Introduction of human papillomavirus (HPV) vaccination into national immunisation schedules in Europe: Results of the VENICE 2007 survey

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The European Union Member States are simultaneously considering introducing HPV vaccination into their national immunisation schedules. The Vaccine European New Integrated Collaboration Effort (VENICE) project aims to develop a collaborative European vaccination network. A survey was undertaken to describe the decision status and the decision-making process regarding the potential introduction of human papillomavirus (HPV) vaccination into their national immunisation schedules. A web-based questionnaire was developed and completed online in 2007 by 28 countries participating in VENICE. As of 31 October 2007, five countries had decided to introduce HPV vaccination into the national immunisation schedule, while another seven had started the decision-making process with a recommendation favouring introduction. Varying target populations were selected by the five countries which had introduced the vaccination. Half of the surveyed countries had undertaken at least one ad hoc study to support the decision-making process. According to an update of the decision-status from January 2008, the number of countries which had made a decision or recommendation changed to 10 and 5 respectively. This survey demonstrates the rapidly evolving nature of HPV vaccine introduction in Europe and the existence of expertise and experience among EU Member States. The VENICE network is capable of following this process and supporting countries in making vaccine introduction decisions. A VENICE collaborative web-space is being developed as a European resource for the decision-making process for vaccine introduction.

Introduction

The availability of a new vaccine requires each country to decide whether to integrate the vaccine into the national immunisation schedule. The need for better knowledge about the decision-making process, and scientific contribution to decision-making regarding the introduction of a new vaccine across European Union (EU) Member States (MS) was one of the main justifications for setting up the VENICE project.

The VENICE project

The Vaccine European New Integrated Collaboration Effort (VENICE) project is a three-year European Commission (DG SANCO) sponsored project that was launched in January 2006. Twenty-eight European countries participate in the project, 26 EU MS (all except Malta) and two European Economic Area/European Free Trade Association countries (Iceland and Norway). The VENICE project aims to create an EU vaccination network capable of collecting and collating information on MS vaccination programmes. One of the ultimate goals of the network is to create a resource able to support MS and the European Commission by integrating available tools and knowledge on vaccine related issues.

In practical terms, the VENICE project is organized in technical work packages, which refer to different areas of activity and relate to the specific objectives of the program [1]. One of the VENICE technical work packages aims to encourage a rational approach to vaccination policy decision-making. This is achieved by promoting the exchange of experience and expertise, whenever a new vaccine is licensed in Europe, through sharing of information about recent and current studies performed, the methodologies used and the outcomes, and about vaccination strategies adopted.

In order to achieve the various objectives of the VENICE project, twenty-eight national gatekeepers were identified, one per participating country. Moreover, in each country, work package-specific contact points have been identified.

HPV vaccines in Europe

Two vaccines protecting against human papillomavirus (HPV) infections have been licensed in the EU based on the positive evaluation from the European Medicines Evaluation Agency (EMEA): a quadrivalent vaccine (Gardasil®) in September 2006 and a bivalent vaccine (Cervarix®) in September 2007 [2, 3, 4, 5]. Both vaccines have a prophylactic indication and aim to prevent pre-cancer lesions (CIN II +) and cancers due to persistent infection with HPVs 16 and 18 in women who have not been previously infected with these HPV types. HPV 16 and 18 have been estimated to cause 73% of cervical cancer cases in Europe [6]. The quadrivalent vaccine also prevents infection with HPV 6 and 11, viruses responsible for 80-90% of genital warts. [7 8].

Despite the high efficacy of these two vaccines, the decision to introduce HPV vaccination into a national immunisation schedule is complex and requires thorough epidemiological and economical analyses. Many factors must be considered, for example high vaccine cost and the added benefit of vaccination over an effective cervical screening programme. [9].

The European licensing of two HPV vaccines means that all MS are simultaneously considering the potential introduction of HPV vaccination into their national or, where applicable, regional immunisation schedules. These circumstances provide a unique opportunity to understand, in real-time, the decision-making process that precedes the introduction of a vaccine.

The objectives of this study were to identify the current decision-status of MS, describe the decision-making process and identify key information and methodologies used in the decision-making process for potential introduction of HPV vaccination into national immunisation schedules.

This report completes the preliminary analysis of this survey that was carried out early in 2007 and published in Eurosurveillance in April 2007 [10], and includes an update from January 2008.

