



**Finalised report on the decision making process, modalities of implementation and current country status for the introduction of human papilloma virus and rotavirus vaccination into national immunisation programmes in Europe.**

**VENICE 2**

**December 2010**

**Work package No. 3**

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### **VENICE 2 National Gatekeepers or Contact Points who completed the human papillomavirus (HPV) and rotavirus vaccination (RV) questionnaires**

**Austria** Jean-Paul Klein  
**Belgium** Martine Sabbe, Pierre Van Damme  
**Bulgaria** Mira Kojouharova  
**Czech Republic** Bohumir Kriz  
**Cyprus** Soteroulla Soteriou  
**Denmark** Steffen Glismann  
**Estonia** Natalia Kerbo  
**Finland** Tuija Leino  
**France** Daniel Levy-Bruhl, Frédérique Dorléans  
**Germany** Sabine Reiter  
**Greece** Theodora Stavrou  
**Hungary** Zsuzsanna Molnàr  
**Iceland** Thorulfur Gudnason  
**Ireland** Suzanne Cotter  
**Italy** Paolo Fortunato D'Ancona, Cristina Giambi  
**Latvia** Jurijs Perevoscikovs  
**Lithuania** Egle Valikonienė  
**Luxemburg** Françoise Berthet  
**Malta** Charmaine Gauci  
**The Netherlands** Hester de Melker  
**Norway** Berit Feiring  
**Poland** Pawel Stefanoff  
**Portugal** Teresa Fernandes  
**Romania** Adriana Pistol, Chichin Gratiana  
**Slovakia** Helena Hudecova  
**Slovenia** Kraigher Alenka  
**Spain** Josepha Masa-Calles, Isabel Pachon-del Amo  
**Sweden** Annika Linde  
**United Kingdom** Richard Pebody

**VENICE 2 Project Office at ISS**

**Project Leader**

Paolo D'Ancona Fortunato (Italy)

**Project Manager**

Cristina Giambi (Italy)

**Project Secretariat**

Eva Appelgren (Italy)

**VENICE 2 Consortium members**

**France - Institut de Veille Sanitaire**

Frédérique Dorléans, Daniel Lévy-Bruhl

**Ireland - National disease Surveillance Centre**

Suzanne Cotter, Jolita Mereckiene, Darina O'Flanagan

**Italy – CINECA**

Chiara Della Casa, Luca Demattè

**Italy - Istituto Superiore di Sanità – CNESPS**

Eva Appelgren, Paolo Fortunato D'Ancona, Cristina Giambi,

**Poland - National Institute of Public Health - National Institute of Hygiene, Department of Epidemiology**

Aleksandra Polkowska, Pawel Stefanoff

## ISO 3166-1 Country Codes

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

## **Executive summary**

In 2006, two vaccines against rotavirus (RV) infections and one against human papillomavirus (HPV) infection were granted licensing authorisations by the European Medicines Agency (EMA). Since then, Member States (MS) have been facing the decision about introducing or not these vaccinations into their national immunisation schedules. During 2007, two surveys were carried out among Member States to investigate the decision-making process undertaken regarding the potential introduction of the HPV or RV vaccinations into MS national immunisation programmes.

As this process of integration has been going on since 2007, two other surveys have been undertaken in 2009/2010 as part of the work of VENICE 2 Work Package 3 to update the previous surveys and to investigate the modalities of implementation of the vaccination programmes into the countries as well as to explore the geographical disparities within the countries, in particular for human papilloma virus vaccination.

The two electronic survey questionnaires were each piloted in four MS (France, Ireland, Italy and Poland) and posted on the VENICE 2 website in February 2010 for HPV vaccination and in July 2010 for RV vaccination. The questionnaires were filled in online by the gatekeepers/contact points in the 29 countries participating in the VENICE 2 project and saved on the website. Participation rate was 100% for both surveys.

### ***Human papillomavirus vaccination***

The process of introducing a new vaccine into a national immunisation schedule in the European countries occurs in two steps. A recommendation from a national advisory body is first made, followed by an official decision taken by the national health authorities. As of July 2010, the vaccination advisory bodies in 21 of the 29 countries had made a recommendation in favour of HPV vaccination, compared to 12 out of 27 countries in February 2008. Of those 21 countries, 18 had actually integrated the HPV vaccination in their national immunisation programme.

The HPV vaccination integration process has occurred in one country in 2006 (Austria), seven countries in 2007 (Belgium, France, Germany, Italy, Portugal, Spain and the United Kingdom), seven countries in 2008 (Denmark, Greece, Ireland, Luxembourg, Norway, Romania, and Sweden) and three countries in 2009 (Latvia, the Netherlands, and Slovenia). Of these 18 countries where routine immunisation had been implemented, nine countries had

decided to implement a catch up programme. In two of the 11 countries where no decision of integration has been taken yet, a tentative schedule for the decision of integration or not of the HPV vaccination has been set up.

At least a disease burden study to support the decision process about HPV vaccine introduction was undertaken by 12 of the surveyed countries (seven completed and five ongoing) and six countries plan to carry out such a study. Studies included as well mathematical modelling projects or economical assessments. Respectively 11 and 23 countries have either completed or are currently conducting HPV mathematical modelling studies or economical assessments to support the decision-making process for the introduction of the HPV vaccination. A Health Technology Assessment has been fully performed by six countries, partially by one country and planned but not performed yet by two countries.

### **Vaccination policy targets**

The adopted vaccination policy targeted only females in all the countries where HPV vaccine has been introduced except in Austria, where both females and males are targeted. A striking feature is the heterogeneity in the target populations for both routine and catch-up vaccination strategies. Adolescents aged 12 years were chosen as target population for routine vaccination in eight of the 18 countries (Austria, Denmark, Latvia, Luxemburg, the Netherlands, Norway, Romania and the United Kingdom), while girls aged 11 (Italy), 13 (Portugal), 14 (France) or an age range including several birth cohorts were chosen in the seven other states. Age ranges for catch-up vaccination are even more heterogeneous: only two countries (Belgium and Luxembourg) opted for the same age group (13-18 years) for catch-up campaigns.

In most of the countries, virtually all HPV vaccinations are performed in the public sector, either in public health centres (Denmark, Italy, Netherlands and Portugal), school health services (Ireland, Norway, Slovenia, Sweden) or both (Latvia, Romania, Spain and United Kingdom). Five countries provide HPV vaccinations mainly through the private sector and one country combines both public and private structures. Of the nine countries with catch-up campaigns, HPV vaccination is mainly administered through public health infrastructures in four countries, through the private sector in three countries or through both channels and/or school health services in two countries.

Routine vaccination is offered free of charge in most countries (15/18), partially at the expense of the vaccinee or private insurance in two countries (Belgium and France) and fully at the vaccinee's expenses in one country (Austria). For catch-up campaigns, vaccination is offered free of charge in seven out of nine countries and partially at the expenses of the vaccinee or private insurance in the two remaining countries.

### **Reasons for not introducing human papillomavirus vaccination**

The main reason provided by the countries who had not introduced HPV vaccination into their national immunisation schedule was financial constraints. Indeed, nine of the 11 concerned countries quoted a lack of funding for the vaccination or a prohibitive vaccine cost. Two of those 11 countries also mentioned uncertainty on the duration of protection and insufficient anticipated epidemiological impact beyond the current screening programme as contributing reason.

