

Educational Session 2

Assessing programs implementation & health education

Advocacy – societal and ethical issues

CHAIR: P. SPAREN (SWEDEN), M. PITTS (AUSTRALIA), F. BORRUTO (ITALY)

CIVIL SOCIETY ADVOCACY IN THE INTRODUCTION OF HPV VACCINATION IN EUROPE: AN ANALYSIS

President of UniversElles, a women's association and Sanofi Pasteur MSD, Lyon, France

Objectives: An analysis to assess the role of civil society, notably patients' groups and women associations, in the introduction of HPV vaccination in Europe. The analysis also looks at future perspectives for civil society advocacy.

Methods: Analysis of processes and trends unfolding in Europe and literature research.

Conclusions: In the evolving environment of vaccinology, it is becoming clear that it is only through the concerted and active efforts of all stakeholders, including policymakers, health care professionals, and crucially civil society that vaccination programmes can be implemented. Civil society advocacy contributed to focus attention and increase market access of HPV vaccines both at EU and country level. How-

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France

ever, some interest groups also posed a challenge to the introduction of vaccination. Despite its inherent limitations, we find that civil society advocacy is bound to play a greater role in vaccines' introduction and implementation. Indeed, the future of health care is going from a disease-centered to a «patient-centered» model of care. Moreover, civil society groups bring health matters closer to the lay public and public support has never been more essential to the sustainability of vaccination programmes. Finally, lessons from the HPV experience will benefit the AIDS community. This experience actually provides an unprecedented opportunity for civil society groups to inform future access strategies and implementation mechanisms for an AIDS vaccine.

A population-based study investigating the awareness and knowledge of HPV among parents of children aged 12-15 years.

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Objectives: We assessed HPV awareness and knowledge among parents to children aged 12-15 years of age to get a better understanding of how knowledge is influenced by various sociodemographic factors.

Methods: We invited 16 000 parents to girls and 4000 parents to boys, randomly selected from the Swedish population. Response rates were 11 187 (70%) and 2 759 (69%), respectively. Awareness of HPV was measured by asking 'Have you heard of a virus called human papillomavirus (HPV) before taking part of this study?'. Binomial logistic regression models were applied to investigate correlates of HPV awareness.

Conclusions: In total 24% (3347) of the parents had heard about HPV (fathers: 17% and mothers: 29%). Knowledge was assessed by asking parents who had heard about HPV if they thought HPV can cause cervical cancer (79% answered yes), if HPV can cause other cancers (21%), if HPV can cause condyloma (52%), if HPV is sexually transmit-

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ted (86%), and if both men and women can be infected (72% and 92%, respectively). A logistic regression analysis of level of HPV knowledge was performed where five correct answers to six questions was considered high knowledge. Sex, country of origin and education were the most important factors associated with high levels of HPV knowledge. Mothers had better knowledge than fathers (OR: 2.49, 95% CI 2.18-2.83). Being born in other country than European was associated with lower knowledge compared to being born in Sweden (OR: 0.48, 95% CI 0.35-0.67) and low education levels were associated with little knowledge compared to having education equal to high school (OR: 2.03, 95% CI 1.49-2.76) or education levels above high school (OR: 6.13, 95% CI 4.51-8.31). Our results suggest that HPV information campaigns should particularly target parents with low education and born outside Sweden when promoting greater and more adequate knowledge of HPV in the population.

HPV vaccine introduction in Europe: lessons learned

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Objective: The 53 countries of the WHO European Region are diverse in income levels and health care systems. To date, 17 countries have introduced the HPV vaccine, with varying success and documentation of their immunization schedules. However, there has been scant documentation of these successes and the challenges encountered with HPV vaccine implementation in the WHO European Region in a consistent, standardized manner to allow for lessons learned. These experiences could benefit other countries in the Region considering HPV vaccine implementation.

Methods: We will conduct a standardized phone interview with the 17 European countries that have introduced the HPV vaccine. Information regarding 15 items such as implementation strategies, target population, communication, funding, challenges, and coverage will be obtained using a standardized data collection questionnaire. Countries agreeing to participate will receive the questionnaire prior to the phone call. Data will be aggregated where similar strategies have been used to implement the vaccine.