Methods

Questionnaire

A web-based HPV vaccine questionnaire was developed in 2006 to explore the decision-making process for the introduction of HPV vaccination. The questionnaire was piloted in five countries (Italy, Ireland, France, Hungary and Greece) in August-September 2006 and posted on the VENICE website in January 2007 for completion by mid-February. The questionnaire was filled in by the project gatekeepers, or a designated contact point, in each country participating in VENICE using the dedicated web-based VENICE platform and stored on a secure domain of the website.

The questionnaire focused on several aspects of the HPV decision-making process, namely data sources available and ongoing or completed ad hoc studies to guide the decision-making process (or reasons not to conduct such studies), and the factors driving the decision to introduce HPV vaccination. Countries were also asked to describe their current status with regard to introduction of HPV vaccination.

After the European Commission (DG SANCO) requested additional information, a second version of the HPV vaccine questionnaire was posted on the VENICE website in September 2007. In addition to questions included in the first version, which could be updated if necessary, the second questionnaire asked for further information on the target population, infrastructure for vaccine administration and cost per dose of the vaccine (in countries where the vaccine had been introduced).

During the preparation of the European report of this survey in January 2008 [11] one of the countries participating in VENICE initiated an update of the results by sending an email to the other participants asking for information on their current HPV vaccine decision status. The received information was not standardised and varied in content and detail, nevertheless, we decided to take it into consideration when writing this article. The data that had been consistently supplied was therefore collated and added to the 2007 survey results.

Data analysis

Data from the completed second version of HPV questionnaires (posted in September 2007) were downloaded from the VENICE website on 31 October 2007 and analysed using Microsoft Excel® and Stata v8®.

Analyses were carried out to examine the factors associated with making a recommendation about the introduction of HPV vaccination. For each factor analysed, the proportion in countries where a national vaccine advisory body had made a recommendation (with or without a follow-on decision made by the national health authorities) was compared to the proportion in countries where a recommendation had not been made. In addition to the factors included in the HPV questionnaire, the analysis also took account of other available data potentially associated with making a recommendation, such as the country's Gross Domestic Product (GDP). Fisher's exact test (two-tailed) was used to generate p values, with $p \leq 0.05$ considered to be statistically significant. Quantitative variables were analysed by t-test comparison of means also using $p \leq 0.05$. It was not possible to conduct multivariable analysis, following univariable analysis, due to the limited number of observations.

Results

Completed second version HPV questionnaires were received from 27 of the 28 participating countries (all except Poland) in September/October 2007 (96% participation rate). The answers given by Poland in the initial questionnaire of January 2007 were used where possible, and so the study denominator value varies from 27 for the additional information requested by DG SANCO to 28 for unchanged questions. Following the email request to update the HPV vaccine decision-status initiated by one of the countries in January 2008, updated information was received from 27 of the 28 VENICE participating countries (all except Czech Republic).

Status of countries concerning the introduction of HPV vaccination

The process of introducing a new vaccine into the national immunisation schedule in European countries commonly occurs in two steps, firstly, a recommendation is made by a national vaccine advisory body, secondly, an official decision is taken by the national health authorities. As of 31 October 2007, the advisory bodies in 12 countries (44%) had made a recommendation (in all cases positive) regarding the introduction of HPV vaccination into the national immunisation schedule (Austria, Belgium, Denmark, France, Germany, Greece, Italy, Luxembourg, Norway, Slovakia, Spain and the United Kingdom (UK)). The national health authorities in five of these countries (Austria, Germany, France, Italy and the UK) had subsequently taken the decision to introduce HPV vaccination into the national immunisation schedule [12,13,14,15,16] whereas a decision was still pending in the remaining seven countries. No distinction was made in the questionnaire regarding the nature of the HPV vaccine (bivalent or quadrivalent) to be used in the national immunisation schedule.

Vaccination policy in countries where HPV vaccination was introduced

The HPV vaccination policies adopted in the five countries where HPV vaccination was included in the national immunisation programme are summarised in Table 1. The variation in the target populations by country is notable, with differences not only in the ages of targeted females, but in the targeting of boys/young males (recommended in Austria) and the catch-up campaigns to be

conducted (France and the UK). Only Italy anticipated differences in policies adopted between national and regional levels, as it is believed that some regions may decide to implement catch-up campaigns for females older than 11 years. The UK recommends administration principally via a school-based programme, but the final decision on delivery will be made at local level. The four remaining countries reported plans to use routine channels for vaccine administration.

The HPV vaccine is offered free of charge to the target population in Germany, Italy and the UK. In France, 65% of the cost is borne by the social security scheme and the remaining 35% is the responsibility of the individual or borne by a complementary voluntary insurance. A decision regarding reimbursement of HPV immunisation is still pending in Austria (as of October 2007).

