HTA for pneumococcal vaccines

Survey on the availability of Health Technology Assessment in the field of pneumococcal vaccines and availability of information to perform one

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VENICE II

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Content

Abbreviations

DRG Diagnosis Related Group
ECDC European Centre for Disease Prevention and Control
EEA European Economic Area
EFTA European Free Trade Association
EU European Union
HTA Health Technology assessment
IPD Invasive pneumococcal disease
SAE Serious adverse events
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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Introduction

This report includes the results of section 3 of a larger survey on "Impact of childhood pneumococcal vaccination programmes and health technology assessment activities for pneumococcal vaccines in the EU an d EEA\EFTA countries".

In order to represent different ways approaching HTA process in Europe ethical, economic and HTA aspects are covered together in the following section. These parts do not represent the whole HTA process but are meaningful because of the heterogeneity of approaches, sources and methods all over the Europe. It has been stated that no two approaches to HTA in Europe follow an identical organizational model. This is clear since these institutions are part of the respective health systems they serve, which in turn show great differences in most of their aspects across Europe. Furthermore, information on why a particular country has chosen a particular model is not available in an analytical form. Scope and contents of HTA report differ from country to country and can have a wide focus such as: clinical effectiveness, organizational issues and ethical concerns or be limited to a single aspect of the technology, as cost effectiveness. Here it has been referred to a classical full HTA reports (i.e. those aiming to provide a comprehensive assessment of clinical, economical, organizational and ethical aspects).

Methodology

The survey was completed in September 2010. For detail regarding the methodology see the main report.

Results

Twenty-eight countries responded to this section of the survey. The only country that did not respond to this section is Portugal due some technical problems. For some questions not all countries provided answers and this is indicated at the bottom of the tables.

Ethical aspects

Eighteen countries (62.1%; 18/29) reported that informed consent was sought from the parents of children who were recommended pneumococcal vaccination. Almost all countries (96.6%; 28/29) monitor adverse events following immunization; in most cases (69%) all types of adverse events are monitored (vs. just serious adverse events 27.6%).

Table 1.1 Presence of an informed consent for the parents of children who undergo anti-pneumococcal vaccination

Informed consent	n.	%	Countries
Yes	18	62.1	AT, DE, DK, EE, FR, ES, GB, HU, IE, IT, LT, LV, MT, NO, PL, SE, SI, SK
No	11	37.9	BE, BG, CY, CZ, FI, GR, IS, LU, NL, PT, RO
Total	29	100.00	

Table 1.2 Monitoring of adverse events

Adverse events	n.	%	Countries
Yes, at national level	28	96.6	AT, BG, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV MT, NL, NO, PL, PT, RO, SI, SE, SK
No	1	3.4	BE
Total	29	100.00	

Table 1.3 Type of adverse events monitored

Adverse events	n	%	Countries
All type of adverse events	20	69.0	AT, BG, CY, DE, DK, EE, FI, FR, GB, HU, IE, LT, NL, NO, PL, PT, RO, SE , SI, SK
Serious adverse events only (SAE)	8	27.6	CZ, ES, GR, IS, IT, LU, LV, MT
Other	1	3.4	BE
Total	29	100.00	

Moreover, almost all (96.6%; 28/29) have a universal adverse events surveillance system. BE defines precisely: “Monitoring of adverse events through a passive surveillance system: notifications to the Federal Agency of Medicines and Health Products Vaccine failures through the network of pediatricians (PediSurv). Information on vaccination however is difficult to gather”.

Table 1.4 Systematical (routinely basis) vaccine failures monitoring

Monitoring of vaccine failures	n.	%	Countries
Yes	14	48.3	BE, CZ, DE, DK, EE, GB, IE, LT, LV, NL, NO, PT, SE, SK
No	15	51.7	AT, BG, CY, ES, FI, FR, GR, HU, IS, IT, LU, MT, PL, RO, SI
Total	29	100.00	

Assessment of costs of diseases related to *S. pneumoniae* and of prevention costs

Countries	n.	%	
Responders	28	96.6	AT, BE, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK
Non responders	1	3.4	BG
Total	29	100.00	

Most participating countries (92.9%; 26/28) have a national database to assess the number of S. pneumoniae-related disease events (cases).