### **Vaccination coverage data**

Thirteen countries of the 18 where HPV vaccination has been introduced declared that a vaccination monitoring system had been implemented. However, only seven of these 13 countries provided vaccination coverage data. Indeed, half of the six remaining countries who had not provided any data yet have only recently introduced HPV vaccination into their national immunisation schedule (2009). Coverage for routine vaccination with three doses varied between 17% and 81% in 2010. Three countries reached a vaccination coverage between 17% and 30% (France, Luxemburg and Norway), two at 56% and 58% (Denmark and Italy) and two at 80% and 81% (Portugal and the United Kingdom). For the catch-up vaccination programmes, apart from one country with a coverage of 73% (Denmark), the five other countries with available data reached a vaccination coverage between 29% and 56% (France, Luxemburg, the Netherlands, Portugal, and the United Kingdom).

### ***Rotavirus vaccination***

As of July 2010, the decision of introducing the RV vaccination in the national schedule has been taken by national health authorities in 8 countries compared to 5 countries in 2008. Of those 8 countries where a decision has already been taken by the health authorities, 5 countries have decided to integrate the RV vaccination in the national schedule and 3 countries have decided not to integrate it. In nine countries, the process of examination by the expert advisory body has already been completed or is currently going on but the decision of integration has not been taken yet while the examination has been planned but has not started yet in 4 countries. Eight countries have no plan for such an examination.

The RV vaccination integration process has been implemented in 4 countries (Austria, Belgium, Luxemburg and Finland) and is still not operational in one country (Latvia). Those five countries expect that the regional policy will be the same than the national policy for the

routine immunization programme. The main reasons why the decision of RV vaccination integration has been taken are the anticipated epidemiological impact on severe cases of gastro-enteritis and the reduction of the burden on hospitals during the RV season. Simultaneously, the two countries (France, Spain) where the RV vaccine has not been introduced declare that the anticipated epidemiological impact is insufficient as well as concerns about vaccine safety. Bulgaria recommends the RV vaccination although the RV vaccine is not integrated in the national schedule and not reimbursed.

Ad hoc studies included disease burden evaluations, mathematical modelling projects or economical assessments have been respectively undertaken by 10, 5 and 13 countries to support the decision making-process for the introduction of the RV vaccination. A Health Technology Assessment has been fully performed by three countries, partially by one country. Two countries having integrated the RV vaccination have a vaccination coverage which is above 80% (Austria and Belgium) and 3 countries where RV vaccination has not been introduced have a vaccination coverage below 10% (France, Poland and Slovakia).

## **Aim of the VENICE 2 Project**

On the 23<sup>rd</sup> of December 2008, VENICE II, a new project funded by the European Centre for Disease Prevention and Control (ECDC) was launched.

VENICE II is coordinated by the National Centre for Epidemiology, Surveillance and Health Promotion of Istituto Superiore di Sanità (Italy). The following partners gathered in the Venice II Consortium are involved in the project: the Institut de Veille Sanitaire (France), the Health Protection Surveillance Centre (Ireland), the National Institute of Public Health (Poland) and the CINECA consortium of public universities for Information and Communication Technology (Italy).

VENICE II has approximately maintained the same network of experts that were contact persons for the previous project and 29 countries/institutions - instead of 28 countries/institutions in 2007- listed below and available on the website [http://venice.cineca.org/participating\\_countries.html](http://venice.cineca.org/participating_countries.html) participated to the new project:

- Austria - Federal Ministry of Health, Family and Youth, Directorate General Public Health
- Belgium-University of Antwerp, Campus 3 Eiken Epidemiology and Social Medecine - Institute of Public Health - Epidemiologie
- Bulgaria- National Center of Infectious and Parasitic Diseases Department Epidemiology and Surveillance of Communicable Diseases
- Cyprus- Medical and Public Health Services Surveillance Unit
- Czech Republic-National Institute of Public Health, Centre Epidemiology and Microbiology
- Denmark- Statens Serum Institut, Department of epidemiology
- Estonia-Health Protection, Inspectorate Epidemiological Department
- Finland- National Public Health Institute
- France- Institut de Veille sanitaire, Département des maladie infectieuses
- Germany-Robert Koch Institute Immunization Unit
- Greece-Hellenic Centre for Diseases Control & Prevention, Department of epidemiological Surveillance & Intervention
- Hungary-National Center for Epidemiology, Department for Communicable Disease Epidemiology
- Iceland- Directorate of Health, Centre for Infectious Disease Control

- Ireland- National disease Surveillance Centre
- Italy- Istituto Superiore di Sanità - CNESPS
- Latvia-Public Health Agency, Department of epidemiological Surveillance of Infectious Diseases
- Lithuania-Centre for Communicable Diseases Prevention and Control, Immunization Department
- Luxemburg-Ministère de la Santé-Direction de la Santé - Division de l'Inspection Sanitaire
- Malta- Ministry for Social Policy
- Netherlands- National Institute of Public Health and the Environment, Department Public Health
- Norway- Norwegian Institute of Public Health, Department of Vaccination and Immunity
- Poland- National Institute of Public Health - National Institute of Hygiene, Department of Epidemiology
- Portugal-Communicable Diseases Division Directorate General of Health
- Romania-Institute of Public Health, Epidemiology Institute of Public Health
- Slovakia-Public Health Authority of the Slovak Republic, Section of Epidemiology
- Slovenia- Institute of Public Health of the Republic of Slovenia, Centre for Communicable Diseases
- Spain-Instituto de Salud Carlos III, Centro Nacional de Epidemiologia
- Sweden-Smittskyddsinstitutet-Department of epidemiology
- United Kingdom-Health Protection Agency Communicable Disease Surveillance Centre

Built on the first VENICE project, the general aim of VENICE II is:

- to collect information on the national vaccination programmes through a network of professionals;
- to share the collected information and to build up a knowledge base endeavouring to improve the overall performance of the immunisation systems;
- to follow up the impact of newly introduced vaccinations in selected member states.

VENICE II will also address the lack of information related to sub-national variations and different population groups. In some countries, in fact, there is significant disparity in the vaccination programmes at sub-national, regional, area or district level, not always well known at national level. Moreover, there is evidence that no vaccination programme will be able to control or eliminate vaccine preventable diseases without efforts dedicated specifically to risk groups and hard to reach populations, including ethnic minorities, migrants and refugees.

The VENICE II project is organized in 5 Work Packages:

**WP1: Establishment of a functioning platform for conducting rapid surveys at European level.**

**WP2. Information on vaccination programmes, including information on practice at sub-national level.**

**WP3. Information on status of introduction and impact of new vaccinations in the EU and EEA/EFTA countries, building up on the previous surveys conducted under the VENICE project.**

**WP4. Assessment of the variability of vaccine coverage at sub-national level and/or in population subgroups for selected pilot vaccinations.**

**WP5. Key documents representing good practice in EU and EEA/EFTA countries and to make them available through the network to a wide audience of professionals.**

## **1.2. Objectives of Work package No. 3**

An updated follow up survey of the previous VENICE I on HPV and RV vaccines introduction in the EU and EEA/EFTA countries have been carried out in 2009/2010. For each country has been collected the following information: current state of decision/recommendation of HPV vaccination and RV vaccination programmes (at national and sub-national levels for HPV), ongoing or available studies, data on vaccination coverage and information on the delivery infrastructures and the financing mechanisms for HPV specifically. The Institut de Veille Sanitaire has been responsible for the coordination of this WP3.

### **1.3 Context and objectives of the surveys on introduction of HPV and RV vaccination**

During 2006/2007, vaccines against HPV infection and RV infection were granted licensing authorisations by the EMEA.

