk-based	July 2004	No	
Belgium	universal	January 2005	2007	2-6 months (3 doses+1)/ 7-11 months (2 doses+1)/ 12-23 months (2 doses)/ad risk and >24 months 1 x
Bulgaria	universal	April 2010	No	
Cyprus	universal	August 2008	2010	Children up to 59 months of age
Czech Republic	universal	January 2010	No	
Denmark	universal	October 2007	2007	4-17 mths
Finland	universal/risk-based	January 2009	No	
France	universal/risk-based	June 2006	2010	24-59months
Germany	universal	July 2006	No	
Greece	universal/risk-based	January 2006	No	
Hungary	universal	October 2008	2008/2009	Children up to 24 months of age
Iceland	risk-based	December 2006	No	
Ireland	universal/risk-based	October 2002	2008/2009	All children < 2 years of age when routine programme commenced in September 2008
Italy	universal/risk-based	May 2005	No	
Latvia	universal	January 2010	No	
Luxemburg	universal	October 2004	2004	children aged 7-11 Mo (3 doses) and 12-24 Mo (2 doses)
Netherlands	universal	June 2006	No	
Norway	universal	July 2006	2006	All children born from 1/1/2006
Poland	risk-based	May 2008	No	
Portugal	risk-based	June 2010	2010	
Slovakia	universal/risk-based	January 2006	No	
Spain	risk-based	June 2001	No	
Sweden	universal	January 2009	No	
United Kingdom	universal	September 2006	2006	Children under 2 years old

ES: universal introduction in the Autonomous Region of Madrid in November 2006.

Vaccination schedule and number of doses differ among countries. Thirteen countries use a vaccination schedule of 3 doses, other thirteen countries use a schedule of 4 doses while two countries (BG, PL) use both. PCV vaccination schedule, number and age of doses are presented in table 19.

Table 19. PCV vaccination schedule

Country	Schedule	1st dose (months)	2nd dose (months)	3rd dose (months)	4th dose (months)
Austria	3+1 dose	3	5	7	12-24
Belgium	2+1 dose	2	4	12	
Bulgaria	3+1 dose /2+1 dose	2	3	4	12
Cyprus	3+1 dose	2	4	6	12-15
Czech Republic	3+1 dose	2	4	6	18
Denmark	2+1 dose	3	5	12	
Estonia	not decided				
Finland	2+1 dose	3	5	12	
France	2+1 dose	2	4	12	
Germany	3+1 dose	2	3	4	11-14
Greece	3+1 dose	2	4	6	12-15
Hungary	2+1 dose	2	4	15	
Iceland	2+1 dose	3	5	12	
Ireland	2+1 dose	2	6	12	
Italy	2+1 dose	3	5	11	
Latvia	3+1 dose	2	4	6	12-15
Lithuania	3+1 dose	2	4	6	24
Luxemburg	3+1 dose	2	3	4	12-15
Malta	3+1 dose	2	4	13	none
Netherlands	3+1 dose	2	3	4	11
Norway	2+1 dose	3	5	12	
Poland	3+1 dose/2+1 dose	NA	NA	NA	NA
Portugal	2+1 dose	2	4	12-15	
Romania	3+1 dose	2	4	6	15-18
Slovakia	2+1 dose	2	4	10	
Slovenia	3+1 dose	2-3	4	6	24
Spain	3+1 dose	2	4	6	15
Sweden	2+1 dose	3	5	12	
United Kingdom	2+1 dose	2	4	13	

PCV vaccination target, in seventeen (58.6%) countries, is represented by all children under two years of age, while in six (20.7%) countries the target is all children under five years of age. In most of these countries, PCV vaccination is also indicated for children under five years of age at clinical risk. In three countries (FI, IS, ES) target groups are represented only by children at clinical risk or patients with cochlear implants. Other specific targets are listed in table 20. Only in two countries (EE, RO) PCV vaccination is indicated in none of the above mentioned groups.