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Conclusions: In the WHO European Region, success of HPV vaccine introduction has varied widely, with some countries obtaining high rates of coverage and others very low. Financing mechanisms have also varied substantially in this economically diverse WHO region. Information from the interviews will be tabulated and presented, with specific examples offered. We will present strategies on the decision to use the vaccine and how it was implemented (mass catch-up campaigns or routine immunization programmes, and whether a comprehensive approach was used). We will collect and present samples of vaccine education offered to providers, patients, and media as well as problem solving strategies for handling adverse events and negative publicity. We will address finance mechanisms in this varied region with middle and high income countries. Disseminating the collective experiences of HPV vaccine implementation successes and challenges is vital to enable assistance to countries as they seek guidance towards introduction of the HPV vaccine.

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R. Rouzier
France

Coverage and compliance of HPV vaccines in Paris: analysis of reimbursements by the social security

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Background: Since July 2007, primary prevention against Human Papilloma Virus (HPV)-related pre-neoplastic and neoplastic lesions through HPV vaccines is reimbursed by the social security (CPAM) in France. The vaccine is routinely recommended for 14 year-old girls and a catch-up vaccination should be offered to girls and women ages 15 to 23 before the first time they had sex or within one year of first having sex. We have little data on coverage and compliance while these aspects influence the effectiveness of a national immunization program.

Objective: To evaluate the coverage and compliance of HPV vaccine in Paris.

Methods: By selecting the female population living in Paris, aged 14 to 23 years (31/12/2008) and affiliated to the social security (n=77744), we analyzed data on reimbursement of HPV vaccines by the CPAM. We evaluated the dynamic of HPV vaccine dose reimbursement between July 2007 and April/May 2009 for this population and studied factors

associated with coverage and compliance.

Results: The coverage rate in the study population was 17% (at least one dose). The compliance was not satisfactory since a complete vaccination scheme was observed in less than 43% of affiliates. Two doses have been reimbursed to 26% and only one dose to 31% of affiliates. The analysis by age and district showed that coverage and compliance depended on age and average family income (higher among 15-17 years, and districts with higher median income).

Perspectives and conclusion: The elasticity of the immunization schedule could allow prompt corrective actions to avoid losing the benefit of vaccination procedures initiated but not completed. To raise awareness on HPV and vaccine in terms of coverage but also compliance should be encouraged to improve effectiveness of primary prevention against cervical cancer in France.

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O. Parant
France

Eligibility and willingness of first-year students entering university to participate in a HPV vaccination catch-up program

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Objectives: In France, Human papillomavirus (HPV) vaccine is routinely recommended for 14-year-old girls; a catch-up vaccination should be offered to girls and women 15-23 years of age before the first time they have sex or within the first year after sexual activity begins. The aim of the present study was to examine the eligibility and willingness of first-year college students of Toulouse University (France) to participate in a HPV vaccination catch-up program, and to estimate their knowledge of HPV vaccination and cervical cancer screening.

Methods: The study was conducted from January to April 2008 simultaneously at the three university medical centres (Science, Literature-Psychology, Law & Social Sciences). Female students entering the University were asked to complete an anonymous questionnaire at the time of their preventive medical visit. The questionnaire included questions on demographics, knowledge about HPV vaccination, sexual behaviour, and willingness to participate in the French vaccination

program. In total, 606 women from the 3 colleges were included. The response rate of the questionnaire was 93%.

Conclusions: The median age of participants was 19 and 8.3% of them had already been vaccinated. Of the respondents, 67% were sexually experienced and 25% of them had their first intercourse less than one-year prior. Among respondents, 43% were eligible for catch-up vaccination according to French recommendations. 64% of eligible students were willing to be vaccinated. The reasons for refusing vaccination were mainly lack of knowledge on the vaccine (57%) and fear of adverse effects (22%). We did not observe significant differences among the three colleges. 74% of questioned students had already heard about HPV and HPV vaccine. However, knowledge of HPV infections, associated diseases, and prevention was limited. That finding indicates the need to pursue educational campaigns about HPV-related diseases and their prevention.