#### **HPV vaccine summary**

A quadrivalent vaccine protecting against the HPV types 6, 11, 16 and 18 (GARDASIL®) was licensed in September 2006. This vaccine is designed for the prevention of high-grade cervical dysplasia (CIN 2/3), cervical carcinoma, high-grade vulvar dysplastic lesions (VIN 2/3), and external genital warts (condyloma acuminata). The primary vaccination series consists of 3 separate 0.5 ml doses administered intramuscularly according to the following schedule: 0, 2, 6 months. The vaccine has demonstrated efficacy in adult females aged 16 to 26 years old and immunogenicity in 9- to 15-years old children and adolescents. A second bivalent vaccine protecting against the HPV types 16 and 18 (CERVARIX®) received EMEA approval in September 2007.

#### **Rotavirus vaccination summary**

Two vaccines against rotavirus infections were licensed in 2006. Both vaccines, Rotarix® and Rotatec®, are indicated for the active immunisation of infants for prevention of gastroenteritis due to rotavirus infection. Vaccination with Rotarix® consists of 2 vaccine doses and vaccination with Rotatec® consists of 3 vaccine doses. For both vaccines, the first dose may be administered from the age of six weeks and there should be intervals of at least 4 weeks between doses. The course of doses must be completed by the 24 weeks (Rotarix®) or 26 weeks (Rotatec®) due to the theoretical risk of occurrence of intussusception in children aged over 6 months.

The licensing of these vaccines means that Member States (MS) have been facing the decision about introducing these vaccinations into their national immunisation schedules. These circumstances provide a unique opportunity to carry out surveys that deconstruct in real-time the decision-making process that precedes the introduction of a vaccine to a national schedule and on a larger scale to facilitate a synergist approach to this process by sharing information and tools across the EU.

Following the decision of integration of the vaccination, the Member States make substantial decisions related to the modalities of implementation of the vaccination: financing

mechanisms, delivery infrastructures, coverage monitoring system, safety surveillance system.

The objective of these surveys was to investigate whether a decision-making process had been undertaken or not regarding the potential introduction of the HPV or RV infection vaccination into MS national immunisation programmes and to explore the modalities of implementation of the vaccination programme in order to:

- Clarify the current status of MSs in terms of introducing HPV and RV vaccinations
- Identify key information and methodologies used in the decision-making process
- Assess MSs willingness to exchange developed methodologies
- Investigate the modalities of implementation of the HPV vaccination programmes
- Explore the regional disparities within a same country where regional policy can differ from national policy

## **2.0 Methods**

Two separate surveys were developed, one for exploring the introduction of HPV vaccination and the modalities of its implementation and the other one for investigating the decision making process for the introduction of RV vaccination.

The electronic survey questionnaires were each piloted in four MS (IT, IE, FR, and PO) and posted on VENICE 2 website in February 2010 for HPV vaccination and in July 2010 for RV vaccination. The questionnaires were filled in online by the gatekeepers/contact points in each MS participating in the VENICE 2 project and saved on the website.

The questionnaires focused on several aspects of the decision-making process and implementation, namely:

- Status of the decision to introduce the vaccination in the national schedule
- Ongoing/completed/planned studies to guide the taking of this decision, or reasons not to conduct them
- Drivers of the decision to introduce/not to introduce the vaccination in the national schedule
- Willingness to exchange developed methodologies and expertise
- Information on the delivery infrastructures and financing sources for HPV vaccination

- Sub national specificities of the HPV vaccination programme

Completed questionnaires were downloaded from the VENICE 2 website and analysed using Microsoft Excel® and Stata v8® by the Institut de Veille Sanitaire. The results of the 2 questionnaires are presented separately.

### 3.0 Results for the HPV vaccination survey

Data from the completed questionnaires were downloaded and analysed in May 2010, then subsequently updated in July and September 2010 and validated as a final version in the report in December 2010.

#### 3.1. Participation in the survey

An initial completed questionnaire was downloaded from the 29 countries participating in the VENICE 2 project, yielding a 100% participation rate.

#### National results

#### 3.2. Status of countries concerning the introduction of HPV vaccination

As of September 2010, the expert advisory body has made the recommendation regarding the introduction of the HPV vaccination into the national immunisation schedule in 21 countries (72%). This recommendation was made 3 years ago in only 12 countries (44%). The national health authorities have additionally taken the decision to introduce the HPV vaccination into the national immunisation schedule in 18 countries (62%) while 5 countries (17.8%) had done so in October 2007. Six countries (35%) specifically mention vaccination against HPV 6 and 11 and 3 countries (18%) mention in their decision a choice between the two vaccines, UK mentioning the bivalent vaccine and FR and SI the quadrivalent vaccine (Table 1).

**Table 1:** Status of countries concerning the introduction of HPV vaccination.

Status concerning HPV vaccination introduction	Countries		
	<i>n</i>	%	
Recommendation made by expert advisory body (N=29)	21	72	AT BE BG CZ DK DE EE FR GR IS IE IT LU LV NL NO PT RO SI SE UK
Recommendation specifically mentions vaccination against HPV 6 and 11 (genital warts) (N=17)	6	35	AT DK ES FR GR LU

Decision taken by national health authorities (N=29)	18	62	AT BE DE DK EE FR GR IE IT LV LU NL NO PT RO SI SE UK
Decision specifically mentions a choice between the two vaccines (N=17)	3	18	FR SI UK

The first recommendation to introduce the HPV vaccine in the national immunization schedule made by an expert advisory body has been done in 2006 in three countries (14%), a few months after the EMEA licensing authorization. Ten countries (48%) have recommended the HPV vaccine introduction in 2007, five countries (24%) in 2008, 2 countries (10%) in 2009 and 1 country (5%) in 2010 (Table 2).

**Table 2:** Date of the recommendation for the introduction of HPV vaccination into the National Immunization Schedule (N=21).

Date of the recommendation for HPV vaccination introduction in the National Immunization Schedule	Countries		
	<i>n</i>	<i>%</i>	
<b>2006</b>	3	14	AT BG FR
<b>2007</b>	10	48	BE DE DK EE GR IT LU NO PT UK
<b>2008</b>	5	24	IE LV NL SI SE
<b>2009</b>	2	10	IS RO
<b>2010</b>	1	5	CZ

Eighteen countries out of the 21 countries where a recommendation has been done have decided to introduce the HPV vaccination in the National Immunization Schedule. One country (6%) has introduced the vaccination in 2006, 7 countries (39%) in 2007, 7 countries (39%) in 2008 and 3 countries (17%) in 2009 (Table 3).

**Table 3:** Date of the introduction of HPV vaccination into the National Immunization Schedule (N=18).

Date of the introduction of HPV vaccination into the National Immunization Schedule	Countries		
	<i>n</i>	<i>%</i>	
<b>2006</b>	1	6	AT
<b>2007</b>	7	39	BE DE EE FR IT PT UK

<b>2008</b>	7	39	DK GR IR LU NO RO SE
<b>2009</b>	3	17	LV NL SI

### 3.3. Basis for the decision taken regarding integration of the HPV vaccination in the national immunisation schedule

The main driver for this decision cited by the countries was the anticipated epidemiological impact on cancerous and pre-cancerous lesions as well as the reassuring safety data from pre-licensing trials (Table 4).

**Table 4:** The principle drivers of the decision to integrate HPV vaccination in the national immunisation schedule (N=17).