Among the five countries that decided to introduce HPV vaccination, France, Italy and the UK reported that vaccine coverage data would be available for the primary target groups. All five countries reported the integration of HPV vaccination safety surveillance into the routine pharmaco-vigilance system. France and Italy also reported putting in place specific studies/systems to follow up the safety in adolescents/adults.

Basis for decision regarding introduction of HPV vaccination into immunisation schedules

Seven countries, including four that had taken the decision to introduce the vaccine (Austria, Germany, France, Italy) and three who in October 2007 anticipated taking such a decision in the future (Greece, Slovenia, Slovakia), reported the drivers for the decision. The principal drivers were favourable cost-effectiveness ratios and anticipated epidemiological impact on pre-cancerous and cancerous lesions (Table 2).

Epidemiological data available and ad hoc studies used to support a decision about vaccine introduction

Cervical cancer screening programmes were reported as operating in 24 countries (86%) (all except Belgium, Bulgaria, Cyprus and Luxemburg). The estimated proportion of the eligible age group reached by each country's screening programme varied from 9% to 100% (among the 16 countries submitting data), with 75% or more in Finland, Iceland, Norway, Poland, Spain, Slovenia, Sweden, UK and 25% or less in Ireland, Latvia and Slovakia.

Twenty-five countries (89%, all except Estonia, Greece and Romania) reported having data available on the incidence/prevalence of pre-cancer lesions (CIN2/3) or on the incidence of cervical cancer. Information on both conditions is available in 17 countries.

At least one ad hoc study was undertaken by 14 (50%) of the surveyed countries to support the decision-making process for HPV vaccine introduction. These included: disease burden studies, mathematical modelling studies and/or economical assessments. At the time of the survey, 11 countries (39%) had either completed or were currently undertaking HPV infection disease burden studies (Denmark, Finland, Germany, Iceland, Italy, The Netherlands, Poland, Portugal, Spain, Sweden, UK), including three of the five countries that have decided to introduce the vaccine.

Mathematical modelling projects to support the decision-making process for HPV vaccination introduction were reported as complete or ongoing by seven countries (Denmark, France, Germany, Italy, Norway, Portugal, UK), including four of the five countries that have decided to introduce the vaccine. Of these countries, two have used 'home-made models' (Denmark and UK) while the remaining five used models developed elsewhere. A state transition static model

Table 1

Details of HPV vaccination introduced into the national immunisation schedules of European countries as of 31 October 2007 (N=5); VENICE* 2007 survey

Characteristic	France	Germany	Italy	Austria	United Kingdom
Target population	14-year-old females	12-17-year-old females	11-year-old females	Females/ boys/ young males before sexually active	12 -13-year-old females
Catch-up campaign	15-23-year-old female virgins or girls who started their sexual life <12 months ago (from July 2007)	No	No (maybe on a regional level)	No	Catch-up campaign to be conducted

Table 2

Principle drivers of decision to introduce HPV vaccination into the national immunisation schedules of European countries as of 31 October 2007 (N=7); VENICE* 2007 survey

Drivers of decision to integrate HPV vaccination	Average score from respondents*
Favourable cost-effectiveness ratios	4.0
Anticipated epidemiological impact on pre-cancer lesions	4.0
Anticipated epidemiological impact on cancer lesions	4.0
Social demand	3.6

* 1 = not considered in taking the decision, 5 = main driver of decision

Table 3

Principle reasons for undertaking neither mathematical modelling nor economical studies to support the HPV decision-making process (N=14*); VENICE* 2007 survey

Reasons for not undertaking studies	Countries	
	n*	%
Similar studies already performed by other countries sufficient	5	36
Lack of available financial resources	5	36
Usually not considered in decision process	3	21
Lack of expertise available	3	21

* Countries could select multiple answers. Numbers in table will therefore not add up to the denominator of 14 (and 100%)

was favoured by two countries (France and Portugal), a dynamic model by four and a combined model by one country (Denmark). All seven countries included the existence or absence of a current screening (pap smears) programme in their models. All, except one (Denmark), tested female-only immunisation strategies. The age range considered for the target population varied from 11-12 years to 10-26 years.

Economic assessments to support the decision-making process for HPV vaccination introduction were reported by 11 countries (39%) (Denmark, Finland, France, Iceland, Italy, Luxembourg, Netherlands, Norway, Portugal, Sweden and UK), including three of the five countries that have decided to introduce the vaccine. All of the countries submitting details of their analyses (N=10) had carried out cost-benefit or cost-effectiveness studies and eight countries (80%) had factored quality of life indicators into their assessment.