Table 2.1 Presence of a source of data available to assess the number of *S. pneumoniae*-related diseases

Sources of data	n.	%	Countries
Presence of a national database	26	92.9	AT, BE, CY, CZ, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV,MT, NL, NO, PL, PT, RO, SE, SI
Absence of a national database	2	7.1	DE, SK
Total	28	100.00	

Of the countries that reported having a national database, 22 (84.6%; 22/26) reported hospitals as a source of data to assess the number of *S. pneumoniae*-related cases at national level, followed by followed by surveillance systems (77%; 20/26), laboratory database (69.2%; 18/26), specific diseases registers (19.2%; 5/26). Three countries selected the "other" option: FI reported as source the outpatient data, LV the patient registry.

Table 2.2 Type of sources of data used in order to assess the number of S. pneumoniae-related diseases at national level

Sources of data	n.	%	Countries
Hospitalization system	22	84.6	AT, BE, CZ, DK, ES, FI, GB, GR, HU, IE, IS, IT, LT, LV, MT, NL, NO, PL, PT, RO, SE, SI
Laboratory database	18	69.2	AT, BE, DK, ES, FI, GB, HU, IE, IS, IT, LU, LV, MT, NL, NO, PL, RO, SI
Surveillance systems	20	77.0	AT, BE, CY, CZ, DK, EE, ES, FI, FR, GB, IE, IT, LT, LV, MT, NL, NO, PL, RO, SE
Specific diseases registers	5	19.2	IT, LT, NL, RO, SE
Other*	3	11.5	FI, LV, PT

* FI: outpatient data; LV: patient registry.

In 22 (78.6%; 22/28) countries there are national sources of data to assess direct costs of S. pneumoniae-related diseases.

Table 2.3 Presence of at least one national source of data used in order to assess direct costs of S.pneumoniae-related diseases

National sources	n.	%	Countries
Yes	22	78.6	AT, BE, CZ, DK, ES, FI, FR, GB, HU, IE, IS, IT, LT, LV, MT, NL, NO, PL, PT, RO, SE, SI
No	6	21.4	CY, DE, EE, GR, LU, SK
Total	28	100.00	

At national level the most frequently used direct cost were those relating to hospitalization fees (95.4%; 21/22), drugs price list (63.6%; 17/22) and outpatients services price lists (77.2%; 14/22). Among the 3 countries that lists "other", NO reported as source the DRG (Diagnosis Related Group) reimbursement and expert judgment, IE the input from clinician with regard to estimated costs, and BE adds the National reference laboratory, the National Christian Sickness Fund and the Federal Ministry Minimal Clinical. Seventy-four percent reports to have data from national publications.

Table 2.4 Direct costs of S. pneumoniae-related diseases that could be assessed at national level

Source for assenting direct costs of *S.pneumoniae*-related diseases	n.	%	Countries
Hospitalization fees	21	95.4	AT, BE, CZ, DK, ES, FI, FR, GB, HU, IE, IS, IT, LT, LV, MT, NL, PL, PT, RO , SE, SI
Outpatients services price lists	14	63.6	ES, FI, GB, IS, IE, IT, LT, LV, NL, NO, PL, PT, SI, SE
Drug price list	17	77.2	CZ, DK, ES, FI, GB, HU, IE, IS, IT, LT, LV, NL, NO, PT, RO, SE, SI
Other*	3	13.6	BE, IE, NO

*NO: DRG reimbursement, expert judgment; IE: input from clinician with regard to estimated costs; BE: National reference laboratory, National Christian Sickness Fund, Federal Ministry Minimal Clinical, Specific Surveys Among Patients

Moreover, regarding the funding of the surveillance for pneumococcal disease, it is relevant to note that for 7 countries it is not funded at all (25%; 7/28).