<b>Drivers of decision to integrate HPV vaccination</b>	<b>Average score from respondents*</b>
Anticipated epidemiological impact on cancer lesions	2.8
Reassuring safety data from pre-licensing trials	2.4
Anticipated epidemiological impact on pre-cancer lesions	2.2
Favourable Cost/Effectiveness ratios	1.8
Social demand	1.7
Others	1.2

\* 1 = not considered in taking the decision, 3= main driver of decision

### 3.4. HPV vaccination policy and target population

Vaccination policy regarding the age differs significantly from one country to another one. Eight countries out of 18 target the population aged 12 years old, 1 country targets the 11 years old, 1 country targets the 13 years old and 1 country targets the 14 years old while 7 countries have chosen to target a population age ranged between 11 and 18 years old (Table 5).

In term of gender targeted, the 18 countries have chosen to target only females except Austria that have chosen to vaccinate both females and males.

**Table 5:** Target age group adopted at the national level for routine immunization (N=18).

<b>Target age group adopted for routine immunization</b>	<b>Countries (N=18)</b>	
	<i>n</i>	<i>%</i>

<b>11</b>	1	5.5	IT
<b>12</b>	8	45.0	AT DK LU LV NO NL RO UK
<b>13</b>	1	5.5	PT
<b>14</b>	1	5.5	FR
<b>[11-14]</b>	1	5.5	EE
<b>[12-17]</b>	1	5.5	DE
<b>[12-18]</b>	1	5.5	BE
<b>[10-12]</b>	1	5.5	SE
<b>[11-12]</b>	1	5.5	SI
<b>[12-15]</b>	1	5.5	GR
<b>[12-13]</b>	1	5.5	IE

Seventeen countries have reported the date when the HPV routine vaccination programme started. Three countries started in 2007, 6 countries in 2008, 4 countries in 2009 and 4 countries in 2010 (Table 6).

**Table 6:** Date of the HPV vaccination routine immunization programme start (N=17).

<b>Date of the HPV vaccination routine immunization programme start</b>	<b>Countries</b>		
	<i>n</i>	<i>%</i>	
<b>2007</b>	3	17.7	BE DE FR
<b>2008</b>	6	35.3	EE GR IT LU PT UK
<b>2009</b>	4	23.5	DK NO SI RO
<b>2010</b>	4	23.5	IE LV NL SE

Nine countries have reported that they had implemented or planned catch-up campaigns. Only females will be targeted by the catch-up programmes and in term of ages, one country has decided to target the 17 years old while the other 7 countries have chosen an age range between 12 and 24 years old (Tables 7, 8 and 9).

**Table 7:** Countries where HPV vaccination catch-up campaigns are implemented or planned (N=18)

HPV vaccination catch-up campaigns implemented	Countries	
	<i>n</i>	%
Yes	9*	50.0
		BE DK FR IT LU NL PT RO UK

\*Sweden has planned catch-up campaigns for 2011 (not included in the 9 countries) and in Italy the catch-up campaigns have started in 8/21 regions

**Table 8:** Target age group adopted at the national level for catch-up campaigns (N=9).

Target age group adopted for catch-up campaigns	Countries	
	<i>n</i>	
17	1	PT
[12-15]	1	DK
[12-24]	1	RO
[13-16]	1	NL
[13-18]	2	BE LU
[13-17]	1	UK
[15-23]	1	FR
14/15/16/17/24*	1	IT

\* Depending on the region

**Table 9:** Date of the HPV vaccination catch-up campaigns start (N=9).

Date of the HPV vaccination catch-up campaign start	Countries	
	<i>n</i>	
2007	2	FR IT
2008	4	BE DK LU UK
2009	2	NL PT
2010	1	RO

### 3.5. HPV vaccination delivery infrastructures

Fifteen countries (88%) mention that the HPV vaccine will be administered through the same infrastructures as the other vaccines for routine immunization.

For routine immunization, eight country use exclusively public health infrastructures (DK, IT, NL, PT) or school health services (IE, NO, SI, SE) for delivering the HPV vaccination and 4 countries use mainly a combination of those infrastructures (EE, LV, RO, UK). Private doctors account for 100% of the vaccination delivery channels in 2 countries (BE, LU), 95% in 2 countries (DE, FR) and 70% in 1 country (GR) and one country (AT) shares its vaccination delivery services between private doctors and private clinics/hospitals (Table 10).

**Table 10:** HPV vaccination delivery infrastructures for routine immunization (N=18)

HPV vaccination delivery infrastructures (Routine immunization)	Countries		
	<i>n</i>	<i>%</i>	
<b>Public health / Primary care doctors Public health nurses / Vaccination clinics</b>	11	61.1	DK IT NL PT (100%) LV (95%) EE (50%) GR (30%) UK (6%) FR DE RO (5%)
<b>School health services</b>	8	47.1	IE NO SI SE (100%) RO (95%) UK (94%) EE (50%) LV (4%)
<b>Private Doctors</b>	7	38.9	BE LU (100%) DE FR (95%) GR (70%) LV (1%) AT
<b>Private clinics / hospitals</b>	1	5.6	AT

For catch-up campaigns, 4 countries channel their HPV vaccination offer through public health infrastructures exclusively (DK IT NL PT) and two countries through the private sector (BE LU). UK uses both the public sector and the schools for delivering HPV vaccination, RO offers its HPV vaccination through a combination of public health infrastructures, school health services, private doctors and public hospitals and FR mainly through private doctors and a very small percentage through public health infrastructures (Table 11).

**Table 11:** HPV vaccination delivery infrastructures for catch-up campaigns (N=9)

HPV vaccination delivery infrastructures (catch-up campaigns)	Countries
	<i>n</i>
<b>Public health / Primary care doctors Public health nurses / Vaccination clinics</b>	7 DK IT NL PT (100%) UK (70%) RO (30%) FR (5%)
<b>School health services</b>	2 RO (30%) UK (30%)
<b>Private Doctors</b>	4 LU BE (100%) FR (95%) RO (20%)
<b>Public hospitals</b>	1 RO (20%)

### 3.6. HPV vaccination financing sources for routine immunization and catch-up campaigns

In most of the countries, the HPV vaccination is fully subsidized by the national health system or a social security scheme.

For routine immunization, in 15 out of the 18 countries (83.3%) the vaccine's cost and administration are fully supported by a national health system or a social security scheme while only 2 countries (11.1%) partially support the vaccination and in 1 country (5.6%) the vaccination cost is fully at the patient's expenses (Table 12).

**Table 12:** HPV vaccination financing sources for routine immunization (N=18)

HPV vaccination financing sources (routine immunization)	Countries		
	<i>n</i>	%	
Vaccine cost and administration of the vaccine fully supported by the national health system, social security scheme	15	83.3	DE DK EE GR IE IT LV LU NL NO PT RO SI SE UK
Vaccine cost and administration of the vaccine partially supported by national health system, social security scheme	2	11.1	BE (75%) FR (65%)
Vaccine and administration of the vaccine fully supported by the patient	1	5.6	AT

For the catch-up campaigns, 7 countries (77.8%) fully subsidize the vaccination and 2 countries (22.2%) partially finance the vaccination (Table 13).

**Table 13:** HPV vaccination financing sources for catch-up campaigns (N=9)

HPV vaccination financing sources (catch-up campaigns)	Countries		
	<i>n</i>	%	
Vaccine cost and administration of the vaccine fully supported by the national health system, social security scheme	7	77.8	DK IT LU NL PT RO UK
Vaccine cost and administration of the vaccine partially supported by national health system, social security scheme	2	22.2	BE (75%) FR (65%)

### 3.7. HPV vaccination costs and availability

Both bivalent and quadrivalent HPV vaccines are available on the private market in the 29 countries. The price of the HPV vaccine per dose varies greatly from a country to another one, from 92.5 Euros in UK up to 191 Euros in Austria.