No studies to support the decision-making process, as defined by this survey, had been undertaken by 14 countries (50%) as of October 2007. In two of these (Greece and Slovakia) a recommendation favouring the introduction of HPV vaccine had been made and in one (Austria) a decision had been taken. The most commonly reported reasons for not embarking on such studies were the lack of available financial resources and the belief that similar investigations performed earlier by other countries were sufficient (Table 3).

Factors associated with making a recommendation about introducing HPV vaccination

The availability of epidemiological data to support analysis for the decision-making process (e.g. cancer registry data, cervical screening coverage figures, incidence of cervical cancer) does not appear to be a factor associated with having made a decision about HPV introduction (Table 4). A greater proportion of countries that made a recommendation had completed a mathematical modelling project or had undertaken an economic assessment although neither association attained statistical significance (Table 4).

In terms of factors not featured in the VENICE survey, larger country population (Eurostat 2006 data) and higher GDP (International Monetary Fund (IMF) 2005 data) were associated with making a recommendation (p values < 0.01) (Table 4). Countries having made a recommendation had a lower mean coverage rate of first dose of measles containing vaccine (MCV) according to World Health Organisation (WHO) 2005 data than countries not having made a recommendation (89.6% versus 94%, p=0.04). Geographic location was not statistically significant; however, 50% (6/12) of countries having made a recommendation about introduction are located in Western Europe (defined as Ireland, UK, France, Belgium, Germany, Austria, Luxembourg, The Netherlands) whereas countries in this region of Europe account for 30% (8/27) of surveyed countries (Table 4).

Table 4

Factors associated with making a recommendation about introducing HPV vaccination into the national immunisation schedule of a country (univariable analysis) (N=27); VENICE* 2007 survey

Factor	Recommendation made (N=12)		Recommendation not made (N=15)		p value
	n	%/mean	n	%/mean	
Data to support analyses for decision-making process					
Availability of different types of epidemiological data to support analyses needed for the decision-making process (score[a] range per country 0-5)[b]	12	3.9[b]	15	3.9[b]	1.0
Ad hoc studies to support decision-making process					
1. HPV infection burden studies (completed project)	1	8	3	20	0.605
2. Mathematical modelling to evaluate the expected epidemiological impact of vaccination (completed project)	3	25	1	7	0.29
3. Economic assessment undertaken	6	50	5	33	0.45
Additional factors investigated					
1. Country population size (millions)[b] (Eurostat 2006 data)	12	30.7[b]	15	5.9[b]	0.004
2. Europe's geographic region:[c]					0.09
north (N=5)	2	17	3	20	
south (N=6)	3	25	3	20	
east (N=8)	1	8	7	47	
west (N=8)	6	50	2	13	
3. National GDP (millions $US)[b] (IMF 2005 data)	12	965,163[b]	15	115,633[b]	0.003
4. Coverage of first dose of MCV [b] (WHO 2005 data)	12	89.6[b]	15	94.0[b]	0.04

[a] Score based on a count of the five types of data surveyed in the questionnaire (five data sources: mandatory notification of cervical cancer, existence of cancer registries including cervical cancer, existence of a cervical cancer screening program, data on the incidence/prevalence of pre-cancer lesions (CIN2/3), data on the incidence of cervical cancer)

[b] Comparison of two means

[c] North: Norway, Sweden, Finland, Denmark, Iceland.
South: Portugal, Spain, Italy, Greece, Slovenia, Cyprus.
East: Estonia, Latvia, Lithuania, Poland, Slovakia, Romania, Bulgaria, Hungary.
West: Ireland, United Kingdom, France, Belgium, Germany, Austria, Luxembourg, the Netherlands.

Update of HPV vaccine decision status, January 2008

A change in the HPV vaccine status of seven countries participating in VENICE was noted as of 31 January 2008. Specifically, the vaccine advisory bodies of Bulgaria and Slovenia recommended the introduction of HPV vaccination, while the national health authorities in Belgium, Greece, Luxembourg, Portugal and Spain decided to introduce HPV vaccination into the national immunisation schedule. This takes the number of European countries that have made a recommendation, all favouring vaccine introduction, to 15 and the number of countries where an official decision has subsequently been taken to 10 (data as of 31 January 2008 for N=27, and 31 October 2007 for Czech Republic).

Discussion

This study is the first documentation of the status of European countries regarding HPV vaccination and it deconstructs the decision-making process which leads to the introduction of a new vaccine into the national immunisation schedule. Within the objectives of the VENICE project, the introduction of HPV vaccination in Europe has provided a unique opportunity for real-time examination of the decision-making process. The high participation rate in this study indicates the high level of interest in this issue among European countries and the effectiveness of the VENICE network as a means of collecting and sharing vaccination information at European level.