Table 20. PCV target group

Target group	Country
children < 2years	AT, BE, CZ, DK, FR, DE, HU, IE, IT, LV, LT, LU, NL, NO, SK, SE, GB (n=17)
children < 5 years	BG, CY, GR, MT, PL, SI (n=6)
cochlear implants patients	BE, DK, FI, FR, DE, HU, IS, IE, IT, LU, PL, PT, SK, ES, SE, GB (n=16)
children < 5 years at clinical risk	AT, BE, DK, FI, FR, DE,HU, IS, IE, IT, LU, MT, NO, PL, PT, SK, ES, SE, GB (n=19)
other:	FI, IE ,PL, PT, SK (n=5)
- *immunocompromised*	FI, IE (n=2)
- *preterm born*	PL, PT (n=2)
- *splenectomy*	IE, SK (n=2)

Pneumococcal conjugate vaccine is universally and actively offered in sixteen countries with differences at sub-national level in IT. Other two countries (DE, LT) offer PCV universally too, but not actively. In all countries where PCV is universally offered the vaccination is free of charge for patients with the exception of Latvia where it's fully charged to patients. In IT, PCV payment could differ among sub-national units. In twenty-one countries PCV is offered to people at clinical risk; in 76% of these countries PCV vaccination is actively offered and free of charge. For the other five countries PVC is fully charged (IS, LT) to the patient or co-payment is required (HU, NO, SE, Table 21).

Pneumococcal Polysaccharide 23-valent vaccine (PPV23) is on the market in 28 countries; only three of them use PPV23 in their routine immunization programme (Table 22).

Table 21. Pneumococcal conjugate vaccine offer

Kind of offer	Universal	Clinical risk groups
Actively offered	BE, BG, CY, CZ, DK, GR, HU, IE, IT*, LV, LU, NL, NO, SK, SE, GB (n=16)	AT, BE, CY, DK, FI, HU, IT, LU, MT, NO, PL, PT, SK, ES, SE*, GB (n=16)
Not actively offered	DE, LT (n=2)	DE, IS, IE, LT, SI (n=5)
Free of charge	BE, BG, CY, CZ, DK, DE, GR, HU, IE, IT*, LV, LU, NL, NO, SK, SE, GB (n=17)	AT, BE, CY, DK, FI, DE, IE, IT, LU, MT, PL, PT, SK, SI, ES, GB (n=16)
Fully charged	LT (n=1)	IS, LT (n=2)
Co-payment	-	HU**, NO, SE*(n=3)

* Differences in sub national units
** For 2-5 years old children

Table 22. Pneumococcal Polysaccharide 23-valent vaccine (PPV23) use

Country	On the market	PPV23 use in routine IP	PPV23 vaccination strategy
Austria	Yes	No	
Belgium	Yes	No	First recommendations of the Superior Health Council were issued in 1997. PPV23 is recommended to: patients who are at risk(functional asplenia or splenectomia)/all adults of 65 and older/ to patients of 50 year and older who have chronic pulmonary conditions, congestive heart disease, alcoholism with or without cirrhosis, HIV patients. At individual level for specific groups of patients.
Bulgaria	Yes	No	Vaccination is recommended for: everyone over 65 years of age; adults and children over 2 years of age who have certain underlying medical conditions.
Cyprus	Yes	No	PPV23 is reccomended for high risk (for pneumococcal related diseases) individuals over 2 years of age and for all people over 65 years. It is offered free of charge.
Czech Republic	Yes	No	
Denmark	Yes	No	See http://www.ssi.dk/sw51372.asp
Estonia	Yes	No	PPV23 is not used in routine childhood immunisation programme yet.
Finland	Yes	Yes	For risk group patients after they are over 2 years old they get this also. So they will get both, first a conjugated vaccine and then this.
France	Yes	Yes	PPV23 is recommended in high-risk* children aged > 2 years: 1 dose given 2 months after the last PCV13 dose then 1 dose / 5 years. *High-risk children : splenectomy, transplantation, immunosupression or immunosupressive treatment, cardiac or renal deficiencies, VIH+, chronic pneumopathy, cochlear implant, drepanocytosis. PPV23 vaccination is offered by practioners.
Germany	Yes	No	Pneumococcal Polysaccharide 23-valent vaccine (PPV 23) is recommended for all over 60 since 2002 and for risk groups over 5 years since 2001.
Greece	Yes	Yes	1. High risk children and adults (5 years-60 years) with the following:congenital immunodeficiencies, HIV infection, Immunocompromised, asplenia or decreased splenic function due to sickle cell disease, nephrotic syndrome, renal insufficiency, diabetes mellitus, chronic cardiac/pulmonary disease, cochliar implants, CSF leak 2. All adults older than 60 years
Hungary	Yes	No	Who like to be vaccinated can buy PPV23 vaccine in the pharmacy after prescription.
Iceland	Yes	No	For adults
Ireland	Yes	No	It is only recommended for at risk children and adults > 2 years of age (since 2002) children < 5 years of age with IPD should be vaccinated irrespecitve of immunisation history. in which case it is up to either clinician to remind individual that they need vaccine or the patient can ask for vaccine. For at risk groups, the vaccine is free but administration fees may apply for some (usually the children patients should not to pay for administration).
Italy	Yes	No	In Italy for children with clinical risk more than 2 years old not previously vaccinated. It is free and it should be actively offered.
Latvia	Yes	No	PCV23 offered for risk groups as commercial vaccine.