The average price per dose for the HPV bivalent vaccine is 131.9 Euros and for the HPV quadrivalent vaccine is 136.4 Euros (Table 14).

**Table 14:** HPV vaccination price per dose (bivalent and quadrivalent) (N=29)

Price per dose in Euros	Countries	
	<i>Bivalent</i>	<i>Quadrivalent</i>

	<i>n</i>		<i>n</i>	
[92 – 112]	6	FR HU IS SI SE UK	6	ES HU SK SI SE UK
[113 – 133]	9	BE CZ ES FI LI LU NL RO SK	7	BE CZ IS LI LU NL RO
[134 – 154]	7	BG CY IE NO PT DE EE	6	BG CY FR IE MA NO
[155 – 175]	4	GR IT MA PO	7	EE FI DE GR IT PO PT
[176 – 196]	1	AT	1	AT
<b>Average price per dose</b>		<b>131.9</b>		<b>136.4</b>

### 3.2.7. Reasons for not integrating the HPV vaccination in the National Immunization Schedule

The main reasons reported by the countries for not integrating HPV vaccination in the National Immunization Programme relate mainly to financial issues (cost too high and lack of funding).

**Table 15:** Drivers of the decision of not integrating HPV vaccination in the National Immunization Programme (N=11).

<b>Drivers of the decision of not integrating HPV vaccination in the National Immunization Schedule</b>	<b>Average score from respondents*</b>
<b>Cost too high</b>	2.7
<b>Lack of funding</b>	2.7
<b>Uncertainty on duration of protection and need for boosters</b>	1.6
<b>Insufficient anticipated epidemiological impact with regards to current screening programme performance</b>	1.5
<b>Unfavourable cost/effectiveness ratio</b>	1.4
<b>Risk for decrease coverage of screening program</b>	1.3
<b>Lag time before an impact on cancer incidence can be observed</b>	1.1
<b>Difficulty in integrating into the schedule (ages to be considered and number of doses needed)</b>	1.0
<b>Remaining safety issue</b>	1.0

\* 1 = not considered in taking the decision, 3 = main driver of decision

Two countries have made a tentative schedule for taking the decision of integrating HPV into the National Immunization Schedule (CY and SK).

### 3.2.8. Ad hoc studies used to support the introduction decision

#### *Disease burden studies*

Without respect to the HPV vaccination status, twelve countries (41.3%) completed or are currently undertaking HPV infection disease burden studies while 6 countries planned to carry out such studies (20.7%) and 11 countries (37.9%) have not planned to undertake a disease burden study (Table 16).

Of the 7 countries that have completed a HPV disease burden study:

- 4 countries (DE DK EE IS) have already published their work
- 1 country (IT) has its manuscript in preparation or is submitting its work
- 2 countries (FR PT) have no plan to publish the work.

**Table 16:** Status of countries in terms of HPV diseases burden studies undertaken (N=29).

Status concerning HPV diseases burden studies	Countries		
	<i>n</i>	<i>%</i>	
Completed	7	24.1	DE DK EE FR IS IT PT
Ongoing	5	17.2	FI IE LU SE UK
Planned	6	20.7	BE GR LI PO RO SI
Not planned	11	37.9	AU BG CY CZ ES HU LV MA NL NO SK

Ten out of the 18 countries (55.5%) where HPV vaccination has been introduced have completed or are working on a disease burden study and 4 (22.2%) have planned to carry out this type of study (Table 16-bis).

**Table 16-bis:** Status of countries where HPV vaccination have been introduced regarding HPV diseases burden studies undertaken (N=18).

Status concerning HPV diseases burden studies	Countries		
	<i>n</i>	<i>%</i>	
Completed	6	33.3	DE DK EE FR IT PT
Ongoing	4	22.2	IE LU SE UK
Planned	4	22.2	BE GR RO SI
Not planned	4	22.2	AT LV NL NO

**Mathematical modelling**

Eleven countries (37.9%) reported having either completed or ongoing mathematical modelling projects to support the decision making process for HPV vaccination introduction and 2 countries (6.9%) have planned to undertake such type of study (Table 17).

For the 13 countries that have completed, having ongoing HPV mathematical modelling projects or have planned such a project, a state transition static model was favoured by 2 countries (BE, FR), a dynamic model by 9 countries (DE, DK, FI, IE, IS, IT, NO, PT and UK) and a combined model by 2 countries (NL, SE).

Of the 7 countries that have completed a HPV mathematical modelling project:

- 3 countries have already published their work (DK, IE, IS)
- 1 country has its manuscript in preparation or is submitting its work (IT)
- 1 country is preparing its work (NO)
- 2 countries have no plan to publish the work (FR, PT).

**Table 17:** Status of countries concerning HPV mathematical modelling studies undertaken (N=29).

Status of HPV mathematical modelling projects	Countries		
	<i>n</i>	%	
Completed	7	24.1	DK FR IE IS IT NO PT
Ongoing	4	13.8	DE FI NL UK
Planned	2	6.9	BE SE
Not planned	16	55.2	AT BG CY CZ EE ES GR HU LI LU LV MA PO RO SI SK

Half of the countries where HPV vaccination has been introduced have either completed or have ongoing mathematical modelling projects (Table 17-bis).

**Table 17-bis:** Status of countries where HPV vaccination has been introduced regarding HPV mathematical modelling studies undertaken (N=18).

Status of HPV mathematical modelling projects	Countries		
	<i>n</i>	%	
Completed	6	33.3	DK FR IE IT NO PT
Ongoing	3	16.7	DE NL UK

Planned	2	11.1	BE SE
Not planned	7	38.9	AT EE GR LU LV RO SI

### ***Economical assessment***

Amongst the whole countries, 23 out of the 29 countries (79.3%) have undertaken a HPV economical assessment (Table 19).

In terms of publication for the countries where HPV economical assessment has been carried out:

- Six have already published their work (DK IE IS NL SE UK).
- Two have a manuscript in preparation or submitted or to be prepared when work is over (IT, NO)
- Four have no plan to publish the work (BE FR LU PT).

**Table 19:** Status of countries regarding HPV economical assessment (N=29).

Status of HPV economical assessment	Countries		
	<i>n</i>	<i>%</i>	
Completed	12	41.4	BE DK FR IE IS IT LU NL NO PT SE UK
Ongoing	11	37.9	AT BU CY DE FI GR HU LV RO SI SK
Planned	1	3.4	ES
Not planned	5	17.2	CZ EE LI MA PO

**Table 19-bis:** Status of countries where HPV vaccination has been introduced regarding HPV economical assessment (N=18).

Status of HPV economical assessment	Countries		
	<i>n</i>	<i>%</i>	
Completed	11	61.1	BE DK FR IE IT LU NL NO PT SE UK
Ongoing	6	33.3	AT DE GR LV RO SI
Planned	0	0	-
Not planned	1	5.6	EE

Amongst the 18 countries where HPV vaccination has been introduced, eleven countries (61.1%) reported having undertaken an economical assessment to support the decision making process for HPV vaccination introduction and 6 countries (33.3%) are in the process of undertaking such a study, while one country (5.6%) has not planned to carry out an economical assessment (Table 19-bis).