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France

Acceptability of HPV vaccination among women of Rhône-Alpes. HPV-fem study – REMPAP project

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Objectives: To assess women's knowledge and acceptability of the papillomavirus (HPV) vaccination, recommended in France for all 14-years old girls and between 15 and 23, only before the end of the first year of sexual activity.

Methods: In July 2008, a self-administered questionnaire on cervical cancer (CC) prevention was proposed to 18-65 year-old women living in the Rhône-Alpes region by 39 general practitioners (GP) representative of Rhône-Alpes GP.

Conclusions: Of the 1,478 responders (mean age 40.5 years), 290 women (19.6%) (mean age 44.8 years) had a daughter aged 14-23 years (aged 14: 48 (16.5%); 15-18: 162 (55.9%); 19-23: 80 (27.6%)). In this group, 162 (55.8%) had a gynaecological follow-up every year, 246 (84.8%) have had a pap smear (PS) in the 3 previous years, and 37 (12.8%) have had an abnormal PS at least once. A total of 196 women (67.5%) exactly knew the role of PS. Among the 136 (46.8%) women asserting that they knew the CC causal agent, 36.8% mentioned HPV (ie. 17.2% of the 290 women). Among the 249 women (85.9%) saying they knew the HPV vaccine, 16.4% cited the suitable ages of vaccination and 31.3% the modalities related to sexual activity. A total of 131 women (45.2%) were favourable to HPV vaccine (21.4%

had at least one daughter already vaccinated and 23.8% decided to vaccinate their daughter); and 42.1% preferred to wait or were opposed (39.3% and 2.8% respectively). Of these, 37.7% thought their daughter was not concerned and 15.5% feared possible side effects or a lack of backward path.

Characteristics associated with HPV vaccine acceptability were age < 50 years (OR=2.9 [1.1-8.0]), having a child previously vaccinated against pneumococcus (OR=2.7, [1.1-6.8]), knowing the target population of the vaccine (OR=4.6 [1.3-15.8]), and not knowing the role of PS (OR=3.3 [1.03-10.8]).

The limited knowledge on the HPV vaccine could be a barrier to vaccination because mothers believe that their daughters are not concerned. Main factors positively associated with HPV vaccine acceptability are knowledge of the target population of this vaccine, previous acceptance of new vaccines and, unexpectedly, the not knowledge of the role of PS; whereas compliance to PS screening had no effect. A better understanding of HPV vaccination could improve parental acceptance of vaccine for the girls. Further results in socially underprivileged women should specify the social and cultural predictors of acceptability.

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United Kingdom

"Why it's not for us": the views of parents and girls in the United Kingdom who declined the HPV vaccination – a qualitative study

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Objectives: The United Kingdom HPV vaccination programme for girls aged 12-13 years commenced in autumn 2008. At the time of implementation it was not known what the vaccination uptake would be, or on what basis decisions to accept or decline the vaccination would be made. As part of a larger study to develop and evaluate key HPV messages relevant to eligible girls, their parents and health professionals, a qualitative study was conducted to explore the reasons for non-uptake among girls and their parents. This is one of the first studies to examine and report on the behavioural responses to HPV vaccination invitation, and the underlying rationales. The findings from this study have the potential to assist in the development of interventions to ensure that vaccination decisions are made not on misunderstandings about HPV and the vaccine, but made on an informed basis.

Methods: Invitations to participate were sent via school nurses within one United Kingdom Primary Care Trust to all girls aged 12-13 years who had declined the offer of the HPV vaccination, and to their parents. In-depth, one-one interviews were carried out with all responding girls

(14), and parents (20). Parents and girls were interviewed individually; a thematic analysis of verbatim transcripts was undertaken.