Lithuania	Yes	No	We recommend to vaccinate babies, children and all persons under 65 years of age.pneummoccocal vaccine is priority vaccine for introducing to the children schedule.
Luxemburg	Yes	No	Target groups: clinical risk groups (chronic pulmonary disease, chronic heart disease, diabetes mellitus, liver cirrhosis, chronic alcoholism, cochlear implant, LCR fistula), long care residents, elderly population (>60), immunocompromised people (asplenia or splenectomy, multiple myeloma, chronic renal insufficiency, nephrotic syndrome, organ transplantation, sickle cell anemia), HIV infection. Introduced in 1997, revised in 2008PPV23 is not reimbursed, even for eligible patients according to target groups.
Malta	Yes	No	High-risk groups including renal transplant patients and immunosuppressed patients
Netherlands	Yes	No	PPV23 is only available for risk groups
Norway	Yes	No	PPV23 is recommended for persons in defined risk groups and all persons aged 65 or older
Poland	Yes	No	PPV 23 is recommended for children above 5 years and for adults
Portugal	Yes	No	Recommended for the same risk groups as PCV from 24 months to 17 yeasr of age.
Romania	Yes	No	Is offered voluntary to the risk groups and age more than 60 together with influenza vaccine (not free of charge)
Slovakia	Yes	No	Vaccination with PPV23 is officially mandatory for persons at the higher risk of infection - for persons housed in social care facilities. Vaccination with PPV23 is officially recommended to persons with severe underlying conditions (chronic lung diseases, cardiovascular, metabolic, renal disorders, immunodeficiency; persons with splenectomy; persons 59 and older.
Slovenia	Yes	No	Children at clinical risk; above 2 years age; last ten years; not actively offered. http://www.ivz.si/?ni=95&pi=5&_5_Filename=1555.pdf&_5_MediaId=1555&_5_AutoResize=false&pl=95-5.3
Spain	Yes	No	PPV23 vaccination are recommended since 2001 for adults included in the following risk groups: patients with chronic heart, respiratory, renal and hepatic diseases, diabetes mellitus, functional or anatomic asplenia, Hodgkin lymphoma, organ transplantation, HIV infection, cochlear implant patients, elderly people living in closed institutions. Some autonomous regions recommend universal immunization to persons aged 60 or more.
Sweden	Yes	No	PPV23 is used for children above the age of 2 years as well as adults. Target group:Children with chronic heart-, lung or kidney disease, immunodeficiencies, cochlear implants, etc. Adults with chronic diseases or states (heart-, lung- and kidney disease, diabetes, alcoholism, cirrosis of the liver and Downâ€™s syndrome), immunodeficiencies due to asplenia, congenital or aquired syndromes, immunosuppresive treatment, etc., adults with fractures of the skull or leakage of liquor as well as the elderly.These recommendations were introduced Oct 14th 1994.The elderly (>65yrs) are actively offered pneumococcal vaccinations in some regions.Persons at risk are offered PPV23 through their treating physicians.The vaccine can be offered free of charge, dependant on the risk group and/or region.
United Kingdom	Yes	No	Not part of routine programme except for 65+ yrs old. At present, a single dose of pneumococcal polysaccharide vaccine (PPV) is offered to all those aged 65 years and older as well as to those less than 65 years with risk factors for