### **Health technology assessment**

Six countries (20.7%) reported having undertaken a health technology assessment to support the decision making process for HPV vaccination introduction, 1 country (3.4%) has an on-going HTA and 2 countries (6.9%) have planned to undertake this type of study (Table 20).

**Table 20:** Status of countries regarding HPV health technology assessment (N=29).

Status of HPV health technology assessment	Countries		
	<i>n</i>	<i>%</i>	
Completed	6	20.7	BE DE DK IR IT SE
Ongoing	1	3.4	FI
Planned	2	6.9	AT RO
Not planned	20	69.0	BG CY CZ EE ES FR GR HU IS LI LU LV MA NL NO PO PT SI SK UK

**Table 20-bis:** Status of countries where HPV vaccination has been introduced regarding HPV health technology assessment (N=18).

Status of HPV health technology assessment	Countries		
	<i>n</i>	<i>%</i>	
Completed	6	33.3	BE DE DK IR IT SE
Ongoing	0	0	-
Planned	2	11.1	AT RO
Not planned	10	55.6	FR GR LU LV NL NO PT SI EE UK

### 3.2.9. Tools to monitor the impact of vaccination introduction

Thirteen of the 18 surveyed countries (72.2%) have reported that there is a national HPV vaccination coverage monitoring system in place for routine immunization and 8 out of the 9 countries which declared that catch-up campaigns were implemented (88.9%). Only seven countries having declared that they have implemented a monitoring system have reported vaccination coverage data for routine immunization and 6 out of 9 for catch-up campaigns (Tables 21, 22 and 23).

**Table 21:** National HPV vaccination coverage monitoring system in place for routine immunization (N=18).

HPV vaccination monitoring system for routine immunization	Countries		
	<i>n</i>	%	
Yes	13	72.2	DK FR IE IT LV LU NL NO PT RO SI SE UK
No	5	27.8	AT BE CZ DE GR

**Table 22:** National HPV vaccination coverage monitoring system in place for catch-up campaigns (N=9)

HPV vaccination monitoring system for catch-up campaign	Countries	
	<i>n</i>	
Yes	8	DK FR IT LU NL PT RO UK
No	1	BE

Vaccination coverages for routine immunization (3 doses) vary according to the country from 17% to 81% with 5 countries having a vaccination coverage below 60% and 2 countries at and above 80%.

#### HPV vaccination coverage for routine immunization and catch-up campaigns

**Table 23:** HPV vaccination coverage for routine immunization (N=7)

Countries	HPV vaccination coverage for RI	
	<i>1 dose</i>	3 doses
Denmark	79% (2010)	58% (2010)

<b>France</b>	-	24% (2008)
<b>Italy</b>	-	35% (2009)
<b>Luxemburg</b>	-	17% (2009)
<b>Norway</b>	62%	30%
<b>Portugal</b>	-	81% (2009)
<b>United Kingdom</b>	-	80 (2009)

For catch-up campaigns, 4 countries have a vaccination coverage below 60% and one country above 60% (Table 24).

**Table 24:** HPV vaccination coverage for catch-up campaigns (N=6)

<b>Countries</b>	<b>HPV vaccination coverage for catch-up campaigns</b>	
	<i>1 dose</i>	3 doses
<b>Denmark</b>	82% (2010)	73% (2010)
<b>France</b>	-	30% (2008)
<b>Luxemburg</b>	-	29% (2009)
<b>Netherlands</b>	-	45% (2010)
<b>Portugal</b>	-	56% (2009)
<b>United Kingdom</b>	-	32% (2009)

### Vaccine safety

Five countries declared that there is an existing system in place to follow up the safety in adults/adolescents (Table 25).

**Table 25:** Existing study/system in place to follow up the safety in adolescents/adults (N=28)

<b>Existing study/system to follow up the safety in adolescents/adults</b>	<b>Countries</b>	
	<i>n</i>	<i>%</i>

Yes 5 17.2 FR IT NL NO SE

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### Sub national results

Two countries have declared that there would be differences between the national and the sub national levels: Italy and Sweden.

#### Italy

In Italy, 21 regions are concerned by the HPV vaccination routine programme and all of those regions have chosen females aged 11 years old as the target group. The routine programme started in two regions in 2007 and in the remaining 19 regions in 2008 (Table 26).

**Table 26:** HPV vaccination routine programme start date according to the region, Italy (N=21)

<b>Start dates for the HPV vaccination routine programme</b>		
	<i>No</i>	<i>Regions</i>
<b>July 2007</b>	1	<i>Basilicata</i>
<b>October 2007</b>	1	<i>Valle d'Aosta</i>
<b>January 2008</b>	1	<i>Toscana</i>
<b>March 2008</b>	6	<i>Emilia Romagna, Veneto, Liguria, Molise, Calabria, Sicilia</i>
<b>April 2008</b>	1	<i>Lazio</i>
<b>June 2008</b>	1	<i>Campania</i>
<b>September 2008</b>	7	<i>Umbria, Provincia di Trento, Abruzzo, Friuli Venezia Giulia, Provincia di Bolzano, Lombardia, Puglia</i>
<b>October 2008</b>	2	<i>Marche, Sardegna</i>
<b>November 2008</b>	1	<i>Piemonte</i>

A monitoring system to collect HPV coverage data every six months has been set up by ISS and the Regional Coordination Group ad hoc after the introduction of HPV vaccination in the

21 Italian regions. Administrative data are used to assess the regional immunisation coverage (Table 27).

**Table 27:** HPV vaccination coverage for routine immunization in Italian regions (N=21).

Italian regions	HPV vaccination coverage for RI	
	<i>1 dose</i>	3 doses
<b>Emilia Romagna</b>	72.6	57.4
<b>Umbria</b>	77.7	64.6
<b>Toscana</b>	80.4	57.4
<b>Piemonte</b>	63.4	22.1
<b>Provincia di Trento</b>	58.3	56.4
<b>Valle d'Aosta</b>	76.9	73.8
<b>Basilicata</b>	88.2	81.2
<b>Abruzzo</b>	68.1	58.1
<b>Friuli Venezia Giulia</b>	63.9	57.5
<b>Veneto</b>	76	32.6
<b>Liguria</b>	68.6	63.4
<b>Sardegna</b>	-	-
<b>Molise</b>	81.3	74.3
<b>Campania</b>	-	-
<b>Lazio</b>	56.3	35.5
<b>Marche</b>	68.1	31
<b>Provincia di Bolzano</b>	26.6	19.1
<b>Lombardia</b>	64	48

<b>Calabria</b>	54.7	46.4
<b>Sicilia</b>	-	-
<b>Puglia</b>	75.7	14.2

Six out of the 21 Italian regions have planned catch-up campaigns (Table 28).

Two regions out of the 6 have chosen the females group aged 14 years old (Basilicata, Friuli Venezia Giulia) and 4 have chosen to target females aged 15 years old (Liguria, Piemonte, Toscana, Valle d'Aosta).

**Table 28:** HPV vaccination catch-up campaigns in six Italian regions (N=6)

<b>Italian regions</b>	<b>HPV vaccination coverage for catch-up campaigns</b>		<b>Start date for catch-up campaign</b>
	<i>1 dose</i>	<i>3 doses</i>	
<b>Toscana</b>	56.5	0.9	January 2009
<b>Piemonte</b>	65.9	20.2	November 2008
<b>Valle d'Aosta</b>	86.6	81.6	October 2007
<b>Basilicata</b>	89.4	81.8	July 2007
<b>Friuli Venezia Giulia</b>	70.2	63.5	September 2008
<b>Liguria</b>	NA	NA	January 2010

The Basilicata region has implemented two additional catch-up campaigns, one targeting the 17 years old females and the other the 24 years old females. Both of them started in July 2007 and coverage assessments showed that immunisation coverage for the 17 years old was 76.4% and 53.2% for the 24 years old population.