Table 2.5 Origin of funds for surveillance for Invasive pneumococcal disease (IPD)

Source	n.	%	Countries
National	16	57.1	CY, DK, EE, FI, FR, HU, IE, IS, IT, LV, MT, NL, NO, PL, PT, SI
National and regional	5	17.9	BE, DE, ES, LT, GB
Not funded	7	25.0	AT, CZ, GR, LU, RO, SE, SK
Total	28	100.00	

Among those countries that reported that the surveillance was funded by the government, six reported that there was a defined budget for surveillance (28.5%; 6/21), in 13 countries there was no defined budget (66.7%, 14/21) and EE reported that the surveillance for pneumococcal disease is part of the national CD surveillance system, funded by government.

Table 2.6 Presence of a defined budget for the surveillance for IPD

Presence	n.	%	Countries
Yes	6	28.5	BE, DK, ES, IS, IT, LT
No	14	66.7	CY, DE, FI, FR*, GB, HU, IE, LV, MT, NL, NO, PL, PT, SI
Partially	1	4.8	EE*
Total	21	100.00	

*The surveillance for pneumococcal infection is part of the national communicable diseases surveillance system, funded by government

National information sources are used in order to assess indirect costs of *S. pneumoniae*-related diseases in 14 countries (50%; 14/28). No countries reported specific information sources at regional level.

Table 2.7 Sources available to assess indirect costs of S. pneumoniae-related diseases

Presence	n.	%	Countries
At national level	14	50.0	BE, CZ, DK, FI, FR, GB, IS, LT, LV, MT, NO, PT, SE, SI
At regional level	0	0	
No	14	50.0	AU, CY, DE, EE, ES, GR, HU, IE, IT, LU, NL, PL, RO, SK
Total	28	100.0	

Only in 5 countries are available national publications of about indirect costs of *S. pneumoniae*-related diseases

Table 2.8 Availability of national publications about the indirect costs of S. pneumonia-related diseases

Availability	n.	%	Countries
Yes	5	18.5	GB, IT, NL, NO, PL
No	22	81.5	BE, CY, CZ DE, DK, EE, ES, FI, FR, GR, HU, IE, IS, LT, LV, LU, MT, PT, RO, SE, SK, SI
Total	27	100.0	

AT did not answer this question

Economic Assessment

The data on national specific quality adjusted life years (QALY) are available in only 9 countries (32.2%; 9/28), not available in 16 countries (57.1%; 16/28) and three countries (IT,NL and ES) reported that such data would be available in the near future.

Table 3.1 Availability of national specific quality adjusted life years (QALY) gained in the country

Availability	n.	%	Countries
Yes	9	32.2	BE, DK, GB, IS, IE, LV, NO, SE, SI
No	16	57.1	AT, CY, CZ, DE, EE, FI, FR, GR, HU, LT, LU, MT, PL, PT, RO, SK
No, but there will be in the near future	3	10.7	IT, NL, ES
Total	28	100,00	

A minority of countries (17.9%; 5/28) had data on national specific disability adjusted life years (DALY), with the same countries as before for the QALYS (IT,NL and ES) reporting where there will be in the near future.

Table 3.2 Availability of national specific disability adjusted life years (DALY) gained in the country

Availability	n.	%	Countries
Yes	5	17.9	BE, DK, LV, SI, GB
No	20	71.4	AT, CY, CZ, EE, FI, FR, DE, GR, HU, IS, IE, LT, LU, MT, NO, PL, PT, RO, SK, SE
No, but there will be in the near future	3	10.7	IT, NL, ES
Total	28	100,00	

The type of economic analysis used by countries varied. Seven countries (CY, DE, EE, LT, LU, MT and SK) utilized only literature review; six countries (BE, DK, IE, IT, NL, PT) reported using cost effectiveness and cost utility AND literature review; five countries (AT, FI, FR, NO and SE) using cost effectiveness AND cost utility; four countries (CZ, IS, PL and ES) cost effectiveness AND literature review; three countries (GB, HU and SI) used only cost effectiveness; and one country (RO) only cost utility. Some countries reported that economic analyses of vaccines are rarely being used (GR) or not yet conducted (LV).