			invasive pneumococcal disease.

Vaccine Coverage

Pneumococcal vaccination coverage is monitored in sixteen countries; 50% of these has routine system for monitoring PCV coverage for entire population while the other 50% has a system for monitoring in some specific age groups (Table 23). Almost all these fifteen countries assess PCV coverage yearly and even more frequently (Table 24). IT assesses it every five years; IS and PT do it not regularly. Thirteen countries (CZ, DK,FR, IS, IE, IT, LV, NL, NO, PT, SK, SE, GB) estimate PCV coverage through medical records or immunization registry. More than one method of VC estimation is used by six countries (Table 25). None of the countries where pneumococcal vaccination is offered have a routine system for monitoring VC in groups at clinical risk.

Table 23. Routine system for monitoring pneumococcal vaccination coverage in general population

Entire population	Some age groups	
DK, FR, IS, IT, NL, PL, PT, GB (n=8)	<= 1 year 1 year - 2 years 2 - 5 years other	CZ, HU, IE, LV, NO, SK (n=6) CZ, HU, IE, LV, NO (n=5) NO (n=1) DE, IE, LV, SK, SE (n=5)

Table 24. PCV vaccine coverage assessment

Vaccine coverage assessment	
Monthly Quarterly Yearly Every five years Not regularly	FR, LV (n=2) HU, IE, GB (n=3) CZ, DK, DE, NL, NO, PL, SK, SE (n=8) IT (n=1) IS, PT (n=2)

Table 25. Method used to estimate coverage

Medical records or immunization registry	Number of distributed/administered doses	Pharmaceutical	Immunization survey	Other
CZ, DK,FR, IS, IE, IT, LV, NL, NO, PT, SK, SE, GB (n=13)	DK, FR, HU, PL (n=4)	DK, FR, DE, IS (n=4)	BE, FR, IT (n=3)	FR, DE, IE (n=3)

BE: Vaccination uptake has been estimated by regional two-stage cluster surveys in Flanders (2008) and Wallonia (2009). These data are not collected at national level.

Most recent pneumococcal vaccination coverage data is available for twelve countries (Table 26).

Table 26. Most recent pneumococcal vaccination coverage data

Country	Universal Coverage	Year of measurement	Age	Method of measurement
Czech Republic	86,3	2010	< 1 year of age	Immunization registry
Denmark	85	2010	<2 years of age	Immunization registry
France	81	2008	6 months	Reimbursement data analysis
Germany	9,10	2009	5-7 years	Coverage at school entry
Hungary	81,10	2009	<2 years of age	Administrative
Ireland	89	2009	12 months	Immunization registry
Italy	55	2008	12-23 months	Cluster-sampling survey
Latvia	51	2010	0	Universal
Netherlands	94	2009	2 years of age	Immunization registry
Norway	90	2009	2 years of age	Immunization registry
Poland	1,70	2008	0-14	Administrative
Portugal	52	2009	24 months	Immunization registry
Slovakia	99,20	2009	< 1 year of age	Administrative vaccination survey
United Kingdom	90	2010	1 year	Immunization registry