In Italy, the routine programme and the catch-up programmes are both fully supported by the national health system or a social security scheme and the HPV vaccine is administered alone.

## **Sweden**

In Sweden, 19 counties (regions) implement their own routine and catch-up vaccination programmes. As of July 2010, financing for catch-up campaigns was available, but the decision to carry them out has not been taken by the county councils yet except for the Orebro county where females aged 11 to 18 years old have been targeted by a catch-up programme since May 2009.

#### 4. Results for the RV vaccination survey

##### 4.1. Participation in the survey

A completed questionnaire was received from all 29 countries participating in the VENICE 2 project, yielding a 100% participation rate.

##### 4.2. Status of countries concerning the introduction of RV vaccination

As of October 2010, a decision had been taken by national health authorities regarding the introduction of rotavirus vaccination in 8 countries (27.6%). A recommendation had been made by expert advisory body but without a decision taken by national health authorities in 3 countries (10.3%), while the issue was currently under examination or was planned to be examined by the expert advisory body in 10 countries (34.5%) and 8 countries had no plan for examination (Table 1).

**Table 1:** Status of countries concerning the introduction of RV vaccination (as of October 2010, N=29).

Status concerning RV vaccination introduction	Countries		
	<i>n</i>	%	
Decision taken by national health authorities	8	27.6	AT BE BG EE FI FR LU LV
Examination by expert advisory body completed and decision made but no decision by health authorities taken yet	3	10.3	IS SK UK
Currently under examination by expert advisory body	6	20.7	DE ES NO PO RO IE
Examination by expert advisory body planned	4	13.8	CZ DK NL SL
No plan for examination by expert advisory body	8	27.6	CY GR HU IT LI MA PT SE

Amongst the 8 countries having taken a decision concerning the introduction of rotavirus vaccination, five countries (AT BE FI LU LV) have chosen the integration of the RV vaccine in the national immunisation schedule, two countries (EE FR) have decided not to integrate the vaccine in the national schedule and one has decided just to recommend it (BG) (Table 2).

**Table 2:** Decision regarding the introduction of RV vaccination in countries where the national health authorities have taken a decision (N=8).

Decision taken by national health authorities	Country
Integration in national immunization schedule	AT BE FI LU LV
No integration in national immunization schedule	EE FR

Other (Recommendation without integration)

BG

**Table 3.** Dates of the decision of introduction of RV vaccination taken by national health authorities (N=8).

Country	Dates of the decision taken by national health authorities
AT	October 2005
EE	October 2006
BE	November 2006
LU	December 2006
FI	December 2008
LV	May 2009
BG	July 2009
FR	May 2010

#### 4.3. Basis for the decision taken regarding integration of the RV vaccination into the immunisation schedule

Eight countries (27.6%, N=29) reported a decision taken by the national health authorities and the main drivers for the decision of RV vaccination introduction was the reduction of the burden on hospitals during rotavirus season, the reassuring safety data from pre-licensing trials and the anticipated epidemiological impact on severe cases of gastro-enteritis due to rotavirus (Table 4).

**Table 4:** The principle drivers of the decision to integrate RV vaccination in the national immunisation schedule (N=8).

Drivers of decision to integrate RV vaccine	Average score from respondents*
Reduction of the burden on hospitals during rotavirus season	2.6
Reassuring safety data from pre-licensing trials	2.6
Anticipated epidemiological impact on severe cases of gastro-enteritis due to rotavirus	2.2
Favourable Cost/Effectiveness ratios	1.8
Political commitment	1.8
Social demand	1.6

Reduction of nosocomial infections	1.4
Other	1

\* 1 = not considered in taking the decision, 3 = main driver of decision

The 2 RV vaccines, Rotatec® and Rotarix®, are available in 4 (AT BE FI LV) of the 5 countries where the decision of integration into the national immunization schedule has been taken and only Rotarix® is available in LU (Table 5). None of these 5 countries mentions a recommendation to use preferentially one or the other vaccine and none has mentioned that the national policy would be different than the sub national one.

**Table 5.** Availability of the 2 Rotavirus vaccines, Rotateq® and Rotarix®, in the country (N=5).

Availability of the vaccines	Country
Rotateq®	AU BE FI LV
Rotarix®	AU BE FI LV LU

Following the decision of integration, 4 countries (AU BE FI LU) have already implemented the vaccination programme while one country (LV) has not started yet. Three out of the four countries have implemented the RV vaccination programme between July and December 2006 (AT BE LU) and one has implemented the programme in September 2009 (FI).

**Table 6.** Dates of implementation of the RV vaccination in the country (N=4).

Country	Dates of implementation of the RV vaccination
AT	July 2006
BE	November 2006
LU	December 2006
FI	September 2009

Two countries have decided not to integrate the RV vaccination into the national immunization schedule (EE and FR). The main drivers for taking such a decision is the insufficient anticipated epidemiological impact expected from RV vaccination and the remaining safety issues.

**Table 7.** The principle drivers of the decision not to integrate RV vaccination into the national immunisation schedule (N=2).

Drivers of decision not to integrate RV vaccine	Average score from respondents*
Insufficient anticipated epidemiological impact	3
Remaining safety concerns	2.5
Cost too high	2
Improved management of acute dehydration preferred to vaccination	2
Unfavourable cost/effectiveness ratios	1.5
Risk of emergence of serotypes not covered by the vaccine	1.5
Other	0.5

\* 1 = not considered in taking the decision, 3 = main driver of decision

Although not integrated into the national immunization schedule, the two vaccines are available on the private markets in EE and FR and in EE, RV vaccination is actively promoted by other groups than National Health Authorities, in particular by paediatricians who recommend it in the private consultations.

#### 4.4 Vaccination coverage

Some countries, whatever the status of introduction of the RV vaccination into the schedule, have monitored their immunization coverage. Two countries (AT BE) report a vaccination coverage reaching at least 80% and 3 countries where RV vaccination has not been introduced report a vaccination coverage which is less than 10% (FR PO SK) (Table 8).

**Table 8.** Immunization coverage monitored in different countries (N=5).

Countries	Immunization coverage (%) - Year (target age group)
<b>RV vaccination introduced</b>	
AT	82% - 2009 (7th post natal week – 6 months)
BE	90% - 2009 (1 year)
<b>RV vaccination not introduced</b>	
FR	9 % - 2009 (age NA)

PO	8% - 2008 (1 year)
SK	3.3% - 2008 (6 weeks – 6 months)

#### 4.5. Ad hoc studies used to support the introduction decision

##### *Infection burden studies*

Seven countries have completed rotavirus infection burden studies, 3 countries are working on this type of study and one country is planning to carry out this type of study.

EE has no plan to publish its work while FI and NL have their manuscript still in preparation or already submitted (Table 9). Amongst the 7 countries having completed a RV burden study, 4 countries (DE IT NO UK) have already published their work.

**Table 9:** Status of countries in term of RV infection burden studies undertaken (N=29)

Rotavirus infection burden studies	Countries		
	<i>n</i>	%	
Completed	7	24.1	DE EE FI IT NL NO UK
On going	3	10.3	HU PO SE
Planned	1	3.5	BE
Not planned	18	62.1	AT BG CY CZ DK ES FR GR IE IS LI LU LV MA PT RO SK SL

In terms of ad hoc studies used to support the decision making process for the countries where a decision has been taken by the national health authorities regarding rotavirus vaccination introduction, 2 countries have completed a rotavirus infection burden study, 1 country has planned such a study and 5 countries have not planned any RV infection burden study (Table 9-bis).

