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Current status of human papillomavirus vaccination implementation in central and eastern Europe

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Abstract

We present a review of the current implementation status of vaccination against human papillomaviruses (HPV) and available data concerning the burden of HPV infection and HPV type-specific distribution in 16 central and eastern European countries: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, the Czech Republic, Estonia, Montenegro, Poland, Romania, Serbia, Slovakia, Slovenia, and The Former Yugoslav Republic of Macedonia. At least one current HPV prophylactic vaccine is registered in all central and eastern European countries except Montenegro. Six counties–Bulgaria, the Czech Republic, Latvia, Romania, Slovenia, and Former Yugoslav Republic of Macedonia–have integrated the HPV vaccination into their national immunization program and currently provide routine vaccination free of charge to the primary target population. Ten countries have not integrated HPV vaccination into the national immunization program. The key reasons for lack of implementation of HPV vaccination into the national immunization program are the high vaccine cost and negative public perception. Vaccination of males is not recommended in any country in the region.

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Introduction

Two prophylactic HPV vaccines have been available since 2006 and can be used as efficient and powerful tools for primary prevention of cervical cancer and other HPV-associated diseases (1–5). The quadrivalent vaccine (Gardasil/Silgard®, Merck & Co., Whitehouse Station, NJ, USA) and bivalent vaccine (Cervarix®, GlaxoSmithKline Biologicals, Rixensart, Belgium) have each been licensed in over 100 countries worldwide. By the beginning of 2012, HPV vaccination had been introduced into national immunization programs in at least 40 countries (6). In 2011, when we started preparing the central and eastern European regional report for the HPV Vaccines Monographs (7), we realized that published data concerning current HPV vaccination implementation in central and eastern European countries are scant, available for only a limited number of countries, or out of date (8–10). Therefore a detailed survey with 28 questions was conducted by the authors of this review from August to October 2011 and used as the main data source. Due to limited space, not all data collected could be included in the manuscript written for the regional report. Thus we decided to separately publish an extended manuscript on this topic, and we updated the survey in January 2013. In this paper, we review the current implementation status of vaccination against human papillomaviruses (HPV) in each of the 16 central and eastern European countries: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Montenegro, Poland, Romania, Serbia, Slovakia, Slovenia, and The Former Yugoslav Republic (FYR) of Macedonia. The key data obtained by survey are summarized in Tables 1 and 2.

Albania

Only the bivalent vaccine is currently registered in Albania (11). It has been licensed since 2009. The HPV vaccination is not integrated into the national immunization program and there are currently no issued recommendations for the use of HPV vaccines. There are initiatives by the Albanian Ministry of Health regarding HPV vaccination, described in the National Cancer Control Program, which includes a number of specific recommendations and actions. The recommendations include the step-by-step building of a national program for vaccination against HPV and emphasize health education (12).

Bosnia and Herzegovina

Both HPV vaccines, quadrivalent and bivalent, have been registered in Bosnia and Herzegovina: the bivalent vaccine since July 2007 and the quadrivalent one since October 2008. In 2011, the Ministry of Health of the Federation of Bosnia and Herzegovina prepared a document entitled Strategy of Prevention, Treatment and Control of Malignant Disease in which HPV vaccination was mentioned for the first time as a possible prevention of cervical cancer. No further explanation or recommendations regarding the use of HPV vaccination were included in the document. The current cost of HPV vaccines is €100 for the bivalent vaccine and €125 to €165 for quadrivalent HPV vaccine, and this depends on the supplier.