Table 3.3 Type(s) of economic analyses of vaccines used in each country

Type(s)	n.	%	Countries
Cost effectiveness	18	64.3	AT, BE, CZ, DK, FI, FR, GB, HU, IE, IS, IT, NL, NO, PL, PT, SE, SI, ES
Literature review	17	60.7	BE, CY, CZ, DE, DK, EE, ES, IE, IS, IT, LT, LU, MT, NL, PL, PT, SK
Cost utility	12	42.9	AT, BE, DK, FI, FR, IE, IT, NL, NO, RO, SE
Other*	2	7.1	GR, LV

*GR: economic analysis rarely used, LV: not yet conducted

The cost to the national health system is the perspective most frequently adopted to perform the economic analysis of vaccines, utilized by 20 countries (71.4%; 20/28).

Table 3.4 Perspective adopted to perform the economic analysis of vaccines in each country

Perspective adopted	n.	%	Countries
The national health system	20	71.4	AU, BE, CY, CZ, DK, EE, HU, IE, IT, LV, MT, NO, PL, PT, RO, SK, SI, ES, SE, GB
The societal perspective	8	28.6	FI, FR, DE, GR, IS, LT, LU, NL
Total	28	100,00	

Regarding the presence of a country-specific threshold value to define the cost-effectiveness, only 8 countries (28.6%; 8/28) reported that there is at national level.

Table 3.5 Availability of a threshold value in each country to define the cost-effectiveness

Availability of a threshold value	n.	%	Countries
Yes, at national level	8	28.6	GB, IE, IT, NL, NO, PL, SE, SI
No	20	71.4	AT, BE, CY, CZ, DE, DK, EE, ES, FI, FR, GR, HU, IS, LT, LU, LV, MT, PT, RO, SK
Total	28	100.00	

Institutional Health Technology Assessment (HTA) aspects

Sixteen countries (57.1%; 16/28) have a National Health Technology Assessment Agency.

Table 4. 1. Presence of Health Technology Assessment Agency in the country

HTA	n	%	
Countries with HTA agency at national level	16	57.1	AT, BE, DK, FI, DE, HU, IS, IE, IT, LV, MT, NO, PL, PT, ES, SE
Countries without HTA agency at national level	12	42.9	CY, CZ, EE, FR, GR, LT, LU, NL, RO, SK, SI, GB
Total	28	100,00	

In all countries with HTA Agency at national level, this is governmental (100%; 16/16); in addition AT, DK and IT reported the presence of HTA Agency at private level. In IE the funding for HTA is done with public funds, but the agency doing the assessment is not necessarily "govenermental".

Table 4.2. Level of Health Technology Assessment Agency

HTA level	n.	%	Countries
Governmental	16	100	AT, BE, DE, DK, ES, FI, HU, IE, IS, IT, LV, MT, NO, PL,PT, SE
Private	3	18.8	AT, DK, IT
Other*	2	12.5	DK, IE

*DK: at Universities level. IE: It is an independent authority reporting to the Minister of Health

Fourteen participating countries (56%; 14/25) reported the introduction of healthcare technologies after a systematic process of evaluation at national level, none at regional level and 11 countries (44%; 11/25) reported the introduction without any systematic process of evaluation.

Table 4.3 . Methodology of introducing healthcare technologies in your country

Methodology	n.	%	Countries
After a systematic process of evaluation at national level	14	56	BE, DE, ES, FI, GB, IE, IS, IT, MT, NO, PT, RO, SE, SI
After a systematic process of evaluation at regional level	0	0	
Without any systematic process of evaluation	11	44	CY, CZ, DK, EE, FR, GR, LT, LU, LV, PL, SK
Total	25	100.00	

AT, HU and NL did not answer

When a systematic process of evaluation is performed, the aspects usually considered are epidemiology of disease, safety of technology (100%; 14/14), clinical aspects and cost of illness (92.9; 13/14) and economic analysis of the technology (85.7%, 12/14).