DK: Coverage is based on individual data and calculated on birth cohorts. Therefore the given 85 percent is an estimate based on this. See also http://www.ssi.dk/sw73282.asp
FR: Vaccination coverage is estimated from an individual reimbursement database. This database includes a representative cohort of French population. Available data for each individual include age(s) at reimbursement and name(s) of the vaccine
DE: Universal vaccination was introduced in 2006, school entry examination 2009 was too early for measuring real uptake
IE: Our programme only started in 2008- therefore we only had data for 12 month old children. Data relating to catch up is currently being analysed
IT: VC=49% in children at clinical risk
LV: The 1st dose of PCV during 6 months of 2010
SK: The vaccination coverage in persons housed in social care facilities was 12.4 within the administrative vaccination survey conducted in 2009

Section 3. Health Technology Assessment

Impact of childhood pneumococcal vaccination

The response for the third section was 100% (29/29 countries); the response for data validation was 86.2% (25/29 countries). The countries that validated data are (BE, CY, CZ, DK, EE, FR, DE, GR, HU, IS, IE, IT, LV, LT, LU, MT, NL, NO, PL, PT, RO, SK, ES, SE, UK).

The impact of childhood pneumococcal vaccination has been assessed in eleven (37.9%) countries; all these countries assessed the trends in serotype distribution; ten countries assessed also the incidence trends of the disease (Table 27). Methods of assessment are listed in table 28.

Seven countries provided references for published studies on vaccine effectiveness and vaccine impact in their country.

Table 27. Assessment of the impact of childhood pneumococcal vaccination

Assessment of the impact of childhood pneumococcal vaccination	
Assessment of incidence trends	BE, CZ, DK, FR, DE, HU, IE, NL, NO, PT (n=10)
Assessment of trends in serotype distribution	BE, CZ, DK, FR, DE, HU, IE, NL, NO, PT, GB (n=11)
Assessment of vaccine effectiveness	BE, DK, NO, GB (n=4)
Other - Assessment of antimicrobial susceptibility	NO, PT (n=2)

Table 28. Method used to assess childhood pneumococcal vaccination impact

Case-control study	Screening method	Descriptive studies
GB (n=1)	DE, GB (n=2)	BE, CZ, DK, FR, HU, IE, NL, NO, PT (n=9)

References

BE: http://www.wiv-isp.be/pedisurv/f_index.htm
DK: http://www.ssi.dk/sw73282.asp
FR: Eurosurveillance 2008 ;13(35):pii=18962. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=18962
DE: Rückinger S; van der Linden M; Reinert R; von Kries R; Burckhardt F; Siedler A. Reduction in the inc
IE: http://ndsc.newsweaver.ie/epiinsight/1hjl4kt5u6r12elq5r7tbh
NL: Emerg Infect Dis. 2010 May;16(5):816-23.
NO: Vestrheim DF, Løvoll O, Aaberge IS, Caugant D, Høiby EA, Bakke H, Bergsaker MR. Effektiveness of 2+1 dose schedule pneumococcal conjugate vaccination programme on invasive pneumococcal disease among children in Norway. Vaccine 2008;26:3277-3281. Vestrheim DF, Høiby EA, Bergsaker MR, Rønning K, Aaberge IS, Caugant DC. Indirect effect of conjugate pneumococcal vaccination in a 2+1 dose schedule. Vaccine 2010;28:2214-2221

Ethical aspects

In 18 (62.1%) countries an informed consent is sought from the parents of receiving PCV children. In 50% (n=9) of these countries informed consent is given orally, in 27.7% (n=5) written consent is sought and for remaining countries it depends on the delivery service. Informed consent is mostly given at the same time of vaccine administration (n=12 66.7%; Table 29).

PCV adverse events are monitored at national level in 28 EU/EEA countries with a universal surveillance system. In 20 of these countries, all adverse events are monitored while serious adverse events (SAE) are monitored in the 8 remaining countries. Vaccine failures are systematically monitored in 14 countries (Table 30).