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Table 1 | **HPV vaccination status in 15 central and eastern European countries.**

Country	Cervarix® date of licensure	Gardasil® date of licensure	National professional recommendation for female HPV vaccination (age range)	Implementation of immunization program	Primary target population (gender/age group)
Albania	2009	Not registered	No recommendation	No	NA
Bosnia and Herzegovina	2007	2008	No recommendation	No	NA
Bulgaria	2007	2007	12–26 years	Implemented since September 2012	Female / 12 years
Croatia	2008	2007	15–26 years	Current organized initiatives for implementation	NA
Czech Republic	2007	2006	9–26 years	Implemented since April 2012	Female / 13–14 years
Estonia	2007	2006	› 12 years	Current organized initiatives for implementation	NA
Hungary	2007	2006	No recommendation	No	NA
Latvia	2007	2006	12 years	Implemented since September 2010	Female / 12 years
Lithuania	2007	2006	No recommendation	Current organized initiatives for implementation	NA
Montenegro	Not registered	Not registered	No recommendation	Current organized initiatives for implementation	NA
Poland	2007	2008	12–13 years	No	NA
Romania	2008	2008	12–24 years	Implemented since November 2008/February 2010	Female / 9–10/12 years
Serbia	2008	2008	No recommendation	No	NA
Slovakia	2007	2007	12 years	Current organized initiatives for implementation	NA
Slovenia	2007	2006	9–26 years	Implemented since September 2009	Female / 11–12 years
FYR of Macedonia	2008	2007	9–26 years	Implemented since September 2009	Female / 12 years

Cervarix®: Cervarix® (GlaxoSmithKline Biologicals, Rixensart, Belgium); Gardasil®: Gardasil® (Merck & Co., Whitehouse Station, NJ, USA); ND: no data available; NA: not applicable

Table 2 | **HPV vaccination status in 15 central and eastern European countries.**

Country	Cervarix® free market price per dose (€)	Gardasil® free market price per dose (€)	Informed consent requirement	Vaccine coverage 2009/2010 (%)	Vaccine coverage 2010/2011 (%)	Vaccine coverage 2011/2012 (%)	Reason(s) for lack of implementation of HPV vaccine in national immunization program
Bosnia and Herzegovina	100	125–165	NA	NA	NA	NA	Vaccine cost
Bulgaria	77	109	Yes	NA	NA	NA	NA
Croatia	100–120	130–150	ND	NA	NA	NA	Financial constraints, negative public perception
Czech Republic	80	140	Yes	NA	NA	NA	NA
Estonia	112	ND	ND	NA	NA	NA	Vaccine cost, lack of national cost-effectiveness data
Hungary	105	105	Yes	NA	NA	NA	Vaccine cost
Latvia	28.5	ND	Yes	47.4[a] (1 dose)	60.6[b] (3 doses)	53.4[c] (3 doses)	NA
Lithuania	110	122	ND	NA	NA	NA	Vaccine implementation planned
Montenegro	NA	NA	NA	NA	NA	NA	Financial constraints
Poland	60	60	ND	NA	NA	NA	financial constraints
Romania	100	105	ND	ND	ND	ND	NA
Serbia	50–55	129	ND	NA	NA	NA	Vaccine cost
Slovakia	68	113	ND	NA	NA	NA	Financial constraints, unsatisfactory evidence of vaccine effectiveness
Slovenia	86	108	Yes	48.7 (3 doses)	55.0 (3 doses)	54.9 (3 doses)	NA
FYR of Macedonia	ND	138	No	36.5 (3 doses)	67.0 (3 doses)	65.0 (3 doses)	NA

Cervarix®: Cervarix® (GlaxoSmithKline Biologicals, Rixensart, Belgium); Gardasil®: Gardasil® (Merck & Co., Whitehouse Station, NJ, USA); ND: no data available; NA: not applicable
[a]data for the first 4 months of vaccination in 2010, [b]data for 2011, [c]data for 2012

Bulgaria

Both vaccines are currently in use in Bulgaria; the quadrivalent one was introduced in 2007, and the bivalent one in 2008. In 2007, an expert advisory body, including members from the Ministry of Health and National Center for Infectious and Parasitic Disease Control, issued official recommendations for the use of HPV vaccines in Bulgaria for girls 12 to 18 years old before first sexual contact, with catch-up vaccinations up to age 26. In June 2009, the Ministry of Health included the HPV vaccine in the recommended vaccination list. In 2012 the National Program for Primary Prevention of Cervical Cancer was approved by the council of ministers. To enable implementation of the program, the parliament approved 2 million leva (about €1 million) for the first year for reimbursement of HPV vaccine for the target population of 12-year-old girls. Catch-up vaccinations up to age 26 are recommended, but are based on personal initiative and are not free of charge. The vaccine is delivered through health centers or primary care providers and the informed consent of parents or guardians is required. Because the program is in its initial stage, it is still early for the vaccination coverage data, but most recent data from the media have shown that in the first 3 to 4 months of the program about 14% of the target population has been vaccinated (Y. Panayotova, personal communication).