Findings: Reported reasons from the girls and parents for non-uptake of the HPV vaccination included: the age of the girls in terms of both the behavioural relevance of vaccination to them at that time, and their physical maturity; feeling pressured to make an immediate decision with insufficient information in a non life-threatening situation; the perception of the girls as 'guinea pigs' for an unproven vaccine; fear of unknown long term side-effects, and the impact of personal health histories and other experiences. This paper will focus specifically on the information needs which underpinned the reasons for non-acceptance of the vaccination, needs which were identified either by the participants, or apparent through their stated (mis)understandings. The implications of these findings to the ongoing implementation of the HPV vaccination programme will be considered and recommendations made.

ES2-8

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Philippines

Acceptability of human papillomavirus vaccine among midadult women

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Objective: To determine midadult women's knowledge, attitudes and perceptions about receiving prophylactic HPV vaccine

Materials and Methods: Two hundred eighty-eight women 27-55 years who consulted at Philippine General Hospital Department of Obstetrics and Gynecology wards from May-June 2008 were made to complete a self-administered questionnaire that included demographic, reproductive and sexual history, knowledge, attitude and perception variables as potential correlates of vaccine acceptability. Chi square test was used to assess association of vaccine acceptability with these variables.

Results: Seventy two percent have heard of the HPV vaccine prior to the conduct of the study mainly from television followed by health centers. 50% have identified HPV as a specific risk factor for developing cervical cancer although 80% think that it is caused by an infection

that is sexually transmitted. Overall acceptability rate is 79.2%. The main reason for wanting the vaccine is prevention of cervical cancer (86.40%) while the main reason for not wanting the vaccine is being in a monogamous relationship (65%). Majority of the respondents (93.86%) thought that men should also be vaccinated against HPV. There was significant association found between vaccine acceptability and age, employment status, gross family income, educational attainment, number of lifetime sexual partner, history of previous abortions and miscarriages, and perceptions of HPV and HPV vaccine.

Conclusion: There is high level of interest and acceptance of the prophylactic HPV vaccine by midadult women however its cost hinders vaccination to many.

ES2-9

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Singapore

CervicalScreen Singapore – gearing up for the next lap

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Objective: In Singapore, cervical cancer is the 6th most common female cancer and the 8th leading cause of cancer-related death in women. Each year, 172 women are diagnosed with cervical cancer and 77 women die from it. A population-based screening programme, CervicalScreen Singapore (CSS), introduced in 2004, encourages women aged 25 to 69 years to go for a Pap smear every 3 years. This paper 1) reports the knowledge and screening behaviour among women in Singapore, and the differences among the 3 main ethnic groups, 2) evaluates the effectiveness of the screening programme, and 3) highlights key gaps and opportunities to improve cervical cancer screening in Singapore.

Method: From the National Health Survey 2004, 80.8% of women were aware of the Pap smear test. The proportion of women who had ever had a Pap smear increased from 64.2% in 1998 to 70.1% in 2004. Women who had never had a Pap smear cited the following key reasons for their non-attendance: 1) "Not necessary as I am healthy" (28.6%), 2) "Never heard about Pap smear test" (22.4%) and 3) "Not sexually active" (13.2%). Between August 2004 to December 2008, 81,087

women were screened in the government clinics under CSS. Of the 1,340 women referred for assessment, 124 pre-invasive cancers and 26 invasive cancers were detected (0.33 per 1,000 women screened). Indian women had the highest lost-to-rescreen rate (75.4%) followed by Malay women (72.4%) and Chinese women (69.5%). Sensitivity for the test was 66.7% for first screens, while specificity was 88%. The proportion of pre-invasive cancer (CIN III) had also increased from 86% to 88% from 2004 to 2008.

Conclusion: While the findings indicate that the diagnostic accuracy and cancer detection rate for CSS are comparable to that of other more established programmes, one key challenge faced is bridging the knowledge-practice gap. To ramp up the coverage of cervical cancer screening, tailored marketing strategies are needed to reduce the barriers towards screening and to increase the rescreen rate, especially among the Indians and Malays. Greater accessibility of cervical cancer screening has also been offered to the community and workplaces through the Chronic Disease Management Programme-GP clinics and mobile screening bus.