**Table 9-bis:** Status of countries in term of RV infection burden studies undertaken – Countries where NHA have taken a decision (N=8)

Rotavirus infection burden studies	Countries	
	<i>n</i>	
Completed	2	EE FI
On going	0	-
Planned	1	BE

Not planned 5 AT BG FR LV LU

\*NHA: National Health Authorities

### **Mathematical modelling project**

Four countries have completed a mathematical modelling project, 1 country is carrying out this type of study and 2 have planned to undertake such a study (Table 10). Amongst those 4 countries having completed a mathematical modelling project, 3 countries (FR IT UK) have already published their work.

**Table 10:** Status of countries in term of mathematical modelling to evaluate the expected epidemiological impact of vaccination (N=29).

RV vaccination mathematical modelling	Countries		
	<i>n</i>	%	
Completed	4	13.8	FI FR IT UK
On going	1	3.5	PO
Planned	2	6.9	BE NO
Not planned	22	75.9	AT BG CY CZ DE DK EE ES GR HU IE IS LI LU LV MA NL PT RO SE SK SL

The majority of surveyed countries where the decision about RV vaccination has been taken have not undertaken any mathematical modelling project to support the decision making process for rotavirus vaccination introduction. Two countries (FI FR) reported having completed their modelling projects while one country has planned to undertake such a study (BE) (Table 10-bis).

BE and FR have used/are planning to use a home made model while FI has used a model developed elsewhere and the three countries have used a state transition static model.

FR has already published its work while FI has its manuscript in preparation and BE plans to prepare a manuscript when work is over.

**Table 10-bis:** Status of countries in term of mathematical modelling to evaluate the expected epidemiological impact of vaccination - Countries where NHA have taken a decision (N=8).

RV vaccination mathematical modelling	Countries	
	<i>n</i>	
Completed	2	FI FR
On going	0	-

Planned	1	BE
Not planned	5	AT BG LV LU EE

### ***Economical assessment project***

Almost half of the surveyed countries have completed an economical assessment project, are conducting or have planned (48.3%) to undertake an economical modelling project (Table 11) and amongst the 10 countries that have completed this type of project, 7 countries have already published their work (BE DE FR IT NL NO UK) and two countries have their manuscript in preparation or already submitted (FI IE).

**Table 11:** Status of countries in term of RV vaccination economical assessment (N=29).

RV vaccination economical assessment	Countries		
	<i>n</i>	%	
Completed	10	34.5	BE DE FI FR IE IT LU NL NO UK
On going	3	10.3	HU PO SE
Planned	1	3.5	SI
Not planned	15	51.7	AT BG CY CZ DK EE ES GR IS LI LV MA PT RO SK

Half of the surveyed countries that have introduced RV vaccination have completed an economical assessment and half have not planned any economical assessment project. Amongst the 4 countries where an economical assessment has been undertaken:

- 3 countries (BE, FI, LU) have undertaken a cost analysis
- 4 countries (BE FI FR LU) have undertaken a cost utility analysis.

BE and FR have already published their work, FI has a manuscript in preparation or submitted and LU has no plan to publish the work (Table 11-bis).

**Table 11-bis:** Status of countries in term of RV vaccination economical assessment - Countries where NHA have taken a decision (N=8).

RV vaccination economical assessment	Countries	
	<i>n</i>	
Completed	4	BE FI FR LU
On going	0	-

Planned	0	-
Not planned	4	AT BG LV EE

### Health technology assessment

Only four countries have completed or have an on-going health technology assessment project.

**Table 12.** Status of countries concerning RV vaccination Health technology Assessment undertaken (N=29).

Status concerning RV HTA	Countries		
	<i>n</i>	%	
Completed	3	10.3	FI IE LU
Ongoing	1	3.5	NO
Planned	0	0	-
Not planned	25	86.2	AT BE BG CY CZ DE DK EE ES FR GR HU IS IT LI LV MA NL PO PT RO SE SK SI UK

Two countries have completed a health technology assessment (FI LU) and FI has published the work while LU has no plan to publish its work.

**Table 12-bis.** Status of countries (RV vaccination integrated) concerning RV vaccination Health technology Assessment undertaken (N=8).

Status concerning RV HTA	Countries	
	<i>n</i>	
Completed	2	FI LU
Ongoing	0	-
Planned	0	-
Not planned	6	AT BE BG EE FR LV

## 5.0 Conclusions

### 5.1. HPV vaccination introduction

- In 21 countries of the 29 MS, a recommendation to introduce HPV vaccination in their national immunisation schedule has been made by the national advisory body. The national health authorities in 18 countries have taken the decision to introduce the vaccination as of July 2010.
- Among the principal drivers for the decision to integrate the HPV vaccination into the immunisation schedule was the anticipated epidemiological impact on pre-cancerous and cancerous lesions, and the reassuring safety data from pre-licensing trials.
- Most the countries which have not taken any decision regarding HPV vaccination integration have declared that financial constraints were the main reason for not achieving the integration process.
- Amongst the 18 countries having taken the decision to introduce HPV vaccination, half have decided to implement catch-up campaigns.
- Females are targeted by the vaccination policy in all the countries, except in Austria where both females and males are concerned by the programme.
- A wide heterogeneity in the target age groups has been reported by the countries, varying from 11 to 17 years old for routine immunization and from 12 to 24 years old for catch-up campaigns.
- Vaccine administration is performed in public infrastructures in twelve countries (public health centres, school health services), in the private sector in 5 countries and in one country in both types of infrastructures.
- For routine immunization, the HPV vaccination is offered free of charge in 15 out of 18 countries and remains partially at the expense of the vaccinee in 2 countries and is fully supported by the patient in one country.
- Although 13 countries declared having implemented a monitoring system, only 7 have provided vaccination coverage data and the coverage results are very heterogeneous, from 17% to 81% of vaccination coverage for routine immunization and between 29% and 73% for catch-up campaigns.
- Seventy nine percent of the countries have undertaken an economical assessment study while 41% have undertaken a disease burden study and 38% a mathematical modelling project to support their decision process.

## 5.2. Rotavirus vaccination introduction

- The decision of introducing or not the RV vaccination in the national immunisation schedule has been taken by the National health Authorities in 8 countries and amongst them, 5 countries have decided to integrate the vaccine. In 2008, only 5 countries had taken a decision and 3 had integrated the RV vaccine.
- Thirteen countries are involved in the process of taking a decision although four of those countries are still at the initial stage of that process (planned examination).
- The main reason reported by the 5 countries for integrating the RV vaccination in the national schedule is the expected reduction of the burden of infections on hospitals during the RV season, the reassuring safety data from pre-licensing trial and the anticipated epidemiological impact on severe gastro-enteritis due to RV.
- The programme has been implemented in 4 countries.
- The two countries where the RV vaccination has not been introduced have declared that they have taken such a decision because of the insufficient anticipated epidemiological impact and the remaining safety issues.
- The vaccination coverage data in AT and BE demonstrate a high coverage, more than 80% in both countries.
- In the eight countries where a decision has been taken, 2 countries have undertaken disease burden studies and 2 have worked on a mathematical modelling project while 4 countries have completed an economical assessment project and 2 countries have undertaken a health technology assessment.