Croatia

Both HPV vaccines have been registered in Croatia: the quadrivalent vaccine since 2007, and the bivalent one since 2008. In 2008, the Croatian Institute of Public Health prepared official recommendations for the use of HPV vaccines and revised the recommendations in 2009. In addition to the institute, several professional medical associations published recommendations for HPV vaccination. According to the recommendations, HPV vaccination is recommended as individual protection to girls and women between ages 9 and 26, preferably before sexual debut. Immunization of schoolgirls and higher-education students is performed at school medical departments affiliated with the county institutes of public health, and working women can be vaccinated by their gynecologist, family physician, or at epidemiology departments at the county institutes of public health. Due to the financial constraints of the Health Insurance Institute, HPV vaccination is not reimbursed. Since 2008, the health administrations of a few cities and counties have funded vaccination campaigns for school-age children, ensuring that all three doses are free of charge to 13-year-old girls. Vaccination response rates have varied from 10% to 70%, depending mostly on the parents' attitudes towards HPV vaccination. The vaccination of males is not currently recommended.

Czech Republic

Both HPV vaccines have been registered and are on the market in the Czech Republic: the quadrivalent vaccine since 2006, and the bivalent one since 2007. In 2006, the Ministry of Health prepared official recommendations for the use of HPV vaccines for females 9 to 25/26 years old. Financial coverage was from personal funds, self-supported. Recommended HPV vaccination has been integrated into the national immunization program since April 2012 by a decision of Ministry of Health on the basis of National Immunization Committee (NIKO) recommendation. HPV vaccination is covered by general health insurance for the target population of adolescent women, 13 years of age. Written informed consent of the girl's parent or guardian is required for vaccination. The bivalent vaccine has been used in the national immunization program and is delivered through pediatricians. A catch-up program has not been implemented in the Czech Republic. As for all other vaccines, vaccination coverage data for HPV vaccination will be collected in all regions manually each year and the results sent to the center. The vaccination of males is not currently recommended.

Estonia

Both HPV vaccines have been registered in Estonia: the quadrivalent vaccine since 2006, and the bivalent one since 2007. The Ministry of Social Affairs issued official recommendations for the use of HPV vaccines in 2009. According to the recommendations, HPV vaccination is recommended for females age 12 and older. Due to the high vaccine cost and lack of the country's cost-effectiveness data, HPV vaccination has not been integrated into the national immunization program and there are no plans to do this in the near future.

Hungary

Both HPV vaccines, the quadrivalent and the bivalent, have been registered in Hungary since 2006 and 2007, respectively, but the vaccination advisory board has not yet produced recommendations for the introduction of HPV vaccination or integrated it into the national immunization program. Two recent modeling studies have confirmed the cost effectiveness of adding either of the available vaccines to the current national screening program in Hungary (13,14), but due to the high cost HPV vaccination has not been integrated into the national immunization program and there are no plans to do so in the near future.

Latvia

Both HPV vaccines are available in Latvia. In 2009, the state immunization board prepared official recommendations for introducing HPV vaccines in the national immunization schedule. This decision was accepted by the Ministry of Health and the cabinet of ministers, and since September 2010 HPV vaccination has been integrated into the national immunization schedule. In general, routine HPV vaccination is provided free of charge to 12-year-old girls by general practitioners and also at several schools in the capital Riga if the parents or guardians have given written informed consent to allow vaccination of their daughters in school. So far, the bivalent vaccine has been used in the national immunization program. A catch-up program has not been implemented in Latvia. According to data from a vaccination monitoring system, the coverage for one dose in Latvia increased from 47.4% in 2010 to 61.4% in 2011, and was 58.7% in 2012. Vaccination coverage for three doses was 60.6% in 2011 and 53.4% in 2012. Currently, vaccination of males is not recommended.