In the sixteen months (up to 31 January 2008) following the European licensing of the first HPV vaccine, Gardasil®, the national health authorities of ten MS decided to introduce HPV vaccination into the national immunisation schedule, while another five countries started the decision-making process with a recommendation favouring introduction. It is noteworthy that all advisory bodies that made a recommendation advised the introduction of the HPV vaccine and all national health authorities that made a decision opted for the integration of the HPV vaccination into the national immunisation programme. This suggests a high public health priority given to HPV vaccination which probably reflects the high expected gain from a vaccine that can prevent cancer.

The survey results show that the countries that decided to introduce HPV vaccination adopted varying vaccination policies. This is particularly evident in terms of target ages and catch-up campaigns. Such a result is not unexpected considering the variety in national immunisation programme delivery services and diversity of health services infrastructures in European countries. Regardless of the vaccination policy adopted, all four MS (as of October 2007) that made a decision about the reimbursement of the vaccine have chosen to reimburse vaccination either fully or partially.

Underlining the need for data to support the decision-making process, four of the five MS (as of October 2007) that decided to introduce HPV vaccination had undertaken at least two ad hoc studies (disease burden study, mathematical modelling study or economic assessment).

Countries where no such projects were undertaken reported the lack of financial resources and the belief that similar studies performed by other countries were sufficient as principle reasons for not carrying out ad hoc studies. This highlights the need for collecting information on such projects at European level and for collaboration between countries to share expertise and experience in order to minimise the number of redundant studies that can drain the limited health resources.

Germany, the UK, France and Italy, four of the five countries where HPV vaccination was introduced (as of October 2007) are the top four ranked European countries in terms of national GDP. This fact could explain the observed association between a higher national GDP and an introduction-decision being already made. A higher national GDP may also reflect a genuine greater capacity to fund routine HPV vaccination in these countries.

It is also worth noting that among the five northern European countries only two (Denmark and Norway) made a recommendation to introduce the HPV vaccination and none actually took the decision (as of January 2008) despite the fact that these countries generally have a well-developed public health infrastructure and also potentially have the resources needed to fund a routine HPV vaccination. Four of these countries (Sweden, Finland, Iceland and Norway) reported a target population coverage rate for the national cervical cancer screening programme above 75%, which raises a question about the possible impact of a successful screening programme on the decision not to introduce HPV vaccination.

The limited number of countries in the survey is likely to have affected the statistical power of the analysis of factors associated with making a recommendation about introducing HPV vaccination. We therefore cannot conclude from these data whether the availability of epidemiological data and the undertaking of ad hoc studies are associated with a more rapid decision making process.

The update initiated by one of the participating countries in January 2008 highlights the rapidly evolving situation once a new vaccine is licensed in Europe and the desire of the relevant authorities to have a European perspective on the introduction process. The VENICE project has developed a European network capable of answering this demand, not just for HPV vaccination but for other recently licensed vaccines such as rotavirus vaccines (for which a survey similar to that described here has been conducted) and combined MMR-varicella vaccines.

Conclusion

The deconstruction of the decision-making process concerning the introduction of HPV vaccine into national immunisation schedules has shown, in real time, that there is expertise and experience available among European countries that could be collated and shared. A collaborative space is being developed on the VENICE website that will serve as an inventory for information of this sort. This inventory will be available to participating countries and European institutions such as the European Centre for Disease Prevention and Control and DG SANCO. It is hoped that this web-based space will facilitate future collaborations between MS relating to vaccine-policy decisions and broader vaccination related activities.

The VENICE project is scheduled for completion in December 2008. It is planned that the European Centre for Disease Prevention and Control will take over responsibility for the project in 2009 with a view to maintaining and further developing an already well functioning network of European vaccination public health professionals.

Acknowledgements

The authors wish to acknowledge the contributions of all the country specific gate keepers, contact points and work package members of the VENICE project to this survey.

Financial support

This work benefited from the financial support received in relation to the VENICE project originated from a European Commission DG SANCO sponsored grant (Grant number: 2004201)

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This article was published on 14 August 2008.

Citation style for this article: King LA, Lévy-Bruhl D, O'Flanagan D, Bacci S, Lopalco PL, Kudjawu Y, Salmaso S, VENICE country specific gate keepers and contact points. Introduction of human papillomavirus (HPV) vaccination into national immunisation schedules in Europe: Results of the VENICE 2007 survey. Euro Surveill. 2008;13(33):pii=18954. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=18954