Table 29. Informed consent

Country	Informed Consent	Form of informed Consent	Time for informed consent
Austria	Yes	Depends on the delivery service	At the same time of the administration of vaccine
Belgium	No		
Bulgaria	No		
Cyprus	No		
Czech Republic	No		
Denmark	Yes	Orally	At the same time of the administration of vaccine
Estonia	Yes	Orally	Before the administration, in a counselling visit
Finland	No		
France	Yes	Orally	At the same time of the administration of vaccine
Germany	Yes	Depends on the delivery service	At the same time of the administration of vaccine
Greece	No		
Hungary	Yes	Written by filling an appropriate form	At the same time of the administration of vaccine
Iceland	No		
Ireland	Yes	Written by filling an appropriate form	Before the administration, in a counselling visit
Italy	Yes	Written by filling a not structured form	At the same time of the administration of vaccine
Latvia	Yes	Orally	Before the administration, in a counselling visit
Lithuania	Yes	Written by filling an appropriate form	Before the administration, in a counselling visit
Luxemburg	No		
Malta	Yes	Orally	Before the administration, in a counselling visit
Netherlands	No		
Norway	Yes	Orally	At the same time of the administration of vaccine
Poland	Yes	Orally	At the same time of the administration of vaccine
Portugal	No		
Romania	No		
Slovakia	Yes	Written by fillng an appropriate form	Before the administration, in a counselling visit
Slovenia	Yes	Depends on the delivery service	At the same time of the administration of vaccine
Spain	Yes	Orally	At the same time of the administration of vaccine
Sweden	Yes	Depends on the delivery service	At the same time of the administration of vaccine
United Kingdom	Yes	Orally	At the same time of the administration of vaccine

Table 30. Monitoring of adverse events

Country	Monitoring of adverse events	Type of monitored adverse events	Method	Monitoring of vaccine failures
Austria	Yes, at national level	All	With a universal surveillance system	No
Belgium	No			Yes
Bulgaria	Yes, at national level	All	With a universal surveillance system	No
Cyprus	Yes, at national level	All	With a universal surveillance system	No
Czech Republic	Yes, at national level	Serious adverse events (SAE)	With a universal surveillance system	Yes
Denmark	Yes, at national level	All	With a universal surveillance system	Yes
Estonia	Yes, at national level	All	With a universal surveillance system	Yes
Finland	Yes, at national level	All	With a universal surveillance system	No
France	Yes, at national level	All	With a universal surveillance system	No
Germany	Yes, at national level	All	With a universal surveillance system	Yes
Greece	Yes, at national level	Serious adverse events (SAE)	With a universal surveillance system	No
Hungary	Yes, at national level	All	With a universal surveillance system	No
Iceland	Yes, at national level	Serious adverse events (SAE)	With a universal surveillance system	No
Ireland	Yes, at national level	All	With a universal surveillance system	Yes
Italy	Yes, at national level	Serious adverse events (SAE)	With a universal surveillance system	No
Latvia	Yes, at national level	Serious adverse events (SAE)	With a universal surveillance system	Yes
Lithuania	Yes, at national level	All	With a universal surveillance system	Yes
Luxemburg	Yes, at national level	Serious adverse events (SAE)	With a universal surveillance system	No
Malta	Yes, at national level	Serious adverse events (SAE)	With a universal surveillance system	No
Netherlands	Yes, at national level	All	With a universal surveillance system	Yes
Norway	Yes, at national level	All	With a universal surveillance system	Yes
Poland	Yes, at national level	All	With a universal surveillance system	No
Portugal	Yes, at national level	All	With a universal surveillance system	Yes
Romania	Yes, at national level	All	With a universal surveillance system	No
Slovakia	Yes, at national level	All	With a universal surveillance system	No
Slovenia	Yes, at national level	All	With a universal surveillance system	Yes
Spain	Yes, at national level	Serious adverse events (SAE)	With a universal surveillance system	No
Sweden	Yes, at national level	All	With a universal surveillance system	Yes
United Kingdom	Yes, at national level	All	With a universal surveillance system	Yes

Discussion

The survey results show that many European countries have an IPD surveillance system. Heterogeneity has been found among them. One of the differences that should be taken into account is the case definition. Overall 50% of the evaluated surveillance systems have adopted the 2008 EC definition, while other two third adopt their own IPD case definition. Since the 2008 survey, the case definition has been changed in several surveillance systems, but a mix of case definitions and laboratory methods for case confirmation remains a weakness for an European surveillance.