Table 4.4 Aspects usually considered during a systematic process of evaluation

Aspects	n.	%	Countries
Epidemiological aspects	14	100	BE, DE, ES, FI, GB, IE, IS, IT, MT, NO, PT, RO, SE, SI
Clinical aspects	13	92.9	BE, DE, ES, FI, GB, IE, IS, IT, NO, PT, RO, SE, SI
Efficacy of technology	11	78.5	BE, DE, ES, FI, GB, IE, IT, NO, PT, SE, SI
Safety of technology	14	100	BE, FI, DE, ES, GB, IE, IS, IT, MT, NO, PT, RO, SE, SI
Cost of illness	13	92.9	BE, DE, ES, FI, GB, IE, IS, MT, NO, PT, RO, SE, SI
Economic analysis of technology	12	85.7	BE, FI, DE, ES, GB, IE, IS, MT, NO, PT, SE, SI
Organizational involvement	9	63.3	BE, ES, GB, IE IS, NO, PT, SE, SI
Social and ethical aspects	10	71.4	BE, DE, ES, IE, IS, NO, PT, RO, SE, SI

Some countries (40.7%; 11/27) have performed a HTA on pneumococcal vaccine, but 16 countries reported that they had not yet done so.

Table 4.5. Health Technology Assessment of Pneumococcal Vaccination

HTA Pneumococcal vaccination	n.	%	Countries
Yes	11	40.7	AT, BE, DE, FI, GB, HU, IE, IT, NO, PT, SE
No	16	59.3	CY, CZ, DK, EE, ES, FR, GR, IS, LT, LU, LV, MT, PL, RO, SK, SI
Total	27	100.00	

NL did not answer

ES: a systematic process of evaluation is conducted before introducing a vaccine into the National Immunization Programme but is not conducted by the HTA Agency in Spain. Other vaccines that have been evaluated with the same systematic process: HPV, Rotavirus and varicella.

Other vaccines have been evaluated with HTA procedure in 13 countries (48.1%; 13/27), mainly the HPV vaccine (46.2%) and Rotavirus (17.6%).

Table 4.6. Health Technology Assessment of Other Type of Vaccinations

HTA other vaccinations	n.	%	Countries
Yes	13	48.1	AT, BE, DE, DK, FI, GB, IE, IT, MT, NO, PT, SE, SI
No	14	51.9	CY, CZ, EE, ES, FR, GR, HU, IS, LT, LU, LV, PL, RO, SK
Total	27	100.00	

NL did not answer

Table 4.7 Type of vaccinations with HTA already performed

HTA other vaccinations	n.	%	Countries
HPV	9	69.2	BE, DE, DK, IE, IT, NO, PT, SE, SI
Rotavirus	3	23.1	BE, FI, IE
Hepatitis B	2	15.3	DE, IE
Hepatitis A	1	7.7	BE
Varicella, influenza vaccination	2	15.4	BE, FI
Measles	1	7.7	DE
Pentavalent DTaP+Polio+HiB	1	7.7	MT
MenC	1	7.7	PT

Links and references

Belgium:http://kce.fgov.be/publication/report/effects-and-costs-of-pneumococcal-conjugate-vaccination-of-belgian-children

Germany: http://portal.dimdi.de/de/hta/hta_berichte/hta202_abstract_en.pdf

Norway: http://www.fhi.no/dav/2C6350BA21.pdf (in Norwegian)

Ireland: http://www.ncbi.nlm.nih.gov/pubmed/18489504

Hungary: Comparative cost-effectiveness of PCV13 and PCV7 in Hungary, Szilágyi Emes, et all. 2010 (in Hungarian)

Sweden: http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/8867/2008-132-1_20081321.pdf (in Swedish)

Conclusions

In recent years Health Technology Assessment methodology has been utilized to evaluate technologies with a multidisciplinary approach: safety, effectiveness, costs, organisational, legal and ethical implications of introducing a new technology. It can be a useful tool to support decision makers at national Public Health level, including the area of vaccinology. HTAs for vaccines is particularly useful because the complexity of introducing a new vaccine into a national programme makes this field suitable for the many-sided approach of HTA.