Lithuania

Both HPV vaccines are currently registered in Lithuania: the quadrivalent one since 2006, and the bivalent one since 2007. The cost of the quadrivalent vaccine per dose is approximately €122, and the cost of the bivalent vaccine per dose is approximately €110. HPV vaccination is not part of the official national immunization

scheme and there are currently no official recommendations for the use of HPV vaccines. However, there are plans to introduce HPV vaccination into the national immunization program in the near future.

Montenegro

None of the existing HPV vaccines have been registered in Montenegro yet, but the registration of both vaccines is in progress. According to the working plan of the newly established National Immunization Technical Advisory Group (NITAG), official recommendations for the eventual integration of HPV vaccination into the national immunization program will be prepared by the end of November 2013. Recommendations will be based on the results of an ongoing study evaluating the prevalence and distribution of HPV genotypes in women with pre-cancerous cervical lesions and cervical cancer. The end of the study is planned for October 2013. The NITAG recommendation for the Ministry of Health is to implement these vaccines into the national immunization program, and the HPV vaccination will be introduced at the beginning of the new school year in 2014, provided that this probable introduction is financially feasible and sustainable.

Poland

The bivalent vaccine has been registered since 2007 and the quadrivalent one since 2009. The price is the same for both vaccines: €60. Official recommendations for the use of HPV vaccines were issued by the Polish Gynecological Society in 2009. The vaccination is recommended for girls 11 to 12 years old and also for girls age 13 to 18 that were not vaccinated previously (15). HPV vaccination is not part of the national immunization program, mainly due to the high cost. There are currently no initiatives to include the HPV vaccination in the national immunization program. Local authorities in some regions have introduced HPV immunization projects for girls age 12 to 13. No central registry of vaccinated women is currently available, nor is there any information on whether all three doses were administered.

Romania

In Romania, both the bivalent and the quadrivalent vaccine have been registered since 2008. There are official recommendations for the use of these vaccines, issued by the Ministry of Health in 2008. Vaccination is recommended for females age 12 to 24. HPV vaccination is performed at local public health centers and school health services. A national school-based program to vaccinate 11-year-old females was first launched in 2008, but was temporarily suspended during the first year due to low acceptance. Only about 2% of the target population was vaccinated. The government analyzed the reasons for the low uptake and subsequently implemented a novel information campaign prior to a re-launch in February 2010, which was discontinued at the end of 2011 due to a negative public reaction, lack of proper communication, and consequent low coverage of the target population (less than 5%). The program was launched for the third time in April 2013.

Serbia

Both the quadrivalent and bivalent HPV vaccine have been registered in Serbia since 2008. In 2008, the Serbian expert group on cervical cancer prevention prepared official recommendations for the use of HPV vaccines. Unfortunately, these recommendations have never been officially announced. HPV vaccination has not been integrated into the national immunization program. Both vaccines are on the market and are available for individual use. The stock of bivalent vaccine expired and currently it cannot be found in pharmacies. Quadrivalent vaccine can be ordered and purchased. Initial campaigns aimed at increasing awareness about HPV vaccination have ceased, and currently there is no structured education on this issue in the country.

Slovakia

Both HPV vaccines, the quadrivalent one and the bivalent one, have been registered in Slovakia since 2007. In 2010, the Working Group for Immunization prepared official recommendations for the use of HPV vaccines and passed these on to the Ministry of Health of the Slovakia. The recommendation was implemented into legislation, and it says that if a doctor considers there to be a need for the vaccination against infections caused by oncogenic HPV, then the vaccination should be given to 12-year-old girls. This group pays 89% of the total price of the bivalent vaccine and 92.5% of the total price of the quadrivalent vaccine. Of course, the non-official recommendation is also designed for other age groups, but these have to pay the total price of the vaccines. Neither routine HPV vaccination nor catch-up programs have been started in Slovakia. HPV vaccination coverage is not monitored, although the number of girls up to 15 years old vaccinated against HPV is monitored. Vaccination of males is currently not recommended.