The results of this survey show also that eight surveillance systems don't collect information on the vaccination status of the IPD case and that the type of vaccine and date of administration are available for few systems.

Another important finding of this survey is the low number of countries that regularly assess the sensitivity of the surveillance system. The representativeness of the surveillance system should be evaluated in order to aim at comparing IPD incidence rates across European countries.

The availability of serotyping and molecular typing data from all surveillance systems should be considered to obtain a detailed picture of pneumococcal serotype distribution across the European countries.

By August 2010, all participating European countries had introduced at least one PCV vaccine in their childhood vaccination schedule. Because of changes in pneumococcal vaccines available on the market, these data should be updated.

Pneumococcal conjugate vaccine is universally and actively offered and free of charge in more than an half of European countries. In twenty-one countries PCV is offered to people at clinical risk and in the 76% of these is also free of charge. In spite of this widespread vaccination strategy, the impact of vaccination has been assessed in eleven countries.

A large variation in the surveillance system and vaccination strategy has been found. This could serve as a starting point to discuss a harmonisation in the epidemiological surveillance across countries. Circulation of public available data should be improved, in order to provide a solid support on burden of disease to decision makers.

Addendum

Major changes in 2011

Estonia:
Since 2011 serotyping is performed on all the samples that arrive at National Reference Laboratory (NRL).

Iceland:
Conjugate-pneumococcal vaccination was added to the general childhood vaccination schedule in April 2011 at 3, 5 and 12 months of age. No catch up campain has been performed. The vaccine used is PCV10. PCV vaccination is recommended to all infants and is free of charge.

Latvia:
Transition from PCV7 to PCV10 will happened in February – March 2012.
A change in the schedule, from 3+1 to 2+1 (2 months, 4 months, 12-15 months) doses is planned in March 2012.

Malta:
The policy of universal vaccination in infants has been approved but the vaccination programme will start during 2012.

Slovakia:
National Reference Laboratory (NRL) for pneumococcal infections was established after filling in the survey in 2010. Laboratory situation changed; PCR and Antibody testing methods are now used. NLR is able to perform serotyping on all samples.

Since 2011 the strategy is PCV10/PCV13.

Updated information on the Pneumococcal disease surveillance systems disseminated during 2011

BE: https://www.wiv-isp.be/epidemio/epifr/plabfr/plabanfr/tt_030f.htm

G. Hanquet, T. Lernout, A. Vergison, J. Verhaegen, E. Kissling, D. Tuerlinckx, A. Malfroot, B. Swennen, and M. Sabbe. Impact of conjugate 7-valent vaccination in Belgium: Addressing methodological challenges. Vaccine, 2011. Vol
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Zprávy Epidemiologie A Mikrobiologie (Szú, Praha) 2011; 20(2) http://www.szu.cz/publikace/zpravy-epidemiologie-a-mikrobiologie/zpravy-em-2-unor-2011

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http://www.medakta.cz/cislo.php?casopis=vakcinologie&rocnik=2011&cislo=3

DK: EPI NEWS, 19 2011, 11 May 2011: PCV 7 coverage & Invasive Pneumococcal Disease (IPD) 2009/20010
http://www.ssi.dk/English/News/EPI-NEWS/2011/No%2019%20-%202011.aspx

FR: http://www.invs.sante.fr/surveillance/epibac/donnees_2010/Pneumocoque_impact_2010.pdf
LT:
http://www.ulac.lt/uploads/downloads/2010_m.%20vakcinomis%20valdomu%20ligu%20epidemiologines%20situacijos%20apzvalga%20lietuvoje.pdf

http://www.ulac.lt/

Most recent pneumococcal vaccination coverage data

DK: Year of VC assessment: 2011. VC value: 85%

FR: Year of VC assessment: 2011. VC value: 95%; VC assessed at 6 months (≥1 dose coverage)

SK: Year of VC assessment: 2011. VC value: 98.8%. According to the administrative vaccination survey conducted in 2011, the vaccination coverage in persons housed in social care facilities is 21.7%.