As the results of this survey show, many countries have the instruments to perform the HTA for pneumococcal vaccination. However there is variation among countries in the detail and extent at which information is assessed. More than half (57.1%) of countries have a National Health Technology Assessment Agency and 78.6% have national sources of data available to them with which to assess direct costs of S. pneumonia related diseases. Regarding ethical aspects, the 96.6% have adverse events monitored.

ECDC European Centre for Disease prevention and Control is planning a system for active surveillance for Invasive pneumococcal disease to assess data at European level. Invasive Pneumococcal Disease (IPD) surveillance is critical if countries are able to ascertain the pre-vaccination epidemiology and disease burden of IPD and therefore make an informed decision on whether and how to introduce vaccination and to choose the more appropriate pneumococcal conjugate vaccine. IPD surveillance will also be important for monitoring and comparing the impact and effectiveness of the different vaccines after their introduction.

The HTA of pneumococcal vaccination was performed by eleven countries (AT, BE, FI, DE, HU, IE, IT, NO, PT, SE, GB), representing 40.7% of our European sample. Almost all of these countries have an HTA agency or access to a body that can undertake this work. The presence in this list of countries densely populated such as DE, GB or IT may exceed the crude number and in terms of population it could be more representative. In fact, due to the largeness of some European countries, HTA of pneumococcal vaccination performed in less than an half of them could be representative for the whole European population in terms of number. Italy is in the singular situation, where the HTA has been performed by Catholic University of Rome in collaboration with pharmaceutical company: the public health aim of HTA, the production of data for public policy decisions is, in this case, undertaken by a private organization with private research funding.

Based on the results from this survey it is evident that HTA could realistically be implemented in most countries to aid country decision making on whether the introduction of new vaccination is cost effective. However it is also evident that the sources of information used by the different countries are not homogeneous, making it difficult to implement a single unique protocol across all countries. To increase the comparability of the findings of HTA, the first step could be to propose a single approach to HTA, defining the core information that should be included in an HTA. Such an approach has not to our knowledge ever been formulated across different countries but should be considered within Europe and by ECDC.

This study found that economic analysis has been done prior to the introduction of other vaccines (i.e. for HPV) without doing a full HTA , but as economic analysis is one component of HTA, we believe that the first step has already been done in many countries.

This survey has a number of limitations: for the survey we recommended that the VENICE gatekeepers (identified among the epidemiologist experts in vaccinology in each country) consult and involve some HTA expert in the survey, but we don't know the degree of this involvement. Furthermore this was a new field for a VENICE survey, introducing aspects of economic evaluation that are not usually part of the routine work or knowledge for the gatekeepers.

We recommend ECDC to explore the possibility to open the discussion among the MS about the usefulness of an HTA-oriented approach for the public policy decision-making process when MSs are considering the introduction of a new vaccine in the national immunization programme, and then to support models of HTA structures that can be followed at European level.

Addendum: additional information

Estonia:
During 2011 the cost-effectiveness analysis of pneumococcal vaccine was performed in Estonia. Direct and indirect costs of S. pneumoniae-related diseases, QUALY and DALY and threshold value to define the cost-effectiveness of PVC vaccination have been estimated.
Due to the fact that the survey was performed in July 2010, Estonian data presented in the following tables is out of date:

Table 2.3 Presence of at least one national source of data used in order to assess direct costs of *S.pneumoniae*-related diseases
Table 2.4 Direct costs of *S. pneumoniae*-related diseases that could be assessed at national level
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Table 3.1 Availability of national specific quality adjusted life years (QALY) gained in the country
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Table 3.3 Type(s) of economic analyses of vaccines used in each country
Table 3.5 Availability of a threshold value in each country to define the cost-effectiveness