ES2-10

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Brazil

Implementing HPV test in public health hospital

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Objectives: To analyse the performance of HPV test assessed with hybrid capture II (HC2) assay in women submitted to the gynaecological examination at Hospital das Clínicas of FMUSP in order to consider the introduction of molecular investigation of HPV as an alternative or complementary tool to Papanicolaou test (PapTest).

Methods: This analysis is part of a cross-sectional study carried out at a large public hospital attending predominantly low-resource population. The rationale of this study was to combine HC2-HPV test with the conventional Pap smear examination in women referred to gynecology examination for different reasons (previous abnormal PapTest, follow up of treated cervical lesion, ecc).

Conclusions: Seven hundred and four women were included in the analysis: 272 HPV positive (mean age of 36.3 years) and 432 HPV negative (mean age of 41.2 years). From HPV negative group, 3 cases

were biopsy proven cervical high grade squamous intraepithelial lesion (HSIL), 2 high grade vaginal lesion (VAIN) and 1 vulvar high grade lesion (VIN); from the HPV+ group 18 were HSIL, 24 low SIL and 45 were cervicitis; also 2 VAIN 2 VIN and two vaginal and vulvar invasive carcinomas were identified. Papanicolaou test revealed 100 LSIL against 26 (26%) LSIL confirmed by biopsy; moreover, from 51 HSIL detected by cytology, only 13 were biopsy-proven. From HPV positive group, 132 biopsies were taken, and 70 of them (53%) have showed lesions. HPV positive test PapTest showed concomitant positive biopsy in 36 cases (53%), but in 13 (18%) cases PapTest showed categorization inferior to the biopsies, including 2 cases of invasive squamous cell carcinoma cytologically classified as HSIL. HPV test has proven to be more sensitive than cytology to recognize cervical alterations, including high grade lesions, in despite of slightly superior specificity of PapTest.

ES2-11

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Canada

HPV vaccine acceptability in university-aged men

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Objectives: While several studies have explored factors related to HPV vaccine acceptability in women, few have studied vaccine acceptability in men. The present study examined HPV and HPV vaccine knowledge, attitudes, and beliefs and vaccine acceptability in university-aged men. **Methods:** 45 male undergraduate university students (mean age = 20.4 years, SD = 1.7) participated. Participants completed a questionnaire assessing: (1) demographics, (2) knowledge about HPV and the HPV vaccine, (3) perceived susceptibility to and severity of HPV, (4) perceived advantages and disadvantages of the HPV vaccine, (5) physicians' and significant others' recommendations, and (6) sexual health and history.

Conclusions: Male undergraduate university students had limited knowledge about HPV and the HPV vaccine. While most had heard of HPV and the vaccine, knowledge was extremely low (M = 8.9 correct knowledge questions out of 22, SD = 4.9). Most men were not aware of the role of HPV in causing cervical cancer and genital warts, or the vaccine's role in preventing HPV infections that may lead to either of

these diseases. Perceived knowledge (what the men thought they knew) about HPV and the HPV vaccine was low overall (M = 8.0 out of 21, SD = 4.3). Men not intending to receive the vaccine (60%) had significantly lower levels of perceived knowledge about HPV and the HPV vaccine, believed that the HPV vaccine was beneficial for women only, and believed that they were not susceptible to HPV. The most common reasons men indicated for receiving the vaccine included to protect themselves and/or their partner and to prevent the spread of HPV. Men who intended to receive the HPV vaccine also reported more favourable recommendations from physicians and significant others regarding the vaccine than those who did not intend to receive the vaccine ($t(25.18) = -3.15, p < .01$). Finally, frequency of condom use ($r = 0.37, p < .05$) was also, related to intentions to receive the HPV vaccine. It may be important to educate men about HPV and the HPV vaccine to increase their knowledge before the vaccine is approved for them. Once the vaccine becomes available for men, physician's recommendation may be a critical factor for vaccine uptake.

Loss of quality of life associated with genital warts: a prospective 6-month study

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Objectives: Of the two HPV vaccines now available, only Gardasil is effective against HPV types 6 and 11, which are responsible for 90% of genital warts (GW). Although valid quality-adjusted life-years (QALY) lost are needed to assess the cost-effectiveness of vaccination, few data are available on the QALY loss attributable to GW. Our aim was to prospectively estimate such data.