Slovenia

Both HPV vaccines have been registered in Slovenia, the quadrivalent one since 2006 and the bivalent one since 2007. In 2007, the Slovenian expert group on HPV prepared official recommendations for the use of HPV vaccines. According to the decision of the board of health at the Slovenian Ministry of Health, HPV vaccination has been included in the National Immunization Program since the beginning of the 2009/2010 school year and has been performed in school health service networks. Routine HPV vaccination, free of charge, is provided to 11- to 12-year-old girls if their parents or guardians give written informed consent to allow vaccination of their daughters. So far, the quadrivalent vaccine has been used in the national immunization program. A catch-up program has not been implemented in Slovenia. According to data from the Slovenian national vaccination coverage monitoring system, the coverage rate (full three-dose) in the target group included in the program increased from 48.7% for the 2009/2010 school year through 55.2% for the 2010/2011 school year to 54.9% for the 2011/2012 school year. Vaccination of males is currently not recommended.

The Former Yugoslav Republic of Macedonia

Both the quadrivalent and bivalent vaccine have been registered in FYR of Macedonia: the quadrivalent one since 2007, and the bivalent one since 2008. The official recommendations for the use of HPV vaccines were issued in 2007 by the Commission for Contagious Diseases within the Ministry of Health, the Macedonian Association of Gynecologists and Obstetricians, the HPV Society of Macedonia, and the Macedonian Society for Cervical Pathol-

ogy and Colposcopy. Vaccination was recommended for females between 9 and 26 years old. By a decision of the Ministry of Health from 2008, HPV vaccination was introduced into the national immunization program in October 2009 as obligatory for 12-year-old girls. The quadrivalent vaccine has been used in the national immunization program and is delivered through a school-based program. The catch-up vaccination is provided for 13- to 26-year-old girls and woman, and is also free of charge and is delivered through healthcare facilities. HPV vaccine coverage is monitored at the national level. Coverage for three doses increased from 37% for the 2009/2010 school year to 67% for the 2010/2011 school year, and then declined to 65% for the 2011/2012 school year.

Conclusions

As shown in Tables 1 and 2, at least one of two current HPV prophylactic vaccines is registered in all central and eastern European countries except Montenegro. Six countries (Bulgaria, the Czech Republic, Latvia, Romania, Slovenia, and FYR of Macedonia) have actually integrated HPV vaccination into their national immunization program and currently provide routine vaccination free of charge to the primary target population (Table 1).

In Slovenia and FYR of Macedonia, HPV vaccination is performed in school health service networks, whereas in the other four countries HPV vaccination is performed in local public health centers and school health services. Informed consent of parents or guardians is required in all countries, and all of them except FYR of Macedonia have initiated a national HPV immunization program. All six countries declared that a vaccination monitoring system had been implemented. However, only three countries were able to provide vaccination coverage data for all three doses. Of the six countries, only FYR of Macedonia decided to implement a catch-up program for the 13 to 26 age group.

In Romania, the re-launched HPV vaccination program was discontinued at the end of 2011 due to a negative public reaction, lack of proper communication, and resulting low coverage in the target population, which did not reach 5%.

Ten countries have not integrated HPV vaccination into the national immunization program (Table 1), the main reasons being high vaccine cost and negative public perception (Table 2). In approximately half of these countries, national professional societies and bodies are generally supportive of the routine HPV vaccination of adolescent girls. Because there is no publicly funded vaccination program, HPV vaccination in these countries is funded by individuals or, in some countries (e.g., Croatia, Poland), by regional or county authorities; but with low coverage achieved. At the time of preparation of the review, vaccination of males was not recommended in any country in the region.

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