Methods: Between 10/2006 – 10/2007, 271 GW cases seeking care for a first (n=131) or recurrent (n=140) episode were recruited. Health-related quality of life (HRQoL) was measured at recruitment, and 2 and 6 months later with several instruments including the EQ-5D. EQ-5D scores were transformed into utility scores for QALY estimation. QALY

loss during study follow-up was calculated by aggregating differences over time between the utility scores of GW cases and age/gender-matched Canadian EQ-5D norms (the reference value of HRQoL without GW). To estimate the QALY loss between GW onset and recruitment, we assumed that HRQoL decreased linearly from the level of Canadian norms at GW onset to the level measured at recruitment.

Conclusions: These results were based on cases with a first GW episode. Median delay between GW onset and recruitment was 2.3 months for women and 10.3 months for men, and 30% of cases were recruited at their first visit for GW. Changes in HRQoL over study follow-up varied according to gender and the delay between GW onset and recruitment. Men recruited < 3 months of GW onset had higher detriments in HRQoL at recruitment (p=0.03) compared to men recruited ≥ 3 months. The HRQoL of men and women recruited < 3 months returned to the norm level by the end of follow-up. The HRQoL of cases recruited ≥ 3 months remained stable during follow-up.

These preliminary results suggest that a first episode of GW produces a QALY loss equivalent to 9 to 40 days of healthy life lost. Considering that recurrence of GW is frequent, analyses assessing QALY loss among recurrent cases may further our understanding of the burden of GW over the entire course of the disease.

	Utility difference at recruitment (95% CI)	QALY loss	
		From GW onset to recruitment	From recruitment to end of follow-up
WOMEN			
< 3 months (n=40)	-0.12 (-0.07;-0.17)	0.004	0.02
≥ 3 months (n=35)	-0.10 (-0.03;-0.18)	0.02	0.04
MEN			
< 3 months (n=11)	-0.08 (-0.03;-0.13)	0.05	0.04
≥ 3 months (n=45)			

These preliminary results suggest that a first episode of GW produces a QALY loss equivalent to 9 to 40 days of healthy life lost. Considering that recurrence of GW is frequent, analyses assessing QALY loss among recurrent cases may further our understanding of the burden of GW over the entire course of the disease.

Drivers and barriers to acceptance of human-papillomavirus vaccination among young women

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Objectives: Human papillomavirus (HPV) is a necessary cause of cervical dysplasia and cancer, and of genital warts. Few studies have examined attitudes to HPV vaccination since the introduction of HPV vaccines. We aimed to investigate the reasons for the acceptance or rejection of the quadrivalent HPV vaccine after its availability in Denmark.

Methods: A literature review assessed attitudes towards HPV vaccination and was used to identify relevant questions for telephone and focus-group interviews with women aged 16–26 who had decided to accept or reject HPV vaccination. 435 women across Denmark were interviewed by telephone. Qualitative focus-group interviews with a total of 33 women who had completed the telephone survey were undertaken. Four focus groups were set up according to age (16–20 and 21–25 years of age) and acceptance or rejection of the vaccine.

Conclusions: Of 839 women initially contacted, 94.6% had heard of HPV vaccination. 49% of the women said they accepted vaccination

but only 24% had actually started or completed the vaccination series. 28.8% said they refused vaccination. Knowledge about HPV and its role in the development of cervical cancer and genital warts was poor. Prevention of cervical cancer was the main driver for acceptance of the vaccine, followed by parental encouragement and financial support, personal experience of someone with cancer and recommendation by health-care professionals. The greatest barrier to vaccination was its cost. A lack of information about the benefits of vaccination for sexually active women was also an important barrier and the older participants in particular considered that they were too old to be vaccinated. The difference between intention to be vaccinated and actually starting vaccination was considerable, and a large proportion of women aged 16–26 did not wish to be vaccinated. If the most important barriers to vaccination were addressed, it is likely that the uptake of vaccination in Denmark would increase substantially.

